

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**Amendment No. 1**  
**to**  
**Form S-1**  
**REGISTRATION STATEMENT**  
*UNDER*  
*THE SECURITIES ACT OF 1933*

**PACIRA PHARMACEUTICALS, INC.**  
(Exact Name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**2834**  
(Primary Standard Industrial  
Classification Code No.)

**51-0619477**  
(I.R.S. Employer  
Identification No.)

**5 Sylvan Way, Suite 125**  
**Parsippany, New Jersey 07054**  
**(973) 254-3560**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**David M. Stack**  
**President and Chief Executive Officer**  
**5 Sylvan Way, Suite 125**  
**Parsippany, New Jersey 07054**  
**(973) 254-3560**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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**Approximate date of commencement of proposed sale to the public:** As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this form are offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended (the "Securities Act") please check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b2 of the Exchange Act.

Large accelerated filer  Accelerated filer   
Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to Section 8(a), may determine.**

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, dated December 3, 2010

PROSPECTUS

Shares



Common Stock

This is the initial public offering of the common stock of Pacira Pharmaceuticals, Inc. We are offering \_\_\_\_\_ shares of our common stock. No public market currently exists for our common stock.

We have applied to list our common stock on The NASDAQ Global Market under the symbol "PCRX."

We anticipate that the initial public offering price will be between \$ \_\_\_\_\_ and \$ \_\_\_\_\_ per share.

*Investing in our common stock involves risks. See "[Risk Factors](#)" beginning on page 10 of this prospectus.*

	<u>Per share</u>	<u>Total</u>
Price to the public	\$	\$
Underwriting discounts and commissions	\$	\$
Proceeds to us (before expenses)	\$	\$

We have granted the underwriters the option to purchase additional shares of common stock on the same terms and conditions set forth above if the underwriters sell more than \_\_\_\_\_ shares of common stock in this offering.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares on or about \_\_\_\_\_, \_\_\_\_\_.

**Barclays Capital**

**Piper Jaffray**

**Wedbush PacGrow Life Sciences**

**Brean Murray, Carret & Co.**

Prospectus dated \_\_\_\_\_, \_\_\_\_\_.

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**You should rely only on the information contained in this prospectus and any free writing prospectus prepared by or on behalf of us or to which we have referred you. We have not authorized anyone to provide you with information that is different. We are offering to sell shares of our common stock, and seeking offers to buy shares of our common stock, only in jurisdictions where offers and sales are permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock.**

For investors outside the United States: neither we nor any of the underwriters have taken any action to permit a public offering of the shares of our common stock or the possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

We obtained the industry, market and competitive position data in this prospectus from our own internal estimates and research as well as from industry and general publications and research, surveys and studies conducted by third parties. Industry publications, studies and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information.

## PROSPECTUS SUMMARY

*This summary highlights information contained elsewhere in this prospectus. You should read the following summary together with the more detailed information appearing in this prospectus, including our consolidated financial statements and related notes, and the risk factors beginning on page 10, before deciding whether to purchase shares of our common stock. Unless the context otherwise requires, we use the terms “Pacira,” “our company,” “we,” “us” and “our” in this prospectus to refer to Pacira Pharmaceuticals, Inc. and its subsidiaries.*

### Overview

We are an emerging specialty pharmaceutical company focused on the development, commercialization and manufacture of proprietary pharmaceutical products, based on our proprietary DepoFoam drug delivery technology, for use in hospitals and ambulatory surgery centers. In September 2010, we filed a New Drug Application, or NDA, for our lead product candidate, EXPAREL, a long-acting bupivacaine (anesthetic/analgesic) product for postsurgical pain management. Our clinical data demonstrates that EXPAREL provides analgesia for up to 72 hours post-surgery, compared with seven hours or less for bupivacaine.

We believe EXPAREL will address a significant unmet medical need for a long-acting non-opioid postsurgical analgesic, resulting in simplified postsurgical pain management and reduced opioid consumption, leading to improved patient outcomes and enhanced hospital economics. We estimate there are approximately 39 million opportunities annually in the United States for EXPAREL to be used. EXPAREL will be launched by certain members of our management team who have successfully launched multiple products in the hospital market.

EXPAREL consists of bupivacaine encapsulated in DepoFoam, both of which are used in FDA-approved products. DepoFoam, our extended release drug delivery technology, is the basis for our two FDA-approved commercial products, DepoCyt(e) and DepoDur, which we manufacture for our commercial partners. DepoFoam-based products have been manufactured for over a decade and have an extensive safety record and history of regulatory approvals in the United States, European countries and other territories. Bupivacaine, a well-characterized, FDA-approved anesthetic/analgesic, has an established safety profile and over 20 years of use in the United States.

EXPAREL has demonstrated efficacy and safety in two multicenter, randomized, double-blind, placebo-controlled, pivotal Phase 3 clinical trials in patients undergoing soft tissue surgery (hemorrhoidectomy) and orthopedic surgery (bunionectomy). In our pivotal Phase 3 hemorrhoidectomy clinical trial, EXPAREL achieved its primary endpoint by providing a statistically significant 30% reduction in pain, as measured by the area under the curve, or AUC, of the NRS-R pain scores, a commonly used patient reported measurement of pain, at 72 hours and all additional time points measured up to 72 hours. In addition, EXPAREL achieved its secondary endpoints in reducing the use of opioid rescue medication, including 45% less opioid usage compared to the placebo treatment group at 72 hours. In our pivotal Phase 3 bunionectomy clinical trial, EXPAREL also met its primary endpoint, demonstrating a statistically significant reduction in pain at 24 hours, and this reduction was also statistically significant at 36 hours. The trial also met secondary endpoints related to pain measurement and the use of opioid rescue medication. Overall, EXPAREL has demonstrated safety in over 1,300 subjects.

We are initially seeking FDA approval of EXPAREL for postsurgical analgesia by local administration into the surgical wound, or infiltration, a procedure commonly employing bupivacaine. Under the Prescription Drug User Fee Act, or PDUFA, guidelines, the FDA has a goal of ten months from the date of NDA filing to make a decision regarding the approval of our filing. We are also pursuing several additional indications for EXPAREL and expect to submit a supplemental NDA, or sNDA, for nerve block and epidural administration.

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Our current product portfolio and product candidate pipeline is summarized in the table below:

Product(s) / Product Candidate(s)	Primary Indication(s)	Status	Commercialization Rights
<b>EXPAREL</b>	Postsurgical analgesia by infiltration	NDA (submitted)	Pacira (worldwide)
	Postsurgical analgesia by nerve block	Phase 2/3 (planning)	Pacira (worldwide)
	Postsurgical analgesia by epidural administration	Phase 1 (completed)	Pacira (worldwide)
<b>DepoCyt(e)</b>	Lymphomatous meningitis	Marketed	Sigma-Tau Pharmaceuticals Mundipharma International
<b>DepoDur</b>	Post-operative pain	Marketed	EKR Therapeutics Flynn Pharmaceuticals
<b>DepoNSAID</b>	Acute pain	Preclinical	Pacira (worldwide)
<b>DepoMethotrexate</b>	Rheumatoid arthritis	Preclinical	Pacira (worldwide)
	Oncology	Preclinical	Pacira (worldwide)

**Limitations of Current Therapies for Postsurgical Pain**

Substantially all surgical patients experience postsurgical pain, with approximately 50% of surgical patients reporting inadequate pain relief according to certain epidemiological studies. Local anesthetics, such as bupivacaine, are usually effective for seven hours or less, and opioids, the mainstay of postsurgical pain management, have a range of potentially severe side effects. The use of opioid-based patient controlled analgesia, or PCA, systems further adds cost and complication to the process of postsurgical pain management.

Non-steroidal anti-inflammatory drugs, or NSAIDS, are commonly used in an attempt to minimize opioid usage, but increase the risk of bleeding and gastrointestinal and renal complications. Elastomeric bags, which are often used to extend the delivery of bupivacaine using a catheter system, are clumsy, difficult to use and may introduce catheter-related issues, including infection.

**EXPAREL**

Based on our clinical trial data, EXPAREL provides continuous and extended postsurgical analgesia for up to 72 hours and reduces the consumption of supplemental opioid medications. We believe this will simplify postsurgical pain management, minimize breakthrough episodes of pain and result in improved patient outcomes and enhanced hospital economics.

Our EXPAREL strategy has four principal elements:

Replace the use of bupivacaine in postsurgical infiltration. We believe EXPAREL:

- extends postsurgical analgesia for up to 72 hours, from seven hours or less;
- utilizes existing postsurgical infiltration administration techniques;
- dilutes easily with saline to reach desired volume;
- is a ready-to-use formulation; and
- facilitates treatment of both small and large surgical wounds.

*Become the foundation of a postsurgical pain management regimen in order to reduce and delay opioid usage.* We believe EXPAREL:

- significantly delays and reduces opioid usage while improving postsurgical pain management as demonstrated in our Phase 3 hemorrhoidectomy trial, in which EXPAREL demonstrated the following:
  - delayed first opioid usage to approximately 14 hours post-surgery, compared to approximately one hour for placebo;
  - significantly increased percentage of patients requiring no opioid rescue medication through 72 hours post-surgery, to 28% compared to 10% for placebo;
  - 45% less opioid usage at 72 hours post-surgery compared to placebo; and
  - increased percentage of patients who are pain free at 24 hours post-surgery compared to placebo; and
- may reduce hospital cost and staff monitoring of PCA systems.

*Improve patient satisfaction.* We believe EXPAREL:

- reduces the need for patients to be constrained by elastomeric bags and PCA systems, which are clumsy, difficult to use and may introduce catheter-related issues, including infection;
- promotes maintenance of early postsurgical pain management, thereby reducing the time spent in the intensive care unit; and
- promotes early ambulation, which potentially reduces the risk of life-threatening blood clots, and allows quicker return of bowel function, thereby leading to a faster switch to oral nutrition and medicine, and thus a faster discharge from the hospital.

*Develop and seek approval of EXPAREL for nerve block and epidural administration.* We believe these additional indications for EXPAREL:

- present a low-risk, low-cost opportunity for clinical development; and
- will enable us to fully leverage our manufacturing and sales infrastructure.

#### **Manufacturing and Intellectual Property**

We manufacture all our DepoFoam-based products, including commercial supplies of DepoCyt(e) and DepoDur for our commercial partners. We currently manufacture clinical supplies of EXPAREL and intend to manufacture and commercialize EXPAREL upon its approval.

We have developed significant know-how regarding our manufacturing process and protect our technology through trade secrets and patents. We have over 15 families of patents and patent applications relating to various aspects of DepoFoam delivery technology. Issued U.S. patents protect the composition of EXPAREL and methods for modifying its rate of drug release. We have also submitted additional patent applications related to the composition of, and manufacturing process for, EXPAREL. Recently, we filed a provisional patent relating to a new process to manufacture EXPAREL and other DepoFoam-based products, which, if granted, could prevent others from using this process until 2031.

## **Our Strategy**

Our goal is to be a leading specialty pharmaceutical company focused on the development, commercialization and manufacture of proprietary pharmaceutical products principally for use in hospitals and ambulatory surgery centers. We plan to achieve this by:

- obtaining FDA approval for EXPAREL in the United States for postsurgical analgesia using local infiltration;
- building a streamlined commercial organization concentrating on major hospitals and ambulatory surgery centers in the United States and targeting surgeons, anesthesiologists, pharmacists and nurses;
- working directly with managed care payers, quality improvement organizations, key opinion leaders, or KOLs, in the field of postsurgical pain management and leading influence hospitals with registry programs to demonstrate the economic benefits of EXPAREL;
- securing commercial partnerships for EXPAREL in regions outside of the United States;
- obtaining FDA approval for nerve block and epidural administration indications for EXPAREL;
- manufacturing all our DepoFoam-based products, including EXPAREL, DepoCyt(e) and DepoDur, in our current Good Manufacturing Practices, or cGMP, compliant facilities; and
- continuing to expand our marketed product portfolio through development of additional DepoFoam-based hospital products utilizing a 505(b)(2) strategy.

## **Recent Developments**

On November 24, 2010, we entered into a \$26.25 million credit facility with Hercules Technology Growth Capital, Inc. and Hercules Technology III, L.P., as lenders, or the Hercules Credit Facility. At the closing of the Hercules Credit Facility, we entered into a term loan in the aggregate principal amount of \$26.25 million, which was the full amount available under the Hercules Credit Facility. As of November 30, 2010, the entire term loan of \$26.25 million was outstanding. As further consideration to the lenders to provide the term loan under the Hercules Credit Facility, we issued to the lenders a warrant to purchase 1,925,000 shares of our Series A convertible preferred stock. If after the closing date of the Hercules Credit Facility and prior to the completion of this offering, we issue equity securities in a private placement then the lenders may, at their option, exercise the warrant for the same class and type of equity securities that we issue in such private placement in lieu of Series A convertible preferred stock. On November 24, 2010, all borrowings under our credit facility with General Electric Capital Corporation, or the GECC Credit Facility, were repaid in full from proceeds of the Hercules Credit Facility, and the GECC Credit Facility was terminated and any and all liens in favor of the lenders under the GECC Credit Facility were released.

## **Risk Factors**

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks are discussed more fully in the “Risk Factors” section of this prospectus immediately following this prospectus summary. These risks include the following:

- We are dependent on the success of our lead product candidate, EXPAREL, and cannot guarantee that this product candidate will receive regulatory approval or be successfully commercialized.
- If we are unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if they are approved, we may be unable to generate product revenues.

- If EXPAREL is approved and we fail to manufacture the product in sufficient quantities and at acceptable quality and pricing levels, or to fully comply with cGMP regulations, we may face delays in the commercialization of this product candidate or be unable to meet market demand, and may lose potential revenues.
- We may not be able to manage our business effectively if we are unable to attract and retain key personnel.
- Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing.
- We may not receive regulatory approval for EXPAREL or any of our other product candidates, or the approval may be delayed for various reasons, including successful challenges to the FDA's interpretation of Section 505(b)(2), which would have a material adverse effect on our business and financial condition.

### **Corporate History and Information**

We were incorporated in Delaware under the name Blue Acquisition Corp. in December 2006 and changed our name to Pacira, Inc. in June 2007. In October 2010, we changed our name to Pacira Pharmaceuticals, Inc.

Pacira Pharmaceuticals, Inc. is the holding company for our California operating subsidiary of the same name, which we refer to as PPI-California. On March 24, 2007, MPM Capital, Sanderling Ventures, OrbiMed Advisors, HBM BioVentures, the Foundation for Research and their co-investors, through Pacira Pharmaceuticals, Inc., acquired PPI-California, from SkyePharma Holding, Inc., which we refer to as the Acquisition. PPI-California was known as SkyePharma, Inc. prior to the Acquisition. In this prospectus, the term Predecessor refers to SkyePharma, Inc. prior to March 24, 2007, or the Acquisition Date, and the term Successor refers to Pacira Pharmaceuticals, Inc. and its consolidated subsidiaries.

Our principal executive offices are located at 5 Sylvan Way, Suite 125, Parsippany, New Jersey 07054, and our telephone number is (973) 254-3560. Our website address is [www.pacira.com](http://www.pacira.com). Information contained on our website is not incorporated by reference into this prospectus, and you should not consider information contained on our website to be part of this prospectus or in deciding whether to purchase shares of our common stock.

Pacira®, DepoFoam®, DepoCyt® (U.S. registration), DepoCyte® (EU registration), DepoDur®, EXPAREL™, the Pacira logo and other trademarks or service marks of Pacira appearing in this prospectus are the property of Pacira. This prospectus contains additional trade names, trademarks and service marks of other companies. In the prospectus, references to DepoCyt(e) mean DepoCyt when discussed in the context of the United States and Canada and DepoCyte when discussed in the context of Europe.



**The Offering**

Common stock offered by Pacira	shares
Common stock to be outstanding after this offering	shares ( shares in the event the underwriters elect to exercise their option to purchase additional shares from us in full)
Use of proceeds	<p>We estimate that the net proceeds to us from this offering, after deducting estimated underwriting discounts and commissions and offering expenses, will be approximately \$ million, or approximately \$ million if the underwriters exercise their option to purchase additional shares from us in full. We intend to use the net proceeds from this offering as follows:</p> <ul style="list-style-type: none"><li>• up to \$ million through the fourth quarter of 2011 for the planned manufacture and commercialization of EXPAREL in the United States;</li><li>• up to \$ million through the fourth quarter of 2011 for the development of EXPAREL for nerve block and epidural administration, which we believe allows us to complete Phase 2 clinical trials and begin Phase 3 clinical trials of EXPAREL for nerve block and potentially begin a Phase 2 clinical trial of EXPAREL for epidural administration; and</li><li>• the balance for working capital and other general corporate purposes, which may include the acquisition or licensing of other products or technologies or the acquisition of other businesses in the biotechnology or specialty pharmaceuticals industry.</li></ul> <p>See “Use of Proceeds.”</p>
Risk factors	<p>You should read the “Risk Factors” section and other information included in this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.</p>
Proposed NASDAQ Global Market symbol	“PCRX”

The number of shares of our common stock to be outstanding after this offering is based on the number of shares of common stock outstanding as of November 30, 2010, and excludes:

- 3,875,000 shares of common stock issuable upon the exercise of warrants outstanding as of November 30, 2010, at a weighted average exercise price of \$0.81 per share;
- 16,178,011 shares of common stock issuable upon the exercise of stock options outstanding as of November 30, 2010, at a weighted average exercise price of \$0.15 per share; and
- 1,248,901 shares of common stock available for future issuance under our equity compensation plans as of November 30, 2010.

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Except as otherwise noted, all information in this prospectus:

- gives effect to a one-for- reverse split of our common stock to be effected prior to the effective date of the registration statement of which this prospectus is a part;
- assumes no exercise of outstanding options or warrants;
- assumes no exercise by the underwriters of their option to purchase additional shares of common stock to cover over-allotments;
- gives effect to the issuance of 68,000,000 shares of common stock upon the automatic conversion of all outstanding shares of our Series A convertible preferred stock into shares of our common stock upon the completion of this offering;
- gives effect to the issuance of 35,112,715 shares of common stock upon the conversion of certain outstanding secured and unsecured notes and accrued interest thereon held by certain of our stockholders; and
- gives effect to the restatement of our certificate of incorporation and amendment and restatement of our bylaws prior to the effective date of the registration statement of which this prospectus is a part.

### Summary Consolidated Financial Data

The following tables summarize our consolidated financial data as of the dates and for the periods indicated. You should read this data together with our financial statements and related notes included elsewhere in this prospectus and the information under “Selected Consolidated Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

- The consolidated financial data as of December 31, 2008 and 2009, and for the years ended December 31, 2007, 2008 and 2009 have been derived from our consolidated financial statements included elsewhere in this prospectus, which have been audited by J.H. Cohn LLP, an independent registered public accounting firm.
- The consolidated financial data as of September 30, 2009 and 2010, and for the nine months ended September 30, 2009 and 2010, have been derived from our unaudited consolidated financial statements included elsewhere in this prospectus.
- The consolidated financial data as of December 31, 2007 have been derived from our consolidated financial statements not contained herein.
- The consolidated financial data as of March 23, 2007, and for the period from January 1, 2007 through March 23, 2007 have been derived from unaudited consolidated financial statements of the Predecessor, SkyePharma, Inc., not included in this prospectus.

The unaudited consolidated financial data include, in the opinion of our management, all adjustments, consisting only of normal recurring adjustments, that are necessary for a fair presentation of our financial position and results of operations for these periods. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period, and our results for any interim period are not necessarily indicative of results to be expected for a full fiscal year.

The term Predecessor refers to SkyePharma, Inc. prior to March 24, 2007, and the term Successor refers to Pacira Pharmaceuticals, Inc. and its consolidated subsidiaries. Our results of operations for the year ended December 31, 2007, while representing a full year for Pacira Pharmaceuticals, Inc., do not reflect the operations of PPI-California until March 24, 2007, after the Acquisition Date. We have presented the Predecessor for the period from January 1, 2007 through March 23, 2007, as we believe it best presents the continuity of operations of the Successor prior to the Acquisition. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations” for a discussion of the presentation of our results for the year ended December 31, 2007.

The pro forma balance sheet data give effect to the conversion of all outstanding shares of our Series A convertible preferred stock into common stock and the conversion of \$40.0 million aggregate principal amount of secured and unsecured notes and accrued interest thereon held by certain of our stockholders into common stock, as of September 30, 2010. The pro forma as adjusted balance sheet data also give effect to our sale of shares of common stock offered by this prospectus at an assumed initial public offering price of \$            per share, the midpoint of the estimated price range shown on the cover of this prospectus, after deducting the estimated underwriting discounts and commissions and offering expenses payable by us.

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	<u>Predecessor</u> <u>January 1</u> <u>to March 23</u> <u>2007</u> <u>(unaudited)</u>	<u>Successor</u>				
		<u>Year Ended December 31,</u>			<u>Nine Months Ended</u>	
		<u>2007</u>	<u>2008</u>	<u>2009</u>	<u>2009</u>	<u>2010</u>
			(audited)		(unaudited)	(unaudited)
(in thousands, except share and per share data)						
<b>Consolidated Statement of Operations Data:</b>						
Revenues	\$ 1,427	\$ 8,341	\$ 13,925	\$ 15,006	\$ 10,722	\$ 12,371
<b>Operating expenses:</b>						
Cost of revenues	2,825	9,492	17,463	12,301	8,823	10,168
Research and development	3,251	20,665	33,214	26,233	18,717	14,954
Selling, general and administrative	2,632	4,170	8,611	5,020	3,920	3,941
Acquired in-process research and development	—	12,400	—	—	—	—
Total operating expenses	8,708	46,727	59,288	43,554	31,460	29,063
(Loss) from operations	(7,281)	(38,386)	(45,363)	(28,548)	(20,738)	(16,692)
Other income (expense)	(13)	16	(224)	367	353	100
<b>Interest:</b>						
Interest income	4	491	235	77	46	112
Interest (expense)	(2,265)	—	—	(1,723)	(990)	(2,577)
Royalty interest obligation	(1,486)	1,686	3,490	(1,880)	(1,407)	(1,048)
Total interest income (expense)	(3,747)	2,177	3,725	(3,526)	(2,351)	(3,513)
<b>Net income (loss)</b>	<b>\$(11,041)</b>	<b>\$ (36,193)</b>	<b>\$ (41,862)</b>	<b>\$ (31,707)</b>	<b>\$ (22,736)</b>	<b>\$ (20,105)</b>
Net (loss) per share applicable to common stockholders—basic and diluted		\$ (7.24)	\$ (7.37)	\$ (5.14)	\$ (3.69)	\$ (3.26)
Weighted average number of common shares used in net (loss) per share calculation—basic and diluted		5,000,000	5,682,481	6,163,884	6,161,112	6,174,576
Pro forma net (loss) per share—basic and diluted (unaudited) (1)				\$ (0.33)		\$ (0.17)
Shares used in computing pro forma loss per share—basic and diluted (unaudited)				91,902,490		108,296,207
(1) Pro forma basic and diluted net loss per share is calculated assuming the conversion of all of our outstanding shares of Series A convertible preferred stock and our secured and unsecured notes and accrued interest thereon into common stock at the beginning of the period or at the original date of issuance, if later.						
As of September 30, 2010						
		<u>Actual</u>	<u>Pro forma</u>	<u>Pro forma</u>		<u>as adjusted</u>
			(unaudited, in thousands)			
<b>Consolidated Balance Sheet Data:</b>						
Cash and cash equivalents		\$ 13,851	\$ 28,851			
Working capital		6,585	6,585			
Total assets		52,756	67,756			
Long-term debt		57,312	29,660			
Convertible preferred stock, par value		68	—			
Common stock, par value		6	109			
Accumulated deficit		(129,867)	(129,867)			
Total stockholders' equity (deficit)		(43,038)	(386)			

## RISK FACTORS

*Investing in our common stock involves a high degree of risk. Before you decide to invest in our common stock, you should consider carefully the risks described below, together with the other information contained in this prospectus, including our financial statements and the related notes appearing at the end of this prospectus. We believe the risks described below are the risks that are material to us as of the date of this prospectus. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment.*

### **Risks Related to the Development and Commercialization of our Product Candidates**

***We are dependent on the success of our lead product candidate, EXPAREL, and cannot guarantee that this product candidate will receive regulatory approval or be successfully commercialized.***

We have invested a significant portion of our efforts and financial resources in the development of our most advanced product candidate, EXPAREL. Our ability to generate revenues in the near term is substantially dependent on our ability to develop and commercialize EXPAREL. In September 2010, we submitted a new drug application, or NDA, with the U.S. Food and Drug Administration, or FDA, seeking approval to commercialize EXPAREL for treatment of postsurgical pain. We cannot commercialize EXPAREL prior to obtaining FDA approval. Even though EXPAREL has completed two pivotal Phase 3 clinical trials with positive results, EXPAREL is still, nonetheless, susceptible to the risks of failure inherent at any stage of product development, including the appearance of unexpected adverse events, the FDA's determination that EXPAREL is not approvable or failure to achieve its primary endpoints in subsequent clinical trials. For example, in 2009, we completed two Phase 3 clinical trials of EXPAREL that did not meet their primary endpoints.

If we do not receive FDA approval for, and commercialize, EXPAREL, we will not be able to generate revenue from EXPAREL in the foreseeable future, or at all. Any significant delays in obtaining approval for and commercializing EXPAREL will have a substantial adverse impact on our business and financial condition.

If approved, our ability to generate revenues from EXPAREL will depend on our ability to:

- create market demand for EXPAREL through our own marketing and sales activities, and any other arrangements to promote this product candidate we may later establish;
- hire, train and deploy a sales force to commercialize EXPAREL in the United States;
- manufacture EXPAREL in sufficient quantities and at an acceptable quality and at an acceptable manufacturing cost to meet commercial demand at launch and thereafter;
- establish and maintain agreements with wholesalers, distributors and group purchasing organizations on commercially reasonable terms;
- create partnerships with, or offer licenses to, third parties to promote and sell EXPAREL outside the United States; and
- maintain patent and trade secret protection and regulatory exclusivity for EXPAREL.

***We face significant competition from other pharmaceutical and biotechnology companies. Our operating results will suffer if we fail to compete effectively.***

The pharmaceutical and biotechnology industries are intensely competitive and subject to rapid and significant technological change. Our major competitors include organizations such as major multinational pharmaceutical companies, established biotechnology companies and specialty pharmaceutical and generic drug companies. Many of our competitors have greater financial and other resources than we have, such as larger research and development staff, more extensive marketing, distribution, sales and manufacturing organizations

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and experience, more extensive clinical trial and regulatory experience, expertise in prosecution of intellectual property rights and access to development resources like personnel generally and technology. As a result, these companies may obtain regulatory approval more rapidly than we are able to and may be more effective in selling and marketing their products. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis technologies and drug products that are more effective or less costly than EXPAREL or any other product candidate that we are currently developing or that we may develop, which could render our products obsolete and noncompetitive or significantly harm the commercial opportunity for EXPAREL.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize EXPAREL. Our competitors may also develop drugs that are more effective, useful or less costly than ours and may be more successful than us in manufacturing and marketing their products.

EXPAREL will compete with well-established products with similar indications. Competing products available for postsurgical pain management include opioids such as morphine, fentanyl, meperidine and hydromorphone, each of which is available generically from several manufacturers, and several of which are available as proprietary products using novel delivery systems. Ketorolac, an injectable non-steroidal anti-inflammatory drug, or NSAID, is also available generically in the United States from several manufacturers, and Caldolor (ibuprofen for injection), an NSAID, has been approved by the FDA for pain management and fever in adults. In addition, EXPAREL will compete with non-opioid products such as bupivacaine, Marcaine, ropivacaine and other anesthetics/analgesics, all of which are also used in the treatment of postsurgical pain and are available as either oral tablets, injectable dosage forms or administered using novel delivery systems. Additional products may be developed for the treatment of acute pain, including new injectable NSAIDs, novel opioids, new formulations of currently available opioids and NSAIDs, long-acting local anesthetics and new chemical entities as well as alternative delivery forms of various opioids and NSAIDs.

We also expect to compete with an extended release bupivacaine product in development by Durect Corporation which has been licensed to Hospira in North America (Posidur) and to Nycomed for Europe (Optesia).

We also anticipate that EXPAREL will compete with elastomeric bag/catheter devices intended to provide bupivacaine over several days. I-FLOW Corporation (acquired by Kimberly-Clark Corporation in 2009) has marketed these medical devices in the United States since 2004.

***If we are unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if they are approved, we may be unable to generate product revenues.***

We currently do not have a commercial infrastructure for the marketing, sale and distribution of pharmaceutical products. In order to commercialize our products, we must build our marketing, sales and distribution capabilities or make arrangements with third parties to perform these services. If EXPAREL is approved by the FDA, we plan to build a commercial infrastructure to launch EXPAREL in the United States, including a specialty sales force of approximately 100 people within three years from launch. We may seek to further penetrate the U.S. market in the future by expanding our sales force or through collaborations with other pharmaceutical or biotechnology companies or third-party manufacturing and sales organizations. We may also seek to commercialize EXPAREL outside the United States, although we currently plan to do so with a marketing and sales collaborator and not with our own sales force.

The establishment and development of our own sales force and related compliance plans to market any products we may develop will be expensive and time consuming and could delay any product launch, and we

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may not be able to successfully develop this capability. We, or our future collaborators, will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. In the event we are unable to develop a marketing and sales infrastructure, we would not be able to commercialize EXPAREL or any other product candidates that we develop, which would limit our ability to generate product revenues.

Although our current plan is to hire most of our sales and marketing personnel only if EXPAREL is approved by the FDA, we will incur expenses prior to product launch in recruiting this sales force and developing a marketing and sales infrastructure. If the commercial launch of EXPAREL is delayed as a result of FDA requirements or other reasons, we would incur these expenses prior to being able to realize any revenue from sales of EXPAREL. Even if we are able to effectively hire a sales force and develop a marketing and sales infrastructure, our sales force and marketing teams may not be successful in commercializing EXPAREL or any other product candidates that we may develop.

To the extent we rely on third parties to commercialize any products for which we obtain regulatory approval, we may receive less revenues than if we commercialized these products ourselves. In addition, we would have less control over the sales efforts of any other third parties involved in our commercialization efforts. In the event we are unable to collaborate with a third-party marketing and sales organization, our ability to generate product revenues may be limited either in the United States or internationally.

***If EXPAREL does not achieve broad market acceptance, the revenues that we generate from its sales will be limited.***

Other than DepoCyt(e) and DepoDur, we have never commercialized a product candidate for any indication. Even if EXPAREL is approved by the appropriate regulatory authorities for marketing and sale, it may not gain acceptance among physicians, hospitals, patients and third-party payers. If our products for which we obtain regulatory approval do not gain an adequate level of acceptance, we may not generate significant additional product revenues or become profitable. Market acceptance of EXPAREL, and any other product candidates that we develop, license or acquire, by physicians, hospitals, patients and third-party payers will depend on a number of factors, some of which are beyond our control. The degree of market acceptance of EXPAREL will depend on a number of factors, including:

- limitations or warnings contained in the product's FDA-approved labeling, including potential limitations or warnings for EXPAREL that may be more restrictive than other pain management products;
- changes in the standard of care for the targeted indications for EXPAREL, which could reduce the marketing impact of any claims that we could make following FDA approval, if obtained;
- the relative convenience and ease of administration of EXPAREL;
- the prevalence and severity of adverse events associated with EXPAREL;
- cost of treatment versus economic and clinical benefit in relation to alternative treatments;
- the availability of adequate coverage or reimbursement by third parties, such as insurance companies and other healthcare payers, and by government healthcare programs, including Medicare and Medicaid;
- the extent and strength of our marketing and distribution of EXPAREL;
- the safety, efficacy and other potential advantages over, and availability of, alternative treatments, including, in the case of EXPAREL, a number of products already used to treat pain in the hospital setting; and
- distribution and use restrictions imposed by the FDA or to which we agree as part of a mandatory risk evaluation and mitigation strategy or voluntary risk management plan.

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Our ability to effectively promote and sell EXPAREL and any other product candidates that we may develop, license or acquire in the hospital marketplace will also depend on pricing and cost effectiveness, including our ability to produce a product at a competitive price and achieve acceptance of the product onto hospital formularies, and our ability to obtain sufficient third-party coverage or reimbursement. Since many hospitals are members of group purchasing organizations, which leverage the purchasing power of a group of entities to obtain discounts based on the collective buying power of the group, our ability to attract customers in the hospital marketplace will also depend on our ability to effectively promote our product candidates to group purchasing organizations. We will also need to demonstrate acceptable evidence of safety and efficacy, as well as relative convenience and ease of administration. Market acceptance could be further limited depending on the prevalence and severity of any expected or unexpected adverse side effects associated with our product candidates. If our product candidates are approved but do not achieve an adequate level of acceptance by physicians, health care payers and patients, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payers on the benefits of our product candidates may require significant resources and may never be successful.

In addition, even if the medical community accepts that EXPAREL is safe and effective for its approved indications, physicians and patients may not immediately be receptive to EXPAREL and may be slow to adopt it as an accepted treatment of postsurgical pain. It is unlikely that any labeling approved by the FDA will contain claims that EXPAREL is safer or more effective than competitive products or will permit us to promote EXPAREL as being superior to competing products. Further, the availability of inexpensive generic forms of postsurgical pain management products may also limit acceptance of EXPAREL among physicians, patients and third-party payers. If EXPAREL is approved but does not achieve an adequate level of acceptance among physicians, patients and third-party payers, we may not generate meaningful revenues from EXPAREL and we may not become profitable.

***We may rely on third parties to perform many essential services for any products that we commercialize, including services related to warehousing and inventory control, distribution, customer service, accounts receivable management, cash collection and adverse event reporting. If these third parties fail to perform as expected or to comply with legal and regulatory requirements, our ability to commercialize EXPAREL will be significantly impacted and we may be subject to regulatory sanctions.***

We may retain third-party service providers to perform a variety of functions related to the sale and distribution of EXPAREL, key aspects of which will be out of our direct control. These service providers may provide key services related to warehousing and inventory control, distribution, customer service, accounts receivable management and cash collection, and, as a result, most of our inventory may be stored at a single warehouse maintained by one such service provider. If we retain this provider, we would substantially rely on them as well as other third-party providers that perform services for us, including entrusting our inventories of products to their care and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter physical or natural damage at their facilities, our ability to deliver product to meet commercial demand would be significantly impaired. In addition, we may engage third parties to perform various other services for us relating to adverse event reporting, safety database management, fulfillment of requests for medical information regarding our product candidates and related services. If the quality or accuracy of the data maintained by these service providers is insufficient, we could be subject to regulatory sanctions.

Distribution of our DepoFoam-based products requires cold-chain distribution provided by third parties, whereby a product must be maintained between specified temperatures. We and our partners have utilized similar cold-chain processes for DepoCyt(e) and DepoDur. If a problem occurs in our cold-chain distribution processes, whether through our failure to maintain our products or product candidates between specified temperatures or because of a failure of one of our distributors or partners to maintain the temperature of the products or product candidates, the product or product candidate could be adulterated and rendered unusable. This could have a material adverse effect on our business, financial condition, results of operations and reputation.



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***We will need to increase the size of our organization, and we may experience difficulties in managing growth.***

As of November 30, 2010, we had 81 employees. We will need to substantially expand our managerial, commercial, financial, manufacturing and other personnel resources in order to manage our operations and prepare for the commercialization of EXPAREL, if approved. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. In addition, we may not be able to recruit and retain qualified personnel in the future, particularly for sales and marketing positions, due to competition for personnel among pharmaceutical businesses, and the failure to do so could have a significant negative impact on our future product revenues and business results. Our need to effectively manage our operations, growth and various projects requires that we:

- continue the hiring and training of an effective commercial organization in anticipation of the potential approval of EXPAREL, and establish appropriate systems, policies and infrastructure to support that organization;
- ensure that our consultants and other service providers successfully carry out their contractual obligations, provide high quality results, and meet expected deadlines;
- continue to carry out our own contractual obligations to our licensors and other third parties; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our development and commercialization goals.

***We may not be able to manage our business effectively if we are unable to attract and retain key personnel.***

We may not be able to attract or retain qualified management and commercial, scientific and clinical personnel due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Diego, California and Northern New Jersey areas. If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the development and manufacturing expertise for our DepoFoam delivery technology and the commercialization expertise of certain members of our senior management. In particular, we are highly dependent on the skills and leadership of our management team, including David Stack, our president and chief executive officer. If we lose one or more of these key employees, our ability to successfully implement our business strategy could be seriously harmed. Replacing key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate additional key personnel.

Mr. Stack, our chief executive officer, is also a managing director at MPM Capital and a managing partner of Stack Pharmaceuticals, Inc. Although Mr. Stack has devoted substantially all of his time to our company over the past 12 months, Mr. Stack's responsibilities at MPM Capital and Stack Pharmaceuticals, Inc. might require that he spend less than all his time managing our company in the future.

Under our consulting agreement with Gary Patou, M.D., our chief medical officer, he is not required to devote all of his time to our company. We cannot assure you that Dr. Patou's time commitment to us will be sufficient to perform the duties of our chief medical officer.

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***We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for DepoCyt(e), DepoDur, EXPAREL or other product candidates that we may develop and may have to limit their commercialization.***

The use of DepoCyt(e), DepoDur, EXPAREL and any other product candidates that we may develop, license or acquire in clinical trials and the sale of any products for which we obtain regulatory approval expose us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- loss of revenue from decreased demand for our products and/or product candidates;
- impairment of our business reputation or financial stability;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- diversion of management attention;
- loss of revenues;
- withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs; and
- the inability to commercialize our product candidates.

We have obtained limited product liability insurance coverage for our products and our clinical trials with a \$10.0 million annual aggregate coverage limit. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of additional commercial products if we obtain FDA approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing, or at all. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

***We are the sole manufacturer of DepoCyt(e) and DepoDur and we only have two FDA approved manufacturing facilities. Our inability to continue manufacturing adequate supplies of DepoCyt(e) and DepoDur could result in a disruption in the supply of DepoCyt(e) and DepoDur to our partners.***

We are the sole manufacturer of DepoCyt(e) and DepoDur. We develop and manufacture DepoCyt(e) and DepoDur at our facilities in San Diego, California, which are the only FDA approved sites for manufacturing DepoCyt(e) and DepoDur in the world. Our San Diego facilities are subject to the risks of a natural or man-made disaster, including earthquakes and fires, or other business disruption. There can be no assurance that we would be able to meet our requirements for DepoCyt(e) and DepoDur if there were a catastrophic event or failure of our current manufacturing system. If we are required to change or add a new manufacturer or supplier, the process would likely require prior FDA and/or equivalent foreign regulatory authority approval, and would be very time consuming. An inability to continue manufacturing adequate supplies of DepoCyt(e) and DepoDur at our facility in San Diego, California could result in a disruption in the supply of DepoCyt(e) and DepoDur to our partners and breach of our contractual obligations.

***If we fail to manufacture DepoCyt(e) and DepoDur we will lose revenues and be in breach of our licensing obligations.***

We have licensed the commercial rights in specified territories of the world to market and sell our products, DepoCyt(e) and DepoDur. Under those licenses we have obligations to manufacture commercial product for our commercial partners. If we are unable to timely fill the orders placed with us by our commercial partners, we will potentially lose revenue and be in breach of our licensing obligations under the agreements. In addition, we would be in breach of our obligations to comply with our supply and distribution agreements for DepoCyt(e) and DepoDur, which would in turn be a breach of our obligations under our amended and restated royalty interests assignment agreement, or the Amended and Restated Royalty Interests Assignment Agreement, with Royalty Securitization Trust I, an affiliate of Paul Capital Advisors, LLC, or Paul Capital. See “Risk Factors—Risks Related to Our Financial Condition and Capital Requirements—Under our financing arrangement with Paul Capital, upon the occurrence of certain events, Paul Capital may require us to repurchase the right to receive royalty payments that we assigned to it, or may foreclose on certain assets that secure our obligations to Paul Capital. Any exercise by Paul Capital of its right to cause us to repurchase the assigned right or any foreclosure by Paul Capital would adversely affect our results of operations and our financial condition.”

We rely on third parties for the timely supply of specified raw materials and equipment for the manufacture of DepoCyt(e) and DepoDur. Although we actively manage these third-party relationships to provide continuity and quality, some events which are beyond our control could result in the complete or partial failure of these goods and services. Any such failure could have a material adverse effect on our financial condition and operations.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls, and the use of specialized processing equipment. We must comply with federal, state and foreign regulations, including current Good Manufacturing Practices, or cGMP, regulations and in the case of the manufacturing of DepoDur required government licenses regarding the storage and use of controlled substances. Any failure to comply with applicable regulations may result in fines and civil penalties, suspension of production, suspension or delay in product approval for sale, product seizure or recall, or withdrawal of product approval, and would limit the availability of our product. Any manufacturing defect or error discovered after products have been produced and distributed could result in even more significant consequences, including costly recall procedures, re-stocking costs, damage to our reputation, product liability claims and litigation.

***Our future growth depends on our ability to identify, develop, acquire or in-license products and if we do not successfully identify develop, acquire or in-license related product candidates or integrate them into our operations, we may have limited growth opportunities.***

An important part of our business strategy is to continue to develop a pipeline of product candidates by developing, acquiring or in-licensing products, businesses or technologies that we believe are a strategic fit with our focus on the hospital marketplace. However, these business activities may entail numerous operational and financial risks, including:

- difficulty or inability to secure financing to fund development activities for such development, acquisition or in-licensed products or technologies;
- incurrence of substantial debt or dilutive issuances of securities to pay for development, acquisition or in-licensing of new products;
- disruption of our business and diversion of our management’s time and attention;
- higher than expected development, acquisition or in-license and integration costs;
- exposure to unknown liabilities;

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- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- inability to retain key employees of any acquired businesses;
- difficulty in managing multiple product development programs; and
- inability to successfully develop new products or clinical failure.

We have limited resources to identify and execute the development, acquisition or in-licensing of products, businesses and technologies and integrate them into our current infrastructure. We may compete with larger pharmaceutical companies and other competitors in our efforts to establish new collaborations and in-licensing opportunities. These competitors likely will have access to greater financial resources than us and may have greater expertise in identifying and evaluating new opportunities. Moreover, we may devote resources to potential development, acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts.

***Our business involves the use of hazardous materials and we must comply with environmental laws and regulations, which can be expensive and restrict how we do business.***

Our manufacturing activities involve the controlled storage, use and disposal of hazardous materials, including the components of our products, product candidates and other hazardous compounds. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling, release and disposal of, and exposure to, these hazardous materials. Violation of these laws and regulations could lead to substantial fines and penalties. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, state or federal authorities may curtail our use of these materials and interrupt our business operations. In addition, we could become subject to potentially material liabilities relating to the investigation and cleanup of any contamination, whether currently unknown or caused by future releases.

***Our business and operations would suffer in the event of system failures.***

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed clinical trials for EXPAREL could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of our product candidates may be delayed.

***Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our product candidates.***

Our business model is to commercialize our product candidates in the United States and generally to seek collaboration arrangements with pharmaceutical or biotechnology companies for the development or commercialization of our product candidates in the rest of the world. Accordingly, we may enter into collaboration arrangements in the future on a selective basis. Any future collaboration arrangements that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaboration arrangements.

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Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision making authority.

Collaborations with pharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

### **Regulatory Risks**

***We may not receive regulatory approval for EXPAREL or any of our other product candidates, or the approval may be delayed for various reasons, including successful challenges to the FDA's interpretation of Section 505(b)(2), which would have a material adverse effect on our business and financial condition.***

We may experience delays in our efforts to obtain regulatory approval from the FDA for EXPAREL or any of our other product candidates, and there can be no assurance that such approval will not be delayed, or that the FDA will ultimately approve these product candidates.

The FDA may require additional data or information as part of its review of our NDA. If additional stability data or other manufacturing data is required, such data may not be available for a significant amount of time, which could further delay the approval of our NDA for EXPAREL and cause us to incur significant additional expenses. The FDA may also require us to study EXPAREL in pediatric patients. Although we have requested a waiver for patients under two years of age and a deferral for patients under 18 years of age, there can be no assurance that the FDA will grant our waiver or deferral and we may be required to perform these additional pediatric trials, which could be expensive and time consuming.

Our NDA approval is subject to a pre-approval inspection of our production facilities for manufacturing for EXPAREL. Our NDA approval for EXPAREL could be delayed if the FDA does not agree that the registration batches submitted in our NDA are fully representative of the manufacturing process and thus meet the requirements for batches that may be used to provide evidence of stability for this product candidate. In such an event, we would be required to potentially manufacture new batches in order to provide the necessary stability data which could delay FDA approval and cause us to incur significant additional expenses.

Additionally, our NDA for EXPAREL may not be approved, or approval may be delayed, as a result of changes in FDA policies for drug approval. For example, although many products have been approved by the FDA in recent years under Section 505(b)(2) under the Federal Food, Drug and Cosmetic Act, objections have been raised by certain brand-name pharmaceutical companies and others to the FDA's interpretation of Section 505(b)(2). If challenges to the FDA's interpretation of Section 505(b)(2) are successful, the agency may be required to change its interpretation, which could delay or prevent the approval of our NDAs for EXPAREL or any of our other product candidates.

Any significant delay in re-submitting an NDA and obtaining FDA approval for EXPAREL, or a non-approval, could negatively impact our ability to ultimately obtain marketing authorization for this product candidate and would have a material adverse effect on our business and financial condition.

***If EXPAREL is approved and we fail to manufacture the product in sufficient quantities and at acceptable quality and pricing levels, or to fully comply with cGMP regulations, we may face delays in the commercialization of this product candidate or be unable to meet market demand, and may lose potential revenues.***

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls, and the use of specialized processing equipment. In order to meet anticipated demand for EXPAREL if this product candidate is approved,

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we plan to install additional specialized processing equipment to expand the manufacturing capacity for EXPAREL in our facilities. This processing equipment is designed based on our specifications and is not generally commercially available. If we are not able to expand our capacity to manufacture EXPAREL on time or at all, our ability to meet our customers' product demands may be materially and adversely impacted.

We purchase raw materials and components from various suppliers in order to manufacture EXPAREL. If we are unable to source the required raw materials from our suppliers, we may experience delays in manufacturing EXPAREL and may not be able to meet our customers' demands for EXPAREL.

In addition, we must comply with federal, state and foreign regulations, including cGMP requirements enforced by the FDA through its facilities inspection program. Any failure to comply with applicable regulations may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval, and would limit the availability of our product. Any manufacturing defect or error discovered after products have been produced and distributed could result in even more significant consequences, including costly recall procedures, re-stocking costs, damage to our reputation and potential for product liability claims.

If we are unable to produce the required commercial quantities of EXPAREL to meet market demand for EXPAREL on a timely basis or at all, or if we fail to comply with applicable laws for the manufacturing of EXPAREL, we will suffer damage to our reputation and commercial prospects and we will lose potential revenues.

***The FDA may determine that EXPAREL or any of our other product candidates have undesirable side effects that could delay or prevent their regulatory approval or commercialization.***

If concerns are raised regarding the safety of a new drug as a result of undesirable side effects identified during clinical testing, the FDA may decline to approve the drug at the end of the NDA review period or issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve the drug. The number of such requests for additional data or information issued by the FDA in recent years has increased, and resulted in substantial delays in the approval of several new drugs. Undesirable side effects caused by EXPAREL or any other product candidate could also result in the inclusion of unfavorable information in our product labeling, denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing and generating revenues from the sale of EXPAREL or any other product candidate.

For example, the side effects observed in the EXPAREL clinical trials completed to date include nausea and vomiting. In addition, the class of drugs that EXPAREL belongs to has been associated with nervous system and cardiovascular toxicities at high doses. We cannot be certain that these side effects and others will not be observed in the future, or that the FDA will not require additional trials or impose more severe labeling restrictions due to these side effects or other concerns. The active component of EXPAREL is bupivacaine and bupivacaine infusions have been associated with the destruction of articular cartilage, or chondrolysis. Chondrolysis has not been observed in clinical trials of EXPAREL, but we cannot be certain that this side effect will not be observed in the future.

If EXPAREL or any of our other product candidates receives regulatory approval and we or others later identify undesirable side effects caused by such products:

- regulatory authorities may require the addition of unfavorable labeling statements, specific warnings or a contraindication;
- regulatory authorities may suspend or withdraw their approval of the product, or require it to be removed from the market;
- regulatory authorities may impose restrictions on the distribution or use of the product;

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- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to product liability claims and litigation; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of EXPAREL or any of our other product candidates and could substantially increase our commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from its sale.

***Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.***

Any regulatory approval is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products and product candidates, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to issue warning letters or untitled letters, suspend or withdraw an approved product from the market, require a recall or institute fines or civil fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business.

***If we are unable to complete pre-commercialization manufacturing development activities for EXPAREL on a timely basis or fail to comply with stringent regulatory requirements, we will face delays in our ability to obtain regulatory approval for, and to commercialize, this product candidate, and our costs will increase.***

As part of the process for obtaining regulatory approval, we must demonstrate that the facilities, equipment and processes used to manufacture EXPAREL are capable of consistently producing a product that meets all applicable quality criteria, and that is comparable to the product that was used in our clinical trials. We must also provide the FDA with information regarding the validation of the manufacturing facilities, equipment and processes and data supporting the stability of our product candidate. If we are not in compliance with cGMP requirements, the approval of our NDA may be delayed, existing product batches may be compromised, and we may experience delays in the availability of this product candidate for commercial distribution.

***Even if EXPAREL receives regulatory approval, it and any other products we may market, including DepoCyt(e) and DepoDur, will remain subject to substantial regulatory scrutiny.***

EXPAREL, DepoCyt(e) and DepoDur and any other product candidates that we may develop, license or acquire will also be subject to ongoing FDA requirements with respect to the manufacturing, labeling, packaging, storage, distribution, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. In addition, the subsequent discovery of previously unknown problems with a product may result in restrictions on the product, including withdrawal of the product from the market.

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If EXPAREL, DepoCyt(e) and DepoDur or any other product that we may develop, license or acquire fails to comply with applicable regulatory requirements, such as cGMP regulations, a regulatory agency may:

- issue warning letters or untitled letters;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- impose fines and other civil or criminal penalties;
- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require a product recall.

For example, the FDA informed us that certain adverse event reports related to DepoCyt(e) and DepoDur submitted to us during the previous two years were not submitted by us to the FDA within the required 15-day timeframe for reporting such events. In response to the FDA's observations, we enhanced our reporting procedures and hired additional personnel to support our pharmacovigilance efforts.

***If we fail to comply with federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.***

As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payers, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We would be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which constrains our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- federal physician self-referral laws, such as the Stark law, which prohibit a physician from making a referral to a provider of certain health services with which the physician or the physician's family member has a financial interest, and prohibit submission of a claim for reimbursement pursuant to a prohibited referral;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial



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insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under the U.S. federal Anti-Kickback Statute, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Recently, several pharmaceutical and other healthcare companies have been prosecuted under the federal false claims laws for allegedly inflating drug prices they report to pricing services, which in turn are used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. To the extent that any product we make is sold in a foreign country, we may be subject to similar foreign laws and regulations. If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in U.S. federal or state health care programs, and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could materially adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

***The design, development, manufacture, supply, and distribution of DepoCyt(e) and DepoDur is highly regulated and technically complex.***

The design, development, manufacture, supply, and distribution of our products DepoCyt(e) and DepoDur is technically complex and highly regulated. We, along with our third-party providers, must comply with all applicable regulatory requirements of the FDA and foreign authorities. In addition, the facilities used to manufacture, store, and distribute our products are subject to inspection by regulatory authorities at any time to determine compliance with applicable regulations.

The manufacturing techniques and facilities used for the manufacture and supply of our products must be operated in conformity with cGMP. In complying with cGMP requirements, we, along with our suppliers, must continually expend time, money and effort in production, record keeping, and quality assurance and control to ensure that our products meet applicable specifications and other requirements for safety, efficacy and quality. In addition, we, along with our suppliers, are subject to unannounced inspections by the FDA and other regulatory authorities.

Any failure to comply with regulatory and other legal requirements applicable to the manufacture, supply and distribution of our products could lead to remedial action (such as recalls), civil and criminal penalties and delays in manufacture, supply and distribution of our products. For instance, in connection with routine inspections of one of our manufacturing facilities in April and May 2008, the FDA issued a Form 483 Notice of Inspectional Observations identifying certain deficiencies with respect to our laboratory control system for Depocyt(e). As a result, we did not release new lots of Depocyt(e) for a limited time period as we validated a new assay. We also submitted the new assay to the FDA in July 2008 and in August 2008 we began releasing new lots of DepoCyt(e).

***If we fail to comply with the extensive regulatory requirements to which we and our products DepoCyt(e) and DepoDur are subject, such products could be subject to restrictions or withdrawal from the market and we could be subject to penalties.***

The testing, manufacturing, labeling, safety, advertising, promotion, storage, sales, distribution, export and marketing, among other things, of our products DepoCyt(e) and DepoDur are subject to extensive regulation by

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governmental authorities in the United States and elsewhere throughout the world. Quality control and manufacturing procedures regarding DepoCyt(e) and DepoDur must conform to cGMP. Regulatory authorities, including the FDA, periodically inspect manufacturing facilities to assess compliance with cGMP. Our failure or the failure of our contract manufacturers to comply with the laws administered by the FDA or other governmental authorities could result in, among other things, any of the following:

- product recall or seizure;
- suspension or withdrawal of an approved product from the market;
- interruption of production;
- operating restrictions;
- warning letters;
- injunctions;
- fines and other monetary penalties;
- criminal prosecutions; and
- unanticipated expenditures.

***If the government or third-party payers fail to provide coverage and adequate coverage and payment rates for DepoCyt(e), DepoDur, EXPAREL or any future products we may develop, license or acquire, if any, or if hospitals choose to use therapies that are less expensive, our revenue and prospects for profitability will be limited.***

In both domestic and foreign markets, sales of our existing products and any future products will depend in part upon the availability of coverage and reimbursement from third-party payers. Such third-party payers include government health programs such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Assuming coverage is approved, the resulting reimbursement payment rates might not be adequate. In particular, many U.S. hospitals receive a fixed reimbursement amount per procedure for certain surgeries and other treatment therapies they perform. Because this amount may not be based on the actual expenses the hospital incurs, hospitals may choose to use therapies which are less expensive when compared to our product candidates. Accordingly, DepoCyt(e), DepoDur, EXPAREL or any other product candidates that we may develop, in-license or acquire, if approved, will face competition from other therapies and drugs for these limited hospital financial resources. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to the satisfaction of hospitals, other target customers and their third-party payers. Such studies might require us to commit a significant amount of management time and financial and other resources. Our future products might not ultimately be considered cost-effective. Adequate third-party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

Third party payers, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payers. Therefore, coverage and reimbursement for drug products can differ significantly from payer to payer.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for our products or product candidates for which we receive regulatory approval may not be available or adequate in either the United States or international markets, which could have a negative effect on our business, results of operations, financial condition and prospects.

***The FDA may not approve our proposed trade name, EXPAREL.***

EXPAREL, or any other trade name that we intend to use for extended-release liposome injection of bupivacaine, must be approved by the FDA irrespective of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office. The FDA conducts a rigorous review of proposed product names, and may reject a product name if it believes that the name inappropriately implies medical claims or if it poses the potential for confusion with other product names. The FDA will not approve this trade name until the NDA for EXPAREL is approved. If the FDA determines that the trade names of other products that are approved prior to the approval of extended-release liposome injection of bupivacaine may present a risk of confusion with our proposed trade name, the FDA may not ultimately approve EXPAREL. If our trade name, EXPAREL, is rejected, we will lose the benefit of any brand equity that may already have been developed for this product candidate, as well as the benefit of our existing trademark applications for this trade name. If the FDA does not approve the EXPAREL trade name, we may be required to launch this product candidate without a brand name, and our efforts to build a successful brand identity for, and commercialize, this product candidate may be adversely impacted.

***We are subject to new legislation, regulatory proposals and healthcare payer initiatives that may increase our costs of compliance and adversely affect our ability to market our products, obtain collaborators and raise capital.***

In March 2010, the President signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, which we refer to collectively as the Health Care Reform Law. The Health Care Reform Law makes extensive changes to the delivery of health care in the United States. Among the provisions of the Health Care Reform Law of greatest importance to the pharmaceutical industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, beginning in 2011;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D, beginning in 2011;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, effective March 23, 2010;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in April 2010 and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing both the volume of sales and manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program, effective in January 2010;
- new requirements to report certain financial arrangements with physicians and others, including reporting any "transfer of value" made or distributed to prescribers and other healthcare providers and reporting any investment interests held by physicians and their immediate family members during each calendar year beginning in 2012, with reporting starting in 2013;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians, effective April 1, 2012;

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- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- creation of the Independent Payment Advisory Board which, beginning in 2014, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations; and
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending, beginning by January 1, 2011.

These measures could result in decreased net revenues from our pharmaceutical products and decrease potential returns from our development efforts. Many of the details regarding the implementation of the Health Care Reform Law are yet to be determined, and at this time, the full effect that the Health Care Reform Law would have on our business remains unclear.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the pharmaceutical industry. In particular, California has enacted legislation that requires development of an electronic pedigree to track and trace each prescription drug at the saleable unit level through the distribution system. California's electronic pedigree requirement is scheduled to take effect in January 2015. Compliance with California and future federal or state electronic pedigree requirements may increase our operational expenses and impose significant administrative burdens. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition and results of operations.

***Public concern regarding the safety of drug products such as EXPAREL could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling, or require us to undertake other activities that may entail additional costs.***

In light of widely publicized events concerning the safety risk of certain drug products, the FDA, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and the establishment of risk management programs that may, for example, restrict distribution of drug products after approval. The Food and Drug Administration Amendments Act of 2007, or FDAAA, grants significant expanded authority to the FDA, much of which is aimed at improving the safety of drug products before and after approval. In particular, the FDAAA authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. It also significantly expands the federal government's clinical trial registry and results databank, which we expect will result in significantly increased government oversight of clinical trials. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties. The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of data from our clinical trials. Data from clinical trials may receive greater scrutiny, particularly with respect to safety, which may make the FDA or other regulatory authorities more likely to require additional preclinical studies or clinical trials. If the FDA requires us to conduct additional preclinical studies or clinical trials prior to approving EXPAREL, our ability to obtain approval of this product candidate will be delayed. If the FDA requires us to provide additional clinical or preclinical data following the approval of EXPAREL, the indications for which this product candidate is approved may be limited or there may be specific warnings or limitations on dosing, and our efforts to commercialize EXPAREL may be otherwise adversely impacted.

***Our product, DepoDur, is subject to regulation by the Drug Enforcement Agency and such regulation may affect the sale of DepoDur.***

Products used to treat and manage pain, especially in the case of opioids, are from time to time subject to negative publicity, including illegal use, overdoses, abuse, diversion, serious injury and death. These events have led to heightened regulatory scrutiny. Controlled substances are classified by the DEA as Schedule I through V substances, with Schedule I substances being prohibited for sale in the United States, Schedule II substances considered to present the highest risk of abuse and Schedule V substances being considered to present the lowest relative risk of abuse. DepoDur contains morphine, and it is regulated as a Schedule II controlled substance. Despite the strict regulations on the marketing, prescribing and dispensing of such substances, illicit use and abuse of morphine does occur. Thus, the marketing of DepoDur by our partners may generate public controversy that may adversely affect sales of DepoDur and decrease the revenue we receive from the sale of DepoDur.

In addition, we and our contract manufacturers are subject to ongoing DEA regulatory obligations, including, among other things, annual registration renewal, security, recordkeeping, theft and loss reporting, periodic inspection and annual quota allotments for the raw material for commercial production of our products. The DEA, and some states, conduct periodic inspections of registered establishments that handle controlled substances. Facilities that conduct research, manufacture, store, distribute, import or export controlled substances must be registered to perform these activities and have the security, control and inventory mechanisms required by the DEA to prevent drug loss and diversion. Failure to maintain compliance, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, results of operations, financial condition and prospects. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

Individual states also have controlled substances laws. Though state controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs, as well. While some states automatically schedule a drug when the DEA does so, in other states there has to be rulemaking or a legislative action. State scheduling may delay commercial sale of any controlled substance drug product for which we obtain federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product. We or our partners must also obtain separate state registrations in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions from the states in addition to those from the DEA or otherwise arising under federal law.

**Risks Related to Intellectual Property**

***The patents and the patent applications that we have covering our products are limited to specific injectable formulations, processes and uses of drugs encapsulated in our DepoFoam drug delivery technology and our market opportunity for our product candidates may be limited by the lack of patent protection for the active ingredient itself and other formulations and delivery technology and systems that may be developed by competitors.***

The active ingredients in EXPAREL, DepoCyt(e) and DepoDur are bupivacaine, cytarabine and morphine, respectively. Patent protection for the bupivacaine, cytarabine and morphine molecules themselves has expired and generic immediate-release products are available. As a result, competitors who obtain the requisite regulatory approval can offer products with the same active ingredients as EXPAREL, DepoCyt(e) and DepoDur so long as the competitors do not infringe any process, use or formulation patents that we have developed for these drugs encapsulated in our DepoFoam drug delivery technology.

For example, we are aware of at least one long acting injectable bupivacaine product in development which utilizes an alternative delivery system to EXPAREL. Such a product is similar to EXPAREL in that it also extends the duration of effect of bupivacaine, but achieves this clinical outcome using a completely different drug delivery system compared to our DepoFoam drug delivery technology.

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The number of patents and patent applications covering products in the same field as EXPAREL indicates that competitors have sought to develop and may seek to market competing formulations that may not be covered by our patents and patent applications. The commercial opportunity for EXPAREL could be significantly harmed if competitors are able to develop and commercialize alternative formulations of bupivacaine that are long acting but outside the scope of our patents.

If EXPAREL is approved by the FDA, one or more third parties may challenge the patents covering this product, which could result in the invalidation or unenforceability of some or all of the relevant patent claims. For example, if a third party files an Abbreviated New Drug Application, or ANDA, for a generic drug product containing bupivacaine and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book with respect to our NDA for EXPAREL; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third-party's generic drug product. A certification that the new product will not infringe the Orange Book-listed patents for EXPAREL, or that such patents are invalid, is called a paragraph IV certification. If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third-party's ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third-party's ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party. If we do not file a patent infringement lawsuit within the required 45-day period, the third-party's ANDA will not be subject to the 30-month stay. Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business, and may result in unfavorable results that could adversely impact our ability to prevent third parties from competing with our products.

***Because it is difficult and costly to protect our proprietary rights, we may not be able to ensure their protection and all patents will eventually expire.***

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for EXPAREL, DepoCyt(e), DepoDur, DepoFoam and for any other product candidates that we may develop, license or acquire and the methods we use to manufacture them, as well as successfully defending these patents and trade secrets against third-party challenges. We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical or biotechnology patents has emerged to date in the United States. The patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

The degree of future protection for our proprietary rights is uncertain, because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we may not have been the first to make the inventions covered by each of our pending patent applications and issued patents;
- we may not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our product candidates or technologies;

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- it is possible that none of the pending patent applications will result in issued patents;
- the issued patents covering our product candidates may not provide a basis for commercially viable active products, may not provide us with any competitive advantages, or may be challenged by third parties;
- we may not develop additional proprietary technologies that are patentable; or
- patents of others may have an adverse effect on our business.

Patent applications in the United States are maintained in confidence for at least 18 months after their earliest effective filing date. Consequently, we cannot be certain we were the first to invent or the first to file patent applications on EXPAREL, our DepoFoam drug delivery technology or any other product candidates that we may develop, license or acquire. In the event that a third party has also filed a U.S. patent application relating to our product candidates or a similar invention, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial and it is possible that our efforts would be unsuccessful, resulting in a material adverse effect on our U.S. patent position. Furthermore, we may not have identified all United States and foreign patents or published applications that affect our business either by blocking our ability to commercialize our drugs or by covering similar technologies that affect our drug market.

In addition, some countries, including many in Europe, do not grant patent claims directed to methods of treating humans, and in these countries patent protection may not be available at all to protect our product candidates. Even if patents issue, we cannot guarantee that the claims of those patents will be valid and enforceable or provide us with any significant protection against competitive products, or otherwise be commercially valuable to us.

Some of our older patents have already expired. In the cases of DepoCyt(e) and DepoDur, key patents providing protection in Europe have expired. In the case of EXPAREL, while pending patent applications, if granted, would provide protection for EXPAREL in Europe and the United States through November 2018, an existing formulation patent for EXPAREL will expire in November 2013. Once our patents covering EXPAREL have expired, we are more reliant on trade secrets to protect against generic competition.

We also rely on trade secrets to protect our technology, particularly where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. While we use reasonable efforts to protect our trade secrets, our licensors, employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If we fail to obtain or maintain patent protection or trade secret protection for EXPAREL, DepoCyt(e), DepoDur, DepoFoam or any other product candidate that we may develop, license or acquire, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and achieve profitability.

***If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in any litigation would harm our business.***

Our ability to develop, manufacture, market and sell EXPAREL, our DepoFoam drug delivery technology or any other product candidates that we may develop, license or acquire depends upon our ability to avoid infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the general fields of pain management and cancer

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treatment and cover the use of numerous compounds and formulations in our targeted markets. Because of the uncertainty inherent in any patent or other litigation involving proprietary rights, we and our licensors may not be successful in defending intellectual property claims by third parties, which could have a material adverse affect on our results of operations. Regardless of the outcome of any litigation, defending the litigation may be expensive, time-consuming and distracting to management. In addition, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that EXPAREL, DepoCyt(e) or DepoDur may infringe. There could also be existing patents of which we are not aware that EXPAREL, DepoCyt(e) or DepoDur may inadvertently infringe.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third party claims that we infringe on their products or technology, we could face a number of issues, including:

- infringement and other intellectual property claims which, with or without merit, can be expensive and time consuming to litigate and can divert management's attention from our core business;
- substantial damages for past infringement which we may have to pay if a court decides that our product infringes on a competitor's patent;
- a court prohibiting us from selling or licensing our product unless the patent holder licenses the patent to us, which it would not be required to do;
- if a license is available from a patent holder, we may have to pay substantial royalties or grant cross licenses to our patents; and
- redesigning our processes so they do not infringe, which may not be possible or could require substantial funds and time.

***We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.***

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

**Risks Related to Our Financial Condition and Capital Requirements**

***Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing.***

Our independent registered public accounting firm stated that our financial statements for the year ended December 31, 2009 were prepared assuming that we would continue as a going concern, and that certain matters raise substantial doubt about our ability to continue as a going concern. Such doubts are based on our recurring losses and our working capital and stockholders' deficits. We continue to experience losses. Our ability to continue as a going concern is subject to our ability to generate a profit and/or obtain necessary funding from outside sources, including by the sale of our securities, obtaining loans from financial institutions or other financing arrangements, where possible. Our continued losses and "going concern" audit report increase the difficulty of our meeting such goals and our efforts to continue as a going concern may not prove successful.

***We have incurred significant losses since our inception and anticipate that we will incur continued losses for the foreseeable future.***

We are an emerging specialty pharmaceutical company with a limited operating history. We have focused primarily on developing EXPAREL with the goal of achieving regulatory approval. We have incurred losses in



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each year since our inception in December 2006, including net losses of \$31.7 million, \$41.9 million and \$36.2 million for the years ended December 31, 2009, 2008 and 2007, respectively. As of September 30, 2010, we had an accumulated deficit of \$129.9 million. These losses, among other things, have had, and will continue to have, an adverse effect on our stockholders' equity (deficit) and working capital (deficit). We incurred increased pre-commercialization expenses during 2009 as we prepared for the potential market launch of EXPAREL, and we expect to incur significant sales, marketing and manufacturing expenses, as well as continued development expenses related to the commercialization of EXPAREL, if approved by the FDA. As a result, we expect to continue to incur significant losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

***We may never become profitable.***

Our ability to become profitable depends upon our ability to generate revenue from EXPAREL and to continue to generate revenue from DepoCyt(e) and DepoDur. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- continue to manufacture DepoCyt(e) and DepoDur for sale by our commercial partners;
- obtain regulatory approval for EXPAREL, or any other product candidates that we may develop, license or acquire;
- manufacture commercial quantities of EXPAREL, if approved, at acceptable cost levels; and
- develop a commercial organization and the supporting infrastructure required to successfully market and sell EXPAREL, if it is approved.

If EXPAREL is approved for commercial sale, we anticipate incurring significant costs associated with its commercialization. We also do not anticipate that we will achieve profitability for a period of time after generating material revenues, if ever. If we are unable to generate revenues, we will not become profitable and may be unable to continue operations without continued funding.

***Under our financing arrangement with Paul Capital, upon the occurrence of certain events, Paul Capital may require us to repurchase the right to receive royalty payments that we assigned to it, or may foreclose on certain assets that secure our obligations to Paul Capital. Any exercise by Paul Capital of its right to cause us to repurchase the assigned right or any foreclosure by Paul Capital would adversely affect our results of operations and our financial condition.***

On March 23, 2007, we entered into the Amended and Restated Royalty Interests Assignment Agreement with affiliates of Paul Capital, pursuant to which we assigned to Paul Capital the right to receive a portion of our royalty payments from DepoCyt(e) and DepoDur. To secure our obligations to Paul Capital, we granted Paul Capital a security interest in collateral which includes the royalty payments we are entitled to receive with respect to sales of DepoCyt(e) and DepoDur, as well as to bank accounts to which such payments are deposited. Under our arrangement with Paul Capital, upon the occurrence of certain events, or the put events, including if we experience a change of control, we or our subsidiary undergo certain bankruptcy events, transfer any or substantially all of our rights in DepoCyt(e) or DepoDur, transfer all or substantially all of our assets, breach certain of the covenants, representations or warranties under the Amended and Restated Royalty Interests Assignment Agreement, or sales of DepoCyt(e) or DepoDur are suspended due to an injunction or if we elect to suspend sales of DepoCyt(e) or DepoDur as a result of a lawsuit filed by certain third parties, Paul Capital may (i) require us to repurchase the rights we assigned to it at a cash price equal to (a) 50% of all cumulative payments made by us to Paul Capital under the Amended and Restated Royalty Interests Assignment Agreement during the preceding 24 months, multiplied by (b) the number of days from the date of Paul Capital's exercise of such option until December 31, 2014, divided by 365. Any exercise by Paul Capital of its right to cause us to repurchase the assigned right or any foreclosure by Paul Capital would adversely affect our results of operations and our financial condition.

***Our debt obligations expose us to risks that could adversely affect our business, operating results and financial condition.***

We have a substantial level of debt. As of September 30, 2010, after giving effect to the Hercules Credit Facility and the application of the proceeds therefrom, we had \$66.25 million in aggregate principal amount of indebtedness outstanding, not including our obligation under the Amended and Restated Royalty Interests Assignment Agreement with Paul Capital. Approximately \$40.0 million of outstanding indebtedness will convert to common stock upon the completion of this offering, and \$26.25 million in aggregate principal amount of our outstanding indebtedness will not convert to common stock upon the completion of this offering and remain outstanding. The level and nature of our indebtedness, among other things, could:

- make it difficult for us to make payments on our outstanding debt from time to time or to refinance it;
- make it difficult for us to obtain any necessary financing in the future for working capital, capital expenditures, debt service, product and company acquisitions or general corporate purposes;
- limit our flexibility in planning for or reacting to changes in our business including life cycle management;
- reduce funds available for use in our operations;
- impair our ability to incur additional debt because of financial and other restrictive covenants;
- make us more vulnerable in the event of a downturn in our business;
- place us at a possible competitive disadvantage relative to less leveraged competitors and competitors that have better access to capital resources;
- restrict the operations of our business as a result of provisions in the Amended and Restated Royalty Interests Assignment Agreement with Paul Capital that restrict our ability to (i) amend, waive any rights under, or terminate any material agreements relating to DepoCyt(e) and DepoDur, (ii) enter into any new agreement or amend or fail to exercise any of our material rights under existing agreements that would materially adversely affect Paul Capital's royalty interest, and (iii) sell any material assets related to DepoCyt(e) or DepoDur; or
- impair our ability to merge or otherwise effect the sale of the Company due to the right of the holders of certain of our indebtedness to accelerate the maturity date of the indebtedness in the event of a change of control of the Company.

We will need to raise additional capital to pay our indebtedness as it comes due. If we are unable to obtain funds necessary to make required payments, or if we fail to comply with the various requirements of our indebtedness, we would be in default, which would permit the holders of our indebtedness to accelerate the maturity of the indebtedness and could cause defaults under any indebtedness we may incur in the future. Any default under our indebtedness would have a material adverse effect on our business, operating results and financial condition. If we are unable to refinance or repay our indebtedness as it becomes due, we may become insolvent and be unable to continue operations.

For example, our loan and security agreement governing the credit facility with Hercules Technology Growth Capital, Inc. and Hercules Technology III, L.P., or the Hercules Credit Facility, contains a number of affirmative and restrictive covenants, including reporting requirements and other collateral limitations, certain limitations on liens and indebtedness, dispositions, mergers and acquisitions, restricted payments and investments, corporate changes and limitations on waivers and amendments to certain agreements, our organizational documents, and documents relating to debt that is subordinate to our obligations under the Hercules Credit Facility. Our failure to comply with the covenants in the loan and security agreement governing the Hercules Credit Facility could result in an event of default that, if not cured or waived, could result in the acceleration of all or a substantial portion of our debt and potential foreclosure on the assets pledged to secure the debt.

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***Our short operating history makes it difficult to evaluate our business and prospects.***

We were incorporated in December 2006 and have only been conducting operations with respect to EXPAREL since March 2007. Our operations to date have been limited to organizing and staffing our company, conducting product development activities, including clinical trials and manufacturing development activities, for EXPAREL and manufacturing and related activities for DepoCyt(e) and DepoDur. Further, in 2010 we began to establish our commercial infrastructure for EXPAREL. We have not yet demonstrated an ability to obtain regulatory approval for or successfully commercialize a product candidate. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

***We will need additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.***

Developing products for use in the hospital setting, conducting clinical trials, establishing outsourced manufacturing relationships and successfully manufacturing and marketing drugs that we may develop is expensive. We will need to raise additional capital to:

- fund our operations and continue our efforts to hire additional personnel and build a commercial infrastructure to prepare for the commercialization of EXPAREL, if approved by the FDA;
- qualify and outsource the commercial-scale manufacturing of our products under cGMP; and
- in-license and develop additional product candidates.

Throughout 2009 and 2010, we generated net proceeds of approximately \$40 million through several private placements of secured and unsecured notes and proceeds of approximately \$26.25 million under the Hercules Credit Facility. We believe that with our currently available cash and cash equivalent balance, along with the net proceeds from this offering, we have sufficient funds to meet our projected operating requirements and service our indebtedness for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong and we could spend our available financial resources faster than we currently expect. Further, we may not have sufficient financial resources to meet all of our objectives if EXPAREL is approved, which could require us to postpone, scale back or eliminate some, or all, of these objectives, including our potential launch activities. Our future funding requirements will depend on many factors, including, but not limited to:

- the potential for delays in our efforts to seek regulatory approval for EXPAREL, and any costs associated with such delays;
- the costs of establishing a commercial organization to sell, market and distribute EXPAREL;
- the rate of progress and costs of our efforts to prepare for the submission of an NDA for any product candidates that we may in-license or acquire in the future, and the potential that we may need to conduct additional clinical trials to support applications for regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates, including any such costs we may be required to expend if our licensors are unwilling or unable to do so;
- the cost and timing of manufacturing sufficient supplies of EXPAREL in preparation for commercialization;
- the effect of competing technological and market developments;
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish;
- if EXPAREL is approved, the potential that we may be required to file a lawsuit to defend our patent rights or regulatory exclusivities from challenges by companies seeking to market generic versions of extended-release liposome injection of bupivacaine; and
- the success of the commercialization of EXPAREL.

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Future capital requirements will also depend on the extent to which we acquire or invest in additional complementary businesses, products and technologies.

Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings, product supply revenue and royalties, corporate collaboration and licensing arrangements, as well as through interest income earned on cash and investment balances. We cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate, one or more of our development programs or our commercialization efforts.

***Our quarterly operating results may fluctuate significantly.***

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- whether the FDA requires us to complete additional, unanticipated studies, tests or other activities prior to approving EXPAREL, which would likely further delay any such approval;
- if EXPAREL is approved, our ability to establish the necessary commercial infrastructure to launch this product candidate without substantial delays, including hiring sales and marketing personnel and contracting with third parties for warehousing, distribution, cash collection and related commercial activities;
- maintaining our existing manufacturing facilities and expanding our manufacturing capacity, including installing specialized processing equipment for the manufacturing of EXPAREL;
- our execution of other collaborative, licensing or similar arrangements and the timing of payments we may make or receive under these arrangements;
- variations in the level of expenses related to our future development programs;
- any product liability or intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting EXPAREL or the product candidates of our competitors; and
- if EXPAREL receives regulatory approval, the level of underlying hospital demand for this product candidate and wholesaler buying patterns.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

***Raising additional funds by issuing securities may cause dilution to existing stockholders and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.***

To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership will be diluted. If we raise additional funds through licensing arrangements, it may be necessary to relinquish potentially valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. Any debt financing we enter into may involve covenants that restrict our operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments.

***We will incur significant increased costs as a result of operating as a public company.***

As a public company, we will incur significant legal, accounting, insurance and other expenses that we have not incurred as a private company, including costs associated with public company reporting requirements. We

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also have incurred and will incur costs associated with complying with the requirements of the Sarbanes-Oxley Act of 2002 and related rules implemented by the Securities and Exchange Commission and The NASDAQ Global Market. The expenses incurred by public companies generally for reporting and corporate governance purposes have been increasing. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any degree of certainty. These laws and regulations could also make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as our executive officers. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions and other regulatory action and potentially civil litigation.

***Compliance with Section 404 of the Sarbanes-Oxley Act of 2002 will require our management to devote substantial time to new compliance initiatives, and if our independent registered public accounting firm is unable to provide an unqualified attestation report on our internal controls, our stock price could be adversely affected.***

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will be required to furnish a report by our management on, and our independent registered public accounting firm to attest to, the effectiveness of our internal control over financial reporting. We have not been subject to these requirements in the past. The internal control report must contain (i) a statement of management's responsibility for establishing and maintaining adequate internal control over financial reporting, (ii) a statement identifying the framework used by management to conduct the required evaluation of the effectiveness of our internal control over financial reporting, (iii) management's assessment of the effectiveness of our internal control over financial reporting as of the end of our most recent fiscal year, including a statement as to whether or not internal control over financial reporting is effective, and (iv) a statement that our independent registered public accounting firm has issued an attestation report on internal control over financial reporting.

To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, hire additional employees for our finance and audit functions, potentially engage outside consultants and adopt a detailed work plan to (i) assess and document the adequacy of internal control over financial reporting, (ii) continue steps to improve control processes where appropriate, (iii) validate through testing that controls are functioning as documented, and (iv) implement a continuous reporting and improvement process for internal control over financial reporting. In addition, in connection with the attestation process by our independent registered public accounting firm, we may encounter problems or delays in completing the implementation of any requested improvements and receiving a favorable attestation. If we cannot favorably assess the effectiveness of our internal control over financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified attestation report on our internal controls, investors could lose confidence in our financial information and our stock price could decline.

***The use of our net operating loss carryforwards and research tax credits may be limited.***

Our net operating loss carryforwards and research and development tax credits may expire and not be used. As of December 31, 2009, we had federal and state net operating loss carryforwards of approximately \$82.4 million and \$59.0 million, respectively, and we also had federal and state research and development tax credit carryforwards of approximately \$2.2 million and \$0.9 million, respectively. Our net operating loss carryforwards will begin expiring in 2026 for federal purposes and 2016 for state purposes if we have not used them prior to that time, and our federal tax credits will begin expiring in 2027 unless previously used. Our state tax credits carryforward indefinitely. Additionally, our ability to use any net operating loss and credit carryforwards to offset taxable income or tax, respectively, in the future will be limited under Internal Revenue

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Code Sections 382 and 383 if we have a cumulative change in ownership of more than 50% within a three-year period. The completion of this offering, together with private placements and other transactions that have occurred, may trigger, or may have already triggered such an ownership change. In addition, since we will need to raise substantial additional funding to finance our operations, we may undergo further ownership changes in the future. Following the Acquisition, we have not completed an analysis as to whether such a change of ownership has occurred, but in such an event, we will be limited regarding the amount of net operating loss carryforwards and research tax credits that could be utilized annually in the future to offset taxable income or tax, respectively. Any such annual limitation may significantly reduce the utilization of the net operating loss carryforwards and research tax credits before they expire. In addition, California and certain states have suspended use of net operating loss carryforwards for certain taxable years, and other states are considering similar measures. As a result, we may incur higher state income tax expense in the future. Depending on our future tax position, continued suspension of our ability to use net operating loss carryforwards in states in which we are subject to income tax could have an adverse impact on our results of operations and financial condition.

***Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic downturn.***

Our results of operations could be materially negatively affected by economic conditions generally, both in the United States and elsewhere around the world. Continuing concerns over inflation, energy costs, geopolitical issues, the availability and cost of credit, the U.S. mortgage market and a declining residential real estate market in the United States have contributed to increased volatility and diminished expectations for the economy and the markets going forward. These factors, combined with volatile oil prices, declining business and consumer confidence and increased unemployment, have precipitated an economic recession and fears of a possible depression. Domestic and international equity markets continue to experience heightened volatility and turmoil. These events and the continuing market upheavals may have an adverse effect on us. In the event of a continuing market downturn, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may further decline.

**Risks Related to this Offering and Ownership of Our Common Stock**

***There is no established public market for our stock and a public market may not be obtained or be liquid and therefore you may not be able to sell your shares.***

Prior to this offering, there has not been a public market for our common stock. If an active trading market for our common stock does not develop following this offering, you may not be able to sell your shares quickly or at the market price. The initial public offering price for the shares will be determined by negotiations between us and representatives of the underwriters and may not be indicative of prices that will prevail in the subsequent trading market.

***The market price of our common stock may be highly volatile, and you may not be able to resell your shares at or above the initial public offering price.***

The trading price of our common stock is likely to be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- any delay in the FDA approving our NDA for EXPAREL;
- the commercial success of EXPAREL, if approved by the FDA;
- results of clinical trials of our product candidates or those of our competitors;
- changes or developments in laws or regulations applicable to our product candidates;
- introduction of competitive products or technologies;
- failure to meet or exceed financial projections we provide to the public;

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- actual or anticipated variations in quarterly operating results;
- failure to meet or exceed the estimates and projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- general economic and market conditions and overall fluctuations in U.S. equity markets;
- developments concerning our sources of manufacturing supply;
- disputes or other developments relating to patents or other proprietary rights;
- additions or departures of key scientific or management personnel;
- issuances of debt, equity or convertible securities;
- changes in the market valuations of similar companies; and
- the other factors described in this “Risk Factors” section.

In addition, the stock market in general, and the market for small pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

***Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.***

Upon completion of this offering, our executive officers, directors and 5% stockholders and their affiliates will beneficially own approximately % of our outstanding voting stock, excluding any shares of common stock that our existing stockholders may purchase in this offering. As a result, these stockholders will have significant influence and may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This concentration of ownership could delay or prevent any acquisition of our company on terms that other stockholders may desire.

***If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.***

The initial public offering price is substantially higher than the net tangible book value per share of our common stock. Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing common stock in this offering will incur immediate dilution of \$ per share. Further, investors purchasing common stock in this offering will contribute approximately % of the total amount invested by stockholders since our inception, but will own only approximately % of the shares of our common stock outstanding.

This dilution is due to the substantially lower price paid by our investors who purchased shares prior to this offering as compared to the price offered to the public in this offering, and the exercise of stock options granted to our employees. In addition, as of November 30, 2010, options to purchase 16,178,011 shares of our common stock at a weighted average exercise price of \$0.15 per share and warrants exercisable for up to 1,700,000 shares of our common stock at weighted average exercise price of \$0.25 per share and up to 2,175,000 shares of our Series A convertible preferred stock, assuming that the warrant issued in connection with the Hercules Credit Facility is exercised for our Series A convertible preferred stock, at weighted average exercise price of \$1.25 per share were outstanding. The exercise of any of these options or warrants would result in additional dilution. As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of a liquidation or sale of our company.

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***Sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to fall.***

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise adequate capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

Substantially all of our existing stockholders are subject to lock-up agreements with the underwriters of this offering that restrict the stockholders' ability to transfer shares of our common stock for at least 180 days from the date of this prospectus, subject to certain exceptions. The lock-up agreements limit the number of shares of common stock that may be sold immediately following the public offering. Subject to certain limitations, 108,874,256 shares will become eligible for sale upon expiration of the lock-up period. In addition, shares issued or issuable upon exercise of options and warrants vested as of the expiration of the lock-up period will be eligible for sale at that time. Sales of stock by these stockholders could have a material adverse effect on the market price of our common stock.

Certain holders of shares of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended, or the Securities Act, subject to the 180-day lock-up arrangement described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by our affiliates as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

***Our management will have broad discretion in the use of the net proceeds from this offering and may not use them effectively.***

Our management will have broad discretion in the application of the net proceeds from this offering and our stockholders will not have the opportunity as part of their investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing instruments and U.S. government securities. These investments may not yield a favorable return to our stockholders.

***Because we do not intend to pay dividends on our common stock, your returns will be limited to any increase in the value of our stock.***

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business and do not anticipate declaring or paying any cash dividends on our common stock for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock, if any.

***Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our restated certificate of incorporation and our bylaws that will become effective following the completion of this offering, as well as provisions of the Delaware General Corporation Law, or DGCL, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;



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- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the DGCL, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders.

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this prospectus regarding our strategy, future operations, regulatory process, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this prospectus include, among other things, statements about:

- our plans to develop and commercialize EXPAREL;
- our plans to continue to manufacture and provide support services for our commercial partners who have licensed DepoCyt(e) and DepoDur;
- the timing of, and our ability to obtain, regulatory approval of EXPAREL;
- the timing of our anticipated commercial launch of EXPAREL;
- the rate and degree of market acceptance of EXPAREL;
- the size and growth of the potential markets for EXPAREL and our ability to serve those markets;
- our plans to expand the indications of EXPAREL to include nerve block and epidural administration;
- our commercialization and marketing capabilities;
- regulatory developments in the United States and foreign countries;
- our ability to obtain and maintain intellectual property protection;
- the accuracy of our estimates regarding expenses and capital requirements; and
- the loss of key scientific or management personnel.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this prospectus, particularly in the “Risk Factors” section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make.

You should read this prospectus and the documents that we have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

## USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately \$ \_\_\_\_\_ million (or approximately \$ \_\_\_\_\_ million if the underwriters exercise their option to purchase additional shares from us in full), based on an assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the estimated price range shown on the cover of this prospectus, and after deducting the estimated underwriting discounts and commissions and offering expenses payable by us.

A \$1.00 increase or decrease in the assumed initial public offering price of \$ \_\_\_\_\_ would increase or decrease the net proceeds to us from this offering by \$ \_\_\_\_\_ million, after deducting the estimated underwriting discounts and commissions and offering expenses payable by us.

We intend to use the net proceeds from this offering as follows:

- up to \$ \_\_\_\_\_ million through the fourth quarter of 2011 for the planned manufacture and commercialization of EXPAREL in the United States;
- up to \$ \_\_\_\_\_ million through the fourth quarter of 2011 for the development of EXPAREL for nerve block and epidural administration, which we believe allows us to complete Phase 2 clinical trials and begin Phase 3 clinical trials of EXPAREL for nerve block and potentially begin a Phase 2 clinical trial of EXPAREL for epidural administration; and
- the balance for working capital and other general corporate purposes, which may include the acquisition or licensing of other products or technologies or the acquisition of other businesses in the biotechnology or specialty pharmaceuticals industry.

The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including:

- the timing and outcome of the FDA's review of the NDA for EXPAREL;
- the extent to which the FDA may require us to perform additional clinical trials for EXPAREL;
- the timing and success of this offering;
- the costs of our commercialization activities for EXPAREL, if it is approved by the FDA;
- the cost and timing of expanding our manufacturing facilities and purchasing manufacturing and other capital equipment for EXPAREL and our other product candidates;
- the scope, progress, results and costs of development for additional indications for EXPAREL and for our other product candidates;
- the cost, timing and outcome of regulatory review of our other product candidates;
- the extent to which we acquire or invest in products, businesses and technologies;
- the extent to which we choose to establish collaboration, co-promotion, distribution or other similar agreements for product candidates;
- the costs of preparing, submitting and prosecuting patent applications and maintaining, enforcing and defending intellectual property claims; and
- any unforeseen or underestimated cash needs.

We therefore cannot estimate the amount of net proceeds to be used for all of the purposes described above. We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of net proceeds.

Following this offering, we believe that our available funds will be sufficient to complete the development of EXPAREL through FDA approval and to fund the expected commercial launch of EXPAREL in the United States in the fourth quarter of 2011. It is possible that we will not achieve the progress that we expect with respect to EXPAREL because the actual costs, timing of development and regulatory approval are difficult to predict and are subject to substantial risks and delays. We have no committed external sources of funds. To the extent that the net proceeds from this offering and our other capital resources are insufficient to complete clinical development of, obtain regulatory approval for, and, if approved, commercially launch EXPAREL, we will need

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to finance our cash needs through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

## **DIVIDEND POLICY**

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain earnings, if any, to finance the growth and development of our business. We do not expect to pay any cash dividends on our common stock in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, restrictions contained in current or future financing instruments, provisions of applicable law and other factors the board deems relevant. Our ability to pay dividends on our common stock is limited by the covenants of our loan and security agreement governing the Hercules Credit Facility and may be further restricted by the terms of any of our future indebtedness. See “Risk Factors—Risks Related to Our Financial Condition and Capital Requirements—Our debt obligations expose us to risks that could adversely affect our business, operating results and financial condition.”

## CAPITALIZATION

The following table sets forth our capitalization as of September 30, 2010:

- on an actual basis;
- on a pro forma basis to reflect (1) the automatic conversion of all outstanding shares of our Series A convertible preferred stock into common stock upon the completion of this offering, (2) the conversion of \$40.0 million aggregate principal amount and all accrued and unpaid interest on secured and unsecured notes held by certain of our stockholders into common stock upon the completion of this offering and (3) the one-for- reverse split of our common stock to be effected prior to the completion of this offering, (4) the filing of our restated certificate of incorporation prior to the completion of this offering; and
- on a pro forma as adjusted basis to reflect (1) the automatic conversion of all outstanding shares of our Series A convertible preferred stock into common stock upon the completion of this offering, (2) the conversion of \$40.0 million aggregate principal amount and all accrued and unpaid interest on secured and unsecured notes held by certain of our stockholders into common stock upon the completion of this offering, (3) the one-for- reverse split of our common stock to be effected prior to the completion of this offering, (4) the filing of our restated certificate of incorporation prior to the completion of this offering, and (5) our issuance and sale of shares of common stock in this offering at an assumed initial public offering price of \$ per share, the midpoint of the estimated price range shown on the cover of this prospectus, after deducting the estimated underwriting discount and offering expenses payable by us.

You should read this table together with our consolidated financial statements and the related notes included elsewhere in this prospectus and the “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Use of Proceeds” and “Selected Consolidated Financial Data.”

	As of September 30, 2010		
	Actual	Pro Forma (1)	Pro Forma As Adjusted
	(in thousands, except per share amounts)		
Cash and cash equivalents	\$ 13,851	\$ 28,851	\$
Related party debt, excluding current portion	\$ 42,652	\$ —	\$
Long-term debt, excluding current portion	11,250	26,250	
Royalty interest obligation, excluding current portion	3,410	3,410	
Total long-term debt	57,312	29,660	
Series A convertible preferred stock, \$0.001 par value: actual, 88,000,000 shares authorized, 68,000,000 shares issued and outstanding; pro forma and pro forma as adjusted, no shares authorized, issued and outstanding	68	—	
Common stock, \$0.001 par value: actual, 120,000,000 shares authorized, 6,183,213 shares issued and 6,171,755 shares outstanding; pro forma, 120,000,000 shares authorized, 109,291,553 shares issued and outstanding; pro forma as adjusted, shares authorized, shares issued and outstanding	6	109	
Additional paid-in capital	86,757	129,374	
Accumulated deficit	(129,867)	(129,867)	
Treasury stock, 11,458 shares at cost	(2)	(2)	
Total stockholders’ equity (deficit)	(43,038)	(386)	
Total capitalization	\$ 14,274	\$ 29,274	\$

- (1) Pro forma includes impact of \$26,250,000 of long-term debt borrowed after September 30, 2010 under the Hercules Credit Facility and the repayment in full of \$11,250,000 principal amount under the GECC Credit Facility.

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Each \$1.00 increase or decrease in the assumed initial public offering price of \$            would increase or decrease each of additional paid-in capital and total stockholders' equity in the pro forma as adjusted column by \$            million, assuming the number of shares offered by us, as set forth on the cover of this prospectus, remains the same and after deducting the estimated underwriting discount and offering expenses payable by us.

The table above does not include:

- 1,950,000 shares of common stock issuable upon the exercise of warrants outstanding and exercisable as of September 30, 2010, at a weighted average exercise price of \$0.38 per share;
- 16,182,011 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2010, at a weighted average exercise price of \$0.15 per share; and
- 1,246,984 shares of common stock available for future issuance under our equity compensation plans as of September 30, 2010.

## DILUTION

If you invest in our common stock, your interest will be diluted immediately to the extent of the difference between the initial public offering price per share you will pay in this offering and the pro forma as adjusted net tangible book value per share of our common stock after this offering. Our pro forma historical net tangible book value as of September 30, 2010 was \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share of common stock. Our pro forma net tangible book value per share set forth below represents our total tangible assets less total liabilities and Series A convertible preferred stock, divided by the number of shares of our common stock outstanding on September 30, 2010, after giving effect to the automatic conversion of all of our outstanding shares of Series A convertible preferred stock into shares of our common stock immediately prior to the completion of this offering and the conversion of \$40.0 million aggregate principal amount and all accrued and unpaid interest on secured and unsecured notes held by certain of our stockholders into common stock immediately prior to the completion of this offering.

After giving effect to our issuance and sale of shares of \_\_\_\_\_ common stock in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the estimated price range shown on the cover of this prospectus, after deducting the estimated underwriting discounts and commissions and offering expenses payable by us, the pro forma as adjusted net tangible book value as of September 30, 2010 would have been \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share. This represents an immediate increase in net tangible book value to existing stockholders of \$ \_\_\_\_\_ per share. The initial public offering price per share will significantly exceed the net tangible book value per share. Accordingly, new investors who purchase shares of common stock in this offering will suffer an immediate dilution of their investment of \$ \_\_\_\_\_ per share. The following table illustrates this per share dilution to the new investors purchasing shares of common stock in this offering without giving effect to the over-allotment option granted to the underwriters:

Assumed initial public offering price per share	\$ _____
Pro forma net tangible book value per share as of September 30, 2010	\$ _____
Increase per share attributable to sale of shares of common stock in this offering	_____
Pro forma as adjusted net tangible book value per share after the offering	_____
Dilution per share to new investors	\$ _____

Each \$1.00 increase or decrease in the assumed initial public offering price of \$ \_\_\_\_\_ per share would increase or decrease the pro forma net tangible book value by \$ \_\_\_\_\_ million, the pro forma net tangible book value per share after this offering by \$ \_\_\_\_\_ per share and the dilution in pro forma net tangible book value per share to investors in this offering by \$ \_\_\_\_\_ per share, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discount and offering expenses payable by us.

If the underwriters exercise their over-allotment option in full, the pro forma as adjusted net tangible book value will increase to \$ \_\_\_\_\_ per share, representing an immediate increase to existing stockholders of \$ \_\_\_\_\_ per share and an immediate dilution of \$ \_\_\_\_\_ per share to new investors. If any shares are issued upon exercise of outstanding options or warrants, you will experience further dilution.



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The following table summarizes, on a pro forma basis as of September 30, 2010, after giving effect to the conversion of all of our outstanding Series A convertible preferred stock into common stock, the differences between the number of shares of common stock purchased from us, the total consideration paid to us and the average price per share paid by existing stockholders and by new investors purchasing shares of common stock in this offering. The calculation below is based on an assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the estimated price range shown on the cover of this prospectus, before the deduction of the estimated underwriting discounts and commissions and offering expenses payable by us:

	<u>Shares Purchased</u>		<u>Total Consideration</u>		<u>Average</u>
	<u>Number</u>	<u>%</u>	<u>Amount</u>	<u>%</u>	<u>Price</u> <u>Per Share</u>
Existing stockholders		%	\$	%	\$
New investors					\$
Total		100%	\$	100%	

The number of shares purchased from us by existing stockholders is based on 109,291,553 shares of our common stock outstanding as of September 30, 2010 after giving effect to the automatic conversion of all of our outstanding shares of Series A convertible preferred stock into common stock upon the completion of this offering and the conversion of \$40.0 million aggregate principal amount and all accrued and unpaid interest on secured and unsecured notes held by certain of our stockholders into common stock upon the completion of this offering. This number excludes:

- 1,950,000 shares of common stock issuable upon the exercise of warrants outstanding and exercisable as of September 30, 2010, at a weighted average exercise price of \$0.38 per share;
- 16,182,011 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2010, at a weighted average exercise price of \$0.15 per share; and
- 1,246,984 shares of common stock available for future issuance under our equity compensation plans as of September 30, 2010.

If the underwriters exercise their option to purchase additional shares from us in full, the number of shares held by new investors will increase to \_\_\_\_\_, or \_\_\_\_\_ % of the total number of shares of common stock outstanding after this offering and the shares held by existing stockholders will decrease to \_\_\_\_\_, or \_\_\_\_\_ % of the total shares outstanding.

## SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data should be read together with our consolidated financial statements and accompanying notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this prospectus. The selected consolidated financial data in this section is not intended to replace our consolidated financial statements and the accompanying notes. Our historical results are not necessarily indicative of our future results.

- The selected consolidated financial data as of December 31, 2008 and 2009, and for the years ended December 31, 2007, 2008 and 2009 have been derived from our consolidated financial statements included elsewhere in this prospectus, which have been audited by J.H. Cohn LLP, an independent registered public accounting firm.
- The selected consolidated financial data as of September 30, 2010, and for the nine months ended September 30, 2009 and 2010, have been derived from our unaudited consolidated financial statements included elsewhere in this prospectus.
- The selected consolidated financial data as of December 31, 2007 have been derived from our consolidated financial statements not contained herein.
- The selected consolidated financial data as of December 31, 2005 and December 31, 2006, and for the years ended December 31, 2005 and December 31, 2006, and for the period from January 1, 2007 through March 23, 2007, have been derived from unaudited consolidated financial statements of the Predecessor, SkyePharma, Inc., not included in this prospectus.

The unaudited consolidated financial data include, in the opinion of our management, all adjustments, consisting only of normal recurring adjustments, that are necessary for a fair presentation of our financial position and results of operations for these periods. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period, and our results for any interim period are not necessarily indicative of results to be expected for a full fiscal year.

The term Predecessor refers to SkyePharma, Inc. prior to March 24, 2007, or the Acquisition Date, and the term Successor refers to Pacira Pharmaceuticals, Inc. and its consolidated subsidiaries. Our results of operations for the year ended December 31, 2007, while representing a full year for Pacira Pharmaceuticals, Inc., do not reflect the operations of PPI-California until March 24, 2007, after the Acquisition Date. We have presented the Predecessor for the period from January 1, 2007 through March 23, 2007, as we believe it best presents the continuity of operations of the Successor prior to the Acquisition. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations” for a discussion of the presentation of our results for the year ended December 31, 2007.

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Predecessor			Successor				
Year Ended December 31,		January 1, 2007 to March 23, 2007	Year Ended			Nine Months Ended	
2005	2006		December 31,		September 30,		
(unaudited)			2007	2008	2009	2009	2010
			(audited)			(unaudited)	

(in thousands, except share and per share data)

**Consolidated Statement of Operations Data:**

Revenues:								
Supply revenue	\$ 3,647	\$ 5,800	\$ 684	\$ 5,444	\$ 6,852	\$ 6,324	\$ 4,273	\$ 7,127
Royalties	1,813	2,784	500	2,388	3,648	4,044	2,906	2,693
Collaborative licensing and development revenue	13,630	3,088	204	509	3,425	4,638	3,543	2,551
Revenue from SkyePharma PLC	1,927	702	39	—	—	—	—	—
Total revenues	21,017	12,374	1,427	8,341	13,925	15,006	10,722	12,371
Operating expenses:								
Cost of revenues	15,312	15,782	2,825	9,492	17,463	12,301	8,823	10,168
Research and development	21,280	16,060	3,251	20,665	33,214	26,233	18,717	14,954
Selling, general and administrative	12,768	8,685	2,632	4,170	8,611	5,020	3,920	3,941
Acquired in-process research and development	—	—	—	12,400	—	—	—	—
Total operating expenses	49,360	40,527	8,708	46,727	59,288	43,554	31,460	29,063
(Loss) from operations:	(28,343)	(28,153)	(7,281)	(38,386)	(45,363)	(28,548)	(20,738)	(16,692)
Other income (expense)	1,525	(2,713)	(13)	16	(224)	367	353	100
Interest income (expense)								
Interest income	25	60	4	491	235	77	46	112
Interest (expense)	(8,485)	(11,221)	(2,265)	—	—	(1,723)	(990)	(2,577)
Royalty interest obligation	961	4,694	(1,486)	1,686	3,490	(1,880)	(1,407)	(1,048)
Net income (loss)	\$ (34,317)	\$ (37,333)	\$ (11,041)	\$ (36,193)	\$ (41,862)	\$ (31,707)	\$ (22,736)	\$ (20,105)
Net (loss) per share applicable to common stockholders								
—basic and diluted				\$ (7.24)	\$ (7.37)	\$ (5.14)	\$ (3.69)	\$ (3.26)
Weighted average number of common shares used in net (loss) per share calculation								
				5,000,000	5,682,481	6,163,884	6,161,112	6,174,576
Pro forma net (loss) per share								
—basic and diluted (unaudited)						\$ (0.33)		\$ (0.17)
Shares used in computing pro forma loss per share								
—basic and diluted (unaudited)						91,902,490		108,296,207

Predecessor		Successor			
December 31,		December 31,			September 30,
2005	2006	2007	2008	2009	2010
(unaudited)		(unaudited)	(audited)		(unaudited)

(in thousands)

**Consolidated Balance Sheet Data:**

Cash and cash equivalents	\$ 911	\$ 627	\$ 7,240	\$ 12,386	\$ 7,077	\$ 13,851
Working capital (deficit)	17,004	27,010	2,354	2,341	(1,868)	6,585
Total assets	61,698	63,188	39,157	50,541	43,954	52,756
Long-term debt	28,789	21,648	8,241	3,618	25,820	57,312
Convertible preferred stock, par value	—	—	36	68	68	68
Common stock, par value	—	—	5	6	6	6
Accumulated deficit	(282,423)	(319,756)	(36,193)	(78,055)	(109,762)	(129,867)
Total stockholders' equity (deficit)	\$ (163,867)	\$ (221,541)	\$ 8,937	\$ 7,490	\$ (22,949)	\$ (43,038)



## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes appearing at the end of this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read the "Risk Factors" section of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

### Overview

We are an emerging specialty pharmaceutical company focused on the development, commercialization and manufacture of proprietary pharmaceutical products, based on our proprietary DepoFoam drug delivery technology, for use in hospitals and ambulatory surgery centers. In September 2010, we filed an NDA for EXPAREL with the United States Food and Drug Administration, or FDA, using a 505(b)(2) application. Our clinical data demonstrates that EXPAREL provides analgesia for up to 72 hours post-surgery, compared with seven hours or less for bupivacaine. We are initially seeking approval for postsurgical analgesia by local administration into the surgical wound, or infiltration, a procedure commonly employed using bupivacaine. Under the Prescription Drug User Fee Act, or PDUFA, guidelines, the FDA has a goal of ten months from the date of NDA filing to make a decision regarding the approval of our filing. We are also pursuing several additional indications for EXPAREL and expect to submit a supplemental NDA, or sNDA, for nerve block and epidural administration. We currently intend to develop and commercialize EXPAREL and our other product candidates in the United States while out-licensing commercialization rights for other territories.

We were incorporated in Delaware under the name Blue Acquisition Corp. in December 2006 and changed our name to Pacira, Inc. in June 2007. In October 2010, we changed our name to Pacira Pharmaceuticals, Inc. Pacira Pharmaceuticals, Inc. is the holding company for our California operating subsidiary of the same name, which we refer to as PPI-California. On March 24, 2007, or the Acquisition Date, MPM Capital, Sanderling Ventures, OrbiMed Advisors, HBM BioVentures, the Foundation for Research and their co-investors, through Pacira Pharmaceuticals, Inc., acquired PPI-California, from SkyePharma Holding, Inc., which we refer to as the Acquisition. PPI-California was known as SkyePharma, Inc. prior to the Acquisition.

Our two marketed products, DepoCyt(e) and DepoDur, and our proprietary DepoFoam extended release drug delivery technology were acquired as part of the Acquisition. DepoCyt(e) is a sustained release liposomal formulation of the chemotherapeutic agent cytarabine and is indicated for the intrathecal treatment of lymphomatous meningitis. DepoCyt(e) was granted accelerated approval by the FDA in 1999 and full approval in 2007. DepoDur is an extended release injectable formulation of morphine indicated for epidural administration for the treatment of pain following major surgery. DepoDur was approved by the FDA in 2004.

Since inception, we have incurred significant operating losses. Our net loss was \$20.1 million for the nine months ended September 30, 2010, including research and development expenses of \$15.0 million. Our net loss was \$31.7 million for the year ended December 31, 2009, including research and development expenses of \$26.2 million. We do not expect our currently marketed products to generate revenue that is sufficient for us to achieve profitability because we expect to continue to incur significant expenses as we advance the development of EXPAREL and our other product candidates, seek FDA approval for our product candidates that successfully complete clinical trials and develop our sales force and marketing capabilities to prepare for their commercial launch. We also expect to incur additional expenses to add operational, financial and management information systems and personnel, including personnel to support our product development efforts and our obligations as a public reporting company. For us to become and remain profitable, we believe that we must succeed in commercializing EXPAREL or other product candidates with significant market potential.

## Financial Operations Overview

### Revenues

Our revenue derived from DepoCyt(e) and DepoDur, our products manufactured by us and sold by our commercial partners, is comprised of two components: supply revenue and royalties. Supply revenue is derived from a contractual supply price paid to us by our commercial partners. Royalties are recognized as the product is sold by our commercial partners and is typically calculated as a percentage of the net selling price, which is net of discounts, returns, and allowances incurred by our commercial partners. Accordingly, the primary factors that determine our revenues derived from DepoCyt(e) and DepoDur are:

- the level of orders submitted by our commercial partners;
- the level of prescription and institutional demand for our products;
- unit sales prices; and
- the amount of gross-to-net sales adjustments realized by our commercial partners.

We also generate collaborative licensing and development revenue from our collaborations with third parties who seek to use our DepoFoam technology to develop extended release formulations of their products and product candidates.

The following table sets forth a summary of our supply revenue, royalties and collaborative licensing and development revenue for the years ended December 31, 2007, 2008 and 2009, and the nine months ended September 30, 2009 and 2010.

	Year Ended December 31,			Nine Months Ended September 30,	
	2007	2008	2009	2009	2010
DepoCyt(e) <sup>(1)</sup>			(in thousands)		
Supply revenue	\$ 4,675	\$ 5,912	\$ 5,882	\$ 3,921	\$ 6,497
Royalties	2,276	3,195	3,708	2,652	2,470
	<u>6,951</u>	<u>9,107</u>	<u>9,590</u>	<u>6,573</u>	<u>8,967</u>
DepoDur <sup>(1)</sup>					
Supply revenue	769	940	442	352	630
Royalties	112	453	336	254	223
	<u>881</u>	<u>1,393</u>	<u>778</u>	<u>606</u>	<u>853</u>
Total DepoCyt(e) and DepoDur revenue <sup>(1)</sup>	7,832	10,500	10,368	7,179	9,820
Collaborative licensing and development revenue	509	3,425	4,638	3,543	2,551
Total revenue	<u>\$ 8,341</u>	<u>\$ 13,925</u>	<u>\$ 15,006</u>	<u>\$ 10,722</u>	<u>\$ 12,371</u>

<sup>(1)</sup> Total DepoCyt(e) and DepoDur revenue does not include collaborative licensing and development revenue related to DepoCyt(e) and DepoDur.

### Cost of Revenues

Cost of revenues consists of the costs associated with producing our products for our commercial partners and providing research and development services to our collaboration partners. In particular, our cost of revenues includes:

- manufacturing overhead and fixed costs associated with running two cGMP manufacturing facilities, including salaries and related costs of personnel involved with our manufacturing activities;
- allocated overhead, personnel conducting research and development, as well as research and development performed by outside contractors or consultants for our collaborative licensing and development activities;

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- royalties due to third parties on our revenues;
- packaging, testing, freight and shipping; and
- the cost of active pharmaceutical ingredients.

### ***Research and Development Expenses***

Our research and development expenses consist of expenses incurred in developing, testing, manufacturing and seeking regulatory approval of our product candidates, including:

- expenses associated with regulatory submissions, clinical trials and manufacturing, including additional expenses to prepare for the commercial manufacture of EXPAREL, such as the hiring and training of additional personnel;
- payments to third-party contract research organizations, contract laboratories and independent contractors;
- payments made to consultants who perform research and development on our behalf and assist us in the preparation of regulatory filings;
- payments made to third-party investigators who perform research and development on our behalf and clinical sites where such research and development is conducted;
- personnel related expenses, such as salaries, benefits, travel and other related expenses, including stock-based compensation;
- expenses incurred to maintain technology licenses; and
- facility, maintenance, and allocated rent, utilities, and depreciation and amortization, and other related expenses.

Clinical trial expenses for our product candidates are a significant component of our current research and development expenses. Product candidates in later stage clinical development, such as EXPAREL, generally have higher research and development expenses than those in earlier stages of development, primarily due to the increased size and duration of the clinical trials. We coordinate clinical trials through a number of contracted investigational sites and recognize the associated expense based on a number of factors, including actual and estimated subject enrollment and visits, direct pass-through costs and other clinical site fees.

From the Acquisition Date through September 30, 2010, we incurred research and development expenses of \$95.1 million, of which \$90.9 million is related to the development of EXPAREL. We incurred research and development expenses associated with the development of EXPAREL of \$14.2 million for the nine months ended September 30, 2010, \$25.2 million for the year ended December 31, 2009 and \$31.9 million for the year ended December 31, 2008.

We expect to incur additional research and development expenses as we accelerate the development of EXPAREL in additional indications. These expenditures are subject to numerous uncertainties regarding timing and cost to completion. Completion of clinical trials may take several years or more and the length of time generally varies according to the type, complexity, novelty and intended use of a product candidate. We are currently unable to determine our future research and development expenses related to EXPAREL because the timing and outcome of the FDA's review of the NDA for EXPAREL is not currently known and the requirements of any additional clinical trials of EXPAREL for additional indications has yet to be determined. The cost of clinical development may vary significantly due to factors such as the scope, rate of progress, expense and outcome of our clinical trials and other development activities.

We acquired in-process research and development projects as part of the Acquisition. The estimated fair value of in-process research and development projects, which had not reached technological feasibility at the

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Acquisition Date and which did not have an alternative future use, were immediately expensed. Accordingly, for the year ended December 31, 2007, we expensed \$12.4 million of acquired in-process research and development related to the Acquisition.

***Selling, General and Administrative Expenses***

Selling, general and administrative expenses consist primarily of salaries, benefits and other related costs, including stock-based compensation, for personnel serving in our executive, finance, accounting, legal, human resource, and sales and marketing functions. Our selling, general and administrative expenses also include facility and related costs not included in research and development expenses and cost of revenues, professional fees for legal, consulting, tax and accounting services, insurance, depreciation and general corporate expenses. We expect that our selling, general and administrative expenses will increase with the continued development and potential commercialization of our product candidates and increased expenses associated with us becoming a public company. Additionally, we plan to build a commercial infrastructure for the anticipated launch of EXPAREL and we currently plan to hire most of our sales force only if EXPAREL is approved by the FDA.

***Interest Income (Expense)***

Interest income (expense) consists of interest income, interest expense, and royalty interest obligation. Interest income consists of interest earned on our cash and cash equivalents, and amortization of discount on a note receivable from one of our commercial partners. Interest expense consists primarily of cash and non-cash interest costs related to our credit facility, our secured and unsecured notes issued to certain of our investors that we expect will convert into common stock upon completion of this offering, and negotiated rent deferral payments. Royalty interest obligation consists of our royalty payments made in connection with the amended and restated royalty interests assignment agreement, or the Amended and Restated Royalty Interests Assignment Agreement, with Royalty Securitization Trust I, an affiliate of Paul Capital Advisors, LLC, or Paul Capital.

We record our royalty interest obligation as a liability in our consolidated balance sheets in accordance with ASC 470-10-25, Sales of Future Revenues. We impute interest expense associated with this liability using the effective interest rate method. The effective interest rate may vary during the term of the agreement depending on a number of factors including the actual sales of DepoCyt(e) and DepoDur and a significant estimation, performed quarterly, of certain of our future cash flows related to these products during the remaining term of the Amended and Restated Royalty Interests Assignment Agreement which terminates on December 31, 2014. The effect of the change in the estimates is reflected in our consolidated statements of operations as interest income (expense). In addition, such cash flows are subject to foreign exchange movements related to sales of DepoCyt(e) and DepoDur denominated in currencies other than U.S. dollars.

***Critical Accounting Policies and Use of Estimates***

We have based our management's discussion and analysis of our financial condition and results of operations on our financial statements that have been prepared in accordance with generally accepted accounting principles, or GAAP, in the United States. The preparation of these financial statements requires us to make estimates that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to clinical trial expenses and stock-based compensation. We base our estimates on historical experience and on various other factors we believe to be appropriate under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully discussed in Note 2 to our audited consolidated financial statements included in this prospectus, we believe that the following accounting policies are critical to



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the process of making significant judgments and estimates in the preparation of our financial statements. We have reviewed these critical accounting policies and estimates with the audit committee of our board of directors.

**Revenue Recognition**

We recognize revenue in accordance with SEC Staff Accounting Bulletin, or SAB, No. 104, *Revenue Recognition*, and Statement of Financial Accounting Standards, or ASC 605, *Revenue Recognition*.

*Supply revenue.* We recognize supply revenue from products manufactured and supplied to our commercial partners, when the following four basic revenue recognition criteria under the related accounting guidance are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. Prior to the shipment of our manufactured products, we conduct initial product release and stability testing in accordance with cGMP. Our commercial partners can return the products within contracted specified timeframes if the products do not meet the applicable inspection tests. We estimate our return reserves based on our experience with historical return rates. Historically, our product returns have not been material.

*Royalties.* We recognize revenue from royalties based on our commercial partners' net sales of products. Royalties are recognized as earned in accordance with contract terms when they can be reasonably estimated and collectability is reasonably assured. Our commercial partners are obligated to report their net product sales and the resulting royalty due to us within 60 days from the end of each quarter. Based on historical product sales, royalty receipts and other relevant information, we accrue royalty revenue each quarter and subsequently true-up when we receive royalty reports from our commercial partners.

*Collaborative licensing and development revenue.* We recognize revenue from reimbursement received in connection with feasibility studies and development work for third parties who desire to utilize our DepoFoam extended release drug delivery technology for their products, when our contractual services are performed, provided collectability is reasonably assured. Our principal costs under these agreements include our personnel conducting research and development, and our allocated overhead, as well as research and development performed by outside contractors or consultants.

We recognize revenues from non-refundable up-front fees received under collaboration agreements ratably over the performance period as determined under the collaboration agreement (estimated development period in the case of development agreements, and contract period or longest patent life in the case of supply and distribution agreements). If the estimated performance period is subsequently modified, we will modify the period over which the up-front fee is recognized accordingly on a prospective basis. Upon termination of a collaboration agreement, any remaining non-refundable licensing fees received by us, which had been deferred, are generally recognized in full. All such recognized revenues are included in collaborative licensing and development revenue in our consolidated statements of operations.

We recognize revenue from milestone payments received under collaboration agreements when earned, provided that the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, we have no further performance obligations relating to the event, and collectability is reasonably assured. If these criteria are not met, we recognize milestone payments ratably over the remaining period of our performance obligations under the collaboration agreement.

**Research and Development Expenses**

We expense all research and development costs as incurred. We rely on third parties to conduct our preclinical and clinical studies and to provide services, including data management, statistical analysis and electronic compilation for our clinical trials. We track and record information regarding third-party research and development expenses for each study or trial that we conduct and recognize these expenses based on the

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estimated progress towards completion at the end of each reporting period. Factors we consider in preparing these estimates include the number of subjects enrolled in studies, milestones achieved and other criteria related to the efforts of our vendors. Historically, any adjustments we have made to these assumptions have not been material. Depending on the timing of payments to vendors and estimated services provided, we may record net prepaid or accrued expenses related to these costs.

We expense the manufacturing costs (labor and overhead) of our clinical supplies as incurred. To date, these expenses have not been material. Unused raw material for manufacturing clinical supplies is included in inventory and expensed when used.

### **Stock-Based Compensation**

We have adopted the fair value recognition provisions of Financial Accounting Standards Board Accounting Standards Codification, or ASC, 718 “*Accounting for Stock Based Compensation*” (formerly Statement of Financial Accounting Standards No. 123(R), Share-Based Payments), which we refer to as ASC 718, using the modified prospective transition method. The modified prospective transition method applies the provisions of ASC 718 to new awards and to awards modified, repurchased or cancelled after the adoption date. Additionally, compensation cost for the portion of the awards for which the requisite service has not been rendered that are outstanding as of the adoption date is recognized in the Statement of Operations over the remaining service period after the adoption date based on the award’s original estimate of fair value. All stock-based awards granted to non-employees are accounted for at their fair value in accordance with ASC 718, and ASC 505, “*Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services,*” under which compensation expense is generally recognized over the vesting period of the award. Determining the amount of stock-based compensation to be recorded requires us to develop estimates of fair values of stock options as of the grant date.

For the years ended December 31, 2007, 2008 and 2009, we recognized employee stock-based compensation expense of \$80,000, \$242,000 and \$524,000, respectively. The intrinsic value of all outstanding vested and non-vested stock-based compensation arrangements, based on the initial public offering price of \$        per share, is \$        million, based on 16,178,011 shares of our common stock issuable upon exercise of stock-based compensation arrangements outstanding at November 30, 2010 at a weighted average exercise price of \$0.15 per share.

We account for stock-based compensation by measuring and recognizing compensation expense for all stock-based payments made to employees and directors based on estimated grant date fair values. We use the straight-line method to allocate compensation cost to reporting periods over each optionee’s requisite service period, which is generally the vesting period. We estimate the fair value of our stock-based awards to employees and directors using the Black-Scholes option valuation model, or Black-Scholes model. The Black-Scholes model requires the input of subjective assumptions, including the expected stock price volatility, the calculation of expected term and the fair value of the underlying common stock on the date of grant, among other inputs.

The following table summarizes our assumptions used in the Black-Scholes model:

	Year Ended December 31,			Nine Months
	2007	2008	2009	Ended September 30, 2010
Expected volatility	75.1%	78.2%	82.0%	80.8%
Expected term (in years)	6.25	6.25	6.25	5.50 – 6.25
Risk-free interest rate	3.6% – 4.9%	1.9% – 3.8%	2.1% – 2.7%	1.7% – 2.8%
Expected dividend yield	0%	0%	0%	0%

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*Expected Volatility.* The expected volatility rate used to value stock option grants is based on volatilities of a peer group of similar companies whose share prices are publicly available. The peer group was developed based on companies in the pharmaceutical and biotechnology industry in a similar stage of development.

*Expected Term.* We elected to utilize the “simplified” method for “plain vanilla” options to estimate the expected term of stock option grants. Under this approach, the weighted average expected life is presumed to be the average of the vesting term and the contractual term of the option.

*Risk-Free Interest Rate.* The risk-free interest rate assumption was based on zero coupon U.S. Treasury instruments that had terms consistent with the expected term of our stock option grants.

*Expected Dividend Yield.* We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future.

The following table summarizes by grant date the number of shares of our common stock subject to options granted in 2007, 2008, 2009 and 2010 through the date of this prospectus and the associated per-share exercise prices.

Grant Date	Number of Options Granted	Per Share Exercise Price	Number of Options Exercised	Number of Options Cancelled	Number of Options Surrendered on March 24, 2009	Number of Options Outstanding
7/20/2007	3,887,250	\$ 0.15	(558,100) <sup>(1)</sup>	(1,917,415)	(1,253,958)	157,777
10/2/2007	109,000	0.15	(67,291)	(37,509)	—	4,200
12/6/2007	2,030,250	0.15	(500,510)	(20,490)	(1,500,000)	9,250
2/1/2008	482,870	0.15	—	(301,150)	(180,000)	1,720
4/17/2008	2,422,030	0.15	(52,937)	(1,074,154)	(1,050,000)	244,939
6/19/2008	615,000	0.20	(6,458)	(472,417)	(110,000)	26,125
6/27/2008	165,000	0.20	—	(30,000)	(135,000)	—
6/30/2008	10,000	0.25	—	(5,000)	—	5,000
7/14/2008	800,000	0.25	—	—	(800,000)	—
8/15/2008	272,000	0.25	—	(202,000)	(55,000)	15,000
9/30/2008	65,000	0.25	—	(10,000)	(55,000)	—
12/9/2008	53,000	0.25	—	(15,000)	—	38,000
4/16/2009	4,000	0.25	—	—	—	4,000
9/23/2009	4,000	0.25	—	—	—	4,000
3/3/2010	36,000	0.25	—	—	—	36,000
5/20/2010	55,000	0.25	—	—	—	55,000
9/2/2010	15,577,000	\$ 0.15	—	—	—	15,577,000
	<u>26,587,400</u>		<u>(1,185,296)<sup>(1)</sup></u>	<u>(4,085,135)</u>	<u>(5,138,958)</u>	<u>16,178,011</u>

(1) Includes 11,458 unvested shares that we repurchased, for a nominal amount, from a stockholder pursuant to the terms of the 2007 Plan. These shares are still available for issuance pursuant to the 2007 Plan.

The exercise price of options to purchase our common stock granted to our employees, directors and consultants was the fair value of our common stock on the date of grant. The fair value of our common stock was determined by our board of directors. Prior to this offering, there has been no public market for our common stock. Our board of directors determined the fair value of our common stock based on several factors, including:

- valuation reports with respect to estimates of the fair values of our common stock;
- the substantial amount of claims of our creditors that are required to be satisfied prior to any payments or distributions to holders of our Series A convertible preferred stock and common stock;

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- the aggregate principal amount of secured and unsecured indebtedness that is required to be discharged prior to any payments or distributions to holders of our Series A convertible preferred stock or common stock;
- the rights, preferences and privileges of our Series A convertible preferred stock relative to our common stock, including a substantial liquidation preference;
- the lack of marketability of our common stock;
- the price at which our Series A convertible preferred stock was sold;
- available data resulting from our clinical studies and development to date;
- our performance and stage of development;
- the likelihood of achieving a liquidity event for the shares of our common stock underlying these stock options, such as an initial public offering or sale of our company, given prevailing market conditions;
- the trading value of common stock of public companies comparable to us; and
- the sale prices of comparable acquisition transactions of public companies comparable to ours.

We obtained valuation reports with respect to estimates of the fair values of our common stock as follows:

- report dated June 27, 2007 for a valuation of our common stock as of April 30, 2007, or the April 2007 Report;
- report dated August 22, 2008 for a valuation of our common stock as of June 30, 2008, or the June 2008 Report; and
- report dated October 1, 2010 for a valuation of our common stock as of August 31, 2010, or the August 2010 Report.

In these reports, industry standard valuation methodologies were used to value our common stock, as described below. In estimating the fair value of our common stock, a probability weighting of the market approach and the income approach was used to first arrive at an enterprise value.

- The income approach is an estimate of the present value of the future monetary benefits expected to flow to the owners of a business. It requires a projection of the cash flows that the business is expected to generate over a forecast period and an estimate of the present value of cash flows beyond that period, which is referred to as residual value. These cash flows are converted to present value by means of discounting, using a rate of return that accounts for the time value of money and the appropriate degree of risks inherent in the business.
- The market approach encompasses (i) the comparable company approach and/or (ii) the recent transaction approach.
  - (i) The comparable company approach relies on an analysis of publicly traded companies similar in industry and/or business model to a company. This approach uses these comparable companies to develop relevant market multiples and ratios such as revenues, earnings before interest and taxes, or EBIT, earnings before interest, taxes, depreciation and amortization, or EBITDA, net income and/or tangible book value. These multiples and values are then applied to a company's results.
  - (ii) The recent transaction approach uses actual prices paid in merger and acquisition transactions for companies similar to a company. Exit multiples of total purchase prices paid to revenues, EBIT, EBITDA, net income and/or book value may be developed for each comparable transaction, if the data is available. These multiples are then applied to a company's latest twelve months and projected performance.

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Since no two companies are perfectly comparable, premiums or discounts may be applied to the subject company if its position in its industry is significantly different from the position of the comparable companies, or if its intangible attributes are significantly different.

After calculation of a company's enterprise value using these approaches, adjusting for cash and debt, the value of a share of common stock is then discounted for lack of marketability, or the inability to readily sell shares, which increases the owner's exposure to changing market conditions and increases the risk of ownership.

After arriving at an enterprise value, the enterprise value was then allocated, adjusting for cash and debt, to our different classes of equity using:

- the probability-weighted expected return method, or PWERM, whereby the value of our common stock was estimated based on an analysis of future values for the equity assuming various future outcomes including liquidity events; and
- the option pricing method, or OPM, whereby the rights of preferred and common stockholders are treated as equivalent to that of call options on any value of the enterprise above certain break points of value based upon the preferred stockholders' liquidation preferences, rights to participation and conversion, and thus, the value of the common stock can be determined by estimating the value of its portion of each of these call option rights.

For the PWERM method, the valuations considered the following scenarios for achieving shareholder liquidity:

- an initial public offering of our common stock, or an IPO;
- our sale at an equity value greater than the aggregate liquidation preference of the preferred stock;
- our sale or liquidation at an equity value equal to or less than the aggregate liquidation reference of the preferred stock; and
- our continued, long term operation as a private company.

In the IPO scenario, the comparable transactions method was applied under the market approach as provided in the AICPA Technical Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, or the AICPA Practice Aid. The selection of comparable companies included companies deemed comparable because of their focus on specialty pharmaceuticals, use of proprietary drug delivery technologies, stage of clinical trials, and size.

In the sale above liquidation preference scenario, the guideline transactions method was applied under the market approach as provided in the AICPA Practice Aid. The selection of transactions took into account the timing of the transactions and the characteristics of the acquired companies. Target companies were selected which were deemed comparable because of their focus on specialty pharmaceuticals, use of proprietary drug delivery technologies, stage of clinical trials, and size. In the liquidation scenario, a sale or liquidation of the company was assumed at an equity value equal to the aggregate liquidation preference of our preferred stock. In the private company scenario, it was assumed that we continued over the long term to operate as a private company. Future values for each scenario are converted to present value by applying a discount rate.

#### ***Options Granted from July 20, 2007 through April 17, 2008***

Our board of directors valued our common stock to be \$0.15 per share for options granted from July 20, 2007 through April 17, 2008. In determining the value of our common stock, our board of directors based its valuation, in part, on the April 2007 Report.

In determining the value of our common stock, the PWERM method was used as described above, employing four scenarios: an IPO, our sale at an equity value greater than the aggregate liquidation preference of

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our Series A convertible preferred stock, our sale or liquidation at an equity value equal to or less than the aggregate liquidation preference of the preferred stock, and our continued, long term operation as a private company. Future values for each scenario are converted to present value by applying a discount rate of 41.0%, arrived at by using a size-adjusted capital asset pricing model, or CAPM. It was determined that using the PWERM method, the value of our common stock was \$0.15 per share.

In addition, using the OPM method, our enterprise value was estimated employing a probability weighting of (i) the income approach, using discounted cash flows, a terminal value based on comparable publicly traded company revenue multiples and a risk-adjusted discount rate of 41.0%, (ii) the income approach, using discounted cash flows, a terminal value based on revenue multiples on comparable merger and acquisition transactions and a risk-adjusted discount rate of 41.0%, (iii) the market approach, using forward revenue multiples based on comparable publicly traded company revenue multiples, (iv) the market approach, using forward revenue multiples based on comparable merger and acquisition transactions and (v) the market approach, using the actual price paid in the Acquisition which occurred in March 2007. After determining our estimated enterprise value, it was then allocated among the various classes of our securities, including our Series A convertible preferred stock, common stock and options to purchase common stock using the Black-Scholes model. This allocation yielded an estimated value per share of our common stock of \$0.21, which was reduced by a discount for lack of marketability of 30.0%, resulting in an estimated value per share of \$0.15.

During this period, we granted options to purchase an aggregate of 8,931,400 shares of our common stock. As of November 30, 2010, options to purchase 417,886 of these shares of our common stock remain outstanding, options to purchase 1,178,838 of those shares were exercised and options to purchase 7,334,676 of these shares have been cancelled or surrendered. A portion of these options was cancelled as a result of employees and consultants terminating their service to us and not exercising the vested portion of their options prior to the expiration date. In addition, in March 2009, we adopted our company sale bonus plan which was amended and restated in March 2010, which is further described in “Executive Compensation—Company Sale Bonus Plan.” As a condition to becoming a participant under the Company Sale Bonus Plan, most of the participants under the plan, including all of our executive officers and non-employee directors, agreed to have their existing option grants cancelled in March 2009.

### ***Options Granted from June 19, 2008 through June 27, 2008***

Our board of directors valued our common stock to be \$0.20 per share for options granted from June 19, 2008 through June 27, 2008. This valuation was partly based on the valuation set forth in the April 2007 Report, the rights, preferences and privileges of our Series A convertible preferred stock relative to our common stock, the lack of marketability of our common stock and the price at which our Series A convertible preferred stock was sold.

During this period, options to purchase an aggregate of 780,000 shares of our common stock were granted. As of November 30, 2010, options to purchase only 26,125 of these shares of our common stock remain outstanding, options to purchase 6,458 of those shares were exercised and options to purchase 747,417 of these shares of our common stock have been cancelled or surrendered. These options were cancelled as a result of employees and consultants terminating their service to us and not exercising the vested portion of their options prior to the expiration date and the forfeiture of such options pursuant to the Company Sale Bonus Plan.

### ***Options Granted from June 30, 2008 through December 9, 2008***

Our board of directors valued our common stock to be \$0.25 per share for options granted from July 30, 2008 through December 9, 2008. Our board of directors based its valuation on the June 2008 Report. In determining the value of our common stock, the PWERM method was used as described above, employing six scenarios: an IPO in 2009, an IPO in 2010, an IPO in 2011, our sale at an equity value greater than the aggregate liquidation preference of our Series A convertible preferred stock, our liquidation, and continued, long term operation as a private company. Future values for each scenario are converted to present value by applying a

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discount rate of 30.0%, arrived at by using a size-adjusted CAPM. Using the PWERM method, the value of our common stock was \$0.25 per share.

This valuation reflects the following positive factor:

- we successfully enrolled our Phase 3 clinical trials for EXPAREL.

The positive factor set forth above was offset by:

- a sharp deterioration in financial markets with accompanying decreases in market capitalization of companies comparable to ours;
- increased risk of running out of cash as the proceeds from the Series A convertible preferred stock financing were becoming exhausted; and
- increased difficulty in raising equity financing with accompanying financing uncertainty.

The value of our common stock from April 2007 to June 2008 increased from \$0.15 per share to \$0.25 per share. The change in value is primarily the result of an increase in our estimated enterprise value, offset by an increase in assigned probability of our sale at an equity value equal to or less than the aggregate liquidation preference of our Series A convertible preferred stock.

The change reflects the following positive factors:

- license of U.S. and EU marketing rights to DepoDur;
- launch of DepoDur in Australia;
- implementation of an expanded Phase 3 clinical development plan for EXPAREL; and
- execution of a license and development agreement with our development partner, Amylin, resulting in an up-front milestone payment of \$8 million and the potential for significant future milestone and royalty payments.

The positive factors set forth above were partially offset by:

- a significant delay in the forecasted generation of material license and product revenues compared to our April 2007 forecast; and
- increased risk of running out of cash as the proceeds from the Series A convertible preferred stock financing were partially exhausted.

While no single factor listed above was specifically quantified or weighted greater than another in estimating our enterprise value, each was taken into account in calculating the discount rate for the discounted cash flow analysis, estimating the time to liquidity and the expense that would be required to achieve liquidity. A discount for lack of marketability of 22.9% was used for these options.

During this period, we granted options to purchase an aggregate of 1,200,000 shares of our common stock. As of September 30, 2010, options to purchase 58,000 of these shares of our common stock remain outstanding and options to purchase 1,142,000 of these shares have been cancelled or surrendered. A portion of these options was cancelled as a result of employees and consultants terminating their service to us and not exercising the vested portion of their options prior to the expiration date. In addition, in March 2009, we adopted our company sale bonus plan which was amended and restated in March 2010, which is further described in “Executive Compensation—Stock Option and Other Compensation Plans—Company Sale Bonus Plan.” As a condition to becoming a participant under the company sale bonus plan, most of the participants under the plan, including all of our executive officers and non-employee directors, agreed to have their existing option grants cancelled in March 2009.

***Options Granted from April 16, 2009 through May 20, 2010***

Our board of directors established an option exercise price of \$0.25 per share for options granted from April 16, 2009 through May 20, 2010. During this period, the valuation was partly based on the valuation set forth in the June 2008 Report, the substantial amount of new secured and unsecured indebtedness that is required to be discharged prior to any payments or distributions to holders of our Series A convertible preferred stock and common stock, the rights, preferences and privileges of our Series A convertible preferred stock relative to our common stock, including an aggregate \$85 million liquidation preference, the lack of marketability of our common stock and the price at which our Series A convertible preferred stock was sold.

During this period, our board of directors believed that the value of our common stock was at or below the value of \$0.25 per share as set forth in the June 2008 Report, because of the following negative factors:

- two of our three Phase 3 clinical trials of EXPAREL did not meet their primary endpoint of superiority over the comparator arm and we discontinued a third trial;
- the proceeds from the Series A convertible preferred stock financing were exhausted; and
- the incurrence of a substantial amount of new secured and unsecured indebtedness during this period that is required to be discharged prior to any payments or distributions to holders of our of our Series A convertible preferred stock and common stock.

These negative factors were partially offset by the fact that our two Phase 3 placebo controlled trials of EXPAREL met their primary endpoint in the fourth quarter of 2009.

While no single factor listed above was specifically quantified or weighted greater than another in estimating the company's enterprise value, each was taken into account in estimating the time to liquidity and the expense that would be required to achieve liquidity.

During this period, we granted options to purchase an aggregate of 99,000 shares of our common stock. As of November 30, 2010, all of these options remained outstanding.

***Options Granted on September 2, 2010***

Our board of directors valued our common stock to be \$0.15 per share for options granted on September 2, 2010, based on the August 2010 Report. In the August 2010 Report, the PWERM method was used employing four scenarios: an IPO early in 2011, an IPO in mid-2011, a merger or sale of the company or an out-license of our lead product candidate that results in an equity value greater than the aggregate liquidation preference of our Series A convertible preferred stock, and a sale of the company at an equity value equal to or less than the aggregate liquidation preference of our Series A convertible preferred stock. Future values for each scenario are converted to present value by applying a discount rate of 25.0%, based on returns to venture capitalist investors as set forth in the AICPA Practice Aid. Using the PWERM method, the value of our common stock at the valuation date was \$0.15 per share. A discount for lack of marketability of 20.0% was used for these options.

The change in value for our common stock to \$0.15 per share on September 2, 2010, as compared to the \$0.25 per share value as of June 2008, is primarily the result of a materially similar estimated enterprise value in September 2010 compared to the enterprise value in June 2008 and the incurrence of secured and unsecured indebtedness in the aggregate principal amount of \$51.25 million, \$9.38 million of such amount was incurred between May 20, 2010 and September 2, 2010.

On \_\_\_\_\_, 2011, we and the underwriters determined a preliminary range for the initial public offering price. The midpoint of the range was \$ \_\_\_\_\_ per share as compared to \$0.15 per share, which was based on the August 2010 Report. We note that, as is typical in initial public offerings, the preliminary range was not derived using a formal determination of fair value, but was determined based upon discussions between us



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and the underwriters. Among the factors considered in setting the preliminary range were prevailing market conditions and estimates of our business potential. In addition to this difference in purpose and methodology, we believe that the difference in value reflected between the midpoint of the preliminary range and management's determination of the value of our common stock on September 2, 2010 was primarily because history has shown that it is reasonable to expect that the completion of an initial public offering will increase the value of stock as a result of the significant increase in the liquidity and ability to trade/sell such securities. However, it is not possible to measure such increase in value with precision or certainty.

Based on the \$ midpoint of the estimated price range shown on the cover of this prospectus, the intrinsic value of the options granted on September 2, 2010, the last date we granted stock options, was approximately \$ . Also based on the \$ midpoint of the estimated price range shown on the cover of this prospectus, the intrinsic value of outstanding options as of November 30, 2010 was \$ million, of which \$ million related to vested options and \$ million related to unvested options.

### Internal Control over Financial Reporting

Effective internal control over financial reporting is necessary for us to provide reliable annual and quarterly financial reports and to prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our operating results and financial condition could be materially misstated and our reputation could be significantly harmed. As a private company, we were not subject to the same standards as a public company. As a public company, we will be required to file annual and quarterly reports containing our consolidated financial statements and will be subject to the requirements and standards set by the Securities and Exchange Commission, or SEC.

### Results of Operations

#### Comparison of Nine Months Ended September 30, 2010 and 2009

	Nine Months Ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2009	2010		
	(dollars in thousands)			
Revenues	\$ 10,722	\$ 12,371	\$ 1,649	15%
Cost of revenues	8,823	10,168	1,345	15%
Research and development	18,717	14,954	(3,763)	(20)%
Selling, general and administrative	3,920	3,941	21	1%
Other income (expense)	353	100	(253)	N.M.
Interest income (expense)	\$ (2,351)	\$ (3,513)	\$ 1,162	49%

*Revenues.* Revenues increased by \$1.6 million, or 15%, to \$12.4 million in the nine months ended September 30, 2010 as compared to \$10.7 million in the nine months ended September 30, 2009. The increase reflects an increase of supply revenue of \$2.9 million, partially offset by a decrease of royalties of \$0.2 million and of collaborative licensing and development revenue of \$1.0 million. Supply revenue increased due to a significant increase in DepoCyt(e) product orders from our European commercial partner, Mundipharma, and from our new U.S. commercial partner, Sigma-Tau, subsequent to its acquisition of the product as part of a larger product portfolio acquisition in January 2010. Royalties declined in part due to lower DepoCyt market sales in the United States in the nine months ended September 30, 2010 as compared to the same period in 2009. The decrease in collaborative licensing and development revenue reflected a reduction in contract development activities for Amylin, for the nine months ended September 30, 2010, as well as a one-time purchase of equipment for which we were reimbursed by Amylin in the nine months ended September 30, 2009.

*Cost of Revenues.* Cost of revenues increased by \$1.3 million, or 15%, to \$10.2 million in the nine months ended September 30, 2010 as compared to \$8.8 million in the nine months ended September 30, 2009. The increase reflects a \$2.0 million increase in cost of supply revenue and royalties, offset by a \$0.7 million decrease

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in cost of collaborative licensing and development revenue as our personnel were re-assigned to internal research and development projects subsequent to the reduction in contract development activities for Amylin.

*Research and Development Expenses.* Research and development expenses decreased by \$3.8 million, or 20%, to \$15.0 million in the nine months ended September 30, 2010 as compared to \$18.7 million in the nine months ended September 30, 2009. The decrease was primarily due to a decrease in clinical study expenses in the nine months ended September 30, 2010 as compared to the comparable period in 2009, during which time the pivotal placebo controlled Phase 3 studies were completed.

In the nine months ended September 30, 2010 and 2009, research and development expenses attributable to EXPAREL were \$14.2 million, or 95%, and \$17.9 million, or 96%, respectively of total research and development expenses. The remaining research and development expenses related to our other product candidates.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses increased by \$21,000, or 1%, to \$3.9 million in the nine months ended September 30, 2010 as compared to \$3.9 million in the nine months ended September 30, 2009. Selling expenses decreased by \$0.3 million, or 43%, to \$0.4 million in the nine months ended September 30, 2010 as compared to \$0.7 million in the nine months ended September 30, 2009. The decrease in selling expenses reflects the termination of our commercial personnel in February 2009. General and administrative expenses increased by \$0.3 million, or 9%, to \$3.5 million in the nine months ended September 30, 2010 as compared to \$3.2 million in the nine months ended September 30, 2009.

*Other Income (Expense).* Other income decreased by \$0.3 million to \$0.1 million in the nine months ended September 30, 2010 as compared to \$0.4 million in the nine months ended September 30, 2009. The decrease was primarily due to a lower amount of gains realized on settlements with trade creditors in 2010 as a result of lower proportionate settlement payments.

*Interest Income (Expense).* Interest expense increased by \$1.2 million, or 49%, to \$3.5 million in the nine months ended September 30, 2010 as compared to \$2.4 million in the nine months ended September 30, 2009. Interest expense increased by \$1.6 million in the nine months ended September 30, 2010 as compared to the nine months ended September 30, 2009, driven by debt financing activities in 2009 and 2010, and was partially offset by a \$0.3 million credit, resulting primarily from the periodic revaluation adjustment of our liability under the Amended and Restated Royalty Interests Assignment Agreement.

#### **Comparison of Years Ended December 31, 2009 and 2008**

	<u>Year Ended December 31,</u>		<u>Increase/ (Decrease)</u>	<u>% Increase/ (Decrease)</u>
	<u>2008</u>	<u>2009</u>		
	(dollars in thousands)			
Revenues	\$ 13,925	\$ 15,006	\$ 1,081	8%
Cost of revenues	17,463	12,301	(5,162)	(30)%
Research and development	33,214	26,233	(6,981)	(21)%
Selling, general and administrative	8,611	5,020	(3,591)	(42)%
Other income (expense)	(224)	367	591	N.M.
Interest income (expense)	\$ 3,725	\$ (3,526)	\$ (7,251)	N.M.

*Revenues.* Revenues increased by \$1.1 million, or 8%, to \$15.0 million in the year ended December 31, 2009 as compared to \$13.9 million in the year ended December 31, 2008. The increase was primarily due to increases of collaborative licensing and development revenue of \$1.2 million and royalties of \$0.4 million, offset by a decrease in supply revenue of \$0.5 million. The increase in collaborative licensing and development revenue reflected in part a \$1.0 million increase in contract development activities for Amylin in 2009, and an increase in 2009 milestone revenue resulting from a milestone payment from our U.S. DepoDur commercial partner, EKR,

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paid at the end of 2008. The increase in royalties in 2009 reflected an increase in end user sales of DepoCyt(e) in 2009, offset by a decline in DepoDur royalties. The decrease in supply revenue in 2009 was primarily due to EKR gradually selling down excess inventory accumulated in 2008.

**Cost of Revenues.** Cost of revenues decreased by \$5.2 million, or 30%, to \$12.3 million in the year ended December 31, 2009 as compared to \$17.5 million in the year ended December 31, 2008. The decrease was primarily due to reduction in cost of supply revenue, driven by cost control measures initiated in December 2008 and April 2009, including a reduction in force of manufacturing and support personnel, decreased reliance on outsourced providers to support our manufacturing activities, and elimination of non-essential activities.

**Research and Development Expenses.** Research and development expenses decreased by \$7.0 million, or 21%, to \$26.2 million in the year ended December 31, 2009 from \$33.2 million in the year ended December 31, 2008. This decrease resulted primarily from a \$6.1 million decrease in clinical trials costs, to \$8.7 million in 2009 from \$14.8 million in 2008. In 2009, we completed our pivotal Phase 3 placebo controlled studies, as compared to in 2008 when we incurred most of the expenses for three Phase 3 comparator studies as well as three Phase 2 studies.

In the years ended December 31, 2009 and 2008, research and development expenses attributable to EXPAREL were \$25.2 million, or 96%, and \$31.9 million, or 96% of total research and development expenses, respectively. The remaining research and development expenses related to our other product candidate initiatives.

**Selling, General and Administrative Expenses.** Selling, general and administrative expenses decreased by \$3.6 million, or 42%, to \$5.0 million in the year ended December 31, 2009 from \$8.6 million in the year ended December 31, 2008. Selling expenses were \$1.6 million lower in 2009 as compared to 2008, as we curtailed our pre-commercial efforts in early 2009, resulting in \$1.0 million decrease in outside services and \$0.3 million decrease in compensation expenses. General and administrative expenses decreased by \$2.0 million in the year ended December 31, 2009 as compared to 2008, primarily due to a \$0.8 million decrease in salary expenses and a \$0.7 million decrease in severance and recruiting expenses.

**Other Income (Expense).** Other income increased by \$0.6 million, to \$0.4 million in the year ended December 31, 2009 as compared to \$0.2 million in other expense in the year ended December 31, 2008. The increase was primarily due to a gain realized on settlement with trade creditors in 2009.

**Interest Income (Expense).** Interest expense increased by \$7.3 million in the year ended December 31, 2009, to \$3.5 million, as compared to interest income of \$3.7 million in the year ended December 31, 2008. The increase was primarily due to the impact of the periodic revaluation adjustment of our liability under the Amended and Restated Royalty Interests Assignment Agreement, resulting in \$5.4 million increase in royalty interest obligations, and due to a \$1.7 million increase of interest expense accrual as a result of our debt financing activities in 2009.

### **Comparison of Years Ended December 31, 2008 and 2007**

The combined statement of operations for the year ended December 31, 2007 represents the statement of operations of the Successor for the year ended December 31, 2007 (for which there was no activity prior to the Acquisition Date).

	<u>Year Ended December 31,</u>		<u>Increase/ (Decrease)</u>	<u>% Increase/ (Decrease)</u>
	<u>2007</u>	<u>2008</u>		
	(dollars in thousands)			
Revenues	\$ 8,341	\$ 13,925	\$ 5,584	67%
Cost of revenues	9,492	17,463	7,971	84%
Research and development	20,665	33,214	12,549	61%
Selling, general and administrative	4,170	8,611	4,441	106%
In-process research and development	12,400	—	(12,400)	100%
Other income (expense)	16	(224)	(240)	N.M.
Interest income (expense)	\$ 2,177	\$ 3,725	\$ 1,548	71%

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*Revenues.* Revenues increased by \$5.6 million, or 67%, to \$13.9 million in the year ended December 31, 2008 as compared to \$8.3 million in the year ended December 31, 2007. The increase was due to increases of collaborative licensing and development revenue of \$2.9 million, of supply revenue of \$1.4 million and of royalties of \$1.3 million. The increase in collaborative licensing and development revenue reflected in part \$1.4 million of contract development activities for Amylin after we entered into an agreement in April 2008, and an increase in 2008 milestone revenue resulting from an up-front milestone payment from Amylin. The increase in supply revenue and royalties in the year ended December 31, 2008 reflected higher end user sales for our commercial partners, as well as 2008 reflecting a full year of operations in comparison to 2007, which reflects operations from the Acquisition Date.

*Cost of Revenues.* Cost of revenues increased by \$8.0 million, or 84%, to \$17.5 million in the year ended December 31, 2008 as compared to \$9.5 million in the year ended December 31, 2007. The increase was primarily due an increase in cost of supply revenue of \$5.7 million and an increase in cost of collaborative licensing and development revenue of \$2.1 million. The increase in cost of supply revenue reflects higher manufacturing and support personnel, higher cost of manufacturing supplies and increased outsourced services in support of the manufacturing activities as well as 2008 reflecting a full year of operations in comparison to 2007 which reflects operations from the Acquisition Date. The increase in cost of collaborative licensing and development revenue reflects the additional personnel and overhead allocated to servicing our collaborative licensing partners as well as 2008 reflecting a full year of operations in comparison to 2007, which reflects operations from the Acquisition Date.

*Research and Development Expenses.* Research and development expenses increased by \$12.5 million, or 61%, to \$33.2 million in the year ended December 31, 2008 as compared to \$20.7 million in the year ended December 31, 2007. This increase resulted primarily from a \$8.2 million increase in clinical trial costs, to \$14.8 million in 2008 from \$6.6 million in 2007. In 2008, we incurred most of the expenses for three Phase 3 clinical trials and three Phase 2 clinical trials, as compared to 2007 when we incurred most of the expenses for three Phase 2 clinical trials and one Phase 1 clinical trial, as well as 2008 reflecting a full year of operations in comparison to 2007, which reflects operations from the Acquisition Date.

In the years ended December 31, 2008 and 2007, research and development expenses attributable to EXPAREL were \$31.9 million, or 96%, and \$19.6 million, or 95% of total research and development expenses, respectively. The remaining research and development expenses are related to our other product candidate initiatives.

*Selling, General and Administrative Expense.* Selling, general and administrative expenses increased by \$4.4 million, or 106%, to \$8.6 million in the year ended December 31, 2008 from \$4.2 million in the year ended December 31, 2007. Selling expenses related to pre-commercial efforts were \$2.4 million in 2008, and we did not incur any selling expenses in 2007. General and administrative expenses increased by \$2.0 million in 2008 as compared to 2007, reflecting a full year of operations in comparison to 2007, which reflects operations from the Acquisition Date.

*In-Process Research and Development Expenses.* There were no in-process research and development expenses in the year ended December 31, 2008, as compared to \$12.4 million in the year ended December 31, 2007. We acquired and expensed \$12.4 million of in-process research and development projects as part of the Acquisition.

*Other Income (Expense).* Other expense increased by \$0.2 million, to \$0.2 million in the year ended December 31, 2008 as compared to \$16,000 in other income in the year ended December 31, 2007. The increase was primarily due to unfavorable foreign currency exchange rate movement between the euro and dollar for DepoCyte sales in Europe and between the pound sterling and dollar for value added tax refunds in Europe.

*Interest Income (Expense).* Interest income increased \$1.5 million, to \$3.7 million in the year ended December 31, 2008 as compared to interest income of \$2.2 million in the year ended December 31, 2007. The

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increase was primarily due to the impact of the periodic revaluation adjustment of our liability under the Amended and Restated Royalty Interests Assignment Agreement, offset by \$0.2 million lower interest income, as well as 2008 reflecting a full year of operations in comparison to 2007, which reflects operations from the Acquisition Date.

### Liquidity and Capital Resources

Since our inception in 2007, we have devoted most of our cash resources to research and development and general and administrative activities primarily related to the development of EXPAREL. We have financed our operations primarily with the proceeds of the sale of convertible preferred stock, secured and unsecured notes and borrowings under debt facilities, supply revenue, royalties and collaborative licensing and development revenue. To date, we have generated limited supply revenue and royalties, and we do not anticipate generating any revenues from the sale of EXPAREL, if approved, until at least the fourth quarter of 2011. We have incurred losses and generated negative cash flows from operations since inception. As of September 30, 2010, we had an accumulated deficit of \$129.9 million, cash and cash equivalents of \$13.9 million and working capital of \$6.6 million.

The following table summarizes our cash flows from operating, investing and financing activities for the years ended December 31, 2007, 2008 and 2009 and the nine months ended September 30, 2009 and September 30, 2010:

	Year Ended December 31,			Nine Months Ended September 30,	
	2007	2008	2009	2009	2010
(in thousands)					
<b>Consolidated Statement of Cash Flows Data:</b>					
Net cash provided by (used in):					
Operating activities	\$ (13,435)	\$ (29,189)	\$ (20,838)	\$ (21,677)	\$ (19,040)
Investing activities	(24,375)	(5,838)	(5,509)	(5,109)	(3,822)
Financing activities	45,050	40,173	21,038	18,812	29,636
Net increase (decrease) in cash and cash equivalents	<u>\$ 7,240</u>	<u>\$ 5,146</u>	<u>\$ (5,309)</u>	<u>\$ (7,974)</u>	<u>\$ 6,774</u>

#### *Operating Activities*

For the nine months ended September 30, 2010 and 2009, our net cash used in operating activities was \$19.0 million and \$21.7 million, respectively. The decrease in net cash used in operating activities in the nine months ended September 30, 2010 resulted from an increase in accounts payable and a decrease in inventory, offset by a decrease in research and development expenses and an increase in accounts receivable related to DepoCyt(e) supply revenue on product shipped to our commercial partners.

For the years ended December 31, 2009, 2008 and 2007, our net cash used in operating activities was \$20.8 million, \$29.2 million and \$13.4 million, respectively. The decrease in net cash used in operating activities in 2009 resulted from lower research and development and selling expenses and a \$3.8 million increase in the deferred revenue balance, primarily due to receipt of license fees from our commercial partners, offset by a decrease in accounts payable of \$4.4 million. The increase in net cash used in operating activities in 2008 resulted from increased spending on research and development expenses and an increase in accounts receivable of \$1.6 million, offset by an increase in accounts payable of \$4.8 million, and an increase in deferred revenue of \$11.3 million primarily due to receipt of license fees.

#### *Investing Activities*

For the nine months ended September 30, 2010 and 2009, our net cash used in investing activities was \$3.8 million and \$5.1 million, respectively. The net cash used in investing activities in the nine months ended

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September 30, 2010 and 2009 was primarily for the purchases of fixed assets of \$3.8 million and \$5.1 million, respectively. For the years ended December 31, 2009, 2008 and 2007, our net cash used in investing activities was \$5.5 million, \$5.8 million and \$24.4 million, respectively. The net cash used in investing activities in 2009 and 2008 was primarily for the purchases of fixed assets of \$5.5 million and \$5.8 million, respectively. The cash used in investing activities in 2007 was primarily to fund the \$19.6 million purchase price of the Acquisition, and for the purchases of fixed assets of \$2.1 million.

### ***Financing Activities***

For the nine months ended September 30, 2010 and 2009, our net cash provided by financing activities was \$29.6 million and \$18.8 million, respectively. The cash provided by financing activities in the nine months ended September 30, 2010 and 2009 was primarily the result of increased borrowings and the issuance and sale of notes payable, for total net proceeds of \$30.0 million and \$19.0 million, respectively.

For the years ended December 31, 2009, 2008 and 2007, our net cash provided by financing activities was \$21.0 million, \$40.2 million and \$45.1 million, respectively. The net cash provided by financing activities in 2009 was primarily due to the sale and issuance of notes payable, for total net proceeds of \$21.0 million. The cash provided by financing activities in 2008 was due primarily to the sale and issuance of our Series A convertible preferred stock, for total net proceeds of \$40.0 million. The cash provided by financing activities in 2007 was due primarily to the sale and issuance of shares of our Series A convertible preferred stock for total net proceeds of \$45.0 million.

### ***Equity Financings***

From inception through September 30, 2010, we have received net proceeds of \$85 million from the sale of our Series A convertible preferred stock. The various issuances of our Series A convertible preferred stock are described in more detail under “Related Person Transactions—Preferred Stock Issuances.”

### ***Debt Facilities***

As of November 30, 2010, we had \$66.25 million in aggregate principal amount of debt outstanding, including \$26.25 million under the Hercules Credit Facility, \$3.75 million pursuant to secured notes we issued to one of our investors and \$36.25 million under various secured and convertible notes that we issued to certain of our investors in 2009 and 2010. Pursuant to an agreement entered into in October 2010 between us and the holders of the convertible and secured notes, the convertible and secured notes will convert into 35,112,715 shares of our common stock upon completion of this offering. The table below shows the principal amount of our indebtedness and the number of shares of our common stock that we expect our indebtedness will convert into.

<u>Debt Issue</u>	<u>Principal amount</u>	<u>Conversion Shares</u>
Hercules Credit Facility	\$26.25 million	—
2009 Convertible Notes	10.63 million	9,374,446
2009 Secured Notes	10.63 million	9,979,369
2010 Secured Notes	15.00 million	12,439,302
HBM Secured Notes	3.75 million	3,319,598

***Hercules Credit Facility.*** On November 24, 2010, we entered into a \$26.25 million credit facility with Hercules Technology Growth Capital, Inc. and Hercules Technology III, L.P., as lenders. At the closing of the Hercules Credit Facility, we entered into a term loan in the aggregate principal amount of \$26.25 million, which was the full amount available under the Hercules Credit Facility. As of November 30, 2010, the entire term loan of \$26.25 million was outstanding. The term loan under the Hercules Credit Facility is comprised of two tranches, Tranche A and Tranche B. The Tranche A portion of the term loan is comprised of \$11.25 million in principal and carries a floating per annum interest rate equal to 10.25% plus the amount, if any, by which the

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prime rate exceeds 4.00%. Upon the release of the investors' guaranty (described below), the interest rate on the Tranche A portion of the term loan will increase to a floating per annum interest rate equal to 11.00% plus the amount, if any, by which the prime rate exceeds 4.00%. The Tranche B portion of the term loan is comprised of \$15.0 million in principal and carries a floating per annum interest rate equal to 12.65% plus the amount, if any, by which the prime rate exceeds 4.00%. As of November 30, 2010, the interest rate on the Tranche A portion was 10.25% and on the Tranche B portion was 12.65%. Interest on the term loan is payable monthly. If there is an event of default under the Hercules Credit Facility, we will be obligated to pay interest at a higher default rate. The proceeds of the term loan under the Hercules Credit Facility have been used to repay the GECC Credit Facility in full and the remainder will be used for other general corporate purposes.

As further consideration to the lenders to provide the term loan to us under the Hercules Credit Facility, we issued to the lenders a warrant to purchase 1,925,000 shares of our Series A convertible preferred stock. If after the closing date of the Hercules Credit Facility and prior to the completion of our proposed initial public offering, we issue equity securities in a private placement then the lenders may, at their option, exercise the warrant for the same class and type of equity securities that we issue in such private placement in lieu of Series A convertible preferred stock. The exercise price for the shares to be issued under the warrant is equal to \$1.25 per share or the price per share paid in a private placement. The warrant is valid from the date of issuance until the earlier to occur of ten (10) years from the date of issuance or five (5) years following the effective date of the registration statement of which this prospectus is a part.

The Hercules Credit Facility provides for an "interest only period" when no principal amounts are due and payable. The interest only period runs initially from November 24, 2010 through August 31, 2011, but can be extended, at our request, to either November 30, 2011 or February 28, 2012 if certain conditions are satisfied. Following the end of the interest only period, the term loan is to be repaid in 33 equal monthly installments of principal and interest beginning on the first business day after the month in which the interest only period ends. Amounts repaid may not be re-borrowed. We can, at any time, prepay all or any part of the term loan provided that so long as the investors' guaranty (as described below) is in effect, we cannot prepay any part of the Tranche A portion of the term loan without the lenders' consent if any of the Tranche B portion is outstanding. If the investors' guaranty is not in effect, then any prepayments are to be applied pro rata across the outstanding balance of both portions of the term loan. In connection with any prepayments of the term loan under the Hercules Credit Facility, we are required to pay, in addition to all principal and accrued and unpaid interest on such term loan, a prepayment charge equal to 1.25% of the principal amount being prepaid. In addition, there is an end of term charge that is payable to the lenders upon the earliest to occur of the maturity date, the prepayment in full of our obligations under the Hercules Credit Facility and the acceleration of our obligations under the Hercules Credit Facility.

The Hercules Credit Facility is secured by a first priority lien on all of our assets other than the assets that secure our obligations under Amended and Restated Royalty Interests Assignment Agreement (as described below). In addition, the Hercules Credit Facility is guaranteed by certain of our investors (other than the entities affiliated with HBM) on a several and not joint basis which guarantee is limited to each investor's pro rata portion of the outstanding principal and accrued and unpaid interest under the Hercules Credit Facility, but in no event exceeding \$11.25 million in the aggregate. The Hercules loan agreement provides that, upon the occurrence of certain circumstances and upon our request, the investors' guarantee may be terminated and released.

The Hercules loan and security agreement also contains a provision that entitles the lenders to, subject to applicable securities laws and regulatory requirements, a limited right to participate in any equity financings that occur between the closing date of the Hercules Credit Facility and the completion of this offering.

The Hercules loan and security agreement contains events of default including payment default, default arising from the breach of the provisions of the Hercules loan and security agreement and related documents (including the occurrence of certain changes in control, including if our chief executive officer ceases under

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certain conditions to be involved in the daily operations or management of the business, or if certain holders of our capital stock cease to retain, after the consummation of certain corporate transactions, shares representing more than 50% of the surviving entity after such transactions (provided that our initial public offering shall not constitute such a change in control)) or the inaccuracy of representations and warranties contained in the loan and security agreement, attachment default, bankruptcy and insolvency, cross-default with respect to certain other indebtedness (including certain events under the Amended and Restated Royalty Interests Assignment Agreement), breach of the terms of any guarantee (including the investors' guarantee) of the Hercules Credit Facility, the occurrence of a material adverse effect (as defined in the Hercules loan and security agreement).

The occurrence of an event of default under the Hercules Credit Facility could trigger the acceleration of our obligations under the Hercules Credit Facility or allow the lenders to exercise other rights and remedies, including rights against our assets that secure the Hercules Credit Facility and rights under guarantees provided to support the obligations under the Hercules Credit Facility.

The Hercules loan and security agreement contains a number of affirmative and restrictive covenants, including reporting requirements and other collateral limitations, certain limitations on liens and indebtedness, dispositions, mergers and acquisitions, restricted payments and investments, corporate changes and waivers and amendments to certain agreements, our organizational documents, and documents relating to debt that is subordinate to our obligations under the Hercules Credit Facility.

*GECC Credit Facility.* On April 30, 2010, we entered into an \$11.25 million credit facility with General Electric Capital Corporation, as both agent and the sole lender, or the GECC Credit Facility. We borrowed the full \$11.25 million under the GECC Credit Facility. On November 24, 2010, all borrowings under the GECC Credit Facility were repaid in full from proceeds of the Hercules Credit Facility, and the GECC Credit Facility was terminated and any and all liens in favor of the lenders under the GECC Credit Facility were released.

*Investor Notes to be Converted into Common Stock.*

*2009 Convertible Notes.* In January 2009, we sold \$10.63 million in aggregate principal amount of convertible promissory notes, or the 2009 Convertible Notes, to certain of our existing investors. In connection with the issuance of the 2009 Convertible Notes, we issued warrants to purchase an aggregate of 1,700,000 shares of our common stock with an exercise price of \$0.25 per share. The 2009 Convertible Notes have an interest rate of 5% per year and all principal and accrued and unpaid interest on the 2009 Convertible Notes was due on December 31, 2010. In connection with entering into the Hercules Credit Facility, the maturity date of the 2009 Convertible Notes was extended to the earliest of (1) a sale of us, (2) the date which is 30 days after the last day of the month that is 33 months after the expiration of the "interest only period" under the Hercules Credit Facility (as described above) and (3) 91 days after the date that all obligations under the Hercules Credit Facility are paid in full and the Hercules Credit Facility is terminated. In connection with entering into the Hercules Credit Facility, the holders of the 2009 Convertible Notes entered into a subordination and intercreditor agreement with the lenders under the Hercules Credit Facility pursuant to which the 2009 Convertible Notes were subordinated to the Hercules Credit Facility. The holders of the 2009 Convertible Notes previously entered into a separate intercreditor agreement with the holders of the 2009 Secured Notes (as described below) and the 2010 Secured Notes (as described below) pursuant to which the 2009 Convertible Notes were subordinated to the 2009 Secured Notes and the 2010 Secured Notes, and the holders of the 2009 Secured Notes agreed to share payments pro rata with the holders of the 2010 Secured Notes. As of November 30, 2010, \$11.5 million aggregate principal and accrued and unpaid interest was outstanding under the 2009 Convertible Notes. All principal and interest due on the 2009 Convertible Notes will be converted into 9,374,446 shares of our common stock upon completion of this offering.

*2009 Secured Notes.* In June 2009, we entered into an agreement with certain of our existing investors to issue \$10.63 million in aggregate principal amount of secured notes, or the 2009 Secured Notes. To secure the performance of our obligations under the purchase agreement for the 2009 Secured Notes, we granted a security



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interest in substantially all of our assets, including our intellectual property assets, except the assets that secure our obligations under our agreement with Paul Capital. In connection with entering into the Hercules Credit Facility, the holders of the 2009 Secured Notes entered into a subordination and intercreditor agreement with the lenders under the Hercules Credit Facility pursuant to which the 2009 Secured Notes were subordinated to the Hercules Credit Facility. As described above under “—Investor Notes to be Converted into Common Stock—2009 Convertible Notes,” the holders of the 2009 Secured Notes previously entered into a separate intercreditor agreement with the holders of the 2009 Convertible Notes and the 2010 Secured Notes which set out certain priorities among those parties.

The 2009 Secured Notes have an interest rate of 12% per year and all principal and accrued and unpaid interest on the 2009 Convertible Notes was due on December 31, 2010. In connection with entering into the Hercules Credit Facility, the maturity date of the 2009 Secured Notes was extended to the earliest of (1) a sale of us, (2) the date which is 30 days after the last day of the month that is 33 months after the expiration of the “interest only period” under the Hercules Credit Facility (as described above) and (3) 91 days after the date that all obligations under the Hercules Credit Facility are paid in full and the Hercules Credit Facility is terminated. As of November 30, 2010, \$12.0 million aggregate principal and accrued and unpaid interest was outstanding under the 2009 Secured Notes. All principal and interest due on the 2009 Secured Notes will be converted into 9,979,369 shares of our common stock upon completion of this offering.

*2010 Secured Notes.* In March 2010, we entered into an agreement with certain of our existing investors to issue \$15.0 million in aggregate principal amount of secured notes and the investors purchased the entire \$15.0 million of 2010 Secured Notes. To secure the performance of our obligations under the purchase agreement for the 2010 Secured Notes, we granted a subordinated security interest in substantially all of our assets, including our intellectual property assets, except the assets that secure our obligations under the Amended and Restated Royalty Interests Agreement. In connection with entering into the Hercules Credit Facility, the holders of the 2010 Secured Notes entered into a subordination and intercreditor agreement with the lenders under the Hercules Credit Facility pursuant to which the 2010 Secured Notes were subordinated to the Hercules Credit Facility. As described above under “—Investor Notes to be Converted into Common Stock—2009 Convertible Notes,” the holders of the 2010 Secured Notes previously entered into a separate intercreditor agreement with the holders of the 2009 Convertible Notes and the 2009 Secured Notes which set out certain priorities among those parties.

The 2010 Secured Notes have an interest rate of 5% per year and all principal and accrued and unpaid interest on the 2010 Secured Notes is due on December 31, 2010. In connection with entering into the Hercules Credit Facility, the maturity date of the 2010 Secured Notes was extended to the earliest of (1) a sale of us, (2) the date which is 30 days after the last day of the month that is 33 months after the expiration of the “interest only period” under the Hercules Credit Facility (as described above) and (3) 91 days after the date that all obligations under the Hercules Credit Facility are paid in full and the Hercules Credit Facility is terminated. As of November 30, 2010, \$15.3 million in aggregate principal and accrued and unpaid interest was outstanding pursuant to the 2010 Secured Notes. All principal and interest due on the 2010 Secured Notes will be converted into 12,439,302 shares of our common stock upon completion of this offering.

*HBM Term Loan.* On April 30, 2010, we entered into a subordinated secured note purchase agreement with entities affiliated with HBM BioVentures, or HBM, to issue \$3.75 million in aggregate principal amount of secured notes, or the HBM Secured Notes. To secure the performance of our obligations under the purchase agreement for the HBM Secured Notes, we granted a subordinated security interest in substantially all of our assets, including our intellectual property assets, other than the assets that secure our obligations under the Amended and Restated Royalty Interests Agreement. The HBM Secured Notes carry an interest rate of approximately 10% per year. In addition, the HBM Secured Notes require a final payment fee if they are prepaid prior to the maturity date. The maturity date of the HBM Secured Notes is the earliest of (1) a sale of us, (2) the date which is 30 days after the last day of the month that is 33 months after the expiration of the “interest only period” under the Hercules Credit Facility (as described above) and (3) 91 days after the date that all obligations under the Hercules Credit Facility are paid in full and the Hercules Credit Facility is terminated. In connection

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with entering into the Hercules Credit Facility, the holders of the HBM Secured Notes entered into a subordination and intercreditor agreement with the lenders under the Hercules Credit Facility pursuant to which the HBM Secured Notes were subordinated to the Hercules Credit Facility. As of November 30, 2010, \$3.8 million in aggregate principal and accrued and unpaid interest was outstanding pursuant to the HBM Secured Notes. All principal and interest due on the HBM Secured Notes will be converted into 3,319,598 shares of our common stock upon completion of this offering.

***Royalty Interests Assignment Agreement***

On March 23, 2007, we entered into the Amended and Restated Royalty Interests Assignment Agreement with Paul Capital, pursuant to which we assigned to Paul Capital the right to receive up to approximately 20% of our royalty payments from DepoCyt(e) and DepoDur. The original agreement was entered into prior to the Acquisition by the Predecessor in order to monetize certain royalty payments from DepoCyt(e) and DepoDur. In connection with the Acquisition, the original agreement with Paul Capital was amended and restated and the responsibility to pay the royalty interest in product sales of DepoCyt(e) and DepoDur was transferred to us and we were required to make payments to Paul Capital upon the occurrence of certain events. To secure our obligations to Paul Capital, we granted Paul Capital a security interest in collateral which includes the royalty payments we are entitled to receive with respect to sales of DepoCyt(e) and DepoDur, as well as to bank accounts to which such payments are deposited. Under our arrangement with Paul Capital, upon the occurrence of certain events, including if we experience a change of control, undergo certain bankruptcy events of us or our subsidiary, transfer any or substantially all of our rights in DepoCyt(e) and/or DepoDur, transfer all or substantially all of our assets, breach certain of the covenants, representations or warranties under the Amended and Restated Royalty Interests Assignment Agreement, or sales of DepoCyt(e) and/or DepoDur are suspended due to an injunction or if we elect to suspend sales of DepoCyt(e) and/or DepoDur as a result of a lawsuit filed by certain third parties, Paul Capital may require us to repurchase the rights we assigned to it at a cash price equal to (a) 50% of all cumulative payments made by us to Paul Capital under the Amended and Restated Royalty Interests Assignment Agreement during the preceding 24 months, multiplied by (b) the number of days from the date of Paul Capital's exercise of such option until December 31, 2014, divided by 365. Under the terms of the Amended and Restated Royalty Interests Assignment Agreement, this offering would not constitute a change of control.

***Future Capital Requirements***

We believe that the net proceeds from this offering, together with our existing cash and cash equivalents and revenue from product sales, will be sufficient to enable us to fund our operating expenses, capital expenditure requirements and service our indebtedness for at least the next 12 months. However, no assurance can be given that this will be the case, and we may require additional debt or equity financing to meet our working capital requirements. We expect that the net proceeds from this offering will be sufficient for our planned manufacture and commercialization of EXPAREL in the United States. Our need for additional external sources of funds will depend significantly on the level and timing of our sales of EXPAREL. Moreover, changing circumstances may cause us to expend cash significantly faster than we currently anticipate, and we may need to spend more cash than currently expected because of circumstances beyond our control.

Our expectations regarding future cash requirements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we make in the future. We have no current understandings, agreements or commitments for any material acquisitions or licenses of any products, businesses or technologies. We may need to raise substantial additional capital in order to engage in any of these types of transactions.

We expect to continue to incur substantial additional operating losses as we seek FDA approval for and commercialize EXPAREL and develop and seek regulatory approval for our other product candidates. If we obtain FDA approval for EXPAREL, we will incur significant sales and marketing and manufacturing expenses.

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In addition, we expect to incur additional expenses to add operational, financial and information systems and personnel, including personnel to support our planned product commercialization efforts. We also expect to incur significant costs to comply with corporate governance, internal controls and similar requirements applicable to us as a public company following the closing of this offering.

Our future use of operating cash and capital requirements will depend on many forward-looking factors, including the following:

- the timing and outcome of the FDA's review of the NDA for EXPAREL;
- the extent to which the FDA may require us to perform additional clinical trials for EXPAREL;
- the timing and success of this offering;
- the costs of our commercialization activities for EXPAREL, if it is approved by the FDA;
- the cost and timing of expanding our manufacturing facilities and purchasing manufacturing and other capital equipment for EXPAREL and our other product candidates;
- the scope, progress, results and costs of development for additional indications for EXPAREL and for our other product candidates;
- the cost, timing and outcome of regulatory review of our other product candidates;
- the extent to which we acquire or invest in products, businesses and technologies;
- the extent to which we choose to establish collaboration, co-promotion, distribution or other similar agreements for our product candidates; and
- the costs of preparing, submitting and prosecuting patent applications and maintaining, enforcing and defending intellectual property claims.

To the extent that our capital resources are insufficient to meet our future operating and capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives. The covenants under the Hercules Credit Facility and the Amended and Restated Royalty Interests Assignment Agreement and the pledge of our assets as collateral limit our ability to obtain additional debt financing. We have no committed external sources of funds. Additional equity or debt financing or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences, that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us.

#### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements, except for operating leases, or relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities.

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## Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2009:

	Payments Due by Period				
	Total	2010	2011 and 2012 (in thousands)	2013 and 2014	2015 and thereafter
<b>Contractual Obligations <sup>(1)</sup>:</b>					
Debt obligations <sup>(2)</sup>	\$26,250	—	\$ 10,904	\$ 15,346	\$ —
Interest payments on debt <sup>(2)</sup>	7,983	520	5,382	2,082	—
Operating lease obligations <sup>(3)</sup>	30,038	6,215	10,647	10,104	3,072
	<u>\$ 64,271</u>	<u>\$ 6,735</u>	<u>\$26,933</u>	<u>\$27,532</u>	<u>\$3,072</u>

<sup>(1)</sup> This table does not include (i) royalties payable to Paul Capital (through 2014 pursuant to the Amended and Restated Royalty Interest Assignment Agreement described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Royalty Interests Assignment Agreement”) and pursuant to the Assignment Agreement with Research Development Foundation; (ii) contingent milestone payments of up to \$62 million related to EXPAREL due to SkyePharma PLC, including \$10 million due upon the first commercial sale of EXPAREL to end users in the United States.

<sup>(2)</sup> Debt obligations and interest payments includes payments under the GECC Credit Facility, which was terminated in November 2010, and obligations and payments under the Hercules Credit Facility entered into on November 24, 2010, and exclude the secured and unsecured notes and accrued interest thereon to be converted into common stock.

<sup>(3)</sup> Includes building and equipment leases.

## Recent Accounting Pronouncements

We have adopted new accounting guidance on fair value measurements effective January 1, 2008, for financial assets and liabilities. In addition, effective January 1, 2009, we adopted this guidance as it relates to nonfinancial assets and liabilities that are not recognized or disclosed at fair value in the financial statements on at least an annual basis. This guidance defines fair value as the price that would be received to sell an asset or paid to transfer a liability, referred to as the exit price, in an orderly transaction between market participants at the measurement date. The guidance outlines a valuation framework and creates a fair value hierarchy in order to increase the consistency and comparability of fair value measurements and the related disclosures. The adoption of this guidance did not have a material impact on our financial statements.

In June 2008, the Financial Accounting Standards Board, or FASB, issued new guidance related to assessing whether an equity-linked financial instrument (or embedded feature) is indexed to an entity’s own stock for the purposes of determining whether such equity-linked financial instrument (or embedded feature) is subject to derivative accounting. We adopted this new guidance effective January 1, 2009. The adoption of this guidance did not have a material impact on our financial statements.

In May 2009, the FASB issued a new standard regarding subsequent events. The standard provides guidance on management’s assessment of subsequent events and incorporates this guidance in accounting literature. The guidance is effective prospectively for interim and annual periods ending after June 15, 2009. We adopted this guidance beginning with the interim period ended June 30, 2009. The adoption of this guidance did not have a material impact on our financial statements.

In April 2009, the FASB issued a staff position requiring fair value disclosures in both interim and annual financial statements in order to provide more timely information about the effects of current market conditions on financial instruments. The guidance is effective for interim and annual periods ending after June 15, 2009. We adopted this guidance beginning with the issuance of our September 30, 2009 financial statements. The adoption of this guidance did not have a material impact on our financial statements.

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In June 2009, the FASB Accounting Standards Codification, or ASC, was issued, effective for financial statements issued for interim and annual periods ending after September 15, 2009. The ASC supersedes literature of the FASB, Emerging Issues Task Force and other sources. The ASC did not change U.S. generally accepted accounting principles. The adoption of this guidance did not have a material impact on our financial statements.

**Quantitative and Qualitative Disclosures about Market Risk**

The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. Our exposure to market risk is confined to our cash and cash equivalents. As of September 30, 2010, we had cash and cash equivalents of \$13.9 million. We do not engage in any hedging activities against changes in interest rates. Because of the short-term maturities of our cash and cash equivalents, we do not believe that an increase in market rates would have any significant impact on the realized value of our investments, but may increase the interest expense associated with our debt.

We have commercial partners for DepoCyte and DepoDur who sell our products in the EU. Under these agreements, we provide finished goods to our commercial partners in exchange for euro-denominated supply revenue, and we also receive euro-denominated royalties on market sales when the products are sold to end users. Under these agreements, we received \$6.8 million in the nine months ended September 30, 2010, \$7.2 million in the year ended December 31, 2009 and \$7.3 million in the year ended December 31, 2008 from these commercial partners.

Because of these agreements, we are subject to fluctuations in exchange rates, specifically in the relative values of the U.S. dollar and the euro. We estimate that an unfavorable fluctuation in exchange rates of 10% would have an impact of approximately \$0.7 million on our annual revenue. Between October 2007 and September 2010 the exchange rate between the U.S. dollar and the Euro ranged between \$1.60 per Euro and \$1.19 per Euro.

**BUSINESS****Overview**

We are an emerging specialty pharmaceutical company focused on the development, commercialization and manufacture of proprietary pharmaceutical products, based on our proprietary DepoFoam drug delivery technology, for use in hospitals and ambulatory surgery centers. We filed a New Drug Application, or NDA, for our lead product candidate, EXPAREL, a long-acting bupivacaine (anesthetic/analgesic) product for postsurgical pain management with the United States Food and Drug Administration, or FDA. Our clinical data demonstrates that EXPAREL provides analgesia for up to 72 hours post-surgery, compared with seven hours or less for bupivacaine. We believe EXPAREL will address a significant unmet medical need for a long-acting non-opioid postsurgical analgesic, resulting in simplified postsurgical pain management and reduced opioid consumption, leading to improved patient outcomes and enhanced hospital economics. We estimate there are approximately 39 million opportunities annually in the United States for EXPAREL to be used. EXPAREL will be launched by certain members of our management team who have successfully launched multiple products in the hospital market.

EXPAREL consists of bupivacaine encapsulated in DepoFoam, both of which are used in FDA-approved products. DepoFoam, our extended release drug delivery technology, is the basis for our two FDA-approved commercial products: DepoCyt(e) and DepoDur, which we manufacture for our commercial partners. DepoFoam-based products have been manufactured for over a decade and have an extensive safety record and regulatory approvals in the United States, European countries and other territories. Bupivacaine, a well-characterized, FDA-approved anesthetic/analgesic, has an established safety profile and over 20 years of use in the United States.

EXPAREL has demonstrated efficacy and safety in two multicenter, randomized, double-blind, placebo-controlled, pivotal Phase 3 clinical trials in patients undergoing soft tissue surgery (hemorrhoidectomy) and orthopedic surgery (bunionectomy). Overall, EXPAREL has demonstrated safety in over 1,300 subjects. In September 2010, we filed an NDA for EXPAREL with the FDA, using a 505(b)(2) application. We are initially seeking approval for postsurgical analgesia by local administration into the surgical wound, or infiltration, a procedure commonly employing bupivacaine. Under the Prescription Drug User Fee Act, or PDUFA, guidelines, the FDA has a goal of ten months from the date of NDA filing to make a decision regarding the approval of our filing. We also plan to expand the indications of EXPAREL to include nerve block and epidural administration, markets where bupivacaine is also used routinely.

Our current product portfolio and product candidate pipeline is summarized in the table below:

<b>Product(s)/ Product Candidate(s)</b>	<b>Primary Indication(s)</b>	<b>Status</b>	<b>Commercialization Rights</b>
<b>EXPAREL</b>	Postsurgical analgesia by infiltration	NDA (submitted)	Pacira (worldwide)
	Postsurgical analgesia by nerve block	Phase 2/3 (planning)	Pacira (worldwide)
	Postsurgical analgesia by epidural administration	Phase 1 (completed)	Pacira (worldwide)
<b>DepoCyt(e)</b>	Lymphomatous meningitis	Marketed	Sigma-Tau Pharmaceuticals Mundipharma International
<b>DepoDur</b>	Post-operative pain	Marketed	EKR Therapeutics Flynn Pharmaceuticals
<b>DepoNSAID</b>	Acute pain	Preclinical	Pacira (worldwide)
<b>DepoMethotrexate</b>	Rheumatoid arthritis	Preclinical	Pacira (worldwide)
	Oncology	Preclinical	Pacira (worldwide)

## **Our Strategy**

Our goal is to be a leading specialty pharmaceutical company focused on the development, commercialization and manufacture of proprietary pharmaceutical products principally for use in hospitals and ambulatory surgery centers. We plan to achieve this by:

- obtaining FDA approval for EXPAREL in the United States for postsurgical analgesia by local infiltration;
- building a streamlined commercial organization concentrating on major hospitals and ambulatory surgery centers in the United States and targeting surgeons, anesthesiologists, pharmacists and nurses;
- working directly with managed care payers, quality improvement organizations, key opinion leaders, or KOLs, in the field of postsurgical pain management and leading influence hospitals with registry programs to demonstrate the economic benefits of EXPAREL;
- securing commercial partnerships for EXPAREL in regions outside of the United States;
- obtaining FDA approval for nerve block and epidural administration indications for EXPAREL;
- manufacturing all our DepoFoam-based products, including EXPAREL, DepoCyt(e) and DepoDur, in our current Good Manufacturing Practices, or cGMP, compliant facilities; and
- continuing to expand our marketed product portfolio through development of additional DepoFoam-based hospital products utilizing a 505(b)(2) strategy.

## **Postsurgical Pain Market Overview**

According to Thomson Reuters, roughly 45 million surgical procedures were performed in the United States during the twelve months ending in October 2007. We estimate there are approximately 39 million opportunities annually in the United States for EXPAREL to be used to improve patient outcomes and enhance hospital economics. Postsurgical pain is a response to tissue damage during surgery that stimulates peripheral nerves, which signal the brain to produce a sensory and psychological response. Numerous studies reveal that the incidence and severity of postsurgical pain is primarily determined by the type of surgery, duration of surgery and the pain treatment choice following surgery. Postsurgical pain is usually greatest the first few days after the completion of a surgical procedure.

## **Limitations of Current Therapies for Postsurgical Pain**

Substantially all surgical patients experience postsurgical pain, with approximately 50% reporting inadequate pain relief according to epidemiological studies. Unrelieved acute pain causes patient suffering and can lead to other health problems, which delays recovery from surgery and may result in higher healthcare costs. According to the Agency for Healthcare Research and Quality, aggressive prevention of pain is better than treatment of pain because, once established, pain is more difficult to suppress. Current multimodal therapy for postsurgical pain includes wound infiltration with local anesthetics combined with the systemic administration of opioid and non-steroidal anti-inflammatory drug, or NSAID, analgesics.

## ***Local Anesthetics***

Treatment of postsurgical pain typically begins at the end of surgery, with local anesthetics, such as bupivacaine, administered by local infiltration. Though this infiltration provides a base platform of postsurgical pain management for the patient, efficacy of conventional bupivacaine and other available local anesthetics is limited, lasting seven hours or less. As local infiltration is not practical after the surgery is complete, and as surgical pain is greatest in the first few days after surgery, additional therapeutics are required to manage postsurgical pain.

## ***Opioids***

Opioids, such as morphine, are the mainstay of postsurgical pain management but are associated with a variety of unwanted and potentially severe side effects, leading healthcare practitioners to seek opioid-sparing strategies for their patients. Opioid side effects include sedation, nausea, vomiting, urinary retention, headache, itching, constipation, cognitive impairment, respiratory depression and death. Side effects from opioids have been demonstrated to reduce the patient's quality of life and result in suboptimal pain relief. These side effects may require additional medications or treatments and prolong a patient's stay in the post-anesthesia care unit and the hospital or ambulatory surgery center, thereby increasing costs significantly.

## ***PCA and Elastomeric Bag Systems***

Opioids are often administered intravenously through patient controlled analgesia, or PCA, systems in the immediate postsurgical period. The total cost of PCA postsurgical pain management for three days can be up to \$500, not including the costs of treating opioid complications. In an attempt to reduce opioid usage, many hospitals employ elastomeric bag systems designed to deliver bupivacaine to the surgical area through a catheter over a period of time. This effectively extends the duration of bupivacaine in the postsurgical site but has significant shortcomings.

PCA systems and elastomeric bag systems are clumsy and difficult to use, which may delay patient ambulation and introduce catheter-related issues, including infection. In addition, PCA systems and elastomeric bags require significant hospital resources to implement and monitor.

## ***NSAIDs***

NSAIDs are considered to be useful alternatives to opioids for the relief of acute pain since they do not produce respiratory depression or constipation. Despite these advantages, the use of injectable NSAIDs, such as ketorolac and ibuprofen, is severely limited in the postsurgical period because they increase the risk of bleeding and gastrointestinal and renal complications.

## **Our Solution—EXPAREL**

Based on our clinical trial data, EXPAREL provides continuous and extended postsurgical analgesia for up to 72 hours and reduces the consumption of supplemental opioid medications. We believe this will simplify postsurgical pain management, minimize breakthrough episodes of pain and result in improved patient outcomes and enhanced hospital economics.

Our EXPAREL strategy has four principal elements:

Replace the use of bupivacaine in postsurgical infiltration. We believe EXPAREL:

- extends postsurgical analgesia for up to 72 hours, from seven hours or less;
- utilizes existing postsurgical infiltration administration techniques;
- dilutes easily with saline to reach desired volume;
- is a ready-to-use formulation; and
- facilitates treatment of both small and large surgical wounds.



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*Become the foundation of a postsurgical pain management regimen in order to reduce and delay opioid usage.* We believe EXPAREL:

- significantly delays and reduces opioid usage while improving postsurgical pain management as demonstrated in our Phase 3 hemorrhoidectomy trial, in which EXPAREL demonstrated the following:
  - delayed first opioid usage to approximately 14 hours post-surgery, compared to approximately one hour for placebo;
  - significantly increased percentage of patients requiring no opioid rescue medication through 72 hours post-surgery, to 28% compared to 10% for placebo;
  - 45% less opioid usage at 72 hours post-surgery compared to placebo; and
  - increased percentage of patients who are pain free at 24 hours post-surgery compared to placebo; and
- may reduce hospital cost and staff monitoring of PCA systems.

*Improve patient satisfaction.* We believe EXPAREL:

- reduces the need for patients to be constrained by elastomeric bags and PCA systems, which are clumsy, difficult to use and may introduce catheter-related issues, including infection;
- promotes maintenance of early postsurgical pain management, thereby reducing the time spent in the intensive care unit; and
- promotes early ambulation, which potentially reduces the risk of life-threatening blood clots, and allows quicker return of bowel function, thereby leading to a faster switch to oral nutrition and medicine, and thus a faster discharge from the hospital.

*Develop and seek approval of EXPAREL for nerve block and epidural administration.* We believe these additional indications for EXPAREL:

- present a low-risk, low-cost opportunity for clinical development; and
- will enable us to fully leverage our manufacturing and sales infrastructure.

#### **EXPAREL Development Program**

EXPAREL has demonstrated efficacy and safety in two multicenter, randomized, double-blind, placebo-controlled, pivotal Phase 3 clinical trials in patients undergoing soft tissue surgery (hemorrhoidectomy) and orthopedic surgery (bunionectomy). At a pre-NDA meeting in February 2010, the FDA acknowledged that the two pivotal Phase 3 clinical trials conducted by us, in patients undergoing hemorrhoidectomy and bunionectomy surgeries, appeared to be appropriately designed to evaluate the safety and efficacy of EXPAREL. Both trials met their primary efficacy endpoints in demonstrating statistically significant analgesia through 72 hours for the hemorrhoidectomy trial and 24 hours for the bunionectomy trial. Both trials also met multiple secondary endpoints, including decreased opioid use and delayed time to first opioid use. These two pivotal Phase 3 clinical trials formed the basis of the evidence for efficacy in the NDA for EXPAREL.

The safety of EXPAREL has been demonstrated in 21 clinical trials consisting of nine Phase 1 trials, seven Phase 2 trials and five Phase 3 trials. EXPAREL was administered to over 1,300 human patients at doses ranging from 10 mg to 750 mg administered by local infiltration into the surgical wound, and by subcutaneous, perineural, epidural and intraarticular administration. In all 21 clinical trials, EXPAREL was well tolerated. The most common treatment emergent adverse events in the EXPAREL and placebo groups were nausea and vomiting and occurred with similar frequency across the EXPAREL and placebo groups. No signal of any of the central nervous system or cardiovascular system adverse events typically observed with high doses of

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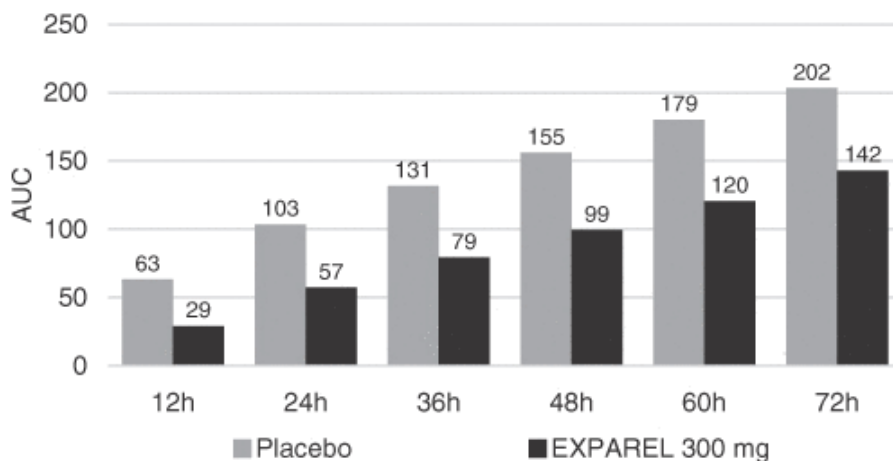
bupivacaine has been observed with EXPAREL. We conducted two thorough QTc studies that demonstrated that EXPAREL did not cause significant QTc prolongation (a measure of cardiac safety mandated by the FDA for all new products) even at the highest dose evaluated. No events of destruction of articular cartilage, or chondrolysis, have been reported in any of the EXPAREL trials. EXPAREL did not require dose adjustment in patients with mild to moderate liver impairment.

**Pivotal Phase 3 Clinical Trials**

**Hemorrhoidectomy.** Our pivotal Phase 3 hemorrhoidectomy clinical trial was a multicenter, randomized, double-blind, placebo-controlled trial conducted in 189 patients at 14 sites in Europe. The study enrolled patients 18 years of age or older undergoing a two or three column excisional hemorrhoidectomy under general anesthesia using the Milligan-Morgan technique, a commonly used method for surgically removing hemorrhoids. We studied a 300 mg dose of EXPAREL with a primary endpoint of pain control for up to 72 hours with morphine rescue medication available to both trial groups. Additional endpoints included the proportion of pain-free patients, proportion of patients requiring opioid rescue medication, total opioid usage, time to first use of opioid rescue medication and patient satisfaction.

The 300 mg dose of EXPAREL provided a statistically significant 30% reduction in pain ( $p < 0.0001$ ), as measured by the area under the curve, or AUC, of the NRS-R pain scores at 72 hours and all additional time points measured up to 72 hours. The numeric rating scale at rest score, or the NRS-R, is a commonly used patient reported measurement of pain. Under the NRS-R, severity of pain is measured on a scale from 0 to 10, with 10 representing the worst possible pain. The AUC of the NRS-R pain score represents a sum of the patient’s pain measured at several time points using the NRS-R, from time of surgery to the specified endpoint. A lower number indicates less cumulative pain. The p-value is a measure of probability that the difference between the placebo group and the EXPAREL group is due to chance (e.g.,  $p = 0.01$  means that there is a 1% ( $0.01 = 1.0\%$ ) chance that the difference between the placebo group and EXPAREL group is the result of random chance as opposed to the EXPAREL treatment). A p-value less than or equal to 0.05 ( $0.05 = 5\%$ ) is commonly used as a criterion for statistical significance.

**Phase 3 Hemorrhoidectomy Clinical Trial: AUC of NRS-R Pain Intensity Scores from Initial Infiltration Timepoint, EXPAREL Compared to Placebo**



Note: Differences between study groups were statistically significant at 72 hours ( $p < 0.0001$ ), the primary endpoint, and all additional time points measured ( $p < 0.0001$ ).

In secondary endpoints, EXPAREL demonstrated efficacy in reducing the use of opioid rescue medication, which was available to both the EXPAREL treatment group and the placebo treatment group. Approximately three times the number of patients in the EXPAREL treatment group avoided opioid rescue medication

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altogether, and patients in the EXPAREL treatment group showed 45% less opioid usage compared to the placebo treatment group at 72 hours. Opioid related secondary endpoints included:

- **Total avoidance of opioid rescue medication.** 28% of patients treated with EXPAREL received no postsurgical opioid rescue pain medication through 72 hours post-dose. By contrast only 10% of placebo treated patients avoided all opioid rescue medication through 72 hours, and this difference was statistically significant ( $p=0.0007$ );
- **Reduced total consumption of opioid rescue medication.** The adjusted mean total postsurgical consumption of supplemental opioid pain medication was 45% lower in patients treated with EXPAREL compared to the placebo treatment group through 72 hours ( $p=0.0006$ ) post-dose; and
- **Delayed use of opioid rescue medication.** EXPAREL delayed the median time to first opioid use from approximately one hour in the placebo treatment group to approximately 14 hours in the EXPAREL treatment group and this difference was statistically significant ( $p<0.0001$ ). At 14 hours post-surgery compared to one hour post-surgery, patients have substantially recovered from the effects of surgical anesthesia and are able to tolerate oral opioids and require less intensive monitoring.

In addition to the reduced usage of opioids compared to patients receiving placebo, secondary endpoints also demonstrated that patients in the EXPAREL treatment group had higher satisfaction scores and more were pain free compared to those in the placebo treatment group.

- **More pain free patients.** A greater percentage of patients treated with EXPAREL were pain free compared to the placebo treatment group, and the difference reached statistical significance at all times up to and through 24 hours post-dose ( $p=0.0448$ ); and
- **Improved patient satisfaction.** A greater percentage of patients treated with EXPAREL were “extremely satisfied” compared to the placebo treatment group, and the difference was statistically significant ( $p=0.0007$ ) at 24 and 72 hours post-dose.

We believe that this combination of reduced opioid usage and continuous and extended postsurgical pain management highlights the efficacy of EXPAREL and its ability to be used as a part of a multimodal, opioid sparing postsurgical pain management strategy.

*Bunionectomy.* Our pivotal Phase 3 bunionectomy clinical trial was a multicenter, randomized, double-blind, placebo-controlled trial conducted in 193 patients at four sites in the United States. The study enrolled patients 18 years of age or older undergoing a bunionectomy. We studied a 120 mg dose of EXPAREL with a primary endpoint of pain control at 24 hours, the critical period for postsurgical pain management in bunionectomy, with opioid rescue medication available to both trial groups. EXPAREL provided a statistically significant reduction in pain, as measured by the AUC of the NRS-R pain scores at 24 hours ( $p=0.0005$ ). This reduction was also statistically significant at 36 hours.

EXPAREL also achieved statistical significance in secondary endpoints related to pain measurement and the use of opioid rescue medication, which was available to both patients in the EXPAREL treatment group and the placebo treatment group, including:

- **Total avoidance of opioid rescue medication.** The difference between treatment groups in the percentage of patients who received opioid rescue pain medication was statistically significant, favoring the group treated with EXPAREL compared to the placebo treatment group through 12 hours ( $p=0.0003$ ) and 24 hours ( $p=0.0404$ );
- **Delayed use of opioid rescue medication.** EXPAREL delayed the median time before first opioid use compared to the placebo treatment group and this difference was statistically significant ( $p<0.0001$ ); and
- **More pain free patients.** A statistically significant increase in the percentage of pain free patients was observed between treatment groups, favoring the group treated with EXPAREL compared to the placebo treatment group at 2 hours ( $p=0.0019$ ), 4 hours ( $p=0.0002$ ), 8 hours ( $p=0.0078$ ) and 48 hours ( $p=0.0153$ ) post-dose. The difference between groups was not statistically significant at 24 hours post-dose.

### ***Other Clinical Trials***

In 2009, we completed two Phase 3 clinical trials comprising 223 patients who received EXPAREL, comparing them to patients who received bupivacaine in a multimodal setting where patients received additional concomitant analgesics. One of these Phase 3 clinical trials was for total knee arthroplasty and the other was for hemorrhoidectomy. Although EXPAREL performed as expected and continued to demonstrate its safety and tolerability, due to the unexpectedly positive results in the control arm, these trials did not meet their primary endpoint. The results of these studies influenced some of the inclusion and exclusion criteria and protocol specified measures used in our successful pivotal Phase 3 clinical trials described above.

Based on the outcome of these two trials, in 2009, we discontinued a Phase 3 clinical trial in breast augmentation early. At the time of discontinuation, we had only enrolled approximately half of the number of patients required to demonstrate statistical significance. EXPAREL demonstrated a positive trend and safety, but did not meet the primary efficacy endpoint. We have collected data on all patients for whom data was available and expect to publish this data in a peer reviewed medical journal.

We have completed seven Phase 2 clinical trials, five of which were in wound infiltration. A total of 452 patients received various doses of EXPAREL and/or bupivacaine in various surgical settings including hernia repair, total knee arthroplasty, hemorrhoidectomy, and breast augmentation. The data from these Phase 2 clinical trials guided the dose selection for our successful pivotal Phase 3 clinical trials, which formed the basis of our NDA.

### ***EXPAREL Health Economic Benefits***

In addition to being efficacious and safe, we believe that EXPAREL provides health economic benefits that play an important role in formulary decision making and these health economic benefits are an often over-looked factor in planning for the commercial success of a pharmaceutical product. Several members of our management team have extensive experience applying health economic outcomes research to support the launch of successful commercial products. Our strategy is to work directly with managed care payers, quality improvement organizations, KOLs in the field of postsurgical pain management and leading influence hospitals with registry programs to demonstrate the economic benefits of EXPAREL.

EXPAREL is designed as a single postsurgical injection intended to replace the current use of clumsy and expensive PCA systems and elastomeric bag systems, reduce the consumption of opioids, and their related side effects, and reduce the length of stay in the hospital, all factors that negatively impact patient outcomes and hospital economics. For example, in our Phase 2 hemorrhoidectomy trial, 300 mg of EXPAREL reduced pain by 47%, as measured by the AUC of the NRS-R pain scores, with a 66% reduction in opioid consumption and a corresponding 89% reduction in opioid related adverse events through 72 hours, compared to the standard 75 mg dose of bupivacaine.

We intend to expand upon the results of this Phase 2 hemorrhoidectomy trial with commercial registry programs designed to confirm that the administration of EXPAREL in the surgical setting improves patient outcomes while consuming fewer resources. We intend to develop publications, abstracts, clinical pharmacology newsletters and meeting presentations that demonstrate the value of EXPAREL as the foundation for effective multimodal postsurgical pain management. In addition, we plan to develop new treatment protocols for postsurgical pain management overall and in specific patient populations.

Reimbursement for surgical procedures is typically capitated, or fixed by third-party payers based on the specific surgical procedure performed regardless of the cost or amount of treatments provided. However, many patients, including those who are elderly, obese, suffer from sleep apnea or are opioid tolerant, are likely to have a high incidence of opioid-related adverse events, increasing the length of stay and the cost relative to the capitated reimbursement. We intend to conduct commercial registry studies to demonstrate reduced opioid use,

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reduced opioid-related adverse effects, lower total resource consumption, reduced length of stay and greater patient satisfaction. Furthermore, the use of EXPAREL to reduce opioid consumption may also present the opportunity to move selected hospital procedures to the ambulatory setting.

***EXPAREL Regulatory Plan***

In September 2010, we filed an NDA for EXPAREL with the FDA, using a 505(b)(2) application. We are initially seeking FDA approval of EXPAREL for postsurgical analgesia by local administration into the surgical wound, or infiltration, a procedure commonly employing bupivacaine. Under the PDUFA guidelines, the FDA has a goal of ten months from the date of an NDA filing to make a decision regarding the approval of our filing. Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or the FDCA, permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant, and for which the applicant has not obtained a right of reference. Supportive information may also include scientific literature and publicly available information contained in the labeling of other medications.

EXPAREL consists of bupivacaine encapsulated in DepoFoam, both of which are used in FDA-approved products:

- Bupivacaine, a well-characterized generic anesthetic/analgesic, has an established safety profile and over 20 years of use in the United States.
- DepoFoam, modified to meet the requirements of each product, is used to extend the release of the active drug substances in the marketed products DepoCyt(e) and DepoDur.

We have requested a clinical trial waiver for children under two years of age. We have also requested and currently expect to receive a deferral for patients 2-18 years of age until patients in these groups can be studied in an appropriate step-wise manner. Three Phase 2/3 trials are planned, first in children 12-18 years old, then 6-11 years old, then 2-5 years old. The waiver and deferral, if granted, will allow us to conduct these trials after the approval of our NDA.

***Additional Indications***

We are pursuing several additional indications for EXPAREL and expect to submit a supplemental NDA, or sNDA, for nerve block and epidural administration. We believe that these additional indications for EXPAREL present a low-risk, low-cost opportunity for clinical development and will allow us to fully leverage our manufacturing and commercial infrastructure.

*Nerve Block.* Nerve block is a general term used to refer to the injection of local anesthetic onto or near nerves for control of pain. Nerve blocks can be single injections but have limited duration of action. When extended pain management is required, a catheter is used to deliver bupivacaine continuously using an external pump. According to Thomson Data over eight million nerve block procedures were conducted in the United States in 2008, with over four million of these procedures utilizing bupivacaine. EXPAREL is designed to provide extended pain management with a single injection utilizing a narrow gauge needle.

We have completed two Phase 2 clinical trials in which 40 patients received EXPAREL for nerve block. EXPAREL demonstrated efficacy and was safe and well tolerated in these clinical trials. We expect to conduct additional clinical trials in this indication.

*Epidural Administration.* An epidural is a form of regional anesthesia involving injection of anesthetic drugs into the outermost part of the spinal canal, or the epidural space. Epidurals can be single injections but have limited duration of action. When extended pain management is required, a catheter is placed into the epidural space and the anesthetic drug is delivered continuously using an external pump. According to IMS and

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Thomson Data, over six million epidural procedures were conducted in the United States in 2007, with over 590,000 of these procedures utilizing local anesthetics, including bupivacaine. EXPAREL is designed to provide extended pain management with a single injection utilizing a narrow gauge needle.

We have completed one Phase 1 clinical trial in which 24 subjects received EXPAREL by epidural administration that demonstrated proof of concept for this indication. EXPAREL was safe and well tolerated in this clinical trial. We expect to conduct additional clinical trials in this indication.

### **Sales and Marketing**

We currently intend to develop and commercialize EXPAREL and our other product candidates in the United States while out-licensing commercialization rights for other territories. Our goal is to retain significant control over the development process and commercial execution for our product candidates, while participating in a meaningful way in the economics of all drugs that we bring to the market.

The members of our management team who will lead the commercialization of EXPAREL, if it is approved, have successfully commercialized multiple products in the hospital market, including Rocephin, Versed, Zantac IV and Angiomax. We are currently developing our commercialization strategy, with the input of KOLs in the field of postsurgical pain management as well as healthcare practitioner and quality improvement organizations. We continue to expand our pre-commercialization activities including EXPAREL positioning and messaging, publication strategy, Phase 3b/4 clinical trials and registry trials, initiatives with payer organizations, and distribution and national accounts strategies.

If EXPAREL is approved, we intend to hire our own dedicated field sales force, consisting of approximately 40 representatives at the time of the commercial launch, to commercialize the product. Within three years of launch we expect to have approximately 100 representatives, which we estimate can effectively cover our hospital and ambulatory surgery customers in the United States. We believe a typical sales representative focused on office-based healthcare practitioners can effectively reach five to seven healthcare practitioners per day; whereas, a typical hospital-focused sales representative can reach many more healthcare practitioners. Notably, a hospital-focused sales representative faces significantly less travel time between sales calls and less wait time in healthcare practitioner offices as a large number of prescribers can be found in a single location. Our sales force will be supported by marketing as well as several teams of healthcare professionals who will support our formulary approval and customer education initiatives.

The target audience for EXPAREL is healthcare practitioners who influence pain management decisions, including surgeons, anesthesiologists, pharmacists and nurses. Our commercial sales force will focus on reaching the top 1,000 U.S. hospitals performing surgical procedures (based on Thomson Reuters benchmark obstetrician and gynecological, general and orthopedic surgical procedures performed within these hospitals), which represent approximately 70% of the market opportunity for EXPAREL. If we obtain regulatory approvals for additional indications for EXPAREL and our other product candidates, our targeted audience may change to reflect new market opportunities.

### **DepoFoam—Our Proprietary Drug Delivery Technology**

Our current product development activities utilize our proprietary DepoFoam drug delivery technology. DepoFoam consists of microscopic spherical particles composed of a honeycomb-like structure of numerous internal aqueous chambers containing an active drug ingredient. Each chamber is separated from adjacent chambers by lipid membranes. Following injection, the DepoFoam particles release drug over an extended period of time by erosion and/or reorganization of the particles' lipid membranes. Release rates are determined by the choice and relative amounts of lipids in the formulation.

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Our DepoFoam formulation provides several technical, regulatory and commercial advantages over competitive technologies, including:

- Convenience. Our DepoFoam products are ready to use and do not require reconstitution or mixing with another solution, and can be used with patient friendly narrow gauge needles and pen systems;
- Multiple regulatory precedents. Our DepoFoam products, DepoCyt(e) and DepoDur, have been approved in the United States and Europe, making regulatory authorities familiar with our DepoFoam technology;
- Extensive safety history. Our DepoFoam products have over ten years of safety data as DepoCyt(e) has been sold in the United States since 1999;
- Administration into privileged sites. Our DepoFoam products are approved for epidural administration (DepoDur) and intrathecal injection (DepoCyt(e)) and may potentially be used for intraocular and intratumoral administration;
- Proven manufacturing capabilities. We continue to make DepoFoam-based products in our cGMP facilities on a daily basis as we prepare for the launch of EXPAREL;
- Flexible time release. Encapsulated drug releases over a desired period of time, from 1 to 30 days;
- Favorable pharmacokinetics. Decrease in adverse events associated with high peak blood levels, thereby improving the utility of the product;
- Shortened development timeline. Does not alter the native molecule potentially enabling the filing of a 505(b)(2) application; and
- Aseptic manufacturing and filling. Enables use with proteins, peptides, nucleic acids, vaccines and small molecules.

### **Other Products**

#### ***Depocyt(e)***

DepoCyt(e) is a sustained-release liposomal formulation of the chemotherapeutic agent cytarabine utilizing our DepoFoam technology. Depocyt(e) is indicated for the intrathecal treatment of lymphomatous meningitis, a life-threatening complication of lymphoma, a cancer of the immune system. Lymphomatous meningitis can be controlled with conventional cytarabine, but because of the drug's short half-life, a spinal injection is required twice per week, whereas DepoCyt(e) is dosed once every two weeks in an outpatient setting. DepoCyt(e) was granted accelerated approval by the FDA in 1999 and full approval in 2007. We received revenue from DepoCyt(e) of \$9.6 million from our commercial partners in 2009.

#### ***DepoDur***

DepoDur is an extended-release injectable formulation of morphine utilizing our DepoFoam technology. DepoDur is indicated for epidural administration for the treatment of pain following major surgery. DepoDur is designed to provide effective pain relief of up to 48 hours and has demonstrated improved patient mobility and freedom from indwelling catheters. DepoDur was approved by the FDA in 2004. We received revenue from DepoDur of \$0.8 million from our commercial partners in 2009.

### **Other Product Candidates**

#### ***DepoNSAID***

Our preclinical product candidates, extended release formulations of NSAIDs, are designed to provide the benefits of injectable NSAIDs with a prolonged duration of action in order to improve patient care and ease of use in the acute pain environment. Currently available injectable products provide a four to six hour duration of action. We believe that there is an unmet medical need for a product which could provide a longer duration of

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action, especially for postsurgical pain management as part of a multimodal pain regimen. Prolonged intra-articular delivery of NSAIDs is also being evaluated for acute pain in major joints due to injury or arthritis. We have DepoFoam formulations for several NSAIDs, and we expect to select a lead product candidate in 2011.

***DepoMethotrexate***

Our preclinical product candidate, an extended release formulation of methotrexate, is designed to improve the market utility of methotrexate, the most commonly used disease modifying anti-rheumatic drug currently being prescribed for over 500,000 patients globally. While methotrexate is the established standard of care for first line therapy in rheumatoid arthritis, this agent is commonly associated with nausea, vomiting and drowsiness due to high peak blood levels immediately following traditional administration. Our product candidate is designed to address the medical need for a patient friendly and cost effective formulation which can be utilized to improve patient compliance and the ability to tolerate methotrexate therapy. We believe DepoMethotrexate will also allow healthcare providers to treat these patients more aggressively, improve efficacy outcomes and avoid the progression to more expensive alternatives such as biologic therapies. We currently have one year of stability data for our desired product formulation.

**Commercial Partners and Agreements**

***SkyePharma***

In connection with the stock purchase agreement related to the Acquisition, we agreed to pay SkyePharma Holdings, Inc., or SPHI, a specified contingent milestone payment related to EXPAREL sales. Additionally, we agreed to pay to SPHI a 3% royalty of our sales of EXPAREL in the United States, Japan, the United Kingdom, France, Germany, Italy and Spain. Such obligations to make contingent milestone payments and royalties will continue for the term in which such sales related to EXPAREL are covered by a valid claim in certain patent rights related to EXPAREL and other biologics products.

We have the right to cease paying royalties in the event that SPHI breaches certain covenants not to compete contained in the stock purchase agreement. In the event that we cease to sell EXPAREL and begin marketing a similar replacement product for EXPAREL, we would no longer be obligated to make royalty payments, but we may be required to make certain milestone payments upon reaching certain sales milestones.

***Research Development Foundation***

Pursuant to an agreement with one of our stockholders, the Research Development Foundation, or RDF, we are required to pay RDF a low single-digit royalty on our gross revenues, as defined in our agreement with RDF, from our DepoFoam-based products, for as long as certain patents assigned to us under the agreement remain valid. RDF has the right to terminate the agreement for an uncured material breach by us, in connection with our bankruptcy or insolvency or if we directly or indirectly oppose or dispute the validity of the assigned patent rights.

***Sigma-Tau Pharmaceuticals***

In December 2002, we entered into a supply and distribution agreement with Enzon Pharmaceuticals Inc. regarding the sale of DepoCyt. Pursuant to the agreement, Enzon was appointed the exclusive distributor of DepoCyt in the United States and Canada for a ten year term. In January 2010, Sigma-Tau Pharmaceuticals, Inc., or Sigma-Tau, acquired the rights to sell DepoCyt from Enzon Pharmaceuticals for the United States and Canada. Under the supply and distribution agreement, we supply unlabeled DepoCyt vials to Sigma-Tau for finished packaging. Under these agreements, we receive a fixed payment for manufacturing the vials of DepoCyt and a royalty in the thirties on sales by Sigma-Tau in the United States and Canada.

We and Sigma-Tau have the right to terminate the agreement for an uncured material breach by the other party or in the event that a generic pharmaceutical product that is therapeutically equivalent to DepoCyt is



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commercialized. We may terminate the agreement if certain minimum sales targets are not met by Sigma-Tau. Sigma-Tau may terminate the agreement if, as a result of a settlement or a final court or regulatory action, the manufacture, use or sale of DepoCyt in the United States is prohibited.

***Mundipharma International Holdings Limited***

In June 2003, we entered into an agreement granting Mundipharma International Holdings Limited, or Mundipharma, exclusive marketing and distribution rights to DepoCyt in the European Union and certain other European countries. This agreement continues in force for a fixed term, and after that term expires, continues year to year unless terminated by us or by Mundipharma upon written notice given within a specified timeframe.

Under the agreement, as amended, and a separate supply agreement, we receive a fixed payment for manufacturing the vials of DepoCyt, as well as a royalty comprised of a fixed sum per vial supplied to Mundipharma, an additional sum payable if Mundipharma's quarterly net sales exceed a certain amount, and a mid single-digit royalty on all sales exceeding a certain amount. We are also entitled to receive milestone payments from Mundipharma upon the achievement by Mundipharma of certain milestone events.

We and Mundipharma have the right to terminate the agreement for an uncured material breach by the other party, in connection with the other party's bankruptcy or insolvency or the repossession of all or any material part of the other party's business or assets. Mundipharma has the right to terminate the agreement if its marketing authorization is cancelled or withdrawn for a certain period, or if it is prevented from selling DepoCyt in any three countries in the territory covered in the agreement by a final non-appealable judgment in respect of infringement by DepoCyt of any third party intellectual property rights.

***EKR Therapeutics Inc.***

In August 2007, we entered into a licensing, distribution and marketing agreement with EKR Therapeutics, Inc., or EKR, granting them exclusive distribution rights to DepoDur in North America, South America and Central America. This agreement continues in force for the longer of 15 years from the first commercial sale of DepoDur in the territory covered by the agreement or until the expiration of the last valid claim in our patents covering DepoDur in such territory. After that term, the agreement continues for consecutive periods of two years, unless terminated earlier by EKR.

Under this agreement, as amended, we receive a fixed payment for manufacturing the vials of DepoDur and a royalty comprised of a fixed amount per vial, a single-digit royalty on any incremental price increase implemented by EKR over the base price specified in the agreement and a fixed advanced royalty payment that was made within three days of the agreement date, which is offset against EKR's future payment obligations.

We and EKR have the right to terminate the agreement for an uncured material breach by the other party, an uncured material misrepresentation in any representation or warranty made in the agreement, in connection with the other party's bankruptcy or insolvency, in connection with the threat of or actual cessation of all or any material part of the other party's business, if the other Party is prevented from performing any of its material obligations by any law, governmental or other action for a period of 120 days, or if force majeure prevents other party from performing any of its material obligations for six months. We have the right to terminate the agreement if EKR fails to make its first commercial sale of DepoDur within a fixed period from the receipt of marketing authorization for any country in the territory covered by the agreement, or if we terminate the supply agreement upon written notice to EKR and all royalties paid by EKR to us in any one year period following the date of such termination are less than a certain amount, unless the difference between that amount and the actual royalties paid by EKR is paid to us within 30 days of notice of such termination. EKR has the right to terminate the agreement at any time without cause upon written notice to us within a specified timeframe. EKR has the right to terminate the agreement as to any country if DepoDur is withdrawn from the market in such country as a

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result of regulatory action by FDA or other governmental entities or there are significant adverse reactions from use of DepoDur.

***Flynn Pharma Limited***

In September 2007, we entered into a marketing agreement with Flynn Pharma Limited, or Flynn, granting them exclusive distribution rights to DepoDur in the European Union, certain other European countries, South Africa and the Middle East. This agreement continues in force for the longer of five years from first commercial sale of DepoDur in the territory covered by the agreement or until the expiration of the last valid claim in our patents covering DepoDur for a maximum term of 15 years from the date of first commercial sale in such territory.

Under this agreement and a separate supply agreement with Flynn, we provide DepoDur manufacturing supply of finished product for sale in the territories licensed by Flynn, and we receive a fixed payment for manufacturing the vials and if net sales of DepoDur in the territory covered by the agreement exceed a certain amount, an additional payment. We are also entitled to receive milestone payments from Flynn upon the achievement by Flynn of certain milestone events.

We and Flynn have the right to terminate the agreement for an uncured material breach by the other party, in connection with the other party's bankruptcy or insolvency or the repossession of all or any material part of the other party's business or assets, or if force majeure prevents other party from performing any of its material obligations for 180 days. We have the right to terminate the agreement if Flynn fails to make its first commercial sale of DepoDur in specified countries covered by the agreement by one year from the later of Flynn's receipt of marketing authorization or pricing approval for DepoDur, or if first commercial sale has not been made within 18 months of Flynn's receipt of marketing authorization or pricing approval for DepoDur.

***Paul Capital***

On March 23, 2007, we entered into an amended and restated royalty interests assignment agreement with Paul Capital, pursuant to which we assigned to Paul Capital the right to receive a portion of our royalty payments from DepoCyt(e) and DepoDur. The original agreement was entered into prior to the Acquisition by the Predecessor in order to monetize certain royalty payments from DepoCyt(e) and DepoDur. In connection with the Acquisition, the original agreement with Paul Capital was amended and restated and the responsibility to pay the royalty interest in product sales of DepoCyt(e) and DepoDur was transferred to us and we were required to make payments to Paul Capital upon the occurrence of certain events. For additional information, see "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Royalty Interests Assignment Agreement" and "Risk Factors—Risks Related to Our Financial Condition and Capital Requirements—Under our financing arrangement with Paul Capital, upon the occurrence of certain events, Paul Capital may require us to repurchase the right to receive royalty payments that we assigned to it, or may foreclose on certain assets that secure our obligations to Paul Capital. Any exercise by Paul Capital of its right to cause us to repurchase the assigned right or any foreclosure by Paul Capital would adversely affect our results of operations and our financial condition."

***Feasibility Agreements with Third Parties***

In the ordinary course of our business activities, we enter into feasibility agreements with third parties who desire access to our proprietary DepoFoam technology to conduct research, feasibility and formulation work. Under these agreements, we are compensated to perform feasibility testing on a third-party product to determine the likelihood of developing a successful formulation of that product using our proprietary DepoFoam technology. If successful in the feasibility stage, these programs can advance to a full development contract. Currently, we are actively engaged in two feasibility assessments for third parties.

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## **Manufacturing**

We manufacture DepoCyt(e) and DepoDur for our various commercial partners. We also manufacture all of our clinical supplies of EXPAREL. We manufacture our products in two manufacturing facilities. These facilities are designated as Building 1 and Building 6 and are located within two miles of each other on two separate and distinct sites in San Diego, California. Both of our facilities are inspected regularly and approved for pharmaceutical manufacturing by the FDA, the European Medicines Agency, or the EMA, the Medicines and Healthcare Products Regulatory Agency, or the MHRA, the Drug Enforcement Administration, or the DEA, and the Environmental Protection Agency, or the EPA.

We provide DepoCyt(e) and DepoDur to our commercial partners on a set cost basis as established by each specific licensing contract. All manufacturing of products, initial product release and stability testing are conducted by us in accordance with cGMP.

Building 1 is an approximately 80,000 square foot concrete structure located on a five acre site. It was custom built as a pharmaceutical R&D and manufacturing facility in August 1995. Activities in this facility include the manufacture of EXPAREL bulk pharmaceutical product candidate in a dedicated production line and its fill/finish into vials, the manufacture of the DepoDur bulk commercial pharmaceutical product, microbiological and quality control testing, product storage, development of analytical methods, research and development, the coordination of clinical and regulatory functions, and general administrative functions. We are renovating the dedicated EXPAREL production line to expand its capacity and expect it to be available for the FDA's pre-approval inspection in 2011. This production line is designed to meet forecasted market demands after initial launch of EXPAREL, if it is approved. We have current plans to further expand our manufacturing capacity to meet future demand.

Building 6 is located in a 17-acre pharmaceutical industrial park. It is a two story concrete masonry structure built in 1977 that we and our predecessors have leased since August 1993. We occupy approximately 22,000 square feet of the first floor. Building 6 houses the current manufacturing process for DepoCyt(e), the fill/finish of DepoCyt(e) and DepoDur into vials, a pilot plant suite for new product development and early stage clinical product production, a microbiology laboratory and miscellaneous support and maintenance areas.

Distribution of our DepoFoam products, including EXPAREL, requires cold-chain distribution, whereby a product must be maintained between specified temperatures. We have validated processes for continuous monitoring of temperature from manufacturing through delivery to the end-user. We and our partners have utilized similar cold-chain processes for DepoCyt(e) and DepoDur.

## **Intellectual Property and Exclusivity**

We seek to protect our product candidates and our technology through a combination of patents, trade secrets, proprietary know-how, regulatory exclusivity and contractual restrictions on disclosure.

### ***Patents and Patent Applications***

We seek to protect the proprietary position of our product candidates by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. As of September 30, 2010, there are over 15 families of patents and patent applications relating to various aspects of the DepoFoam delivery technology. Patents have been issued in numerous countries, with an emphasis on the North American, European and Japanese markets. These patents generally have a term of 20 years from the date of the nonprovisional filing unless referring to an earlier filed application. Some of our U.S. patents have a term from 17 years from the grant date. Our issued patents expire at various dates in the future, with the last currently issued patent expiring in 2019. All of these patent families are assigned solely to us, with the exception of one family relating to DepoFoam formulations of insulin-like growth factor I, which is jointly assigned to us and Novartis Vaccines and Diagnostics, Inc. (formerly Chiron Corporation). In addition, two provisional patents have been filed within the last year relating to either DepoFoam-based products or processes for making DepoFoam.

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In regard to patents providing protection for EXPAREL, issued patents in the United States relating to the composition of the product candidate and methods for modifying the rate of drug release of the product candidate expire in November 2013 and January 2017, respectively. Pending U.S. applications relating to the composition of the product candidate and the process for making the product candidate, if granted, would expire in September 2018 and November 2018, respectively. In Europe, granted patents related to the composition of the product candidate expire in November 2014 and September 2018. Pending applications in Europe relating to methods of modifying the rate of drug release of the product candidate and the process for making the product candidate, if granted, would expire in January 2018 and November 2018, respectively. Recently, a provisional patent was filed relating to a new process to manufacture EXPAREL and other DepoFoam-based products. The process offers many advantages to the current process, including larger scale production and lower manufacturing costs. A strategic decision will be made within the next year as to whether this process will be kept as a trade secret (provisional patents are not publicly disclosed if a subsequent non-provisional application is not filed) or pursued as a non-provisional application. The provisional patent, if granted, could prevent others from using this process until 2031.

### ***Trade Secrets and Proprietary Information***

Trade secrets play an important role in protecting DepoFoam-based products and provide protection beyond patents and regulatory exclusivity. The scale-up and commercial manufacture of DepoFoam products involves processes, custom equipment, and in-process and release analytical techniques that we believe are unique to us. The expertise and knowledge required to understand the critical aspects of DepoFoam manufacturing steps requires knowledge of both traditional and non-traditional emulsion processing and traditional pharmaceutical production, overlaid with all of the challenges presented by aseptic manufacturing. We seek to protect our proprietary information, including our trade secrets and proprietary know-how, by requiring our employees, consultants and other advisors to execute proprietary information and confidentiality agreements upon the commencement of their employment or engagement. These agreements generally provide that all confidential information developed or made known during the course of the relationship with us be kept confidential and not be disclosed to third parties except in specific circumstances. In the case of our employees, the agreements also typically provide that all inventions resulting from work performed for us, utilizing our property or relating to our business and conceived or completed during employment shall be our exclusive property to the extent permitted by law. Where appropriate, agreements we obtain with our consultants also typically contain similar assignment of invention obligations. Further, we require confidentiality agreements from entities that receive our confidential data or materials.

### **Competition**

The pharmaceutical and biotechnology industries are intensely competitive and subject to rapid and significant technological change. Our competitors include organizations such as major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and generic drug companies. Many of our competitors have greater financial and other resources than we have, such as more commercial resources, larger research and development staffs and more extensive marketing and manufacturing organizations. As a result, these companies may obtain marketing approval more rapidly than we are able and may be more effective in selling and marketing their products. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Our competitors may succeed in developing, acquiring or licensing on an exclusive basis technologies and drug products that are more effective or less costly than EXPAREL or any other products that we are currently selling through partners or developing or that we may develop, which could render our products obsolete and noncompetitive. We expect any products that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price and the availability of reimbursement from government and other third-party payers. We also expect to face competition in our efforts to identify appropriate collaborators or partners to help commercialize our product candidates in our target commercial markets.

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We anticipate EXPAREL will compete with currently marketed bupivacaine and opioid analgesics such as morphine. We also expect to compete with an extended release bupivacaine product in development by Durect Corporation which has been licensed to Hospira in North America (Posidur) and to Nycomed for Europe (Optesia).

We also anticipate that EXPAREL will compete with elastomeric bag/catheter devices intended to provide bupivacaine over several days. I-FLOW Corporation (acquired by Kimberly-Clark Corporation in 2009) has marketed these medical devices in the United States since 2004.

### **Government Regulation**

#### ***Federal Food, Drug and Cosmetic Act***

Prescription drug products are subject to extensive pre- and post-market regulation by the FDA, including regulations that govern the testing, manufacturing, distribution, safety, efficacy, approval, labeling, storage, record keeping, reporting, advertising and promotion of such products under the FDCA, and its implementing regulations, and by comparable agencies and laws in foreign countries. Failure to comply with applicable FDA or other regulatory requirements may result in, among other things, warning letters, clinical holds, civil or criminal penalties, recall or seizure of products, injunction, debarment, partial or total suspension of production or withdrawal of the product from the market. The FDA must approve any new drug, including a new dosage form or new use of a previously approved drug, prior to marketing in the United States. All applications for FDA approval must contain, among other things, information relating to safety and efficacy, pharmaceutical formulation, stability, manufacturing, processing, packaging, labeling and quality control.

#### ***New Drug Applications***

Generally, the FDA must approve any new drug before marketing of the drug occurs in the United States. This process generally involves:

- completion of preclinical laboratory and animal testing and formulation studies in compliance with the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin in the United States;
- approval by an independent institutional review board, or IRB, at each clinical trial site before each trial may be initiated;
- performance of human clinical trials, including adequate and well-controlled clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each intended use;
- submission of an NDA to the FDA;
- satisfactory completion of an FDA pre-approval inspection of the product's manufacturing facility or facilities to assess compliance with the FDA's cGMP regulations, and to ensure that the facilities, methods and controls are adequate to preserve the drug's identity, quality and purity;
- satisfactory completion of an FDA advisory committee review, if applicable; and
- approval by the FDA of the NDA.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that the FDA will grant approvals for any of our product candidates on a timely basis, if at all. Preclinical tests include laboratory evaluation of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals. The results of preclinical tests, together with manufacturing information, analytical data and a proposed clinical trial protocol and other information, are

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submitted as part of an IND application to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the trial on a clinical hold because of, among other things, concerns about the conduct of the clinical trial or about exposure of human research subjects to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Our submission of an IND may not result in FDA authorization to commence a clinical trial. In addition, the FDA requires sponsors to amend an existing IND for each successive clinical trial conducted during product development. Further, an independent institutional review board, or IRB, covering each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial and informed consent information for subjects before the clinical trial commences at that center, and it must monitor the clinical trial until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time, or from time to time, on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. For purposes of an NDA submission and approval, typically, the conduct of human clinical trials occurs in the following three pre-market sequential phases, which may overlap:

- *Phase 1:* sponsors initially conduct clinical trials in a limited population to test the product candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients, such as cancer patients.
- *Phase 2:* sponsors conduct clinical trials generally in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted indications and to determine dose tolerance and optimal dosage. Sponsors may conduct multiple Phase 2 clinical trials to obtain information prior to beginning larger and more extensive Phase 3 clinical trials.
- *Phase 3:* these include expanded controlled and uncontrolled trials, including pivotal clinical trials. When Phase 2 evaluations suggest the effectiveness of a dose range of the product and acceptability of such product's safety profile, sponsors undertake Phase 3 clinical trials in larger patient populations to obtain additional information needed to evaluate the overall benefit and risk balance of the drug and to provide an adequate basis to develop labeling.

In addition, sponsors may elect to conduct, or be required by the FDA to conduct, Phase 4 clinical trials to further assess the drug's safety or effectiveness after NDA approval. Such post approval trials are typically referred to as Phase 4 clinical trials.

Sponsors submit the results of product development, preclinical studies and clinical trials to the FDA as part of an NDA. NDAs must also contain extensive information relating to the product's pharmacology, chemistry, manufacture, controls and proposed labeling, among other things. In addition, 505(b)(2) applications must contain a patent certification for each patent listed in FDA's "Orange Book" that covers the drug referenced in the application and upon which the third-party studies were conducted. For some drugs, the FDA may require risk evaluation and mitigation strategies, or REMS, which could include medication guides, physician communication plans, or restrictions on distribution and use, such as limitations on who may prescribe the drug or where it may be dispensed or administered. Upon receipt, the FDA has 60 days to determine whether the NDA is sufficiently complete to initiate a substantive review. If the FDA identifies deficiencies that would preclude substantive review, the FDA will refuse to accept the NDA and will inform the sponsor of the deficiencies that must be corrected prior to resubmission. If the FDA accepts the submission for substantive review, the FDA typically reviews the NDA in accordance with established timeframes. Under PDUFA, the FDA agrees to specific goals for NDA review time through a two-tiered classification system, Priority Review and Standard Review. A Priority Review designation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. For a Priority Review application, the FDA aims to complete the

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initial review cycle in six months. Standard Review applies to all applications that are not eligible for Priority Review. The FDA aims to complete Standard Review NDAs within a ten-month timeframe. We anticipate that the FDA will grant our product candidate a Standard Review. Review processes often extend significantly beyond anticipated completion dates due to FDA requests for additional information or clarification, difficulties scheduling an advisory committee meeting, negotiations regarding REMS, or FDA workload issues. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to the application's approval. The recommendations of an advisory committee do not bind the FDA, but the FDA generally follows such recommendations.

Under PDUFA, NDA applicants must pay significant NDA user fees upon submission. In addition, manufacturers of approved prescription drug products must pay annual establishment and product user fees.

Before approving an NDA, the FDA may inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to ensure consistent production of the product within required specifications. Additionally, the FDA will typically inspect one or more clinical sites to ensure compliance with GCP before approving an NDA.

After the FDA evaluates the NDA and the manufacturing facilities, it may issue an approval letter or a Complete Response Letter, or CRL, to indicate that the review cycle for an application is complete and that the application is not ready for approval. CRLs generally outline the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we do. The FDA could also require a REMS plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, a commitment to conduct one or more post-market studies or clinical trials and the correction of identified manufacturing deficiencies, including the development of adequate controls and specifications. If and when the deficiencies have been addressed to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

### ***Section 505(b)(2) New Drug Applications***

As an alternate path to FDA approval, particularly for modifications to drug products previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, and permits the submission of an NDA where at least some of the information required for approval comes from clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA interprets Section 505(b)(2) of the FDCA to permit the applicant to rely upon the FDA's previous findings of safety and effectiveness for an approved product. The FDA may also require companies to perform additional clinical trials or measurements to support any change from the previously approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

Section 505(b)(2) applications are subject to any non-patent exclusivity period applicable to the referenced product, which may delay approval of the 505(b)(2) application even if FDA has completed its substantive review and determined the drug should be approved. In addition, 505(b)(2) applications must include patent certifications to any patents listed in the Orange Book as covering the referenced product. If the 505(b)(2) applicant seeks to obtain approval before the expiration of an applicable listed patent, the 505(b)(2) applicant

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must provide notice to the patent owner and NDA holder of the referenced product. If the patent owner or NDA holder bring a patent infringement lawsuit within 45 days of such notice, the 505(b)(2) application cannot be approved for 30 months or until the 505(b)(2) applicant prevails, whichever is sooner. If the 505(b)(2) applicant loses the patent infringement suit, FDA may not approve the 505(b)(2) application until the patent expires, plus any period of pediatric exclusivity.

In the NDA submissions for our product candidates, we intend to follow the development and approval pathway permitted under the FDCA that we believe will maximize the commercial opportunities for these product candidates.

***Post-Approval Requirements***

After approval, the NDA sponsor must comply with comprehensive requirements governing, among other things, drug listing, recordkeeping, manufacturing, marketing activities, product sampling and distribution, annual reporting and adverse event reporting. There are also extensive U.S. Drug Enforcement Agency, or DEA, regulations applicable to marketed controlled substances.

If new safety issues are identified following approval, the FDA can require the NDA sponsor to revise the approved labeling to reflect the new safety information; conduct post-market studies or clinical trials to assess the new safety information; and implement a REMS program to mitigate newly-identified risks. The FDA may also require post-approval testing, including Phase 4 studies, and surveillance programs to monitor the effect of approved products which have been commercialized, and the FDA has the authority to prevent or limit further marketing of a product based on the results of these post-marketing programs. Drugs may be marketed only for approved indications and in accordance with the provisions of the approved label. Further, if we modify a drug, including any changes in indications, labeling or manufacturing processes or facilities, the FDA may require us to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional preclinical studies and clinical trials.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use.

If after approval the FDA determines that the product does not meet applicable regulatory requirements or poses unacceptable safety risks, the FDA may take other regulatory actions, including initiating suspension or withdrawal of the NDA approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.



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The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet, and off-label promotion. While physicians may prescribe for off label uses, manufacturers may only promote for the approved indications and in accordance with the provisions of the approved label. The FDA has very broad enforcement authority under the FDCA, and failure to abide by these regulations can result in penalties, including the issuance of a warning letter directing entities to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and state and federal civil and criminal investigations and prosecutions.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution, including a drug pedigree which tracks the distribution of prescription drugs.

### ***DEA Regulation***

One of our marketed products, DepoDur, is regulated as a “controlled substance” as defined in the Controlled Substances Act of 1970, or CSA, which establishes registration, security, recordkeeping, reporting, storage, distribution and other requirements administered by the DEA. The DEA is concerned with the control of handlers of controlled substances, and with the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use, and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. DepoDur, a sustained-release injectable morphine sulfate, is listed as a Schedule II controlled substance under the CSA. Consequently, its manufacture, shipment, storage, sale and use is subject to a high degree of regulation. For example, generally, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription.

Annual registration is required for any facility that manufactures, tests, distributes, dispenses, imports or exports any controlled substance. Except for certain defined co-incident activities, each registration is specific to the particular location, activity and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration must specify which schedules of controlled substances are authorized.

The DEA typically inspects a facility to review its security measures prior to issuing a registration and, thereafter, on a periodic basis. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Required security measures include background checks on employees and physical control of inventory through measures such as vaults, cages, surveillance cameras and inventory reconciliations. Records must be maintained for the handling of all controlled substances, and periodic reports made to the DEA, for example distribution reports for Schedule I and II controlled substances, Schedule III substances that are narcotics, and other designated substances. Reports must also be made for thefts or significant losses of any controlled substance, and to obtain authorization to destroy any controlled substance. In addition, special authorization, notification and permit requirements apply to imports and exports.

In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II. Distributions of any Schedule I or II controlled substance must also be accomplished using special order forms, with copies provided to the DEA. Because DepoDur, a sustained-release injectable morphine

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sulfate, is regulated as a Schedule II controlled substance, it is subject to the DEA's production and procurement quota scheme. The DEA establishes annually an aggregate quota for how much morphine may be produced in total in the United States based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. This limited aggregate amount of morphine that the DEA allows to be produced in the United States each year is allocated among individual companies, who must submit applications annually to the DEA for individual production and procurement quotas. We must receive an annual quota from the DEA in order to produce or procure any Schedule I or Schedule II substance, including morphine sulfate for use in manufacturing DepoDur. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. Our quota of an active ingredient may not be sufficient to meet commercial demand or complete the manufacture or purchase of material required for clinical trials. Any delay or refusal by the DEA in establishing our quota for controlled substances could delay or stop our clinical trials or product launches, or interrupt commercial sales of our products which could have a material adverse effect on our business, financial position and results of operations.

The DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in enforcement action that could have a material adverse effect on our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could eventuate in criminal proceedings.

Individual states also regulate controlled substances, and we are subject to such regulation by several states with respect to the manufacture and distribution of these products.

### ***International Regulation***

In addition to regulations in the United States, we are subject to a variety of foreign regulations governing clinical trials and the commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

For example, in the EEA (which is comprised of the 27 Member States of the EU plus Norway, Iceland and Liechtenstein), medicinal products can only be commercialized after obtaining a Marketing Authorization (MA). There are two types of marketing authorizations:

- The Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use (CHMP) of the EMA, and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA (the Reference Member State or RMS), this National MA can be recognized in other Member

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States (the Concerned Member States or CMS) through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure, an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics, or SPC, and a draft of the labeling and package leaflet, which are sent to the CMS for their approval. If the CMS raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e. in the RMS and the CMS). If one or more CMS raise objections based on a potential serious risk to public health, the application is referred to the Coordination group for mutual recognition and decentralized procedure for human medicinal products (the CMDh), which is composed of representatives of the EEA Member States. If a consensus cannot be reached within the CMDh the matters is referred for arbitration to the CHMP, which can reach a final decision binding on all EEA Member States. A similar process applies to disputes between the RMS and the CMS in the Mutual Recognition Procedure.

As with FDA approval we may not be able to secure regulatory approvals in Europe in a timely manner, if at all. Additionally, as in the United States, post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution, would apply to any product that is approved in Europe, and failure to comply with such obligations could have a material adverse effect on our ability to successfully commercialize any product.

The conduct of clinical trials in the EU is governed by the EU Clinical Trials Directive (Directive 2001/20/EC of 4 April 2001, of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use). The provisions of the EU Clinical Trials Directive were required to be implemented and applied by the EEA Member States before May 2004. The EU Clinical Trials Directive harmonizes the regulatory requirements of the Member States of the EEA for the conduct of clinical trials in their respective territories. The EU Clinical Trials Directive requires sponsors of clinical trials to submit formal applications to, and to obtain the approval of, national ethics committees and regulatory authorities prior to the initiation of clinical trials.

In addition to regulations in Europe and the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial distribution of any future products.

### ***Third Party Payer Coverage and Reimbursement***

The commercial success of our product candidates will depend, in part, upon the availability of coverage and reimbursement from third-party payers at the federal, state and private levels. Government payer programs, including Medicare and Medicaid, private health care insurance companies and managed care plans may deny coverage or reimbursement for a product or therapy in whole or in part if they determine that the product or therapy is not medically appropriate or necessary. Also, third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular procedures or drug treatments. The United States Congress and state legislatures from time to time propose and adopt initiatives aimed at cost containment, which could impact our ability to sell our products profitably.

For example, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, which we refer to collectively as the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the

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health industry and impose additional health policy reforms. Effective October 1, 2010, the Health Care Reform Law revises the definition of “average manufacturer price” for reporting purposes, which could increase the amount of Medicaid drug rebates owed to states by pharmaceutical manufacturers. The Health Reform Law also establishes a new Medicare Part D coverage gap discount program, in which drug manufacturers must provide 50% point-of-sale discounts on products covered under Part D beginning in 2011. Further, also beginning in 2011, the new law imposes a significant annual, nondeductible fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare practitioners. We will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products.

The cost of pharmaceuticals continues to generate substantial governmental and third-party payer interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Our results of operations could be adversely affected by current and future healthcare reforms.

Some third-party payers also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers that use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and to operate profitably.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. There can be no assurance that our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third-party payers, that an adequate level of reimbursement will be available so that the third-party payers’ reimbursement policies will not adversely affect our ability to sell our products profitably.

***Marketing/Data Exclusivity***

The FDA may grant three or five years of marketing exclusivity in the United States for the approval of new or supplemental NDAs, including Section 505(b)(2) NDAs, for, among other things, new indications, dosages or dosage forms of an existing drug, if new clinical investigations that were conducted or sponsored by the applicant are essential to the approval of the application. Additionally, six months of marketing exclusivity in the United States is available under Section 505A of the FDCA if, in response to a written request from the FDA, a sponsor submits and the agency accepts requested information relating to the use of the approved drug in the pediatric population. This six month pediatric exclusivity period is not a standalone exclusivity period, but rather is added to any existing patent or non-patent exclusivity period for which the drug product is eligible. Based on our clinical trial program for EXPAREL, we plan to seek at least three years of marketing exclusivity upon receipt of FDA approval for EXPAREL (anticipated exclusivity through at least the third quarter of 2014). We may also seek an additional period of six months exclusivity from the FDA if the FDA requests, and we successfully complete, pediatric clinical trials for EXPAREL.

***Manufacturing Requirements***

We must comply with applicable FDA regulations relating to FDA’s cGMP regulations. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and

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labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. The manufacturing facilities for our products must meet cGMP requirements to the satisfaction of the FDA pursuant to a pre-approval inspection before we can use them to manufacture our products. We and any third-party manufacturers are also subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations. Failure to comply with these and other statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including warning letters, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations and civil and criminal penalties. Adverse experiences with the product must be reported to the FDA and could result in the imposition of market restrictions through labeling changes or in product removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

### ***Healthcare Fraud and Abuse Laws***

We are subject to various federal, state and local laws targeting fraud and abuse in the healthcare industry. For example, in the United States, there are federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services or reward past purchases or recommendations. Violations of these laws can lead to civil and criminal penalties, including fines, imprisonment and exclusion from participation in federal healthcare programs. These laws are potentially applicable to manufacturers of products regulated by the FDA, such as us, and hospitals, physicians and other potential purchasers of such products.

In particular, the federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. The term “remuneration” is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. In addition, the recently enacted Health Care Reform Law, among other things, amends the intent requirement of the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 U.S.C. § 1320a-7b effective March 23, 2010. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of 42 U.S.C. § 1320a-7b constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute, which imposes a penalty of \$5000 against any person who is determined to have presented or caused to be presented claims to a federal health care program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Moreover, the lack of uniform court interpretation of the Anti-Kickback Statute makes compliance with the law difficult.

Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the healthcare industry, the U.S. Department of Health and Human Services’ Office of Inspector General, or OIG, issued regulations in July of 1991, and periodically since that time, which the OIG refers to as “safe harbors.” These safe harbor regulations set forth certain provisions which, if met in form and substance, will assure pharmaceutical companies, healthcare providers and other parties that they will not be prosecuted under the federal Anti-Kickback Statute. Additional safe harbor provisions providing similar protections have been published intermittently since 1991. Although full compliance with these provisions ensures against prosecution under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued. However, conduct and business arrangements that do not

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fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities, such as the OIG or federal prosecutors. Additionally, there are certain statutory exceptions to the federal Anti-Kickback Statute, one or more of which could be used to protect a business arrangement, although we understand that OIG is of the view that an arrangement that does not meet the requirements of a safe harbor cannot satisfy the corresponding statutory exception, if any, under the federal Anti-Kickback Statute.

Additionally, many states have adopted laws similar to the federal Anti-Kickback Statute. Some of these state prohibitions apply to referral of patients for healthcare items or services reimbursed by any third-party payer, not only the Medicare and Medicaid programs, and do not contain identical safe harbors. Government officials have focused their enforcement efforts on marketing of healthcare services and products, among other activities, and have brought cases against numerous pharmaceutical and medical device companies, and certain sales and marketing personnel for allegedly offering unlawful inducements to potential or existing customers in an attempt to procure their business or reward past purchases or recommendations.

Another development affecting the healthcare industry is the increased use of the federal civil False Claims Act and, in particular, actions brought pursuant to the False Claims Act's "whistleblower" or "qui tam" provisions. The civil False Claims Act imposes liability on any person or entity who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The qui tam provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In recent years, the number of suits brought by private individuals has increased dramatically. In addition, various states have enacted false claim laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third-party payer and not merely a federal healthcare program. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of \$5,500 to \$11,000 for each separate false claim. There are many potential bases for liability under the False Claims Act. Liability arises, primarily, when an entity knowingly submits, or causes another to submit, a false claim for reimbursement to the federal government. The False Claims Act has been used to assert liability on the basis of inadequate care, kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, improper use of Medicare numbers when detailing the provider of services, improper promotion of off-label uses (i.e., uses not expressly approved by FDA in a drug's label), and allegations as to misrepresentations with respect to the services rendered. Our activities relating to the reporting of discount and rebate information and other information affecting federal, state and third-party reimbursement of our products, and the sale and marketing of our products and our service arrangements or data purchases, among other activities, may be subject to scrutiny under these laws. We are unable to predict whether we would be subject to actions under the False Claims Act or a similar state law, or the impact of such actions. However, the cost of defending such claims, as well as any sanctions imposed, could adversely affect our financial performance.

Also, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, created several new federal crimes, including health care fraud, and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private third-party payers. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services.

In addition, under California law, pharmaceutical companies must adopt a comprehensive compliance program that is in accordance with both the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, or OIG Guidance, and the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals, or the PhRMA Code. The PhRMA Code seeks to promote transparency in relationships between health care professionals and the pharmaceutical industry and to ensure that pharmaceutical marketing activities comport with the highest ethical standards. The PhRMA Code contains strict

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limitations on certain interactions between health care professionals and the pharmaceutical industry relating to gifts, meals, entertainment and speaker programs, among others. Also, certain states, such as Massachusetts and Minnesota, have imposed restrictions on the types of interactions that pharmaceutical and medical device companies or their agents (e.g., sales representatives) may have with health care professionals, including bans or strict limitations on the provision of meals, entertainment, hospitality, travel and lodging expenses, and other financial support, including funding for continuing medical education activities.

***Healthcare Privacy and Security Laws***

We may be subject to, or our marketing activities may be limited by, HIPAA, and its implementing regulations, which established uniform standards for certain “covered entities” (healthcare providers, health plans and healthcare clearinghouses) governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information. The American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, included sweeping expansion of HIPAA’s privacy and security standards called the Health Information Technology for Economic and Clinical Health Act, or HITECH, which became effective on February 17, 2010. Among other things, the new law makes HIPAA’s privacy and security standards directly applicable to “business associates”—independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney’s fees and costs associated with pursuing federal civil actions.

**Employees**

As of November 30, 2010, we employed 81 employees, with 8 in research and development, 55 in operations, and 18 in general and administrative. All of our employees are located in the United States. None of our employees are represented by a labor union, and we consider our current employee relations to be good.

**Facilities**

Our research and development and manufacturing facilities are located in San Diego, California, where we occupy two facilities totaling approximately 106,000 square feet under leases expiring in July 2015. We use these facilities for research and development, manufacturing and general and administrative purposes. In addition, we maintain our executive offices, commercial and business development facility in Parsippany, New Jersey.

We believe that our manufacturing facilities are sufficient for our current needs. We intend to add new facilities or expand existing facilities as we add employees or expand our geographic markets, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

**Legal Proceedings**

From time to time, we have been and may again become involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any material litigation and we are not aware of any pending or threatened litigation against us that could have a material adverse effect on our business, operating results, financial condition or cash flows.

## MANAGEMENT

### Executive Officers and Directors

Our executive officers and directors, their current positions and their ages as of November 30, 2010 are set forth below:

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>
David Stack	59	President and Chief Executive Officer, Director
James Scibetta	46	Chief Financial Officer
Gary Patou, M.D.	52	Chief Medical Officer
William Lambert, Ph.D.	51	Senior Vice President, Pharmaceutical Development
Mark Walters	55	Senior Vice President, Technical Operations
Fred Middleton <sup>(2)</sup>	61	Chairman of the Board of Directors
Luke Evnin, Ph.D. <sup>(2)</sup>	47	Director
Carl Gordon, Ph.D. <sup>(1)</sup>	46	Director
John Longenecker, Ph.D. <sup>(1)(2)(3)</sup>	63	Director
Gary Pace, Ph.D. <sup>(1)(3)</sup>	63	Director
Andreas Wicki, Ph.D.	52	Director

<sup>(1)</sup> Member of audit committee upon completion of this offering.

<sup>(2)</sup> Member of compensation committee upon completion of this offering.

<sup>(3)</sup> Member of nominating and corporate governance committee upon completion of this offering.

**David Stack** has served as our president and chief executive officer and as a director since November 2007. Mr. Stack has been a managing director of MPM Capital since 2005 and a managing partner of Stack Pharmaceuticals, Inc. since 1998. From 2001 to 2004, he was president and chief executive officer of The Medicines Company (NASDAQ: MDCO). Previously, Mr. Stack was president and general manager at Innovex, Inc. He was vice president, business development/marketing at Immunomedics from 1993 until 1995. Prior to that, he was with Roche Laboratories in positions of increasing responsibility from 1981 until 1993, including therapeutic world leader in infectious disease and director, business development and planning, infectious disease, oncology, and virology. He currently serves as a member of the board of directors of PepTx, Inc., and Molecular Insight Pharmaceuticals, Inc. (NASDAQ: MIPI). Mr. Stack holds a B.S. in pharmacy from Albany College of Pharmacy and a B.S. in Biology from Siena College. We believe Mr. Stack's qualifications to sit on our board of directors include his extensive experience with pharmaceutical companies, his financial expertise and his years of experience providing strategic and financial advisory services to pharmaceutical and biotechnology organizations, including evaluating business plans involving clinical trials.

**James Scibetta** has served as our chief financial officer since August 2008. Prior to that, Mr. Scibetta was chief financial officer of Bioenvision, Inc. (NASDAQ: BIVN) from 2006 until its acquisition by Genzyme, Inc. in 2007. From 2001 to 2006, Mr. Scibetta was executive vice president and chief financial officer of Merrimack Pharmaceuticals, Inc., and he was a member of the board of directors of Merrimack from 1998 to 2004. Mr. Scibetta formerly served as a senior investment banker at Shattuck Hammond Partners, LLC and PaineWebber Inc., providing capital acquisition, merger and acquisition, and strategic advisory services to healthcare companies. He currently serves as chairman of the board and audit committee of Nephros, Inc. (NASDAQ: NEPH). Mr. Scibetta holds a B.S. in physics from Wake Forest University, and an M.B.A. in finance from the University of Michigan. He completed executive education studies in the Harvard Business School Leadership & Strategy in Pharmaceuticals and Biotechnology program.

**Gary Patou, M.D.** has served as our chief medical officer since March 2009. Dr. Patou has been a managing director of MPM Capital since 2005. He has served as chief medical officer of the following MPM Capital portfolio companies: Peplin, Ltd. (ASX: PLI), from July 2006 to April 2007 and from June 2008 to May 2009, Cerimon Pharmaceuticals, Inc., from June 2005 to June 2006, and Oscient Pharmaceuticals, Inc., from



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February 2004 to April 2005. Dr. Patou currently spends part of his time as the acting chief executive officer of Cerimon Pharmaceuticals, Inc. From 2001 to 2004, he was president of Genesoft and from 1995 to 2000, Dr. Patou worked at SmithKline Beecham Pharmaceuticals, now a unit of GlaxoSmithKline (LSE: GSK), where he held positions of increasing responsibility including senior vice president and director, project and portfolio management. From 1991 to 1995, he held increasing senior, director level positions at Vernalis (LSE:VER), formerly British Biotechnology. He currently serves as a member of the board of directors of Xenon Pharmaceuticals, Inc. Dr. Patou has held a number of academic appointments at University College & Middlesex School of Medicine in London and holds an M.D. from University College, London.

**William Lambert, Ph.D.** has served as our senior vice president, pharmaceutical development since the Acquisition in March 2007. Dr. Lambert has served as senior vice president pharmaceutical development since he joined SkyePharma, Inc. in January 2006. From July 1997 until January 2006, Dr. Lambert held director positions at Eisai Inc., in drug delivery technology and pharmaceutical and analytical research and development, for almost ten years. Prior to Eisai, Dr. Lambert worked at Pfizer Inc. (NYSE: PFE) and The Upjohn Company (now Pfizer Inc.) as a research investigator with increasing levels of responsibility. Dr. Lambert is on the advisory council for the National Institute for Pharmaceutical Technology and Education, a U.S. Pharmacopeia Expert Committee, and on the advisory boards of the Journal of Pharmaceutical Sciences and the Handbook of Pharmaceutical Excipients. Dr. Lambert received his Ph.D. in pharmaceutics from the University of Utah and his B.S. in pharmacy from the University of Rhode Island.

**Mark Walters** has served as our senior vice president, technical operations since February 2008, and served as our vice president, business and commercial development since the Acquisition in March 2007. From January 2001 until March 2007, Mr. Walters was with SkyePharma, Inc. (LSE: SKP) serving as the vice president of business and commercial development and as director of both strategic sourcing and product management. From 1989 until 2001 Mr. Walters served in the positions of program director, project director and product director in the imaging and liquid ventilation areas for Alliance Pharmaceutical Corp. Mr. Walters received his B.A. in biology from Hamilton College.

**Fred Middleton** has served as our director since our inception in December 2006. Since 1987, he has been a general partner/managing director of Sanderling Ventures, a firm specializing in biomedical venture capital. From 1984 through 1986, he was the managing general partner of Morgan Stanley Ventures, an affiliate of Morgan Stanley & Co. Earlier in his career, Mr. Middleton was part of the of the founding management team at Genentech, Inc., a biotechnology company, serving there from 1978 through 1984 as vice president of finance and corporate development, and chief financial officer. During the last 30 years, he has participated in active management roles and as an investor and director in over 20 start-up biomedical companies. He currently serves as chairman of the board of Stereotaxis, Inc. (NASDAQ: STXS), a medical device company that markets magnetically guided robotic surgery systems in cardiology. He also currently serves as a board member of Cardionet, Inc. (NASDAQ: BEAT), a company that markets devices and services for wireless 24/7 real time monitoring of patients. He also serves as a director of seven other privately-held biomedical companies, engaged in the development of therapeutic and diagnostic products in healthcare. Mr. Middleton received a B.S. degree in chemistry from the Massachusetts Institute of Technology and an M.B.A. from Harvard Business School. We believe Mr. Middleton's qualifications to sit on our board of directors include his extensive experience with biopharmaceutical and biotechnology companies, his financial expertise and his years of experience providing strategic advisory services to diverse companies.

**Luke Evnin, Ph.D.** has served as our director since our inception in December 2006. Dr. Evnin has served as a general partner or managing director at MPM Capital since co-founding the firm in 1998. Prior to joining MPM, Dr. Evnin was at Accel Partners from 1990 to 1997 serving as general partner from 1994 to 1997. Dr. Evnin has served as director of several public companies, including Epix Medical, Inc. (NASDAQ: EPIX), Metabasis Therapeutics, Inc., Oscient Pharmaceuticals Company, Restore Medical, Inc., Otix Global, Inc. (NASDAQ: OTIX), formerly known as Sonic Innovations, Inc. and Signal Pharmaceuticals, Inc. and is currently or has been a director of several private healthcare companies in both the medical device and biopharmaceutical

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sectors. Dr. Evin earned his Ph.D. in biochemistry from the University of California, San Francisco and his A.B. in molecular biology from Princeton University. We believe Dr. Evin's qualifications to sit on our board of directors include his extensive experience with biopharmaceutical and biotechnology companies, his financial expertise and his years of experience providing strategic advisory services to diverse companies.

**Carl Gordon, Ph.D.** has served as our director since our inception in December 2006. Dr. Gordon is a founding general partner of OrbiMed Advisors. Dr. Gordon is active in both private equity and small-capitalization public equity investments. Prior to founding OrbiMed Advisors in January 1998, Dr. Gordon was a senior biotechnology analyst at Mehta & Isaly from 1995 to 1997. He was a fellow at The Rockefeller University from 1993 to 1995. Dr. Gordon received a Ph.D. in molecular biology from the Massachusetts Institute of Technology where his doctoral work involved studies of protein folding and assembly. He received a B.S. from Harvard College. We believe Dr. Gordon's qualifications to sit on our board of directors include his extensive experience with biopharmaceutical and biotechnology companies, his financial expertise and his years of experience providing strategic advisory services to diverse companies.

**John Longenecker, Ph.D.** has served as our director since July 2007. From February 2002 to January 2009, Dr. Longenecker was the president and chief executive officer of Favril, Inc. In 1992, Dr. Longenecker joined DepoTech as senior vice president of research, development and operations and then served as president and chief operating officer from February 1998 to March 1999. Under Dr. Longenecker's leadership, DepoTech took its lead product, DepoCyt(e), from early pre-clinical research and development through to commercial launch. Following SkyePharma PLC's acquisition of DepoTech in 1999, Dr. Longenecker served as president for the U.S. operations of SkyePharma, Inc. and as a member of the executive committee for SkyePharma PLC. From 1982 to 1992, Dr. Longenecker was at Scios Inc. (Cal Bio), a biotechnology company where he served as vice-president and director of development. Dr. Longenecker was also a director of a number of Cal Bio subsidiaries during this period including Meta Bio and Karo Bio. Dr. Longenecker holds a B.S. in chemistry from Purdue University and a Ph.D. in biochemistry from The Australian National University. He was a post doctoral fellow at Stanford University from 1980 to 1982. Dr. Longenecker's experience as the chief executive officer of a public company, demonstrates his leadership capability and extensive knowledge of complex financial and operational issues that public companies face and a thorough understanding of our business and industry and business acumen to our board of directors. We believe Dr. Longenecker's extensive experience in the pharmaceutical and biotechnology industries provides valuable background and insight to our board of directors.

**Gary Pace, Ph.D.** has served as our director since June 2008. He is currently founder and chairman of the privately held Sova Pharmaceuticals Inc., founded in 2010, founder, director and consultant to QRxPharma Ltd. (ASX:QRX) founded in 2001, a Director of ResMed (NYSE:RMD) since 1994 and Transition Therapeutics Inc. (CDNX:TTH) since 2002. From 2002 to 2007, Dr. Pace was founder, chairman and chief executive officer of QRxPharma Ltd. and from 1995 to 2001, he was president and chief executive officer of RTP Pharma and from 2000 to 2002, Dr. Pace was chairman and chief executive officer of Waratah Pharmaceuticals Inc., a spin-off company from RTP Pharma. From 1993 to 1994, he was the founding president and chief executive officer of Transcend Therapeutics Inc. (formerly Free Radical Sciences Inc.), a biopharmaceutical company. From 1989 to 1993, he was senior vice president of Clintec International, Inc., a Baxter/Nestle joint venture and manufacturer of clinical nutritional products. Dr. Pace holds a B.S. with honors from the University of New South Wales and a Ph.D. from Massachusetts Institute of Technology. We believe Dr. Pace's qualifications to sit on our board of directors include his financial expertise and his years of experience providing strategic advisory services to complex organizations, including as a public company director.

**Andreas Wicki, Ph.D.** has served as our director since our inception in December 2006. Dr. Wicki is a life sciences entrepreneur and investor with over 16 years of experience in the pharmaceutical and biotechnology industries. Dr. Wicki has been chief executive officer of HBM Partners AG and HBM BioVentures AG since 2001. From 1998 to 2001, Dr. Wicki was the senior vice president of the European Analytical Operations at MDS Inc. From 1990 to 1998, he was co-owner and chief executive officer of ANAWA Laboratorien AG and Clinserve AG, two life sciences contract research companies. Dr. Wicki holds an M.Sc. and Ph.D. in chemistry

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and biochemistry from the University of Bern, Switzerland. He currently serves on the board of directors of Buchler GmbH, HBM BioPharma India Ltd., HBM BioVentures (Cayman) Ltd., HBM Partners Ltd. and PharmaSwiss SA. We believe Dr. Wicki's qualifications to sit on our board of directors include his extensive experience with pharmaceutical companies, his financial expertise and his years of experience providing strategic and advisory services to pharmaceutical and biotechnology organizations.

### **Family Relationships**

There are no family relationships among any of our directors or executive officers.

### **Board Composition**

Our board of directors currently consists of seven members, all of whom were elected as directors pursuant to a voting agreement that we have entered into with the holders of our Series A convertible preferred stock. The voting agreement will terminate upon the completion of this offering and there will be no further contractual obligations regarding the election of our directors. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal.

In accordance with the terms of our restated certificate of incorporation and bylaws that will become effective upon the completion of this offering, our board of directors will be divided into three classes, class I, class II and class III, with each class serving staggered three-year terms. Upon the expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of stockholders in the year in which their term expires.

Our restated certificate of incorporation and amended and restated bylaws that will become effective upon the completion of this offering provide that the authorized number of directors may be changed only by resolution of the board of directors. Our restated certificate of incorporation and amended and restated bylaws that will become effective upon the completion of this offering also provide that our directors may be removed only for cause by the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in an annual election of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

We have no formal policy regarding board diversity. Our priority in selection of board members is identification of members who will further the interests of our stockholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business and understanding of the competitive landscape.

### **Director Independence**

Under The NASDAQ Marketplace Rules, a director will only qualify as an "independent director" if, in the opinion of our board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Our board of directors has determined that each of our directors, with the exception of David Stack, is an "independent director" as defined under Rule 5605(a)(2) of The NASDAQ Marketplace Rules. In making such independence determination, the board of directors considered the relationships that each such non-employee director has with us and all other facts and circumstances that the board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director. In considering the independence of the directors listed above, our board of directors considered the association of our directors with the holders of more than 5% of our common stock.

## **Board Committees**

Our board of directors has established an audit committee, a compensation committee and, upon the completion of this offering, a nominating and corporate governance committee. Each of these committees will operate under a charter that has been approved by our board of directors.

### *Audit Committee*

Upon completion of this offering, the members of our audit committee will be John Longenecker, Gary Pace and Carl Gordon, and Dr. Gordon will chair the audit committee. Our board of directors has determined that Dr. Longenecker and Dr. Pace, two of the three directors serving on our audit committee, are independent within the meaning of The NASDAQ Marketplace Rules and Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act. In addition, our board of directors has determined that Dr. Gordon qualifies as an audit committee financial expert within the meaning of SEC regulations and The NASDAQ Marketplace Rules. In making this determination, our board has considered the formal education and nature and scope of his previous experience, coupled with past and present service on various audit committees. Our audit committee assists our board of directors in its oversight of our accounting and financial reporting process and the audits of our financial statements.

Upon the completion of this offering, our audit committee's responsibilities will include:

- appointing, evaluating, retaining and, when necessary, terminating the engagement of our independent registered public accounting firm;
- overseeing the independence of our independent registered public accounting firm, including obtaining and reviewing reports from the firm;
- setting the compensation of our independent registered public accounting firm;
- overseeing the work of our independent registered public accounting firm, including receiving and considering reports made by our independent registered public accounting firm regarding accounting policies and procedures, financial reporting and disclosure controls;
- reviewing and discussing with management and our independent registered public accounting firm our audited financial statements and related disclosures;
- preparing the annual audit committee report required by SEC rules;
- coordinating internal control over financial reporting, disclosure controls and procedures and code of conduct;
- reviewing our policies with respect to risk assessment and risk management;
- establishing procedures related to the receipt, retention and treatment of complaints regarding accounting, internal accounting controls or auditing matters, and the confidential, anonymous submission by employees of concerns regarding accounting or auditing matters;
- reviewing our policies and procedures for reviewing and approving or ratifying related person transactions, including our related person transaction policy; and
- meeting independently with management and our independent registered public accounting firm.

All audit services to be provided to us and all non-audit services, other than de minimis non-audit services, to be provided to us by our independent registered public accounting firm must be approved in advance by our audit committee.

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***Compensation Committee***

Upon completion of this offering, the members of our compensation committee will be Luke Evnin, John Longenecker and Fred Middleton, and Dr. Longenecker will be the chair of the compensation committee. Our compensation committee assists our board of directors in the discharge of its responsibilities relating to the compensation of our executive officers. Upon the completion of the offering, our compensation committee's responsibilities will include:

- reviewing and recommending to the board of directors our chief executive officer's compensation, and approving the compensation of our other executive officers reporting directly to our chief executive officer;
- overseeing the evaluation of our senior executives;
- overseeing, administering, reviewing and making recommendations to the board of directors with respect to our incentive compensation and equity-based plans;
- reviewing and making recommendations to the board of directors with respect to director compensation;
- reviewing and discussing with management the compensation discussion and analysis required by SEC rules; and
- preparing the annual compensation committee report required by SEC rules.

***Nominating and Corporate Governance Committee***

Upon completion of this offering, the members of our nominating and corporate governance committee will be John Longenecker and Gary Pace, and Dr. Pace will be the chair of the nominating and corporate governance committee. Upon the completion of the offering, the nominating and corporate governance committee's responsibilities will include:

- recommending to the board of directors the persons to be nominated for election as directors or to fill any vacancies on the board of directors, and to be appointed to each of the board's committees;
- developing and recommending to the board of directors corporate governance guidelines; and
- overseeing an annual self-evaluation of the board of directors.

**Compensation Committee Interlocks and Insider Participation**

None of our executive officers serves, or in the past has served, as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any entity that has one or more executive officers who serve as members of our board of directors or our compensation committee. None of the members of our compensation committee is an officer or employee of our company. Other than John Longenecker, who was the president and chief operating officer of DepoTech, the predecessor to PPI-California, none of the members of our compensation committee have ever been an officer or employee of our company.

**Code of Business Conduct and Ethics**

Prior to the completion of this offering, we will adopt a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Following the completion of this offering, a current copy of the code will be posted on the Corporate Governance section of our website, which is located at [www.pacira.com](http://www.pacira.com). If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

### **Board Leadership Structure and Board's Role in Risk Oversight**

The positions of our chairman of the board and chief executive officer are separated. Separating these positions allows our chief executive officer to focus on our day-to-day business, while allowing the chairman of the board to lead the board of directors in its fundamental role of providing advice to and independent oversight of management. Our board of directors recognizes the time, effort and energy that the chief executive officer must devote to his position in the current business environment, as well as the commitment required to serve as our chairman, particularly as the board of directors' oversight responsibilities continue to grow. Our board of directors also believes that this structure ensures a greater role for the independent directors in the oversight of our company and active participation of the independent directors in setting agendas and establishing priorities and procedures for the work of our board of directors. This leadership structure also is preferred by a significant number of our stockholders. Our board of directors believes its administration of its risk oversight function has not affected its leadership structure.

Although our bylaws that will be in effect upon the completion of this offering will not require our chairman and chief executive officer positions to be separate, our board of directors believes that having separate positions is the appropriate leadership structure for us at this time and demonstrates our commitment to good corporate governance.

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including those described under "Risk Factors." Our board of directors is actively involved in oversight of risks that could affect us. This oversight is conducted primarily by our full board of directors, which has responsibility for general oversight of risks.

Following the completion of this offering, our board of directors will satisfy this responsibility through full reports by each committee chair regarding the committee's considerations and actions, as well as through regular reports directly from officers responsible for oversight of particular risks within our company. Our board of directors believes that full and open communication between management and the board of directors is essential for effective risk management and oversight.

### **Director Compensation**

Other than reimbursement for expenses related to attending meetings, our non-employee directors did not receive any compensation for serving as directors during the year ended December 31, 2009.

Our board of directors has approved a compensation policy for our non-employee directors that will become effective upon the completion of this offering. This policy provides for the following compensation to our non-employee directors following the completion of this offering:

- each non-employee director is entitled to receive an annual fee from us of \$35,000 and an additional \$25,000 fee if the non-employee director is the chairman of our board of directors;
- the chair of our audit committee will receive an annual fee from us of \$15,000 and other members of our audit committee will receive \$7,500;
- the chair of our compensation committee will receive an annual fee from us of \$15,000 and other members of our compensation committee will receive \$7,500;
- the chair of our nominating and corporate governance committee will receive an annual fee from us of \$10,000 and other members will receive \$5,000; and
- each non-employee director will be entitled to an annual grant of options to purchase 25,000 shares of our common stock under our 2007 Stock Option/Issuance Plan, or the 2007 Plan, or any other equity incentive plan we may adopt in the future.

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In addition, each non-employee director received an option grant to purchase 50,000 shares of our common stock, which will begin vesting upon the effective date of the registration statement for this offering. Fifty percent of the shares underlying these options will vest on each anniversary of the completion of this offering, such that all of the shares underlying such options will have vested on the second anniversary of the completion of this offering. Upon a change in control of us, as defined in the 2007 Plan, 100% of the shares underlying these options shall become vested and exercisable immediately prior to such change in control.

Each non-employee director that joins our board of directors following the completion of this offering will also receive an initial option grant to purchase 50,000 shares of our common stock. Fifty percent of the shares underlying each of these options will vest each year on the anniversary of the grant date, such that all of the shares underlying such options will have vested on the second anniversary of the grant date. Upon a change in control of us, as defined in the 2007 Plan, 100% of the shares underlying these options shall become vested and exercisable immediately prior to such change in control.

All fees under the director compensation policy will be paid on a rolling annual basis and no per meeting fees will be paid. We will also reimburse non-employee directors for reasonable expenses incurred in connection with attending board of director and committee meetings.

## EXECUTIVE COMPENSATION

This section discusses the material elements of our executive compensation policies and decisions and the most important factors relevant to an analysis of these policies and decisions. It provides qualitative information regarding the manner and context in which compensation is awarded to and earned by our executive officers named in the “Summary Compensation Table,” or our “named executive officers,” and is intended to place in perspective the data presented in the tables and the narrative that follows.

In preparing to become a public company, we have begun a thorough review of all elements of our executive compensation program, including the function and design of our equity incentive programs. We have begun, and we expect to continue in the coming months, to evaluate the need for revisions to our executive compensation program to ensure our program is competitive with the companies with which we compete for executive talent and is appropriate for a public company.

### Overview of our Executive Compensation Process

*Roles of Our Board, Chief Executive Officer and Compensation Committee in Compensation Decisions.* As a private company, our chief executive officer and compensation committee have historically overseen our executive compensation program. Our compensation committee, either as a committee or together with the other independent directors, makes all compensation decisions regarding our chief executive officer. Our chief executive officer may make recommendations to the compensation committee regarding the compensation of our executive officers other than the chief executive officer, but the compensation committee either makes all compensation decisions regarding our other executive officers or makes recommendations concerning executive compensation to our board of directors, with the independent directors making such decisions. In his role, our chief executive officer has reviewed all compensation decisions relating to our executive officers other than himself. He has annually reviewed the performance of each of our other executive officers, and, based on these reviews, has made recommendations to our compensation committee regarding salary adjustments, annual incentive bonus payments and equity incentive awards for our executive officers.

*Competitive Market Data and Use of Compensation Consultants.* Historically, we have not formally benchmarked our executive compensation against compensation data of a peer group of companies, but rather have relied on the business judgment and experience in the pharmaceutical industry of our chief executive officer and members of our compensation committee. We have developed substantial information about compensation practices and levels at comparable companies through extensive recruiting, networking and industry research. Our compensation committee may in the future elect to engage an independent compensation consulting firm to provide advice regarding our executive compensation program and general information regarding executive compensation practices in our industry. Although the compensation committee would consider such a compensation consulting firm’s advice in establishing and approving the various elements of our executive compensation program, our chief executive officer and the compensation committee would ultimately make their own decisions, or make recommendations to our board of directors, about these matters.

*Objectives and Philosophy of Our Executive Compensation Program.* Our primary objective with respect to executive compensation is to attract, retain and motivate highly talented individuals who have the skills and experience to successfully execute our business strategy. Our executive compensation program is designed to:

- reward the achievement of our annual and long-term operating and strategic goals;
- recognize individual contributions;
- align the interests of our executives with those of our stockholders by rewarding performance that meets or exceeds established goals, with the ultimate objective of increasing stockholder value; and
- retain and build our executive management team.

To achieve these objectives, our executive compensation program ties a portion of each executive’s overall compensation to key corporate financial goals and to individual goals. We have also provided a portion of our



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executive compensation in the form of option awards that vest over time, which we believe helps to retain our executive officers and aligns their interests with those of our stockholders by allowing them to participate in our long-term performance as reflected in the trading price of shares of our common stock.

*Elements of Our Executive Compensation Program.* The primary elements of our executive compensation program are:

- base salaries;
- annual incentive bonuses;
- company sale bonus plan;
- equity incentive awards; and
- other employee benefits.

We have not adopted any formal or informal policies or guidelines for allocating compensation among these elements.

*Base Salaries.* We use competitive base salaries to attract and retain qualified candidates to help us achieve our growth and performance goals. Base salaries are intended to recognize an executive officer's immediate contribution to our organization, as well as his or her experience, knowledge and responsibilities.

Historically, our chief executive officer (with respect to executive officers other than himself) and our vice president, human resources have annually evaluated and recommended adjustments to executive officer base salary levels to our compensation committee or board of directors based on factors determined to be relevant, including:

- the executive officer's skills and experience;
- the particular importance of the executive officer's position to us;
- the executive officer's individual performance;
- the executive officer's growth in his or her position; and
- base salaries for comparable positions within our company and at other companies.

Our chief executive officer's base salary has been determined by the non-management members of our board of directors, taking into account these same factors.

We have historically made annual base salary adjustments at the end of each year, with the adjustments taking effect at the beginning of the following year. In 2009, we made no adjustments to the base salaries for our chief executive officer or any of our other named executive officers.

Following the completion of this offering, our compensation committee will perform such annual evaluations, and we expect that it will consider similar factors, as well as perhaps the input of a compensation consulting firm and peer group benchmarking data, in making any adjustments to executive officer base salary levels.

*Annual Incentive Bonuses.* In addition to the corporate goals described below, members of management, including each of our executive officers, were assigned personal achievement goals near the beginning of fiscal 2007. For our executive officers other than our chief executive officer, these individual goals were set by our chief executive officer in collaboration with our executive management team and the individual goals for our chief executive officer were set by our board of directors, taking into account discussions with our chief executive officer.

We do not currently have a formal annual incentive bonus program. The company did pay cash bonuses based on the achievement of approved operational milestones in 2007. The 2007 bonus program was targeted at

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75% based on the achievement of corporate goals and 25% based on personal achievement goals. A total pool of \$57,570 was shared equally between six executives. The compensation committee did not establish a formal annual incentive bonus program in 2008 or 2009, and we have not paid any bonuses based on corporate goals or personal achievement goals in 2008 or 2009. Although our 2008 and 2009 corporate goals were informal, they were focused on the achievement of certain objectives. In 2008, the objectives were (1) developing and executing Phase 3 clinical trials for EXPAREL, (2) scaling up for post FDA approval manufacturing and (3) obtaining additional financing. In 2009, the objectives were (1) successful completion of additional Phase 3 clinical trials of EXPAREL and (2) obtaining additional financing. For 2008 and 2009, our compensation committee made the decision not to pay annual bonuses based on the need to manage expenses and allocate resources to our clinical development programs, and did not formally evaluate whether our 2008 or 2009 corporate goals had been achieved. We did not have additional individual performance goals for our executive officers in 2008 or 2009. Our compensation committee has the authority to award discretionary performance-based cash bonuses to our executive officers and certain non-executive employees. Our compensation committee considers awarding such discretionary bonuses in the event of extraordinary short-term efforts and achievements by our executives and employees, as recommended by management. No such discretionary bonuses were awarded in 2008 or 2009. We do expect that our compensation committee will establish a formal cash incentive program in the future, and that our executive officers will participate in that program.

*Company Sale Bonus Plan.* In March 2009, we adopted a company sale bonus plan, amended and restated in March 2010, that provides for a potential cash bonus payment to specified employees and consultants, including our executive officers, and our non-employee directors, in the event of a sale of our company. The purpose of the company sale bonus plan is to provide these employees, consultants and directors with an additional incentive in connection with a transaction that is in our and our stockholders' best interests, but which may otherwise create personal uncertainties. Under the company sale bonus plan, upon the closing of a sale transaction that satisfies specified criteria, each participant in the company sale plan would receive either a bonus in an amount equal to a portion of the sale proceeds multiplied by a specified percentage for that participant or a fixed bonus payment. As a condition to becoming participants under the plan, most of the participants, including all of our executive officers and non-employee directors, agreed to have their existing option grants cancelled. The participants in the bonus plan were determined by our board of directors. This bonus plan terminates upon the completion of this offering. As a condition to becoming a participant under the Company Sale Bonus Plan, most of the participants under the plan, including all of our executive officers and non-employee directors, agreed to have their existing option grants cancelled in March 2009.

*Equity Incentive Compensation.* We believe that our long-term performance is enhanced through equity awards. Equity awards reward executives and employees for maximizing stockholder value over time and align the interests of our employees and management with those of the stockholders. We granted stock options to our employees, including our named executive officers, in connection with their initial employment with us. In connection with the adoption of our company sale bonus plan, most of the participants under the plan, including all of our executive officers and non-employee directors, agreed to have their existing option grants cancelled. Subsequent to the cancellation, in September 2010, our board of directors granted new options to all of our employees, including our executive officers, and our non-employee directors, including options to purchase an aggregate of 8,705,000 shares of common stock to our named executive officers.

*Equity Incentive Awards.* Our equity incentive award program is the primary vehicle for offering long-term incentives to our executive officers. To date, equity incentive awards to our executive officers have been made in the form of stock options. We believe that equity incentive awards:

- provide our executive officers with a strong link to our long-term performance by enhancing their accountability for long-term decision making;
- create an ownership culture by aligning the interests of our executive officers with the creation of value for our stockholders; and
- further our goal of executive retention.

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Employees who are considered important to our long-term success are eligible to receive equity incentive awards. Equity incentive awards have been granted to all of our current employees and certain of our non-employee directors. On September 2, 2010, we granted options to purchase an aggregate of 8,705,000 shares of common stock to our named executive officers.

Historically, all equity incentive awards granted to our executive officers have been approved by our board of directors, with input from our chief executive officer, our executive management team and our compensation committee. In determining the size of equity incentive awards to executive officers, our board and chief executive officer have generally considered the executive's experience, skills, level and scope of responsibilities, existing equity holdings, and comparisons to comparable positions in our company.

Our compensation committee has the authority to make equity awards to our executive officers and to administer our equity incentive plans.

We do not have any equity ownership guidelines or requirements for our executive officers.

*Other Employee Benefits.* We maintain broad-based benefits that are provided to all employees, including our 401(k) retirement plan, flexible spending accounts, medical and dental care plans, life insurance, short- and long-term disability policies, vacation and company holidays. Our executive officers are eligible to participate in each of these programs on the same terms as non-executive employees; however, employees at the director level and above are eligible for life insurance coverage equal to three times (rather than twice) their annual base salary.

*Severance and Change of Control Arrangements.* We have entered into employment agreements with David Stack, our chief executive officer, James Scibetta, our chief financial officer, Gary Patou, our chief medical officer, Mark Walters, our senior vice president, technical operations and William Lambert, our senior vice president, pharmaceutical development. Each of these agreements provides the executive officer with certain severance benefits in connection with certain terminations of the executive's employment or, in the case of Dr. Patou, consulting arrangement, both before and after a change of control of us. See "Executive Compensation—Employment Agreements, Severance and Change in Control Arrangements" below.

*Risk Considerations in our Compensation Program.* We have reviewed and evaluated the standards on which our compensation plans have been developed and implemented across our company. It is our belief that our compensation programs do not encourage inappropriate actions by our executive officers. Specifically, we believe that our compensation policies and practices avoid:

- a compensation mix overly weighted toward annual bonus awards;
- an excessive focus on stock option awards that would cause behavior to drive short-term stock price gains in lieu of long-term value creation; and
- unreasonable financial goals or thresholds that would encourage efforts to generate near-term revenue with an adverse impact on long-term success.

We believe that our current business process and planning cycle fosters the following behaviors and controls that would mitigate the potential for adverse risk caused by the action of our executives.

- Annual review of corporate and individual objectives of the executive officers to align these goals with our annual operating and strategic plans and do not encourage unnecessary or excessive risk taking.
- Incentive awards are based on a review of a variety of indicators, including both financial performance and strategic achievements, reducing the potential to concentrate on one indicator as the basis of an annual incentive award.
- The mixes between fixed and variable and cash and equity compensation are designed to encourage strategies and actions that are in our long-term best interests.

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- Discretionary authority by the compensation committee to adjust annual bonus funding and payments reduces business risk associated with our cash bonus program.
- Stock option awards vest over a period of time. As a result of the longer time horizon to receive the value of a stock option award, the prospect of short-term or risky behavior is mitigated.

As a result, we do not believe that any risks arising from our employee compensation policies and practices are reasonably likely to have a material adverse effect on us. In addition, we do not believe that the mix and design of the components of our executive compensation program encourage management to assume excessive risks.

**Tax Considerations.** Section 162(m) of the U.S. Internal Revenue Code of 1986, as amended, which we refer to as the Code, generally disallows a tax deduction for compensation in excess of \$1.0 million paid by a public company to its chief executive officer and to each other officer (other than its chief financial officer) whose compensation is required to be reported to stockholders by reason of being among the three other most highly paid executive officers. Qualifying performance-based compensation is not subject to the deduction limitation if specified requirements are met. We will periodically review the potential consequences of Section 162(m) on the various elements of our executive compensation program, and we generally intend to structure the equity incentives component of our executive compensation program, where feasible, to comply with exemptions in Section 162(m) so that the compensation remains tax deductible to us. However, our board of directors or compensation committee may, in its judgment, authorize compensation payments that do not comply with the exemptions in Section 162(m) when it believes that such payments are appropriate to attract and retain executive talent.

Section 409A of the Code applies to plans, agreements and arrangements that provide for the deferral of compensation, and imposes penalty taxes on employees if those plans, agreements and arrangements do not comply with Section 409A. We have sought to structure our executive compensation arrangements to be exempt from, or comply with, Section 409A.

### Summary Compensation Table

The following table sets forth information regarding compensation earned by our chief executive officer, our chief financial officer and each of our three other most highly compensated executive officers during our fiscal year ended December 31, 2009. We refer to these individuals as our named executive officers.

<u>Name</u>	<u>Principal Position</u>	<u>Salary (\$)</u>	<u>All Other Compensation<sup>(1)</sup> (\$)</u>	<u>Total (\$)</u>
David Stack	Chief Executive Officer	400,000	1,504	401,504
James Scibetta	Chief Financial Officer	270,000	1,504	271,504
Gary Patou	Consultant <sup>(2)</sup>	317,604	—	317,604
Mark Walters	Senior Vice President	250,000	1,600	251,600
William Lambert	Senior Vice President	220,000	1,483	221,483

<sup>(1)</sup> Amounts represent the value of perquisites and other personal benefits which are further detailed in the table below:

<u>Name</u>	<u>Group Life Insurance (\$)</u>
David Stack	1,504
James Scibetta	1,504
Gary Patou	—
Mark Walters	1,600
William Lambert	1,483

<sup>(2)</sup> Dr. Patou, a managing director at MPM, is a consultant to us and provided the services customarily expected of a chief medical officer. Pursuant to the Services Agreement with MPM Asset Management LLC, or MPM AM and Dr. Patou, we paid a service fee of \$26,467 per month to MPM AM for the services provided by Dr. Patou and MPM AM. For more information, see "Executive Compensation—Services Agreement with MPM and Gary Patou."

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**Grants of Plan-Based Awards in 2009**

During the year ended December 31, 2009 there were no grants of plan-based awards to our named executive officers.

**Outstanding Equity Awards at Year End**

None of our named executive officers held any equity awards as of December 31, 2009.

**Option Exercises and Stock Vested**

None of our named executive officers exercised any options during the year ended December 31, 2009.

**Potential Payments Upon Termination or Change of Control**

The table below summarizes the potential payment to each of our named executive officers if he were to be terminated without cause on December 31, 2009.

<u>Name</u>	<u>Cash Severance Payment (\$)</u>	<u>Other Payments (\$)</u>
David Stack	400,000	—
James Scibetta	—	—
Gary Patou	—	—
Mark Walters	—	—
William Lambert	—	—

In addition, each of our named executive officers would be entitled to payments under our company sale bonus plan. See “Executive Compensation—Company Sale Bonus Plan” below.

**Employment Agreements, Severance and Change in Control Arrangements**

We entered into employment agreements with each of our named executive officers other than Gary Patou. The agreements with each of our named executive officers provide for “at will” employment which means we or the executive can terminate his or her employment at any time, with or without cause. Pursuant to the agreements, each of our named executive officers will be entitled to a base salary and certain benefits as previously described.

If any of our named executive officers, other than our chief executive officer, (i) is terminated for any reason other than for “cause,” or (ii) terminates his or her employment for “good reason,” then such executive officer will be entitled to:

- earned and accrued base salary, bonus, vacation time and other benefits;
- monthly salary continuation payments for a period of nine months from the effective date of the release required to be provided as a condition to receiving these payments;
- health insurance coverage, subject to cost sharing, for nine months following the effective date of the release required to be provided as a condition to receiving this coverage; and
- immediate vesting of the portion of the unvested options granted to him or her in connection with the agreement that would have become vested during the nine month period following the date of termination.

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If our chief executive officer (i) is terminated for any reason other than for “cause,” or (ii) terminates his employment for “good reason,” then he will be entitled to:

- earned and accrued base salary, bonus, vacation time and other benefits;
- monthly salary continuation payments for a period of 12 months from the effective date of the release required to be provided as a condition to receiving these payments;
- health insurance coverage, subject to cost sharing, for 12 months following the effective date of the release required to be provided as a condition to receiving this coverage; and
- immediate vesting of the portion of the unvested options granted to him in connection with the agreement that would have become vested during the 12 month period.

If, within 30 days prior to, or 12 months following, a “change in control,” any of our named executive officers, including our chief executive officer, (i) is terminated for any reason other than for “cause,” or (ii) terminates his or her employment during the agreement term for “good reason,” then, in addition to the severance payments described above, such executive officer will also be entitled to immediate vesting of the entire unvested portion of all equity compensation granted to him or her.

Our obligation to make the severance payments described above will be conditioned upon the executive officer’s continued compliance with the non-competition and confidentiality obligations set forth in his or her employment agreement and the executive officer’s execution of a general release of claims against us.

Under the employment agreements, “cause” means: (i) failure to substantially perform the duties owed to us after receiving written notice that sets forth in detail the specific respects in which our board of directors believes that the duties have not been substantially performed, and failure to correct the failure within 30 days after receiving a demand for substantial performance and opportunity to cure; (ii) fraud, misconduct, dishonesty, gross negligence or other acts either injurious to us or conducted with intentional disregard for our best interests; (iii) failure to follow reasonable and lawful instructions from our board of directors and failure to cure such failure after receiving 20 days advance written notice; (iv) material breach of the terms of the employment agreement or our employee proprietary information and inventions assignment agreement or any other similar agreement that may be in effect from time to time; or (v) conviction of, or pleading guilty or nolo contendere to, any misdemeanor involving dishonesty or moral turpitude or related to our business, or any felony.

Under the employment agreements, “good reason” means, without the executive officer’s prior written consent: (i) any material reduction of the executive officer’s then effective base salary that is not in accordance with his employment agreement or related to a cross-executive team salary reduction; (ii) any material breach by us of the executive officer’s employment agreement; or (iii) a material reduction in the executive officer’s responsibilities or duties, not including a mere reassignment following a change of control to a position that is substantially similar to the position held prior to the change of control; provided, however, that no such event or condition shall constitute good reason unless (x) the executive officer gives us a written notice of termination for good reason not more than 90 days after the initial existence of the condition, (y) the grounds for termination (if susceptible to correction) are not corrected by us within 30 days of our receipt of such notice and (z) the termination date occurs within one (1) year following our receipt of such notice.

Under the employment agreements, a “change of control” means (i) a merger or consolidation of either us or PPI-California into another entity in which the stockholders of us or PPI-California (as applicable) do not control 50% or more of the total voting power of the surviving entity (other than a reincorporation merger); (ii) the sale, transfer or other disposition of all or substantially all of our assets in a liquidation or dissolution; or (iii) the sale or transfer of more than 50% of our outstanding voting stock. In the case of each of the foregoing clauses (i), (ii) and (iii), a change of control as a result of a financing transaction entered into by us or PPI-California shall not constitute a change of control for purposes of these agreements.

### **Services Agreement with MPM and Gary Patou**

In March 2009, we entered into a services agreement with Dr. Patou and MPM Asset Management LLC, or MPM AM. Pursuant to the services agreement, Dr. Gary Patou provided the services to us customarily expected of a chief medical officer. Mr. Patou's principal duties were to manage and lead our clinical team as well as oversee development of protocols and clinical trials designed to provide a path for regulatory approval of EXPAREL. In March 2010, we amended and restated the services agreement to, among other things, extend the term of the services until the deadline for filing the NDA for EXPAREL to October 15, 2010 or until either party gives 10 days prior written notice. In consideration of the services performed under the services agreement, we paid a service fee of \$26,467 per month to MPM AM. In addition, we paid a bonus to Dr. Patou upon the successful completion of an NDA submission for EXPAREL.

In October 2010, we entered into a new services agreement with Dr. Patou and MPM AM. Pursuant to this services agreement, Dr. Gary Patou continues to provide the services to us customarily expected of a chief medical officer. Dr. Patou's principal duties include obtaining approval for the EXPAREL NDA in the United States, filing the EXPAREL dossier in the European Union, developing additional clinical indications for EXPAREL and assisting with our product pipeline development. Under the new services agreement, we pay a service fee of \$26,467 per month to MPM AM which is adjusted based on the total amount of time Dr. Patou devotes to us during the term of the services agreement. If we terminate our consulting relationship with Dr. Patou and MPM AM other than for "cause" or the consulting relationship is terminated by Dr. Patou and MPM AM for "good reason", then MPM AM will be entitled to continuation of the then effective monthly service fee for a period of nine months following the date of termination and Dr. Patou will be entitled to immediate vesting of the portion of the unvested options that would have vested during the nine month period following the date of termination. In addition, if within 30 days prior to, or 12 months following, a "change of control," the consulting relationship is terminated other than for "cause" or for "good reason", then in addition to the service payments above, Dr. Patou will also be entitled to immediate vesting of the entire unvested portion of his stock options.

### **Stock Option and Other Compensation Plans**

#### ***2007 Stock Option/Stock Issuance Plan***

In January 2007, our board of directors approved our 2007 Stock Option/Stock Issuance Plan, or the 2007 Plan. The 2007 Plan was approved by our stockholders in June 2007.

We initially reserved 7,000,000 shares of our common stock for issuance under the 2007 Plan. In April 2008, our board of directors amended the 2007 Plan to, among other things, increase the number of authorized plan shares from 7,000,000 to 11,475,000 shares of our common stock. This increase was approved by our stockholders in May 2008. In September 2010, our board of directors further amended the 2007 Plan to increase the number of authorized plan shares from 11,475,000 to 18,600,750 shares of our common stock. This increase was approved by our stockholders in October 2010.

The material terms of the 2007 Plan are summarized below. The 2007 Plan will be filed as an exhibit to the registration statement of which this prospectus is a part.

*Administration.* Our board of directors (or a committee of the board of directors) administers the 2007 Plan. Subject to the terms and conditions of the 2007 Plan, the administrator has the authority to select the persons to whom awards are to be made, to determine the type or types of awards to be granted to each person, determine the number of awards to grant, determine the number of shares to be subject to such awards, and the terms and conditions of such awards, and make all other determinations and decisions and to take all other actions necessary or advisable for the administration of the 2007 Plan. The plan administrator is also authorized to establish, adopt, amend or revise rules relating to administration of the 2007 Plan, subject to certain restrictions.

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*Eligibility.* Options and restricted stock may be granted under the 2007 Plan to individuals who are then our employees, consultants or members of our board of directors or our subsidiaries. Only employees may be granted incentive stock options, or ISOs.

*Awards.* The 2007 Plan provides that our administrator may grant or issue stock options and restricted stock. The administrator considers each award grant subjectively, considering factors such as the individual performance of the recipient and the anticipated contribution of the recipient to the attainment of our long-term goals. Each award is set forth in a separate agreement with the person receiving the award and indicates the type, terms and conditions of the award.

- Non-qualified stock options, or NQSOs, provide for the right to purchase shares of our common stock at a specified price which may not be less than 85% of the fair market value of a share of stock on the date of grant, and usually will become exercisable (at the discretion of our compensation committee or the board of directors, in the case of awards to non-employee directors) in one or more installments after the grant date, subject to the participant's continued employment or service with us and/or subject to the satisfaction of performance targets established by our compensation committee (or the board of directors, in the case of awards to non-employee directors). NQSOs may be granted for any term specified by our compensation committee (or the board of directors, in the case of awards to non-employee directors), but the term may not exceed ten years.
- Incentive stock options, or ISOs, are designed to comply with the provisions of the Internal Revenue Code and are subject to specified restrictions contained in the Internal Revenue Code applicable to ISOs. Among such restrictions, ISOs must have an exercise price of not less than the fair market value of a share of common stock on the date of grant, may only be granted to employees, must expire within a specified period of time following the optionee's termination of employment, and must be exercised within ten years after the date of grant. In the case of an ISO granted to an individual who owns (or is deemed to own) more than 10% of the total combined voting power of all classes of our capital stock on the date of grant, the 2007 Plan provides that the exercise price must be more than 110% of the fair market value of a share of common stock on the date of grant and the ISO must expire on the fifth anniversary of the date of its grant.
- Restricted stock may be granted to participants and made subject to such restrictions as may be determined by the administrator. Restricted stock may be repurchased by us at the original purchase price or, if no cash consideration was paid for such stock, forfeited for no consideration if the conditions or restrictions are not met, and the restricted stock may not be sold or otherwise transferred to third parties until restrictions are removed or expire. Recipients of restricted stock, unlike recipients of options, may have voting rights and may receive dividends, if any, prior to when the restrictions lapse.

*Corporate Transactions.* In the event of a change of control where the acquiror does not assume awards granted under the 2007 Plan, awards issued under the 2007 Plan may be subject to accelerated vesting (at the discretion of the plan administrator) such that 100% of the awards will become vested and exercisable or payable, as applicable, immediately prior to a change in control. Under the 2007 Plan, a change of control is generally defined as:

- a merger, consolidation or other reorganization approved by our stockholders, unless securities representing more than 50% of the total combined voting power of the voting securities of the successor corporation are immediately thereafter beneficially owned, directly or indirectly and in substantially the same proportion, by the persons who beneficially owned our outstanding voting securities immediately prior to such transaction;
- the acquisition, directly or indirectly by any person or related group of persons (other than us, our subsidiaries, or a person or entity that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, us), of beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of securities possessing more than 50% of the total combined



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voting power of our outstanding securities pursuant to a tender or exchange offer made directly to our stockholders; or

- a stockholder-approved sale, transfer or other disposition of all or substantially all our assets in a complete liquidation or dissolution.

*Amendment of the 2007 Plan.* Our board of directors may amend or modify the 2007 Plan in any and all respects. However, stockholder approval of any amendment to the 2007 Plan must be obtained to the extent necessary and desirable to comply with any applicable law, regulation or stock exchange rule, or for any amendment to the 2007 Plan that increases the number of shares available under the 2007 Plan. The administrator may, with the consent of the affected option holders, cancel any or all outstanding awards under the 2007 Plan and grant new awards in substitution. The 2007 Plan will terminate on the tenth anniversary of the date of its initial approval by our board of directors.

#### ***Company Sale Bonus Plan***

In March 2009, we adopted a company sale bonus plan amended and restated in March 2010, that provides for a potential cash bonus payment to specified employees and consultants, including our executive officers, and our non-employee directors, in the event of a sale of our company. The purpose of the company sale bonus plan is to provide these employees and directors with an additional incentive in connection with a transaction that is in our and our stockholders' best interests, but which may otherwise create personal uncertainties. Under the company sale bonus plan, upon the closing of a sale transaction that satisfies specified criteria, each participant in the company sale bonus plan would receive either a bonus in an amount equal to a portion of the sale proceeds multiplied by a specified percentage for that participant or a fixed bonus payment. The participants in the bonus plan were determined by our board of directors. This bonus plan terminates upon the completion of this offering. As a condition to becoming participants under the plan, most of the participants, including all of our executive officers and non-employee directors, agreed to have their existing option grants cancelled.

#### ***401(k) Retirement Plan***

We maintain a 401(k) retirement plan that is intended to be a tax-qualified defined contribution plan under Section 401(k) of the Internal Revenue Code. In general, all of our employees are eligible to participate, beginning on the first day of the month following commencement of their employment. The 401(k) plan includes a salary deferral arrangement pursuant to which participants may elect to reduce their current compensation by up to the statutorily prescribed limit, equal to \$16,500 in 2009, and have the amount of the reduction contributed to the 401(k) plan.

#### **Limitation of Liability and Indemnification**

As permitted by Delaware law, our restated certificate of incorporation and restated bylaws, which will become effective upon the completion of this offering, limit or eliminate the personal liability of our directors. Our restated certificate of incorporation limits the liability of directors to the maximum extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breaches of their fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any unlawful payments related to dividends or unlawful stock repurchases, redemptions or other distributions; or
- any transaction from which the director derived an improper personal benefit.

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These limitations do not apply to liabilities arising under federal securities laws and do not affect the availability of equitable remedies, including injunctive relief or rescission. If Delaware law is amended to authorize the further elimination or limiting of director liability, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law as so amended.

As permitted by Delaware law, our restated certificate of incorporation and restated bylaws that will become effective upon the completion of this offering also provide that:

- we will indemnify our directors and officers to the fullest extent permitted by law;
- we may indemnify our other employees and other agents to the same extent that we indemnify our officers and directors, unless otherwise determined by the board of directors; and
- we will advance expenses to our directors and executive officers in connection with legal proceedings to the fullest extent permitted by law.

The indemnification provisions contained in our restated certificate of incorporation and restated bylaws that will become effective upon the completion of this offering are not exclusive.

In addition to the indemnification provided for in our restated certificate of incorporation and restated bylaws, prior to completion of this offering we intend to enter into indemnification agreements with each of our directors and executive officers. Each indemnification agreement will provide that we will indemnify the director or executive officer to the fullest extent permitted by law for claims arising in his or her capacity as our director, officer, employee or agent, provided that he or she acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to, our best interests and, with respect to any criminal proceeding, had no reasonable cause to believe that his or her conduct was unlawful. In the event that we do not assume the defense of a claim against a director or executive officer, we are required to advance his or her expenses in connection with his or her defense, provided that he or she undertakes to repay all amounts advanced if it is ultimately determined that he or she is not entitled to be indemnified by us.

We believe that these provisions and agreements are necessary to attract and retain qualified persons as directors and executive officers. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling our company pursuant to the foregoing provisions, the opinion of the SEC is that such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

In addition, we maintain standard policies of insurance under which coverage is provided to our directors and officers against losses rising from claims made by reason of breach of duty or other wrongful act, and to us with respect to payments which may be made by us to such directors and officers pursuant to the above indemnification provisions or otherwise as a matter of law.

#### **Rule 10b5-1 Sales Plans**

Prior to the completion of this offering, our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or executive officer when entering into the plan, without further direction from the director or executive officer. The director or executive officer may amend or terminate the plan in some circumstances. Our directors and executive officers may also buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material, nonpublic information.

## RELATED PERSON TRANSACTIONS

The following is a description of transactions since inception to which we have been a party, in which the amount involved in the transaction exceeds \$120,000, and in which any of our directors, executive officers or beneficial owners of more than 5% of our voting securities, or affiliates or immediate family members of any of our directors, executive officers or beneficial owners of more than 5% of our voting securities, had or will have a direct or indirect material interest. We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, from unrelated third parties.

### Debt Financings

#### *2009 Convertible Note Financing*

In January 2009, we sold \$10.63 million in aggregate principal amount of convertible promissory notes, or the 2009 Convertible Notes, in a private placement to certain of our existing investors. In connection with the issuance of the 2009 Convertible Notes, we issued warrants to purchase an aggregate of 1,700,000 shares of our common stock with an exercise price of \$0.25 per share. The 2009 Convertible Notes have an interest rate of 5% per year and all principal and accrued and unpaid interest on the 2009 Convertible Notes was due on December 31, 2010. In connection with entering into the Hercules Credit Facility, the maturity date was extended to the earliest of (1) a sale of us, (2) the date which is 30 days after the last day of the month that is 33 months after the expiration of the “interest only period” under the Hercules Credit Facility (as described above) and (3) 91 days after the date that all obligations under the Hercules Credit Facility are paid in full and the Hercules Credit Facility is terminated. In connection with entering into the Hercules Credit Facility, the holders of the 2009 Convertible Notes entered into a subordination and intercreditor agreement with the lenders under the Hercules Credit Facility pursuant to which the 2009 Convertible Notes were subordinated to the Hercules Credit Facility. The holders of the 2009 Convertible Notes previously entered into a separate intercreditor agreement with the holders of the 2009 Secured Notes and the 2010 Secured Notes pursuant to which the 2009 Convertible Notes were subordinated to the 2009 Secured Notes and the 2010 Secured Notes, and the holders of the 2009 Secured Notes agreed to share payments pro rata with the holders of the 2010 Secured Notes.

All principal and interest due under the 2009 Convertible Notes will be converted into 9,374,446 shares of our common stock upon completion of this offering.

Purchasers of the 2009 Convertible Notes included certain holders of more than 5% of our capital stock, or entities affiliated with them. The following table sets forth the aggregate principal amount of 2009 Convertible Notes purchased by each such holder and the warrants received in connection with the purchase of the 2009 Convertible Notes.

<u>Purchaser</u>	<u>Aggregate Principal Amount of Notes</u>	<u>Number of Warrant Shares</u>
HBM BioVentures	\$ 2,500,000	400,000
Entities affiliated with MPM Capital	2,500,000	399,999
Entities affiliated with OrbiMed Advisors	2,500,000	400,000
Entities affiliated with Sanderling Ventures	2,500,000	400,001

#### *2009 Secured Debt Financing*

In June 2009, we entered into an agreement with certain of our existing investors to issue \$10.63 million in aggregate principal amount of secured notes, or the 2009 Secured Notes. To secure the performance of our obligations under the purchase agreement for the 2009 Secured Notes, we granted a security interest in substantially all of our assets, including our intellectual property assets, except the assets that secure our obligations under our agreement with Paul Capital. In connection with entering into the Hercules Credit Facility, the holders of the 2009 Secured Notes entered into a subordination and intercreditor agreement with the lenders under the Hercules Credit Facility pursuant to which the 2009 Secured Notes were subordinated to the Hercules Credit Facility. The holders of the 2009 Secured Notes previously entered into a separate intercreditor agreement with the holders of the 2009 Convertible Notes and the 2010 Secured Notes pursuant to which the 2009 Convertible Notes were subordinated to the 2009 Secured Notes and the 2010 Secured Notes, and the holders of the 2009 Secured Notes agreed to share payments pro rata with the holders of the 2010 Secured Notes.

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The 2009 Secured Notes have an interest rate of 12% per year and all principal and accrued and unpaid interest on the 2009 Secured Notes was due on December 31, 2010. In connection with entering into the Hercules Credit Facility, the maturity date was extended to the earliest of (1) a sale of the Company, (2) the date which is 30 days after the last day of the month that is 33 months after the expiration of the “interest only period” under the Hercules Credit Facility (as described above) and (3) 91 days after the date that all obligations under the Hercules Credit Facility are paid in full and the Hercules Credit Facility is terminated.

All principal and interest due under the 2009 Secured Notes will be converted into 9,979,369 shares of our common stock upon completion of this offering. Purchasers of the 2009 Secured Notes included certain holders of more than 5% of our capital stock, or entities affiliated with them. The following table sets forth the amount of notes purchased by each such holder and the date of purchase:

<u>Date of Purchase</u>	<u>Purchaser</u>	<u>Aggregate Principal Amount of Notes Purchased on Such Date</u>
August 4, 2009	Entities affiliated with HBM BioVentures	\$ 988,235
	Entities affiliated with MPM Capital	988,235
	Entities affiliated with OrbiMed Advisors	988,235
	Entities affiliated with Sanderling Ventures	988,235
September 1, 2009	Entities affiliated with HBM BioVentures	988,235
	Entities affiliated with MPM Capital	988,235
	Entities affiliated with OrbiMed Advisors	988,235
	Entities affiliated with Sanderling Ventures	988,235
October 22, 2009	Entities affiliated with HBM BioVentures	523,529
	Entities affiliated with MPM Capital	523,529
	Entities affiliated with OrbiMed Advisors	523,529
	Entities affiliated with Sanderling Ventures	523,529

### ***2010 Secured Debt Financing***

In March 2010, we entered into an agreement with certain of our existing investors to issue \$15.0 million in aggregate principal amount of secured notes, or the 2010 Secured Notes, in a private placement and the investors purchased the entire \$15.0 million of 2010 Secured Notes. To secure the performance of our obligations under the purchase agreement for the 2010 Secured Notes, we granted a subordinated security interest in substantially all of our assets, including our intellectual property assets, to the investors. In connection with entering into the Hercules Credit Facility, the holders of the 2010 Secured Notes entered into a subordination and intercreditor agreement with the lenders under the Hercules Credit Facility pursuant to which the 2010 Secured Notes were subordinated to the Hercules Credit Facility. The holders of the 2010 Secured Notes previously entered into a separate intercreditor agreement with the holders of the 2009 Convertible Notes and the 2009 Secured Notes pursuant to which the 2009 Convertible Notes were subordinated to the 2010 Secured Notes and the 2009 Secured Notes, and the holders of the 2010 Secured Notes agreed to share payments pro rata with the holders of the 2009 Secured Notes.

The 2010 Secured Notes have an interest rate of 5% per year and all principal and accrued and unpaid interest on the 2010 Secured Notes was due on December 31, 2010. In connection with entering into the Hercules Credit Facility, the maturity date was further extended to the earliest of (1) a sale of the Company, (2) the date which is 30 days after the last day of the month that is 33 months after the expiration of the “interest only period” under the Hercules Credit Facility (as described above) and (3) 91 days after the date that all obligations under the Hercules Credit Facility are paid in full and the Hercules Credit Facility is terminated.

All principal and interest due under the 2010 Secured Notes will be converted into 12,439,302 shares of our common stock upon completion of this offering. Purchasers of the 2010 Secured Notes included certain holders of more than 5% of our capital stock, or entities affiliated with them. The following table sets forth the amount of notes purchased by each such holder and the date of purchase.

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<u>Date of Purchase</u>	<u>Purchaser</u>	<u>Aggregate Principal Amount of Notes Purchased on Such Date</u>
March 10, 2010	Entities affiliated with HBM BioVentures	\$ 1,875,000
	Entities affiliated with MPM Capital	1,875,000
	Entities affiliated with OrbiMed Advisors	1,875,000
	Entities affiliated with Sanderling Ventures	1,875,000
June 30, 2010	Entities affiliated with HBM BioVentures	937,500
	Entities affiliated with MPM Capital	937,500
	Entities affiliated with OrbiMed Advisors	937,500
	Entities affiliated with Sanderling Ventures	937,500
September 1, 2010	Entities affiliated with HBM BioVentures	937,500
	Entities affiliated with MPM Capital	937,500
	Entities affiliated with OrbiMed Advisors	937,500
	Entities affiliated with Sanderling Ventures	937,500

**HBM Term Loan**

On April 30, 2010, we entered into a subordinated secured note purchase agreement with entities affiliated with HBM BioVentures, or HBM, to issue \$3.75 million in aggregate principal amount of secured notes, or the HBM Secured Notes, in a private placement. HBM purchased the entire \$3.75 million of the HBM Secured Notes. To secure the performance of our obligations under the purchase agreement for the HBM Secured Notes, we granted a subordinated security interest in substantially all of our assets, including our intellectual property assets, other than the assets that secure our obligations under the Amended and Restated Royalty Interests Assignment Agreement. The HBM Secured Notes carry an interest rate of approximately 10% per year. In addition, the HBM Secured Notes require a final payment fee if they are prepaid prior to the maturity date. The maturity date of the HBM Secured Notes is the earliest of (1) a sale of the Company, (2) the date which is 30 days after the last day of the month that is 33 months after the expiration of the “interest only period” under the Hercules Credit Facility (as described above) and (3) 91 days after the date that all obligations under the Hercules Credit Facility are paid in full and the Hercules Credit Facility is terminated. In connection with entering into the Hercules Credit Facility, the holders of the HBM Secured Notes entered into a subordination and intercreditor agreement with the lenders under the Hercules Credit Facility pursuant to which the HBM Secured Notes were subordinated to the Hercules Credit Facility.

All principal and interest due under the HBM Secured Notes will be converted into 3,319,598 shares of our common stock upon completion of this offering. Purchasers of the HBM Secured Notes included certain holders of more than 5% of our capital stock, or entities affiliated with them.

**Stockholder Guarantee under Hercules Credit Facility**

On November 24, 2010, we entered into a \$26.25 million credit facility with Hercules Technology Growth Capital, Inc. and Hercules Technology III, L.P., as lenders, or the Hercules Credit Facility. We borrowed under the Hercules Credit Facility an aggregate principal amount of \$26.25 million.

The Hercules Credit Facility is guaranteed by MPM Capital, Sanderling Ventures and OrbiMed Advisors, and entities affiliated with them, which are holders of more than 5% of our voting securities, on a several and not joint basis, which guarantee is limited to each such stockholder’s pro rata portion of the outstanding principal and accrued and unpaid interest under the Hercules Credit Facility, but in no event to exceed \$11.25 million in the aggregate. The obligations of these stockholders under the guarantee is not triggered until the earlier to occur of (i) 30 days after written notice from the agent that our obligations under the Hercules Credit Facility have been accelerated, and (ii) the occurrence of a bankruptcy or insolvency event with respect to the borrower under the Hercules Credit Facility, us or any of the guarantors. The guarantee by these stockholders of the Hercules Credit Facility also includes covenants that require each such investor to maintain at all times unfunded commitments

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from its fund investors in an amount equal to at least one and one-half times the maximum amount that the investor may be obligated for under the stockholder guarantee, and also includes certain control requirements with respect to such stockholders. The guarantee by these stockholders of the Hercules Credit Facility replaced the guarantee under the GECC Credit Facility which was terminated in November 2010.

### Preferred Stock Issuances

In March 2007, we entered into a Series A Preferred Stock Purchase Agreement pursuant to which we issued and sold to investors an aggregate of 68,000,000 shares of Series A convertible preferred stock in four separate closings held in March 2007, February 2008, July 2008 and October 2008, at a purchase price of \$1.25 per share. The aggregate consideration for the Series A convertible preferred stock was \$85 million in cash.

The following table sets forth the shares of our Series A convertible preferred stock issued to our directors, officers or holders of more than 5% of our common stock and their affiliates:

<u>Investor</u>	<u>Shares of Series A Convertible Preferred Stock</u>
Entities affiliated with MPM Capital <sup>(1)</sup>	16,000,000
Entities affiliated with Sanderling Ventures <sup>(2)</sup>	16,000,000
Entities affiliated with OrbiMed Advisors <sup>(3)</sup>	16,000,000
Entities affiliated with HBM BioVentures <sup>(4)</sup>	16,000,000

<sup>(1)</sup> Consists of (i) 14,995,856 shares of Series A convertible preferred stock held by MPM BioVentures IV-QP, L.P., (ii) 577,727 shares of Series A convertible preferred stock held by MPM BioVentures IV GmbH & Co. Beteiligungs KG, and (iii) 426,417 shares of Series A convertible preferred stock held by MPM Asset Management Investors BV4 LLC. Dr. Patou and Dr. Evinin are members of MPM BioVentures IV LLC, the direct or indirect general partner or manager of the above mentioned funds, which has the ultimate voting and investment power over shares of record held by MPM BioVentures IV-QP, L.P., MPM BioVentures IV GmbH & Co. Beteiligungs KG, and MPM Asset Management Investors BV4 LLC and they may be deemed to have voting and investment power over shares held of record by MPM BioVentures IV-QP, L.P., MPM BioVentures IV GmbH & Co. Beteiligungs KG, and MPM Asset Management Investors BV4 LLC. Dr. Patou, Dr. Evinin and Mr. Stack each disclaim beneficial ownership over the shares held by MPM Capital and its affiliates, except to the extent of their pecuniary interest therein.

<sup>(2)</sup> Consists of (i) 7,921,950 shares of Series A convertible preferred stock held by Sanderling Venture Partners VI, L.P.; (ii) 267,493 shares of Series A convertible preferred stock held by Sanderling VI Beteiligungs GmbH & Co. KG, (iii) 318,716 shares of Series A convertible preferred stock held by Sanderling VI Limited Partnership, (iv) 7,331,841 shares of Series A convertible preferred stock held by Sanderling Venture Partners VI Co-Investment Fund, L.P., and (v) 160,000 shares of Series A convertible preferred stock held by Sanderling Ventures Management VI. Mr. Middleton is a managing director of Middleton, McNeil, Mills & Associates VI, LLC, which has the ultimate voting and investment power over shares held of record by Sanderling Venture Partners VI, L.P., Sanderling VI Beteiligungs GmbH & Co. KG, Sanderling VI Limited Partnership and Sanderling Venture Partners VI Co-Investment Fund, L.P. and he may be deemed to have voting and investment power over shares held of record by Sanderling Venture Partners VI, L.P., Sanderling VI Beteiligungs GmbH & Co. KG, Sanderling VI Limited Partnership and Sanderling Venture Partners VI Co-Investment Fund, L.P. Mr. Middleton is the owner of Sanderling Ventures Management VI and he may be deemed to have voting and investment power over shares held of record by Sanderling Ventures Management VI. Mr. Middleton disclaims beneficial ownership over the shares held by Sanderling Ventures and its affiliates, except to the extent of his pecuniary interest therein.

<sup>(3)</sup> Consists of (i) 15,849,056 shares of Series A convertible preferred stock held by OrbiMed Private Investments III, LP, and (ii) 150,944 shares of Series A convertible preferred stock held by OrbiMed Associates III, LP. OrbiMed Capital GP III LLC is the general partner of OrbiMed Private Investments III, LP and OrbiMed Advisors LLC is the managing member of OrbiMed Capital GP III LLC. OrbiMed Advisors LLC is also the general partner of OrbiMed Associates III, LP. Samuel D. Isaly is the managing member of and owner of a controlling interest in OrbiMed Advisors LLC and may be deemed to have voting and investment power over the shares held by OrbiMed Private Investments III, LP and OrbiMed Associates III, LP noted above. Mr. Isaly disclaims beneficial ownership of such shares, except to the extent of his pecuniary interest therein. Dr. Gordon, a member of our board of directors, is an affiliate of the above-mentioned funds.

<sup>(4)</sup> Consists of 16,000,000 shares of Series A convertible preferred stock held by HBM BioVentures (Cayman) Ltd. Dr. Wicki disclaims beneficial ownership over the shares held by HBM BioVentures and its affiliates, except to the extent of his pecuniary interest therein.

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## Common Stock Issuances

In connection with our formation, we issued an aggregate of 5,000,000 shares of common stock for total aggregate consideration of \$50,000. The following table sets forth the aggregate number of shares of common stock acquired by our directors, executive officers or holders of more than 5% of our common stock and their affiliates:

<u>Investor</u>	<u>Shares of Common Stock</u>
Entities affiliated with Sanderling Ventures <sup>(1)</sup>	2,000,000
Entities affiliated with MPM Capital <sup>(2)</sup>	1,000,000
Entities affiliated with OrbiMed Advisors <sup>(3)</sup>	1,000,000
Entities affiliated with HBM BioVenture <sup>(4)</sup>	1,000,000

<sup>(1)</sup> Consists of (i) 1,352,985 shares of common stock held by Sanderling Venture Partners VI, L.P.; (ii) 21,453 shares of common stock held by Sanderling VI Beteiligungs GmbH & Co. KG, (iii) 25,562 shares of common stock held by Sanderling VI Limited Partnership, and (iv) 600,000 shares of common stock held by Sanderling Ventures Management VI. Mr. Middleton is a managing director of Middleton, McNeil, Mills & Associates VI, LLC, which has the ultimate voting and investment power over shares held of record by Sanderling Venture Partners VI, L.P., Sanderling VI Beteiligungs GmbH & Co. KG, and Sanderling VI Limited Partnership and he may be deemed to have voting and investment power over shares held of record by Sanderling Venture Partners VI, L.P., Sanderling VI Beteiligungs GmbH & Co. KG, and Sanderling VI Limited Partnership. Mr. Middleton is the owner of Sanderling Ventures Management VI and he may be deemed to have voting and investment power over shares held of record by Sanderling Ventures Management VI. Mr. Middleton disclaims beneficial ownership over the shares held by Sanderling Ventures and its affiliates, except to the extent of his pecuniary interest therein.

<sup>(2)</sup> Consists of (i) 937,241 shares of common stock held by MPM BioVentures IV-QP, L.P., (ii) 36,108 shares of common stock held by MPM BioVentures IV GmbH & Co. Beteiligungs KG, and (iii) 26,651 shares of common stock held by MPM Asset Management Investors BV4 LLC. Dr. Patou and Dr. Evnin are members of MPM BioVentures IV LLC, the direct or indirect general partner or manager of the above mentioned funds, which has the ultimate voting and investment power over shares of record held by MPM BioVentures IV-QP, L.P., MPM BioVentures IV GmbH & Co. Beteiligungs KG, and MPM Asset Management Investors BV4 LLC and they may be deemed to have voting and investment power over shares held of record by MPM BioVentures IV-QP, L.P., MPM BioVentures IV GmbH & Co. Beteiligungs KG, and MPM Asset Management Investors BV4 LLC. Dr. Patou, Dr. Evnin and Mr. Stack each disclaim beneficial ownership over the shares held by MPM Capital and its affiliates, except to the extent of their pecuniary interest therein.

<sup>(3)</sup> Consists of (i) 990,566 shares of common stock held by OrbiMed Private Investments III, LP, and (ii) 9,434 shares of common stock held by OrbiMed Associates III, LP. OrbiMed Capital GP III LLC is the general partner of OrbiMed Private Investments III, LP and OrbiMed Advisors LLC is the managing member of OrbiMed Capital GP III LLC. OrbiMed Advisors LLC is also the general partner of OrbiMed Associates III, LP. Samuel D. Isaly is the managing member of and owner of a controlling interest in OrbiMed Advisors LLC and may be deemed to have voting and investment power over the shares held by OrbiMed Private Investments III, LP and OrbiMed Associates III, LP noted above. Mr. Isaly disclaims beneficial ownership of such shares, except to the extent of his pecuniary interest therein. Dr. Gordon, a member of our board of directors, is an affiliate of the above-mentioned funds.

<sup>(4)</sup> Consists of 1,000,000 shares of common stock held by HBM BioVentures (Cayman) Ltd. Dr. Wicki disclaims beneficial ownership over the shares held by HBM BioVentures and its affiliates, except to the extent of his pecuniary interest therein.

## Investors' Rights Agreement

In March 2007, we entered into an investors' rights agreement with purchasers of our Series A convertible preferred stock. This agreement provides the purchasers of our Series A convertible preferred stock with certain rights relating to the registration of their shares of common stock issuable upon conversion of their Series A convertible preferred stock, a right of first offer to purchase future securities sold by us and certain additional covenants made by us. Except for the registration rights, all rights under this agreement will terminate upon completion of this offering. The registration rights will continue following the completion of this offering and will terminate five years following the completion of this offering, or for any particular holder with registration rights, at such time following the completion of this offering when all securities held by that stockholder may be sold pursuant to Rule 144 under the Securities Act. All holders of our Series A convertible preferred stock are parties to this agreement. See "Description of Capital Stock—Registration Rights" for additional information.

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**Voting Agreement**

In March 2007, we entered into a voting agreement with certain of our stockholders. Pursuant to the voting agreement the following directors were each elected to serve as members on our board of directors and, as of the date of this prospectus, continue to so serve: Luke Evnin, Carl Gordon, John Longenecker, Fred Middleton, Gary Pace, David Stack and Andreas Wicki. Pursuant to the voting agreement, Mr. Stack, as our chief executive officer, was initially selected to serve on our board of directors as a “CEO director.” Messrs. Evnin, Gordon, Middleton, and Wicki were initially selected to serve on our board of directors as representatives of our Series A convertible preferred stockholders, as designated by MPM Capital, OrbiMed Advisors, Sanderling Ventures and HBM BioVentures, respectively.

The voting agreement will terminate upon completion of this offering, and members previously elected to our board of directors pursuant to this agreement will continue to serve as directors until they resign, are removed or their successors are duly elected by holders of our common stock. The composition of our board of directors after this offering is described in more detail under “Management—Board Composition.”

**Employment Agreements**

We entered into employment agreements with the following executive officers and key employees: David Stack, our chief executive officer, James Scibetta, our chief financial officer, Mark Walters, our senior vice president, technical operations, William Lambert, our senior vice president, pharmaceutical development. For further information, see “Executive Compensation—Employment Agreements, Severance and Change in Control Arrangements.”

**Services Agreements**

We entered into a services agreement with Gary Patou, our chief medical officer, and MPM AM. For further information, see “Executive Compensation—Services Agreement with MPM and Gary Patou.”

In addition to the amounts paid to Gary Patou, MPM AM provides clinical management and subscription services to us. During the period from January 1, 2009 to November 30, 2010, we paid an aggregate of \$27,293 to MPM AM for these services.

In February 2008, we entered into a services agreement with Stack Pharmaceuticals, Inc., or SPI, an entity controlled by David Stack, our chief executive officer. Pursuant to the agreement, SPI provided us with the use of SPI’s office facilities which included the use of office space for our employees, office furnishings, phone system, internet connections, printers and other related office amenities such as conference rooms. The office facilities are located at 5 Sylvan Way, Parsippany, New Jersey. Pursuant to the agreement, we paid SPI \$10,500 each month during the term of the services agreement. The term of the agreement was one year and was renewable upon consent of both parties and the agreement may be cancelled with 60 days written notice by either party. In February 2009, we renewed the agreement on a month-to-month basis.

In August 2010, we entered into a new services agreement with SPI that replaced the agreement that we entered into in February 2008. Pursuant to the new agreement, SPI provides us with the use of SPI’s office facilities which includes the use of office space for our employees, office furnishings, phone system, internet connections, printers and other related office amenities such as conference rooms. In addition, SPI provides consulting services and commercial leadership related to EXPAREL regarding the development of strategic plans and analyses for the commercialization of EXPAREL, support in the development of documents, data and materials for investor and commercial partner presentations and documents, and commercial leadership in support of our website. SPI provides these services from time to time as we request from August 2010 through December 2010. We pay SPI \$2,500 for each day of services provided by SPI up to a maximum of five days per week. We also reimburse SPI for travel expenses incurred by SPI personnel.



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In addition, during 2008, 2009 and 2010, upon our request, SPI performed various projects, all of which have been completed by SPI. These projects included a business analysis and commercial recommendation for our DepoDur product, a market research project related to the development of a DepoMethotrexate product, market research and forecasting in support of clinical development of EXPAREL for the potential additional indications of nerve block and epidural administration and reimbursement for access to Datamonitor reports for commercial analysis and partnering discussions regarding EXPAREL.

During the period from January 1, 2009, through November 30, 2010, we have paid SPI an aggregate of \$513,952 for the above services provided by SPI.

In April 2010, we signed a statement of work for a feasibility study with Rhythm Pharmaceuticals, Inc. We earned contract revenue of approximately \$290,000 from this statement of work during the period from April 2010 through November 30, 2010. MPM Capital and its affiliates are holders of more than 5% of our capital stock. We have been informed that MPM Capital and its affiliates are holders of more than 10% of the capital stock of Rhythm Pharmaceuticals, Inc. and a managing director of MPM Capital is a member of the board of directors of Rhythm Pharmaceuticals, Inc.

#### **Indemnification of Officers and Directors**

Our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective upon the completion of this offering, will provide that we will indemnify each of our directors and officers to the fullest extent permitted by the Delaware General Corporation Law. Further, we intend to enter into indemnification agreements with each of our directors and officers, and we have purchased a policy of directors' and officers' liability insurance that insures our directors and officers against the cost of defense, settlement or payment of a judgment under certain circumstances. For further information, see "Executive Compensation—Limitation of Liability and Indemnification."

#### **Policies and Procedures for Related Person Transactions**

In connection with this offering, our board of directors will adopt a written related person transaction policy to set forth the policies and procedures for the review and approval or ratification of related person transactions. This policy will cover any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, the amount involved exceeds \$120,000, and a related person had or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness, and employment by us of a related person.

Any related person transaction proposed to be entered into by us will be required to be reported to our chief financial officer and will be reviewed and approved by the audit committee in accordance with the terms of the policy, prior to effectiveness or consummation of the transaction, whenever practicable. If our chief financial officer determines that advance approval of a related person transaction is not practicable under the circumstances, the audit committee will review and, in its discretion, may ratify the related person transaction at the next meeting of the audit committee, or at the next meeting following the date that the related person transaction comes to the attention of our chief financial officer. Our chief financial officer, however, may present a related person transaction arising in the time period between meetings of the audit committee to the chair of the audit committee, who will review and may approve the related person transaction, subject to ratification by the audit committee at the next meeting of the audit committee.

In addition, any related person transaction previously approved by the audit committee or otherwise already existing that is ongoing in nature will be reviewed by the audit committee annually to ensure that such related person transaction has been conducted in accordance with the previous approval granted by the audit committee, if any, and that all required disclosures regarding the related person transaction are made.

Transactions involving compensation of executive officers will be reviewed and approved by the compensation committee in the manner specified in the charter of the compensation committee.

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A related person transaction reviewed under this policy will be considered approved or ratified if it is authorized by the audit committee in accordance with the standards set forth in our related person transaction policy after full disclosure of the related person's interests in the transaction. As appropriate for the circumstances, the audit committee will review and consider:

- the related person's interest in the related person transaction;
- the approximate dollar value of the amount involved in the related person transaction;
- the approximate dollar value of the amount of the related person's interest in the transaction without regard to the amount of any profit or loss;
- whether the transaction was undertaken in the ordinary course of business;
- whether the transaction with the related person is proposed to be, or was, entered into on terms no less favorable to us than terms that could have been reached with an unrelated third party;
- the purpose of, and the potential benefits to us of, the transaction; and
- any other information regarding the related person transaction or the related person in the context of the proposed transaction that would be material to stockholders in light of the circumstances of the particular transaction.

The audit committee will review all relevant information available to it about the related person transaction. The audit committee may approve or ratify the related person transaction only if the audit committee determines that, under all of the circumstances, the transaction is in, or is not inconsistent with, our best interests. The audit committee may, in its sole discretion, impose conditions as it deems appropriate on us or the related person in connection with approval of the related person transaction.

## PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding the beneficial ownership of our common stock as of November 30, 2010, by:

- each of our directors;
- each of our named executive officers;
- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock; and
- all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with SEC rules. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities and include shares of common stock issuable upon the exercise of stock options and warrants that are immediately exercisable or exercisable within 60 days after November 30, 2010. Except as otherwise indicated, all of the shares reflected in the table are shares of common stock and all persons listed below have sole voting and investment power with respect to the shares beneficially owned by them, subject to applicable community property laws. The information is not necessarily indicative of beneficial ownership for any other purpose.

Percentage ownership calculations for beneficial ownership prior to this offering are based on 109,286,553 shares outstanding as of November 30, 2010, assuming the conversion of all of the outstanding Series A convertible preferred stock and assuming the conversion of \$40.0 million aggregate principal amount and all accrued and unpaid interest outstanding under our secured and unsecured notes held by certain of our investors into common stock upon completion of this offering. Percentage ownership calculations for beneficial ownership after this offering also include the shares we are offering hereby. Except as otherwise indicated in the table below, addresses of named beneficial owners are in care of Pacira Pharmaceuticals, Inc., 5 Sylvan Way, Suite 125, Parsippany, New Jersey 07054.

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In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed shares of common stock subject to options and warrants held by that person that are currently exercisable or exercisable within 60 days of September 30, 2010 to be outstanding. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Beneficial ownership representing less than 1% is denoted with an asterisk (\*).

<u>Name and Address of Beneficial Owner</u>	<u>Number of Shares Beneficially Owned</u>	<u>Percentage Before the Offering</u>	<u>Percentage After the Offering</u>
<b>5% Stockholders</b>			
HBM BioVentures (Cayman) Ltd. <sup>(1)</sup>	28,383,267	25.9%	
MPM Capital and its affiliates <sup>(2)</sup>	25,063,663	22.9%	
OrbiMed Advisors and its affiliates <sup>(3)</sup>	25,063,668	22.9%	
Sanderling Ventures and its affiliates <sup>(4)</sup>	26,063,658	23.8%	
<b>Officers and Directors</b>			
David Stack <sup>(5)</sup>	1,366,667	1.2%	
James Scibetta <sup>(6)</sup>	466,667	*	
Gary Patou <sup>(7)</sup>	370,417	*	
William Lambert <sup>(8)</sup>	333,333	*	
Mark Walters <sup>(9)</sup>	333,333	*	
Luke Evnin <sup>(10)</sup>	25,063,663	22.9%	
Carl Gordon <sup>(11)</sup>	25,063,668	22.9%	
John Longenecker <sup>(12)</sup>	66,667	*	
Fred Middleton <sup>(13)</sup>	25,063,658	23.8%	
Gary Pace <sup>(14)</sup>	46,667	*	
Andreas Wicki <sup>(15)</sup>	28,383,267	25.9%	
All current executive officers and directors as a group (11 persons)	107,558,007	94.6%	

<sup>(1)</sup> The address for HBM BioVentures (Cayman) Ltd. is Centennial Towers, Suite 305, 2454 West Bay Road, Grand Cayman, Cayman Islands, B.V.I. Consists of (i) 16,000,000 shares of Series A convertible preferred stock held by HBM BioVentures (Cayman) Ltd., (ii) 1,000,000 shares of common stock held by HBM BioVentures (Cayman) Ltd., (iii) 400,000 shares of common stock issuable upon exercise of warrants held by HBM BioVentures (Cayman) Ltd., and (iv) 10,983,267 shares of common stock issuable upon conversion of notes held by HBM BioVentures (Cayman) Ltd. The board of directors of HBM BioVentures (Cayman) Ltd. has sole voting and investment power with respect to the shares by held by such entity and acts by majority vote. The board of directors of HBM BioVentures (Cayman) Ltd. is comprised of John Arnold, Richard Coles, Sophia Harris, Dr. Andreas Wicki and John Urquhart, none of whom has individual voting or investment power with respect to such shares.

<sup>(2)</sup> The address for funds managed by MPM Capital is 200 Clarendon St., 54th Floor, Boston, MA 02116. Consists of (i) 14,995,856 shares of Series A convertible preferred stock held by MPM BioVentures IV-QP, L.P., (ii) 577,727 shares of Series A convertible preferred stock held by MPM BioVentures IV GmbH & Co. Beteiligungs KG, (iii) 426,417 shares of Series A convertible preferred stock held by MPM Asset Management Investors BV4 LLC, (iv) 937,241 shares of common stock held by MPM BioVentures IV-QP, L.P., (v) 36,108 shares of common stock held by MPM BioVentures IV GmbH & Co. Beteiligungs KG, (vi) 26,651 shares of common stock held by MPM Asset Management Investors BV4 LLC, (vii) 374,896 shares of common stock issuable upon exercise of warrants held by MPM BioVentures IV-QP, L.P., (viii) 14,443 shares of common stock issuable upon exercise of warrants held by MPM BioVentures IV GmbH & Co. Beteiligungs KG, (ix) 10,660 shares of common stock issuable upon exercise of warrants held by MPM Asset Management Investors BV4 LLC, (x) 7,182,705 shares of common stock issuable upon conversion of notes held by MPM BioVentures IV-QP, L.P., (xi) 276,718 shares of common stock issuable upon conversion of notes held by MPM BioVentures IV GmbH & Co. Beteiligungs KG, and (xii) 204,241 shares of common stock issuable upon conversion of notes held by MPM Asset Management Investors BV4 LLC. Dr. Patou is a Managing Director of MPM Asset Management LLC. MPM Asset Management LLC is the Management Company of MPM BioVentures IV LLC. MPM BioVentures IV LLC is the Managing Member of MPM BioVentures IV GP LLC, which is the General Partner of MPM BioVentures IV-QP, LP. and the Managing Limited Partner of MPM BioVentures IV GmbH & Co. Beteiligungs KG. MPM BioVentures IV LLC is the Manager of MPM Asset Management Investors BV4 LLC. Dr. Evnin is a Member of MPM BioVentures IV LLC. Dr. Evnin has a shared power to vote, acquire, hold and dispose of all shares and warrants. Dr. Evnin disclaims beneficial ownership of the securities except to the extent of their pecuniary interest therein.

<sup>(3)</sup> The address for funds managed by OrbiMed Advisors is 767 3rd Avenue, 30th Floor, New York, NY 10017. Consists of (i) 15,849,056 shares of Series A convertible preferred stock held by OrbiMed Private Investments III, LP, (ii) 150,944 shares of Series A convertible preferred stock held by OrbiMed Associates III, LP, (iii) 990,566 shares of common stock held by OrbiMed Private Investments III, LP, (iv) 9,434 shares of common stock held by OrbiMed Associates III, LP, (v) 396,226 shares of common stock issuable upon exercise of warrants held by OrbiMed Private Investments III, LP, (vi) 3,774 shares of common stock issuable upon exercise of warrants held by OrbiMed Associates III, LP, (vii) 7,591,371 shares of common stock issuable upon conversion of notes held by OrbiMed Private Investments III, LP, and (viii) 72,297 shares of common stock issuable upon conversion of notes held by OrbiMed Associates III, LP. OrbiMed Capital GP III LLC is the general partner of OrbiMed Private Investments III, LP and OrbiMed Advisors LLC is the managing member of OrbiMed Capital GP III LLC. OrbiMed Advisors LLC is also the general partner of OrbiMed Associates III, LP. Samuel D.

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Isaly is the managing member of and owner of a controlling interest in OrbiMed Advisors LLC and may be deemed to have voting and investment power over the shares held by OrbiMed Private Investments III, LP and OrbiMed Associates III, LP noted above. Mr. Isaly disclaims beneficial ownership of such shares, except to the extent of his pecuniary interest therein. Dr. Gordon, a member of our board of directors, is an affiliate of the above-mentioned funds.

- (4) The address for funds managed by Sanderling Ventures is 400 South El Camino Real, Suite 1200, San Mateo, California 94402. Consists of (i) 7,921,950 shares of Series A convertible preferred stock held by Sanderling Venture Partners VI, L.P., (ii) 267,493 shares of Series A convertible preferred stock held by Sanderling VI Beteiligungs GmbH & Co. KG, (iii) 318,716 shares of Series A convertible preferred stock held by Sanderling VI Limited Partnership, (iv) 7,331,841 shares of Series A convertible preferred stock held by Sanderling Venture Partners VI Co-Investment Fund, L.P., (v) 160,000 shares of Series A convertible preferred stock held by Sanderling Ventures Management VI, (vi) 1,352,985 shares of common stock held by Sanderling Venture Partners VI, L.P., (vii) 21,453 shares of common stock held by Sanderling VI Beteiligungs GmbH & Co. KG, (viii) 25,562 shares of common stock held by Sanderling VI Limited Partnership, (ix) 600,000 shares of common stock held by Sanderling Ventures Management VI, (x) 193,304 shares of common stock issuable upon exercise of warrants held by Sanderling Venture Partners VI, L.P., (xi) 6,769 shares of common stock issuable upon exercise of warrants held by Sanderling VI Beteiligungs GmbH & Co. KG, (xii) 8,065 shares of common stock issuable upon exercise of warrants held by Sanderling VI Limited Partnership, (xiii) 191,863 shares of common stock issuable upon exercise of warrants held by Sanderling Venture Partners VI Co-Investment Fund, L.P., (xiv) 3,703,541 shares of common stock issuable upon conversion of notes held by Sanderling Venture Partners VI, L.P., (xv) 129,677 shares of common stock issuable upon conversion of notes held by Sanderling VI Beteiligungs GmbH & Co. KG, (xvi) 154,510 shares of common stock issuable upon conversion of notes held by Sanderling Venture Partners VI, L.P., (xvii) 3,675,929 shares of common stock issuable upon conversion of notes held by Sanderling Venture Partners VI Co-Investment Fund, L.P. Mr. Middleton is a managing director of Middleton, McNeil, Mills & Associates VI, LLC, which has the ultimate voting and investment power over shares held of record by Sanderling Venture Partners VI, L.P., Sanderling VI Beteiligungs GmbH & Co. KG, Sanderling VI Limited Partnership and Sanderling Venture Partners VI Co-Investment Fund, L.P. and he may be deemed to have voting and investment power over shares held of record by Sanderling Venture Partners VI, L.P., Sanderling VI Beteiligungs GmbH & Co. KG, Sanderling VI Limited Partnership and Sanderling Venture Partners VI Co-Investment Fund, L.P. Mr. Middleton is the owner of Sanderling Ventures Management VI and he may be deemed to have voting and investment power over shares held of record by Sanderling Ventures Management VI. Mr. Middleton disclaims beneficial ownership over the shares held by Sanderling Ventures and its affiliates, except to the extent of his pecuniary interest therein.
- (5) Consists of (i) 200,000 shares of common stock held by Stack Schroon Mohawk FLP and (ii) 1,166,667 shares of common stock issuable upon exercise of stock options within 60 days of November 30, 2010, including options that become exercisable upon completion of this offering. Mr. Stack is the general partner of Stack Schroon Mohawk FLP.
- (6) Consists of 466,667 shares of common stock issuable upon exercise of stock options within 60 days of November 30, 2010, including options that become exercisable upon completion of this offering.
- (7) Consists of 370,417 shares of common stock issuable upon exercise of stock options within 60 days of November 30, 2010, including options that become exercisable upon completion of this offering.
- (8) Includes 333,333 shares of common stock issuable upon exercise of stock options within 60 days of November 30, 2010, including options that become exercisable upon completion of this offering.
- (9) Includes 333,333 shares of common stock issuable upon exercise of stock options within 60 days of November 30, 2010, including options that become exercisable upon completion of this offering.
- (10) Consists of (i) 14,995,856 shares of Series A convertible preferred stock held by MPM BioVentures IV-QP, L.P., (ii) 577,727 shares of Series A convertible preferred stock held by MPM BioVentures IV GmbH & Co. Beteiligungs KG, (iii) 426,417 shares of Series A convertible preferred stock held by MPM Asset Management Investors BV4 LLC, (iv) 937,241 shares of common stock held by MPM BioVentures IV-QP, L.P., (v) 36,108 shares of common stock held by MPM BioVentures IV GmbH & Co. Beteiligungs KG, (vi) 26,651 shares of common stock held by MPM Asset Management Investors BV4 LLC., (vii) 374,896 shares of common stock issuable upon exercise of warrants held by MPM BioVentures IV-QP, L.P., (viii) 14,443 shares of common stock issuable upon exercise of warrants held by MPM BioVentures IV GmbH & Co. Beteiligungs KG, (ix) 10,660 shares of common stock issuable upon exercise of warrants held by MPM Asset Management Investors BV4 LLC., (x) 7,182,705 shares of common stock issuable upon conversion of notes held by MPM BioVentures IV-QP, L.P., (xi) 276,718 shares of common stock issuable upon conversion of notes held by MPM BioVentures IV GmbH & Co. Beteiligungs KG, and (xii) 204,241 shares of common stock issuable upon conversion of notes held by MPM Asset Management Investors BV4 LLC. Dr. Evnin is a Member of MPM BioVentures IV LLC. MPM BioVentures IV LLC is the Managing Member of MPM BioVentures IV GP LLC, which is the General Partner of MPM BioVentures IV-QP, LP and the Managing Limited Partner of MPM BioVentures IV GmbH & Co. Beteiligungs KG. MPM BioVentures IV LLC is the Manager of MPM Asset Management Investors BV4 LLC. Dr. Evnin has a shared power to vote, acquire, hold and dispose of all shares and warrants. Dr. Evnin disclaims beneficial ownership of the securities except to the extent of their pecuniary interest therein.
- (11) Consists of the shares described in Note (3) above. Dr. Gordon disclaims beneficial ownership of the shares described in Note (3), except to the extent of his pecuniary interest therein.

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- (12) Consists of 66,667 shares of common stock issuable upon exercise of stock options within 60 days of September 30, 2010, including options that become exercisable upon completion of this offering.
- (13) Consists of (i) 7,921,950 shares of Series A convertible preferred stock held by Sanderling Venture Partners VI, L.P., (ii) 267,493 shares of Series A convertible preferred stock held by Sanderling VI Beteiligungs GmbH & Co. KG, (iii) 318,716 shares of Series A convertible preferred stock held by Sanderling VI Limited Partnership, (iv) 7,331,841 shares of Series A convertible preferred stock held by Sanderling Venture Partners VI Co-Investment Fund, L.P., (v) 160,000 shares of Series A convertible preferred stock held by Sanderling Ventures Management VI, (vi) 1,352,985 shares of common stock held by Sanderling Venture Partners VI, L.P., (vii) 21,453 shares of common stock held by Sanderling VI Beteiligungs GmbH & Co. KG, (viii) 25,562 shares of common stock held by Sanderling VI Limited Partnership, (ix) 600,000 shares of common stock held by Sanderling Ventures Management VI, (x) 193,304 shares of common stock issuable upon exercise of warrants held by Sanderling Venture Partners VI, L.P., (xi) 6,769 shares of common stock issuable upon exercise of warrants held by Sanderling VI Beteiligungs GmbH & Co. KG, (xii) 8,065 shares of common stock issuable upon exercise of warrants held by Sanderling VI Limited Partnership, (xiii) 191,863 shares of common stock issuable upon exercise of warrants held by Sanderling Venture Partners VI Co-Investment Fund, L.P., (xiv) 3,703,541 shares of common stock issuable upon conversion of notes held by Sanderling Venture Partners VI, L.P., (xv) 129,677 shares of common stock issuable upon conversion of notes held by Sanderling VI Beteiligungs GmbH & Co. KG, (xvi) 154,510 shares of common stock issuable upon conversion of notes held by Sanderling Venture Partners VI, L.P., (xvii) 3,675,929 shares of common stock issuable upon conversion of notes held by Sanderling Venture Partners VI Co-Investment Fund, L.P. Mr. Middleton is a managing director of Middleton, McNeil, Mills & Associates VI, LLC, which has the ultimate voting and investment power over shares held of record by Sanderling Venture Partners VI, L.P., Sanderling VI Beteiligungs GmbH & Co. KG, Sanderling VI Limited Partnership and Sanderling Venture Partners VI Co-Investment Fund, L.P. and he may be deemed to have voting and investment power over shares held of record by Sanderling Venture Partners VI, L.P., Sanderling VI Beteiligungs GmbH & Co. KG, Sanderling VI Limited Partnership and Sanderling Venture Partners VI Co-Investment Fund, L.P. Mr. Middleton is the owner of Sanderling Ventures Management VI and he may be deemed to have voting and investment power over shares held of record by Sanderling Ventures Management VI. Mr. Middleton disclaims beneficial ownership over the shares held by Sanderling Ventures and its affiliates, except to the extent of his pecuniary interest therein.
- (14) Consists of 46,667 shares of common stock issuable upon exercise of stock options within 60 days of September 30, 2010, including options that become exercisable upon completion of this offering.
- (15) Consists of (i) 16,000,000 shares of Series A convertible preferred stock held by HBM BioVentures (Cayman) Ltd., (ii) 1,000,000 shares of common stock held by HBM BioVentures (Cayman) Ltd., (iii) 400,000 shares of common stock issuable upon exercise of warrants held by HBM BioVentures (Cayman) Ltd., and (iv) 10,983,267 shares of common stock issuable upon conversion of notes held by HBM BioVentures (Cayman) Ltd. The board of directors of HBM BioVentures (Cayman) Ltd. has sole voting and investment power with respect to the shares by held by such entity and acts by majority vote. The board of directors of HBM BioVentures (Cayman) Ltd. is comprised of John Arnold, Richard Coles, Sophia Harris, Dr. Andreas Wicki and John Urquhart, none of whom has individual voting or investment power with respect to such shares.

## DESCRIPTION OF CAPITAL STOCK

### General

Following the completion of this offering, our authorized capital stock will consist of \_\_\_\_\_ shares of common stock, par value \$0.001 per share, and 5,000,000 shares of preferred stock, par value \$0.001 per share, all of which preferred stock will be undesignated.

The following description of our capital stock and provisions of our restated certificate of incorporation and bylaws are summaries and are qualified by reference to the certificate of incorporation and the bylaws that will be in effect upon completion of this offering. Copies of these documents will be filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part. The descriptions of the common stock and preferred stock reflect changes to our capital structure that will occur upon the completion of this offering.

### Common Stock

As of November 30, 2010, there were 109,286,553 shares of our common stock outstanding, held of record by 35 stockholders, assuming the conversion of all outstanding shares of Series A convertible preferred stock and assuming the conversion of \$40.0 million aggregate principal amount and all accrued and unpaid interest outstanding under our secured and unsecured notes held by certain of our investors into common stock upon completion of this offering.

*Voting Rights.* Each holder of common stock is entitled to one vote per share on all matters properly submitted to a vote of the stockholders, including the election of directors. Our restated certificate of incorporation and bylaws will not provide for cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose. An election of directors by our stockholders is determined by a plurality of the votes cast by stockholders entitled to vote on the election.

*Dividends.* Subject to preferences that may be applicable to any then outstanding preferred stock, the holders of our outstanding shares of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

*Liquidation.* In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

*Rights and Preferences.* Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

### Series A Convertible Preferred Stock

In March 2007, we entered into a Series A Preferred Stock Purchase Agreement pursuant to which we issued and sold to investors an aggregate of 68,000,000 shares of Series A convertible preferred stock in four separate closings held in March 2007, February 2008, July 2008 and October 2008, at a purchase price of \$1.25 per share. The aggregate consideration for the Series A Preferred Stock was \$85 million in cash.

Each holder of our Series A convertible preferred stock has the right, at the option of the holder at any time, to convert its shares of Series A convertible preferred stock into shares of our common stock at a current conversion ratio of one-to-one, subject to adjustment for stock splits, certain capital reorganizations and dilutive

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stock issuances. Each share of our Series A convertible preferred stock will automatically convert into shares of our common stock, at the then effective applicable conversion ratio upon the earlier of: (i) the closing of the sale of our common stock pursuant to a firmly underwritten public offering in which the Company receives gross proceeds of at least \$25,000,000 or (ii) the consent of the holders of at least 66 <sup>2</sup>/<sub>3</sub>% of the then outstanding shares of Series A convertible preferred stock.

The holders of our Series A convertible preferred stock are entitled to receive, when, as and if declared by our board of directors out of legally available funds, non-cumulative dividends in an amount to any dividends declared, paid or set aside on shares of our common stock. As of September 30, 2010, no dividends have been declared by our board of directors.

In the event of any liquidation, dissolution or winding up of the company, the holders of our Series A convertible preferred stock will be entitled to receive in preference to the holders of our common stock, the amount of their original purchase price per share, plus declared and unpaid dividends, if any. If the assets and funds available to be distributed among the holders of our Series A convertible preferred stock are insufficient to permit the payment to such holders of the full preference, then the entire assets and funds legally available for distribution to such holders shall be distributed ratably based on the total due each holder of our Series A convertible preferred stock. Any remaining assets of the Company will be distributed ratably among the holders of our common stock.

Holders of our Series A convertible preferred stock are entitled to the number of votes they would have upon conversion of their Series A convertible preferred stock into common stock at the then applicable conversion rate. The holders of Series A convertible preferred stock have been granted certain rights with regard to the election of board members and various other corporate actions.

### **Stock Options**

As of November 30, 2010, options to purchase 16,178,011 shares of common stock at a weighted average exercise price of \$0.15 per share were outstanding.

### **Warrants**

Assuming no warrants have been exercised as of November 30, 2010, upon the completion of this offering there will be outstanding 11 warrants to purchase an aggregate of 1,700,000 shares of common stock, each at an exercise price of \$0.25 per share and each of which expire on January 21, 2014 and two warrants to purchase an aggregate of 250,000 shares of common stock, each at an exercise price of \$1.25 per share and each of which expire on the earlier of (i) July 2, 2016 or (ii) the fifth anniversary of the completion of this offering. In addition, upon the completion of this offering, there will be an outstanding warrant to purchase 1,925,000 shares of common stock at an exercise price of \$1.25 per share, which expires upon the earlier to occur of (i) November 24, 2020 or (ii) five years following the effective date of the registration statement of which this prospectus is a part.

The warrants to purchase Series A convertible preferred stock have a net exercise provision under which the warrant holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares based on the fair market value of our common stock at the time of exercise of the warrant after deduction of the aggregate exercise price. Each of the warrants also contains provisions for the adjustment of the exercise price and the aggregate number of shares issuable upon the exercise of the warrant in the event of stock dividends, split-ups, reclassifications, mergers, consolidations, combinations or exchanges of shares, separations, reorganizations or liquidations.

The holders of the warrants to purchase common stock are entitled to registration rights under our Investors' Rights Agreement, as described in more detail under "Description of Capital Stock—Registration Rights."



## Registration Rights

Upon the completion of this offering, holders of a total of 111,737,715 shares of our common stock as of November 30, 2010, including shares of our common stock issuable upon exercise of outstanding warrants and shares issuable upon conversion of all of our outstanding secured and unsecured notes and accrued interest thereon, will have the right to require us to register these shares under the Securities Act, under specified circumstances, pursuant to the terms of the Investor Rights Agreement. After registration pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act. These registration rights will terminate upon the earlier of (i) the date that is five years following the completion of this offering or, (ii) for any particular holder with registration rights, at such time following this offering when all of our securities held by that stockholder may be sold pursuant to Rule 144 under the Securities Act.

*Demand and Form S-3 Registration Rights.* Subject to specified limitations, the holders of at least thirty percent of our Series A convertible preferred stock having registration rights may demand that we register all or a portion of their registrable shares under the Securities Act. We are not obligated to file a registration statement pursuant to this provision:

- until 180 days after the completion of this offering; and
- on more than three occasions.

In addition, the holders of our registrable shares may demand that we register on Form S-3 all or a portion of the registrable shares held by them. We are not obligated to file a Form S-3 pursuant to this provision on more than two occasions in any 12-month period.

*Incidental Registration Rights.* If at any time after the completion of this offering we propose to file a registration statement to register any of our securities under the Securities Act, either for our own account or for the account of any of our stockholders, the holders of our registrable shares are entitled to notice of registration and are entitled to include their shares of common stock in the registration.

*Limitations and Expenses.* In the event that any registration in which the holders of registrable shares participate pursuant to the Investor Rights Agreement is an underwritten public offering, the number of registrable shares to be included may, in specified circumstances, be limited due to market conditions. Pursuant to the Investor Rights Agreement, we are required to pay all registration expenses, including the fees and expenses of one counsel to represent the selling holders, other than any underwriting discounts, selling commissions and similar discounts relating to underwriters or commissions related to sales, related to any demand or incidental registration. We are also required to indemnify each participating holder with respect to each registration of registrable shares that is effected.

## Delaware Anti-Takeover Law and Provisions of Our Restated Certificate of Incorporation and Our Bylaws

*Delaware Anti-Takeover Law.* We are subject to Section 203 of the DGCL. Section 203 generally prohibits a public Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the interested stockholder attained such status with the approval of our board of directors, the business combination is approved in a prescribed manner or the interested stockholder acquired at least 85% of our outstanding voting stock in the transaction in which it became an interested stockholder. A “business combination” includes, among other things, a merger or consolidation involving us and the “interested stockholder” and the sale of more than 10% of our assets. In general, an “interested stockholder” is any entity or person beneficially owning 15% or more of our outstanding voting stock and any entity or person affiliated with or controlling or controlled by such entity or person.

*Restated Certificate of Incorporation and Bylaws.* Provisions of our restated certificate of incorporation and our bylaws, which will become effective upon the completion of this offering, may delay or discourage

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transactions involving an actual or potential change of control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our restated certificate of incorporation and our bylaws:

- authorize the issuance of “blank check” preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- divide our board of directors into three classes with staggered three-year terms;
- prohibit stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminate the ability of stockholders to call a special meeting of stockholders; and
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

The amendment of any of these provisions by the stockholders would require the approval of the holders at least 66 <sup>2</sup>/<sub>3</sub>% of our then outstanding common stock.

### **Listing on The NASDAQ Global Market**

We have applied to have our common stock listed on The NASDAQ Global Market under the symbol “PCRX.”

### **Authorized but Unissued Shares**

The authorized but unissued shares of common stock and preferred stock are available for future issuance without stockholder approval, subject to any limitations imposed by the Nasdaq Marketplace Rules. These additional shares may be used for a variety of corporate finance transactions, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could make it more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is

## SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock, and a liquid public trading market for our common stock may not develop or be sustained after this offering. Future sales of significant amounts of our common stock, including shares issued upon exercise of outstanding options or warrants, in the public market after this offering, or the anticipation of those sales, could adversely affect public market prices prevailing from time to time and could impair our ability to raise capital through sales of our equity securities. We have applied to have our common stock listed on The Nasdaq Global Market under the symbol "PCRX."

Upon the completion of this offering, we will have outstanding an aggregate of \_\_\_\_\_ shares of common stock, assuming the automatic conversion of all outstanding shares of our Series A convertible preferred stock and the conversion of \$40.0 million aggregate principal amount and all accrued and unpaid interest outstanding under our secured and unsecured notes held by certain of our stockholders into an aggregate of 35,112,715 shares of common stock upon the completion of this offering and the issuance of shares of common stock offered by us in this offering. Of these shares, all shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except for any shares purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act, whose sales would be subject to the Rule 144 resale restrictions described below, other than the holding period requirement.

The remaining \_\_\_\_\_ shares of common stock will be "restricted securities," as that term is defined in Rule 144 under the Securities Act. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below.

Subject to the lock-up agreements described below and the provisions of Rules 144 and 701 under the Securities Act, these restricted securities will be available for sale in the public market as follows:

<u>Date available for sale</u>	<u>Shares eligible for sale</u>	<u>Comment</u>
Date of prospectus		Shares sold in the offering and shares saleable under Rule 144 that are not subject to a lock-up
90 days after date of prospectus		Shares saleable under Rules 144 and 701 that are not subject to a lock-up
180 days after date of prospectus		Lock-up released; shares saleable under Rules 144 and 701

In addition, of the 16,178,011 shares of our common stock that were subject to stock options outstanding as of November 30, 2010, options to purchase 4,607,672 shares of common stock were exercisable as of November 30, 2010 and, upon exercise, these shares will be eligible for sale subject to the lock-up agreements and securities laws described below. The 3,875,000 shares of our common stock that were subject to warrants outstanding as of November 30, 2010, were exercisable as of November 30, 2010 and, assuming a cashless exercise, these shares will be eligible for sale subject to the lock-up agreements and securities laws described below.

### Rule 144

In general, a person who has beneficially owned shares of our common stock for at least six months would be entitled to sell their shares of common stock in the public market provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the three months preceding, a sale and (ii) we are and have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale and have filed all required reports during that time period. In addition, a person who has beneficially owned shares of our common stock for at least 12 months would be entitled to sell their shares of common stock

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in the public market provided that such person is not deemed to have been one of our affiliates at the time of, or at any time during the three months preceding, a sale. Persons who have beneficially owned shares of our common stock for at least six months but who are our affiliates at the time of, or any time during the three months preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of shares that does not exceed the greater of either of the following:

- 1% of the number of shares of our common stock then outstanding (approximately \_\_\_\_\_ shares immediately after this offering); or
- the average weekly trading volume in our common stock on The NASDAQ Global Market during the four calendar weeks immediately preceding the date on which the notice of sale is filed with the SEC;

provided, in each case, that we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale and have filed all required reports during that time period. Such sales by affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.

Approximately \_\_\_\_\_ shares of our common stock that are not subject to the lock-up agreements described below will be eligible for sale immediately upon the completion of this offering.

Upon expiration of the 180-day lock-up period described below, approximately \_\_\_\_\_ shares of our common stock will be eligible for sale under Rule 144, including shares eligible for resale immediately upon the completion of this offering as described above. We cannot estimate the number of shares of our common stock that our existing stockholders will elect to sell under Rule 144.

### **Rule 701**

In general, under Rule 701, any of an issuer's employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

The SEC has indicated that Rule 701 will apply to typical stock options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act.

### **Lock-up Agreements**

Our officers and directors and the holders of substantially all of our outstanding shares of capital stock have agreed with the underwriters, subject to certain exceptions, not to dispose of or hedge any of their common stock or securities convertible into or exchangeable for shares of common stock for a period through the date 180 days after the date of this prospectus, as modified as described below, except with the prior written consent of Barclays Capital Inc. and Piper Jaffray & Co. on behalf of the underwriters.

The 180-day restricted period will be automatically extended or reduced under the following circumstances: (1) during the last 17 days of the 180-day restricted period, if we issue an earnings release or announce material news or a material event, the restrictions described in the preceding paragraph will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the announcement of the material news or material event; or (2) prior to the expiration of the 180-day restricted period, if we announce

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that we will release earnings results or other material news during the 16-day period following the last day of the 180-day period, the restrictions described in the preceding paragraph will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or other material news.

**Stock Options and Warrants**

As of November 30, 2010, we had outstanding options to purchase 16,178,011 shares of common stock, of which options to purchase 4,607,672 shares of common stock were vested as of November 30, 2010. Following this offering, we intend to file registration statements on Form S-8 under the Securities Act to register all of the shares of common stock subject to outstanding options and options and other awards issuable pursuant to our 2007 Plan and any equity incentive plan we may adopt. As of November 30, 2010, we also had outstanding and exercisable warrants to purchase 1,700,000 shares of common stock and 2,175,000 shares of our Series A convertible preferred stock.

## CERTAIN MATERIAL U.S. FEDERAL TAX CONSIDERATIONS

The following is a general discussion of the material U.S. federal income and estate tax considerations applicable to non-U.S. holders with respect to their ownership and disposition of shares of our common stock issued pursuant to this offering. This discussion is not tax advice. Accordingly, all prospective non-U.S. holders of our common stock should consult their own tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock. In general, a non-U.S. holder means a beneficial owner of our common stock who is not for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation or any other organization taxable as a corporation for U.S. federal income tax purposes, created or organized in the United States or under the laws of the United States or of any state thereof or the District of Columbia;
- an estate, the income of which is included in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust if (1) a U.S. court is able to exercise primary supervision over the trust's administration and one or more U.S. persons have the authority to control all of the trust's substantial decisions or (2) the trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person.

This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, which we refer to as the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, publicly available and in effect as of the date of this prospectus, all of which are subject to change and to differing interpretation, possibly with retroactive effect. Any change or differing interpretation could alter the tax consequences to non-U.S. holders described in this prospectus. We assume in this discussion that a non-U.S. holder holds shares of our common stock as a capital asset, generally property held for investment.

This discussion does not address all aspects of U.S. federal income and estate taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances nor does it address any aspects of U.S. state, local or non-U.S. taxes. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

- insurance companies;
- tax-exempt organizations;
- financial institutions;
- brokers or dealers in securities;
- pension plans;
- controlled foreign corporations;
- passive investors;
- owners that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment; and
- certain U.S. expatriates.

In addition, this discussion does not address the tax treatment of partnerships or persons who hold their common stock through partnerships or other pass-through entities for U.S. federal income tax purposes. A partner in a partnership or other pass-through entity that will hold our common stock should consult his, her or its own tax advisor regarding the tax consequences of acquiring, holding and disposing of our common stock through a partnership or other pass-through entity, as applicable.

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There can be no assurance that the Internal Revenue Service, which we refer to as the IRS, will not challenge one or more of the tax consequences described herein, and we have not obtained, nor do we intend to obtain, an opinion of counsel with respect to the U.S. federal income or estate tax consequences to a non-U.S. holder of the purchase, ownership or disposition of our common stock.

### **Distributions on Our Common Stock**

Distributions on our common stock generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such holder's tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in "Gain on Sale, Exchange or Other Disposition of Our Common Stock."

Dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence. If we determine, at a time reasonably close to the date of payment of a distribution on our common stock, that the distribution will not constitute a dividend because we do not anticipate having current or accumulated earnings and profits, we intend not to withhold any U.S. federal income tax on the distribution as permitted by U.S. Treasury Regulations. If we or another withholding agent withholds tax on such a distribution, a non-U.S. holder may be entitled to a refund of any excess tax withheld, which the non-U.S. holder may claim by timely filing a U.S. tax return with the IRS.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same graduated U.S. federal income tax rates applicable to U.S. persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN (or successor form) and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing a U.S. tax return with the IRS.

### **Gain on Sale, Exchange or Other Disposition of Our Common Stock**

In general, a non-U.S. holder will not be subject to any U.S. federal income tax or withholding tax on any gain realized upon such holder's sale, exchange or other disposition of shares of our common stock unless:

- the gain is effectively connected with a U.S. trade or business and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed base maintained by such non-U.S. holder, in which case the non-U.S. holder generally will be taxed at the graduated U.S. federal income tax rates applicable to U.S. persons (as defined in the Code) and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in "Distributions on Our Common Stock" also may apply, unless an applicable tax treaty provides otherwise;

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- the non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence) on the net gain derived from the disposition, which may be offset by U.S. source capital losses of the non-U.S. holder, if any; or
- we are, or have been, at any time during the five-year period preceding such disposition (or the non-U.S. holder's holding period, if shorter) a "U.S. real property holding corporation," unless (1) our common stock is regularly traded on an established securities market and (2) the non-U.S. holder holds no more than 5% of our outstanding common stock, directly or indirectly, actually or constructively, during the shorter of (i) the 5-year period ending on the date of the disposition or (ii) the period that the non-U.S. holder held our common stock. If we are determined to be a U.S. real property holding corporation, provided that our common stock is regularly traded on an established securities market, no U.S. withholding tax would apply to the proceeds payable to a non-U.S. holder from a sale of our common stock. However, in the event we are determined to be a U.S. real property holding corporation, if the non-U.S. holder holds more than 5% of our common stock as described above the non-U.S. holder generally will be taxed on its net gain derived from the disposition at the graduated U.S. federal income tax rates applicable to U.S. persons (as defined in the Code). Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

### **U.S. Federal Estate Tax**

Shares of our common stock that are owned or treated as owned at the time of death by an individual who is not a citizen or resident of the United States, as specifically defined for U.S. federal estate tax purposes, are considered U.S. situs assets and will be included in the individual's gross estate for U.S. federal estate tax purposes. Such shares, therefore, may be subject to U.S. federal estate tax, unless an applicable estate tax or other treaty provides otherwise.

### **Backup Withholding and Information Reporting**

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on our common stock paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders may have to comply with specific certification procedures to establish that the holder is not a U.S. person (as defined in the Code) in order to avoid backup withholding at the applicable rate, currently 28% through December 31, 2010 and scheduled to increase to 31% for taxable years thereafter, with respect to dividends on our common stock. Dividends paid to non-U.S. holders subject to the U.S. withholding tax, as described above in "Distributions on Our Common Stock," generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding will generally apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.



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Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS.

***New Legislation Relating to Foreign Accounts***

Newly enacted legislation may impose withholding taxes on certain types of payments made to "foreign financial institutions" and certain other non-U.S. entities. Under this legislation, the failure to comply with additional certification, information reporting and other specified requirements could result in withholding tax being imposed on payments of dividends and sales proceeds to U.S. holders who own shares of our common stock through foreign accounts or foreign intermediaries and certain non-U.S. holders. The legislation imposes a 30% withholding tax on dividends on, or gross proceeds from the sale or other disposition of, our common stock paid to a foreign financial institution or to a foreign non-financial entity, unless (1) the foreign financial institution undertakes certain diligence and reporting obligations or (2) the foreign non-financial entity either certifies it does not have any substantial U.S. owners or furnishes identifying information regarding each substantial U.S. owner. In addition, if the payee is a foreign financial institution, it must enter into an agreement with the U.S. Treasury requiring, among other things, that it undertake to identify accounts held by certain U.S. persons or U.S.-owned foreign entities, annually report certain information about such accounts and withhold 30% on payments to account holders whose actions prevent it from complying with these reporting and other requirements. The legislation applies to payments made after December 31, 2012. Prospective investors should consult their tax advisors regarding this legislation.

## UNDERWRITING

Barclays Capital Inc. and Piper Jaffray & Co. are acting as the representatives of the underwriters and the joint book-running managers of this offering. Under the terms of an underwriting agreement, which is filed as an exhibit to the registration statement, each of the underwriters named below has severally agreed to purchase from us the respective number of common stock shown opposite its name below:

<u>Underwriters</u>	<u>Number of Shares</u>
Barclays Capital Inc.	
Piper Jaffray & Co.	
Wedbush Securities Inc.	
Brean Murray, Carret & Co., LLC	
Total	

The underwriting agreement provides that the underwriters' obligation to purchase shares of common stock depends on the satisfaction of the conditions contained in the underwriting agreement including:

- the obligation to purchase all of the shares of common stock offered hereby (other than those shares of common stock covered by their option to purchase additional shares as described below), if any of the shares are purchased;
- the representations and warranties made by us to the underwriters are true;
- there is no material change in our business or the financial markets; and
- we deliver customary closing documents to the underwriters.

### Commissions and Expenses

The following table summarizes the underwriting discounts and commissions we will pay to the underwriters. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares. The underwriting fee is the difference between the initial price to the public and the amount the underwriters pay to us for the shares.

<u>Per share</u>	<u>No Exercise</u>	<u>Full Exercise</u>
Total		

The representatives of the underwriters have advised us that the underwriters propose to offer the shares of common stock directly to the public at the public offering price on the cover of this prospectus and to selected dealers, which may include the underwriters, at such offering price less a selling concession not in excess of \$ \_\_\_\_\_ per share. After the offering, the representatives may change the offering price and other selling terms. Sales of shares made outside of the United States may be made by affiliates of the underwriters.

The expenses of the offering that are payable by us are estimated to be \$ \_\_\_\_\_ (excluding underwriting discounts and commissions).

### Option to Purchase Additional Shares

We have granted the underwriters an option exercisable for 30 days after the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of \_\_\_\_\_ shares at the public offering price less underwriting discounts and commissions. This option may be exercised if the underwriters sell more than \_\_\_\_\_ shares in connection with this offering. To the extent that this option is exercised, each underwriter will

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be obligated, subject to certain conditions, to purchase its pro rata portion of these additional shares based on the underwriter's underwriting commitment in the offering as indicated in the table at the beginning of this Underwriting section.

### **Lock-Up Agreements**

We, all of our directors and executive officers and holders of more than 5% of our outstanding stock have agreed that, subject to certain exceptions, without the prior written consent of each of Barclays Capital Inc. and Piper Jaffray, we will not directly or indirectly, (1) offer for sale, sell, pledge, or otherwise dispose of (or enter into any transaction or device that is designed to, or could be expected to, result in the disposition by any person at any time in the future of) any shares of our common stock (including, without limitation, shares of our common stock that may be deemed to be beneficially owned by them in accordance with the rules and regulations of the Securities and Exchange Commission and shares of common stock that may be issued upon exercise of any options or warrants) or securities convertible into or exercisable or exchangeable for our common stock, (2) enter into any swap or other derivatives transaction that transfers to another, in whole or in part, any of the economic benefits or risks of ownership of the shares of our common stock, (3) make any demand for or exercise any right or file or cause to be filed a registration statement, including any amendments thereto, with respect to the registration of any shares of our common stock or securities convertible, exercisable or exchangeable into shares of our common stock or any of our other securities, or (4) publicly disclose the intention to do any of the foregoing for a period of 180 days after the date of this prospectus.

The 180-day restricted period described in the preceding paragraph will be extended if:

- during the last 17 days of the 180-day restricted period we issue an earnings release or material news or a material event relating to us occurs; or
- prior to the expiration of the 180-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 180-day restricted period,

in which case the restrictions described in the preceding paragraph will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the announcement of the material news or occurrence of a material event, unless such extension is waived in writing by Barclays Capital Inc. and Piper Jaffray.

Barclays Capital Inc. and Piper Jaffray, in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time with or without notice. When determining whether or not to release common stock and other securities from lock-up agreements, Barclays Capital Inc. and Piper Jaffray will consider, among other factors, the holder's reasons for requesting the release, the number of shares of common stock and other securities for which the release is being requested and market conditions at the time.

### **Offering Price Determination**

Prior to this offering, there has been no public market for our common stock. The initial public offering price will be negotiated between the representatives and us. In determining the initial public offering price of our common stock, the representatives will consider:

- the history and prospects for the industry in which we compete;
- our financial information;
- the ability of our management and our business potential and earning prospects;
- the prevailing securities markets at the time of this offering; and
- the recent market prices of, and the demand for, publicly traded shares of generally comparable companies.

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**Indemnification**

We have agreed to indemnify the underwriters against certain liabilities under the Securities Act relating to losses or claims resulting from material misstatements in or omissions from this prospectus, the registration statement of which this prospectus forms a part, certain free writing prospectuses that may be used in the offering and in any marketing materials used in connection with the offering, and to contribute to payments that the underwriters may be required to make for these liabilities.

**Stabilization, Short Positions and Penalty Bids**

The representatives may engage in stabilizing transactions, short sales and purchases to cover positions created by short sales, and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of the common stock, in accordance with Regulation M under the Securities Exchange Act of 1934, as amended:

- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.
- A short position involves a sale by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase in the offering, which creates the syndicate short position. This short position may be either a covered short position or a naked short position. In a covered short position, the number of shares involved in the sales made by the underwriters in excess of the number of shares they are obligated to purchase is not greater than the number of shares that they may purchase by exercising their option to purchase additional shares. In a naked short position, the number of shares involved is greater than the number of shares in their option to purchase additional shares. The underwriters may close out any short position by either exercising their option to purchase additional shares and/or purchasing shares in the open market. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through their option to purchase additional shares. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.
- Syndicate covering transactions involve purchases of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions.
- Penalty bids permit the representatives to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of the common stock. As a result, the price of the common stock may be higher than the price that might otherwise exist in the open market. These transactions may be effected on The NASDAQ Global Market or otherwise and, if commenced, may be discontinued at any time.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of the common stock. In addition, neither we nor any of the underwriters make representation that the representatives will engage in these stabilizing transactions or that any transaction, once commenced, will not be discontinued without notice.

**Electronic Distribution**

A prospectus in electronic format may be made available on the Internet sites or through other online services maintained by one or more of the underwriters and/or selling group members participating in this offering, or by their affiliates. In those cases, prospective investors may view offering terms online and, depending upon the particular underwriter or selling group member, prospective investors may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares for sale to online brokerage account holders. Any such allocation for online distributions will be made by the representatives on the same basis as other allocations.

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Other than the prospectus in electronic format, the information on any underwriter's or selling group member's web site and any information contained in any other web site maintained by an underwriter or selling group member is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter or selling group member in its capacity as underwriter or selling group member and should not be relied upon by investors.

**The NASDAQ Global Market**

We have applied to list our shares of common stock for quotation on The NASDAQ Global Market under the symbol "PCR.X."

**Discretionary Sales**

The underwriters have informed us that they do not intend to confirm sales to discretionary accounts that exceed 5% of the total number of shares offered by them.

**Stamp Taxes**

If you purchase shares of common stock offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus.

**Relationships**

Certain of the underwriters and/or their affiliates may in the future engage in commercial and investment banking transactions with us in the ordinary course of their business. They expect to receive customary compensation and expense reimbursement for these commercial and investment banking transactions.

**Selling Restrictions**

*European Economic Area*

In relation to each member state of the European Economic Area that has implemented the Prospectus Directive (each, a relevant member state), with effect from and including the date on which the Prospectus Directive is implemented in that relevant member state (the relevant implementation date), an offer of securities described in this prospectus may not be made to the public in that relevant member state other than:

- to any legal entity that is authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- to any legal entity that has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000 and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts;
- to fewer than 100 natural or legal persons (other than qualified investors as defined in the Prospectus Directive) subject to obtaining the prior consent of the representatives; or
- in any other circumstances that do not require the publication of a prospectus pursuant to Article 3 of the Prospectus Directive,

provided that no such offer of securities shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive.

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For purposes of this provision, the expression an “offer of securities to the public” in any relevant member state means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe the securities, as the expression may be varied in that member state by any measure implementing the Prospectus Directive in that member state, and the expression “Prospectus Directive” means Directive 2003/71/EC and includes any relevant implementing measure in each relevant member state.

We have not authorized and do not authorize the making of any offer of securities through any financial intermediary on their behalf, other than offers made by the underwriters with a view to the final placement of the securities as contemplated in this prospectus. Accordingly, no purchaser of the securities, other than the underwriters, is authorized to make any further offer of the securities on behalf of us, or the underwriters.

*United Kingdom*

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive (“Qualified Investors”) that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the “Order”) or (ii) high net worth entities, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as “relevant persons”). This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant persons should not act or rely on this document or any of its contents.

*Australia*

No prospectus or other disclosure document (as defined in the Corporations Act 2001 (Cth) of Australia (“Corporations Act”)) in relation to the securities has been or will be lodged with the Australian Securities & Investments Commission (“ASIC”). This document has not been lodged with ASIC and is only directed to certain categories of exempt persons. Accordingly, if you receive this document in Australia:

- (a) you confirm and warrant that you are either:
  - (i) a “sophisticated investor” under section 708(8)(a) or (b) of the Corporations Act;
  - (ii) a “sophisticated investor” under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant’s certificate to us which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;
  - (iii) a person associated with the company under section 708(12) of the Corporations Act; or
  - (iv) a “professional investor” within the meaning of section 708(11)(a) or (b) of the Corporations Act,

and to the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this document is void and incapable of acceptance; and

- (b) you warrant and agree that you will not offer any of the securities for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

*Hong Kong*

The securities may not be offered or sold in Hong Kong, by means of any document, other than (a) to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made under that Ordinance or (b) in other circumstances which do not result in the document being a

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“prospectus” as defined in the Companies Ordinance (Cap. 32, Laws of Hong Kong) or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the securities may be issued or may be in the possession of any person for the purpose of the issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to the securities which are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) or any rules made under that Ordinance.

*India*

This prospectus has not been and will not be registered as a prospectus with the Registrar of Companies in India or with the Securities and Exchange Board of India. This prospectus or any other material relating to these securities is for information purposes only and may not be circulated or distributed, directly or indirectly, to the public or any members of the public in India and in any event to not more than 50 persons in India. Further, persons into whose possession this prospectus comes are required to inform themselves about and to observe any such restrictions. Each prospective investor is advised to consult its advisors about the particular consequences to it of an investment in these securities. Each prospective investor is also advised that any investment in these securities by it is subject to the regulations prescribed by the Reserve Bank of India and the Foreign Exchange Management Act and any regulations framed thereunder.

*Japan*

No securities registration statement (“SRS”) has been filed under Article 4, Paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) (“FIEL”) in relation to the securities. The securities are being offered in a private placement to “qualified institutional investors” (tekikaku-kikan-toshika) under Article 10 of the Cabinet Office Ordinance concerning Definitions provided in Article 2 of the FIEL (the Ministry of Finance Ordinance No. 14, as amended) (“QIIs”), under Article 2, Paragraph 3, Item 2 i of the FIEL. Any QII acquiring the securities in this offer may not transfer or resell those shares except to other QIIs.

*Korea*

The securities may not be offered, sold and delivered directly or indirectly, or offered or sold to any person for reoffering or resale, directly or indirectly, in Korea or to any resident of Korea except pursuant to the applicable laws and regulations of Korea, including the Korea Securities and Exchange Act and the Foreign Exchange Transaction Law and the decrees and regulations thereunder. The securities have not been registered with the Financial Services Commission of Korea for public offering in Korea. Furthermore, the securities may not be resold to Korean residents unless the purchaser of the securities complies with all applicable regulatory requirements (including but not limited to government approval requirements under the Foreign Exchange Transaction Law and its subordinate decrees and regulations) in connection with the purchase of the securities.

*Singapore*

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the securities may not be circulated or distributed, nor may the securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Future Act, Chapter 289 of Singapore (the “SFA”), (ii) to a “relevant person” as defined in Section 275(2) of the SFA, or any person pursuant to Section 275 (1A), and in accordance with the conditions, specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

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Where the securities are subscribed and purchased under Section 275 of the SFA by a relevant person which is:

- (a) a corporation (which is not an accredited investor as defined in Section 4A of the SFA) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- (b) a trust (where the trustee is not an accredited investor (as defined in Section 4A of the SFA)) whose sole whole purpose is to hold investments and each beneficiary is an accredited investor,

shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferable within six months after that corporation or that trust has acquired the securities under Section 275 of the SFA except:

- (i) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA) and in accordance with the conditions, specified in Section 275 of the SFA;
- (ii) (in the case of a corporation) where the transfer arises from an offer referred to in Section 275(1A) of the SFA, or (in the case of a trust) where the transfer arises from an offer that is made on terms that such rights or interests are acquired at a consideration of not less than S\$200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets;
- (iii) where no consideration is or will be given for the transfer; or
- (iv) where the transfer is by operation of law.

By accepting this prospectus, the recipient hereof represents and warrants that he is entitled to receive it in accordance with the restrictions set forth above and agrees to be bound by limitations contained herein. Any failure to comply with these limitations may constitute a violation of law.



## LEGAL MATTERS

The validity of the shares of common stock offered hereby is being passed upon for us by Wilmer Cutler Pickering Hale and Dorr LLP, Palo Alto, California. The underwriters are represented by Latham & Watkins LLP, New York, New York, in connection with certain legal matters related to this offering.

## EXPERTS

The consolidated financial statements as of December 31, 2008 and 2009 and for each of the three years in the period ended December 31, 2009 included in this prospectus have been audited by J.H. Cohn LLP, an independent registered public accounting firm, as stated in their report, which includes an explanatory paragraph relating to our ability to continue as a going concern, appearing elsewhere in this prospectus. Such consolidated financial statements are included in reliance upon the report of such firm given on the authority of said firm as experts in accounting and auditing.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock to be sold in the offering. This prospectus, which constitutes part of the registration statement, does not include all of the information contained in the registration statement and the exhibits, schedules and amendments to the registration statement. Some items are omitted in accordance with the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement and to the exhibits and schedules to the registration statement filed as part of the registration statement. Statements contained in this prospectus about the contents of any contract or any other document filed as an exhibit are not necessarily complete, and, in each instance, we refer you to the copy of the contract or other documents filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You may read and copy the registration statement of which this prospectus is a part at the SEC's public reference room, which is located at 100 F Street, NE, Room 1580, Washington, D.C. 20549. You can request copies of the registration statement by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the SEC's public reference room. In addition, the SEC maintains an Internet website, which is located at [www.sec.gov](http://www.sec.gov), that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. You may access the registration statement of which this prospectus is a part at the SEC's Internet website.

Upon completion of the offering, we will become subject to the full informational and periodic reporting requirements of the Exchange Act. We will fulfill our obligations with respect to such requirements by filing periodic reports and other information with the SEC. We intend to furnish our stockholders with annual reports containing consolidated financial statements certified by an independent registered public accounting firm. We also maintain a website at [www.pacira.com](http://www.pacira.com). Our website is not a part of this prospectus.

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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders  
Pacira Pharmaceuticals, Inc.

We have audited the consolidated balance sheets of Pacira Pharmaceuticals, Inc. and subsidiaries as of December 31, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2009. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Pacira Pharmaceuticals, Inc. and subsidiaries as of December 31, 2009 and 2008, and their results of operations and cash flows for each of the three years in the period ended December 31, 2009, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses and as of December 31, 2009 has a working capital and stockholders' deficit that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ J.H. Cohn LLP

Roseland, New Jersey  
November 1, 2010, except for the  
effects of the matter discussed in Note 1  
("Correction of Immaterial Errors")  
which are as of December 3, 2010

**Pacira Pharmaceuticals, Inc.**  
**Consolidated Balance Sheets**  
**as of December 31, 2009 and 2008**

	December 31,	
	2009	2008
(in thousands, except share and per share amounts)		
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 7,077	\$ 12,386
Restricted cash	1,216	1,182
Trade accounts receivable	1,455	2,585
Inventories, net	1,729	2,028
Prepaid expenses and other current assets	1,072	1,176
Total current assets	12,549	19,357
Fixed assets, net	19,560	18,037
Intangibles, net	11,178	13,084
Other assets, net	667	63
Total assets	<u>\$ 43,954</u>	<u>\$ 50,541</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 6,994	\$ 11,794
Accrued expenses	3,478	1,733
Current portion of royalty interest obligation	1,599	1,443
Current portion of deferred revenue	2,346	2,046
Total current liabilities	14,417	17,016
Related party debt, including accrued interest	22,173	—
Royalty interest obligation, excluding current portion	3,647	3,618
Deferred revenue, excluding current portion	20,387	16,894
Contingent purchase liability	2,042	2,042
Deferred rent	1,177	874
Other long-term liabilities	3,060	2,607
Total liabilities	<u>66,903</u>	<u>43,051</u>
Commitments and Contingencies		
Stockholders' equity (deficit):		
Preferred stock, par value \$0.001, 88,000,000 shares authorized, 68,000,000 issued and outstanding at December 31, 2009 and 2008 (liquidation preference of \$85,000,000)	68	68
Common stock, par value \$0.001, 120,000,000 shares authorized, 6,172,641 and 6,153,725 shares issued and outstanding at December 31, 2009 and 2008, respectively	6	6
Additional paid-in capital	86,739	85,471
Accumulated deficit	(109,762)	(78,055)
Total stockholders' equity (deficit)	<u>(22,949)</u>	<u>7,490</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 43,954</u>	<u>\$ 50,541</u>

*See accompanying notes to consolidated financial statements.*

**Pacira Pharmaceuticals, Inc.**  
**Consolidated Statements of Operations**  
**Years Ended December 31, 2009, 2008, and 2007**

	Years Ended December 31,		
	2009	2008	2007
	(in thousands, except share and per share data)		
Revenues:			
Supply revenue	\$ 6,324	\$ 6,852	\$ 5,444
Royalties	4,044	3,648	2,388
Collaborative licensing and development revenue	4,638	3,425	509
Total revenues	<u>15,006</u>	<u>13,925</u>	<u>8,341</u>
Operating expenses:			
Cost of revenues	12,301	17,463	9,492
Research and development	26,233	33,214	20,665
Selling, general and administrative	5,020	8,611	4,170
Acquired in-process research and development	—	—	12,400
Total operating expenses	<u>43,554</u>	<u>59,288</u>	<u>46,727</u>
Loss from operations	(28,548)	(45,363)	(38,386)
Other income (expense)	367	(224)	16
Interest:			
Interest income	77	235	491
Interest (expense)	(1,723)	—	—
Royalty interest obligation	(1,880)	3,490	1,686
Net loss	<u>\$ (31,707)</u>	<u>\$ (41,862)</u>	<u>\$ (36,193)</u>
Net loss per common share:			
Basic and diluted net loss per share	\$ (5.14)	\$ (7.37)	\$ (7.24)
Weighted average shares outstanding—basic and diluted	6,163,884	5,682,481	5,000,000

*See accompanying notes to consolidated financial statements.*

**Pacira Pharmaceuticals, Inc.**  
**Consolidated Statements of Stockholders' Equity (Deficit)**  
**Years Ended December 31, 2009, 2008, and 2007**

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balances, January 1, 2007	—	\$ —	—	\$ —	\$ —	\$ —	\$ —
Issuance of preferred stock	36,000	36			44,964		45,000
Issuance of common stock			5,000	5	45		50
Share-based compensation					80		80
Net loss						(36,193)	(36,193)
Balances, December 31, 2007	36,000	36	5,000	5	45,089	(36,193)	8,937
Issuance of preferred stock	32,000	32			39,968		40,000
Exercise of stock options			1,154	1	172		173
Share-based compensation					242		242
Net loss						(41,862)	(41,862)
Balances, December 31, 2008	68,000	68	6,154	6	85,471	(78,055)	7,490
Exercise of stock options			19		3		3
Share-based compensation					524		524
Issue of warrants to landlord					204		204
Debt discount from beneficial conversion features and issuance of warrants with convertible notes					537		537
Net loss						(31,707)	(31,707)
Balances, December 31, 2009	<u>68,000</u>	<u>\$ 68</u>	<u>6,173</u>	<u>\$ 6</u>	<u>\$ 86,739</u>	<u>\$(109,762)</u>	<u>\$(22,949)</u>

*See accompanying notes to consolidated financial statements.*

**Pacira Pharmaceuticals, Inc.**  
**Consolidated Statements of Cash Flows**  
**Years Ended December 31, 2009, 2008, and 2007**

	Years Ended December 31,		
	2009	2008 (in thousands)	2007
<b>Operating activities:</b>			
Net loss	\$ (31,707)	\$ (41,862)	\$ (36,193)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	4,146	4,227	3,159
Amortization of other assets and unfavorable lease obligation	(314)	(396)	(297)
Amortization of note discounts and warrants	600	—	—
Write-off of in-process research and development	—	—	12,400
Impairment loss	—	125	—
Loss (gain) on disposal of fixed assets	1,707	301	(2)
Share-based compensation	524	242	80
Change in royalty interest obligation	185	(5,183)	(2,756)
Changes in operating assets and liabilities, net of acquisition:			
Restricted cash	(34)	248	(1,430)
Trade accounts receivable	1,130	(1,562)	(173)
Inventories	299	277	(623)
Other current assets	244	(40)	(573)
Accounts payable	(4,438)	4,807	3,528
Other liabilities	2,724	(2,122)	1,593
Deferred revenue	3,793	11,303	7,424
Deferred rent	303	446	428
Net cash used in operating activities	<u>(20,838)</u>	<u>(29,189)</u>	<u>(13,435)</u>
<b>Investing activities:</b>			
Purchase of fixed assets	(5,509)	(5,840)	(2,124)
Proceeds from sale of fixed assets	—	2	4
Acquisition of intangibles	—	—	(1,442)
Acquisition of SkyePharma, Inc., net of cash acquired of \$175	—	—	(20,813)
Net cash used in investing activities	<u>(5,509)</u>	<u>(5,838)</u>	<u>(24,375)</u>
<b>Financing activities:</b>			
Proceeds from issuance of preferred stock	—	40,000	45,000
Proceeds from exercise of stock options and issuance of common stock	3	173	50
Proceeds from convertible notes	10,625	—	—
Proceeds from secured promissory notes	10,625	—	—
Financing costs	(215)	—	—
Net cash provided by financing activities	<u>21,038</u>	<u>40,173</u>	<u>45,050</u>
Net (decrease) increase in cash and cash equivalents	(5,309)	5,146	7,240
Cash and cash equivalents, beginning of year	12,386	7,240	—
Cash and cash equivalents, end of year	<u>\$ 7,077</u>	<u>\$ 12,386</u>	<u>\$ 7,240</u>
Supplemental cash flow information:			
Cash paid for interest	\$ 1,714	\$ 1,692	\$ 1,070
Non-cash investing and financing activities:			
Accrual for repurchase of intangibles	\$ 323	\$ 294	\$ —
Accrued fixed asset purchases	\$ 2,254	\$ 3,682	\$ —
Value of warrants issued with convertible debt and beneficial conversion feature	\$ 537	\$ —	\$ —
Value of warrants issued to landlord	\$ 204	\$ —	\$ —

*See accompanying notes to consolidated financial statements.*

**Pacira Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements**

**1. BUSINESS**

Pacira Pharmaceuticals, Inc., and its subsidiaries (collectively, the “Company” or “Pacira”) is an emerging specialty pharmaceutical company focused on the development, commercialization and manufacture of proprietary pharmaceutical products, based on its proprietary DepoFoam drug delivery technology, for use in hospitals and ambulatory surgery centers.

The Company was incorporated in Delaware under the name Blue Acquisition Corp. in December 2006 and changed its name to Pacira, Inc. in June 2007. In October 2010, the Company changed its name to Pacira Pharmaceuticals, Inc. Pacira Pharmaceuticals, Inc. is the holding company for the Company’s California operating subsidiary of the same name, which we refer to as PPI-California. The consolidated financial statements include the Company’s wholly owned subsidiaries PPI-California and Pacira Limited.

As further discussed in Note 4, on March 24, 2007, or the Acquisition Date, MPM Capital, Sanderling Ventures, OrbiMed Advisors, HBM BioVentures, the Foundation for Research and their co-investors, or the Investors, through Pacira Pharmaceuticals, Inc., acquired PPI-California, from SkyePharma Holding, Inc., which we refer to as the Acquisition. PPI-California was known as SkyePharma, Inc. prior to the Acquisition.

***Risks and Uncertainties***

The Company is subject to risks common to companies in similar industries and stages of development, including, but not limited to, competition from larger companies, reliance on revenue from few customers and products, new technological innovations, dependence on key personnel, reliance on third-party service providers and vendors, protection of proprietary technology, and compliance with government regulations.

***Going Concern***

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has reported net losses of \$31.7 million, \$41.9 million, and \$36.2 million and negative cash flows from operating activities of \$20.8 million, \$29.2 million and \$13.4 million for the years ended December 31, 2009, 2008 and 2007, respectively. As of December 31, 2009, the Company had a net working capital deficit of \$1.9 million and stockholders’ deficit of \$22.9 million. The Company has incurred losses and negative operating cash flow since inception and future losses are anticipated. The Company’s continued operations will depend on its ability to raise additional funds through sources such as equity and debt financing and revenues from the commercial sale of EXPAREL. Insufficient funds could require the Company to delay, scale back or eliminate one or more of its research and development programs. The ability of the Company to continue as a going concern is dependent on improving the Company’s profitability and cash flow and securing additional financing. While the Company believes in the viability of its strategy to increase revenues and profitability and in its ability to raise additional funds, and believes that the actions presently being taken by the Company provide the opportunity for it to continue as a going concern, there can be no assurance that such financing will be available on acceptable terms, or at all. These consolidated financial statements do not include any adjustments related to the recoverability and classification of asset amounts or the amounts and classification of liabilities that might be necessary if the Company is unable to continue as a going concern.



**Pacira Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements—(continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

***Basis of Presentation and Principles of Consolidation***

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries PPI-California and Pacira Limited. Pacira Limited was incorporated in the United Kingdom and its functional currency is the U.S. dollar. Intercompany accounts and transactions have been eliminated in consolidation.

Although the consolidated financial statements of Pacira reflect the operations of the Company for the year ended December 31, 2007, it had no substantive operations prior to the acquisition of SkyePharma, Inc. on March 24, 2007 and do not reflect the operations of PPI-California until March 24, 2007, after the Acquisition Date.

***Correction of Immaterial Errors***

The Company identified certain immaterial errors in its previously issued consolidated financial statements for the years ended December 31, 2009, 2008 and 2007, as follows:

- the improper separate accounting for an embedded derivative related to the Company's royalty interest obligation; and
- the improper classification of patent costs as a component of research and development expenses rather than as a component of selling, general and administrative expenses.

The error in the accounting for the embedded derivative resulted in an understatement of the 2009 net loss of \$562,000, an overstatement of the 2008 net loss of \$673,000 and an understatement of the 2007 net loss of \$1,025,000.

The error in the classification of patent costs had the effect of overstating research and development expenses and understating selling, general and administrative expenses by \$809,000, \$853,000 and \$581,000 for 2009, 2008 and 2007, respectively, but had no effect on reported loss from operations or net loss.

The Company reviewed the accounting errors utilizing SEC Staff Accounting Bulletin No. 99, "Materiality" ("SAB 99") and SEC Staff Accounting Bulletin No. 108, "Effects of Prior Year Misstatements on Current Year Financial Statements" ("SAB 108") and determined the impact of the errors to be immaterial to any prior period's presentation. The accompanying 2009, 2008, and 2007 consolidated financial statements reflect the corrections of the aforementioned immaterial errors.

***Use of Estimates***

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities, including disclosure of contingent assets and contingent liabilities, at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. The Company's critical accounting policies are those that are both most important to the Company's consolidated financial condition and results of operations and require the most difficult, subjective or complex judgments on the part of management in their application, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Because of the uncertainty of factors surrounding the estimates or judgments used in the preparation of the consolidated financial statements, actual results may materially vary from these estimates.

**Pacira Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements—(continued)**

***Cash and Cash Equivalents***

All highly-liquid investments with maturities of 90 days or less when purchased are considered cash equivalents.

***Restricted Cash***

As further discussed in Note 10, the Company has entered into a financing agreement with Royalty Securitization Trust I (“RST”) for the sale of a royalty interest in its DepoCyt(e) and DepoDur supply revenue and royalties. As part of this financing agreement, the Company and RST maintain a lockbox, where all DepoCyt(e) and DepoDur supply revenue and royalties are received. The Company has no minimum payment obligations under this agreement. Commencing on April 1 of every year, the first \$2.5 million received in the lockbox is restricted and will be used to make quarterly payments due to RST, if any, under the agreement during the subsequent 12 month period. On March 31 of the subsequent year, the balance of cash in the lockbox, if any, is remitted to Pacira. The RST agreement terminates on December 31, 2014. The royalty interest agreement pertains only to DepoCyt(e) and DepoDur, and does not include revenue related to EXPAREL or any other product candidates.

***Credit Risk***

The Company performs ongoing credit evaluations of its customers, as warranted, and generally does not require collateral. Revenues from the supply of manufactured product for the Company’s commercial partners, royalties, contractual services provided to its collaboration partners and licensing and development fees are primarily derived from major pharmaceutical companies that generally have significant cash resources. Allowances for doubtful accounts receivable are maintained based on historical payment patterns, aging of accounts receivable and actual write-off history. As of December 31, 2009 and 2008, no allowances for doubtful accounts were deemed necessary by the Company on its trade accounts receivable.

***Concentration of Major Customers***

The Company’s customers are its commercial and collaborative and licensing partners. For the year ended December 31, 2009, the Company’s three largest customers accounted for 44%, 23% and 20%, individually, of the Company’s net revenues. For the year ended December 31, 2008, the Company’s four largest customers accounted for 46%, 20%, 16% and 12%, respectively, of the Company’s net revenues. For the year ended December 31, 2007, the Company’s two largest customers accounted for 49% and 34%, respectively, of the Company’s net revenues. No other individual customers accounted for more than 10% of net revenues. As of December 31, 2009, the Company’s three largest customers accounted for 56%, 26% and 13%, respectively, of the Company’s trade accounts receivables. As of December 31, 2008, the Company’s four largest customers accounted for 29%, 23%, 23% and 12%, individually, of the Company’s trade accounts receivables. The Company is dependent on these commercial partners to market and sell DepoCyt(e) and DepoDur, from which a substantial portion of its revenues is derived; therefore, the Company’s future revenues from these products are highly dependent on these collaboration and distribution arrangements.

Domestic net revenues for the years ended December 31, 2009, 2008 and 2007 accounted for 52%, 48% and 49% of the Company’s net revenues, respectively. Export revenues for the years ended December 31, 2009, 2008 and 2007 accounted for 48%, 52%, and 51% of the Company’s net revenues, respectively.

***Inventories***

Inventories consist of finished goods held for sale and distribution, raw materials and work in process, and are stated at the lower of cost, which includes amounts related to material, labor and overhead, and is determined

**Pacira Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements—(continued)**

using the first-in, first-out (“FIFO”) method, or market (net realizable) value. The Company periodically reviews its inventory to identify obsolete, slow-moving or otherwise unsalable inventories, and establishes allowances for situations in which the cost of the inventory is not expected to be recovered.

***Fixed Assets***

Property, plant and equipment are recorded at cost, net of accumulated depreciation and amortization. The Company reviews its property, plant and equipment assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

Depreciation of equipment, furniture and fixtures is provided over their estimated useful lives on a straight-line basis. Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or the related lease terms. Useful lives by asset category are as follows:

<u>Asset Category</u>	<u>Years</u>
Manufacturing and laboratory equipment	5 to 10 years
Computer equipment and software	1 to 3 years
Office furniture and equipment	5 years
Leasehold improvements	1 to 9 years (up to the lease term)

***Impairment of Long-Lived Assets***

Intangible assets are recorded at cost, net of accumulated amortization. Amortization of intangible assets is provided over their estimated useful lives on a straight-line basis. Management reviews long-lived assets, including fixed assets, for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the assets exceeds the fair value of the assets. Fair value for the Company’s long-lived assets is determined using the expected cash flows discounted at a rate commensurate with the risk involved.

***Acquired in-Process Research and Development***

The Company acquired in-process research and development (“IPR&D”) projects as part of the Acquisition (see Note 4). The estimated fair value of IPR&D projects, which had not reached technological feasibility at the date of acquisition and which did not have an alternative future use, were immediately expensed. Accordingly, in 2007, the Company wrote off \$12.4 million of acquired IPR&D related to the Acquisition.

***Settlement of Trade Payables***

During April 2009, the Company initiated a payables settlement program with its trade creditors using various settlement arrangements. As of April 30, 2009, total outstanding unsecured trade payables subject to these settlement arrangements was \$14.3 million. These creditors agreed to settle their outstanding balances for an aggregate of \$12.5 million resulting in reduction in payables of \$1.8 million. The Company has recorded a \$1.3 million reduction to the carrying amount of fixed assets and included a \$0.4 million gain in other income on the Company’s consolidated statement of operations for the year ended December 31, 2009. The remaining \$0.1 million additional gain will be recorded as these obligations are paid. As of December 31, 2009, \$5.5 million related to these settlement arrangements remained outstanding and was included in accounts payable in the Company’s consolidated balance sheet.

**Pacira Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements—(continued)**

***Foreign Currencies***

Realized gains and losses from foreign currency transactions are reflected in the consolidated statements of operations and were not significant in any period in the years ended December 31, 2009, 2008 or 2007. All foreign currency receivables and payables are measured at the applicable exchange rate at the end of the reporting period.

***Income Taxes***

The Company uses the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. To the extent a deferred tax asset cannot be recognized under the preceding criteria, allowances are established. As of December 31, 2009 and 2008, all deferred tax assets were fully offset by a valuation allowance.

Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) Topic 740, Income Taxes (“ASC 740”), clarifies the accounting for uncertainty in income taxes recognized in the financial statements. ASC 740 provides that a tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits of the position. Income tax positions must meet a more-likely-than-not recognition threshold to be recognized. ASC 740 also provides guidance on measurement, derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company adopted these provisions of ASC 740 on January 1, 2007, and the adoption did not have a material impact on its consolidated financial position or results of operations.

The Company accrues interest and penalties, if any, on underpayment of income taxes related to unrecognized tax benefits as a component of income tax expense in its consolidated statements of operations.

***Revenue Recognition***

*Supply Revenue*—The Company recognizes revenue from products manufactured and supplied to its commercial partners, when the following four basic revenue recognition criteria under the related accounting guidance are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. The product can be returned within contracted specified time frames if it does not meet the applicable inspection tests. The Company estimates its return reserves based on its experience of historical return rates.

*Royalties*—The Company recognizes revenue from royalties based on sales of its products into the marketplace by its commercial partners. Royalties are recognized as earned in accordance with contract terms when they can be reasonably estimated and collectability is reasonably assured. The Company’s commercial partners are obligated to report their net product sales and the resulting royalty due to the Company within 60 days from the end of each quarter. Based on historical product sales, royalty receipts and other relevant information, the Company accrues royalty revenue each quarter.

*Collaborative licensing and development revenue*—The Company recognizes revenue from reimbursements received in connection with feasibility studies and development work for third parties who desire to utilize its

**Pacira Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements—(continued)**

DepoFoam extended release drug delivery technology for their products, when the Company's contractual services are performed, provided collectability is reasonably assured. The Company's principal costs under these agreements include its personnel conducting research and development, and its allocated overhead, as well as research and development performed by outside contractors or consultants.

The Company recognizes revenues from non-refundable up-front fees received under collaboration agreements ratably over the performance period as determined under the collaboration agreement (estimated development period in the case of development agreements, and contract period or longest patent life in the case of supply and distribution agreements). If the estimated performance period is subsequently modified, the Company will modify the period over which the up-front fee is recognized accordingly on a prospective basis. Upon termination of a collaboration agreement, any remaining non-refundable licensing fees received by the Company, which had been deferred, are generally recognized in full. All such recognized revenues are included in collaborative licensing and development revenue in the Company's consolidated statements of operations.

The Company recognizes revenue from milestone payments received under collaboration agreements when earned, provided that the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, the Company has no further performance obligations relating to the event, and collectability is reasonably assured. If these criteria are not met, the Company recognizes milestone payments ratably over the remaining period of the Company's performance obligations under the collaboration agreement. All such recognized revenues are included in collaborative licensing and development revenue in the Company's consolidated statements of operations. All of the milestone payments received in 2009, 2008 and 2007 are recognized ratably over the period of the Company's performance obligations.

***Research and Development Expenses***

Research and development expenses consist of costs associated with products being developed internally, and include related personnel expenses, laboratory supplies, active pharmaceutical ingredients, manufacturing supplies, facilities costs, preclinical and clinical trial costs, and other outside service fees. The Company expenses research and development costs as incurred. A significant portion of the Company's development activities are outsourced to third parties, including contract research organizations. In such cases, the Company may be required to make estimates of related service fees to be accrued.

***Per Share Data***

Net loss per share is determined in accordance with the two-class method. This method is used for computing basic net loss per share when companies have issued securities other than common stock that contractually entitle the holder to participate in dividends and earnings of the Company. Under the two-class method, net loss is allocated between common shares and other participating securities based on their participation rights in both distributed and undistributed earnings. The Company's Series A convertible preferred stock are participating securities, since the stockholders are entitled to share in dividends declared by the board of directors with the common stock based on their equivalent common shares.

Basic net loss per share is computed by dividing net loss available (attributable) to common stockholders by the weighted average number of shares of common stock outstanding during the period. Because the holders of the Series A Convertible Preferred Stock are not contractually required to share in the Company's losses, in applying the two-class method to compute basic net loss per common share no allocation to preferred stock was made for the years ended December 31, 2009, 2008, and 2007.

Diluted net loss per share is calculated by dividing net loss available (attributable) to common stockholders as adjusted for the effect of dilutive securities, if any, by the weighted average number of common stock and

**Pacira Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements—(continued)**

dilutive common stock outstanding during the period. Potential common shares include the shares of common stock issuable upon the exercise of outstanding stock options and a warrant (using the treasury stock method) and the conversion of the shares of Series A convertible preferred stock (using the more dilutive of the (a) as converted method or (b) the two-class method). Potential common shares in the diluted net loss per share computation are excluded to the extent that they would be anti-dilutive. No potentially dilutive securities are included in the computation of any diluted per share amounts as the Company reported a net loss for all periods presented. Potentially dilutive securities that would be issued upon the conversion of convertible notes, conversion of Series A convertible preferred stock and the exercise of outstanding warrants and stock options, were 77.1 million, 70.7 million and 36.0 million as of December 31, 2009, 2008, and 2007, respectively.

***Share-Based Compensation***

The Company's share-based compensation programs include grants of stock options to employees, consultants and non-employee directors. The expense associated with these programs is recognized in the Company's consolidated statements of operations based on their fair values as they are earned by the employees, consultants and non-employee directors under the applicable vesting terms.

The valuation of stock options is an inherently subjective process, since market values are generally not available for long-term, non-transferable stock options. Accordingly, the Company uses an option pricing model to derive an estimated fair value. In calculating the estimated fair value of stock options granted, the Company uses the Black-Scholes option pricing model which requires the consideration of the following variables for purposes of estimating fair value:

- the stock option exercise price;
- the expected term of the option;
- the grant date fair value of the Company's common stock, which is issuable upon exercise of the option;
- the expected volatility of the Company's common stock;
- expected dividends on the Company's common stock; and
- the risk-free interest rate for the expected option term.

Of the variables above, the Company believes that the selection of an expected term and expected stock price volatility are the most subjective. The Company's historical stock option exercise experience does not provide a reasonable basis upon which to estimate expected term. Accordingly, the Company uses a term based on a simplified method, pursuant to SEC Staff Accounting Bulletin No. 107, *Share-based Payment*, for "plain vanilla" options. For calculating stock price volatility, the Company utilizes historical stock prices of publicly traded companies that are similar to Pacira.

The Company estimates the level of award forfeitures expected to occur, and records compensation cost only for those awards that are ultimately expected to vest.

***Segment Reporting***

The Company currently operates in a single operating segment. The Company generates revenue from various sources that result primarily from its revenue from DepoCyt(e) and DepoDur underlying research and development activities. In addition, financial results are prepared and reviewed by management as a single operating segment.

**Pacira Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements—(continued)**

**3. RECENT ACCOUNTING PRONOUNCEMENTS**

In October 2009, the FASB issued Accounting Standards Update No. 2009-13, “Multiple-Deliverable Revenue Arrangements” (“ASU 2009-13”). ASU 2009-13, amends existing revenue recognition accounting pronouncements that are currently within the scope of ASC Subtopic 605-25. This authoritative guidance provides principles for allocation of consideration among its multiple-elements, allowing more flexibility in identifying and accounting for separate deliverables under an arrangement. ASU 2009-13 introduces an estimated selling price method for valuing the elements of a bundled arrangement if vendor-specific objective evidence or third-party evidence of selling price is not available, and significantly expands related disclosure requirements. This guidance is effective on a prospective basis for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Alternatively, adoption may be on a retrospective basis, and early application is permitted. The Company is currently evaluating the impact that the adoption of this guidance will have on its consolidated results of operations, financial position or cash flows.

In April 2010, the FASB issued Accounting Standards Update No. 2010-17, “Milestone Method of Revenue Recognition (Topic 605)” (“ASU 2010-17”). This update provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. Authoritative guidance on the use of the milestone method did not previously exist. This guidance is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. Alternatively, retrospective adoption is permitted for all prior periods. The Company is currently evaluating the impact that the adoption of this guidance will have on its consolidated results of operations, financial position or cash flows.

Other pronouncements issued by the FASB or other authoritative accounting standards groups with future effective dates are either not applicable or not significant to the consolidated financial statements of the Company.

**4. ACQUISITION OF SKYEPHARMA, INC.**

Pacira Pharmaceuticals, Inc., a Delaware corporation, is the holding company for a California operating subsidiary of the same name, which we refer to as PPI-California. On the Acquisition Date, MPM Capital, Sanderling Ventures, OrbiMed Advisors, HBM Bioventures, the Foundation for Research and their co-investors, through Pacira Pharmaceuticals, Inc., acquired PPI-California, from SkyePharma Holding, Inc., which is referred to herein as the Acquisition. PPI-California was known as SkyePharma, Inc. prior to the Acquisition. The Investors acquired PPI-California to develop the DepoFoam extended release drug delivery technology and purchase the DepoFoam-based marketed products and product pipeline, most notably EXPAREL, a bupivacaine-based product candidate for postsurgical pain management.

**Pacira Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements—(continued)**

The initial purchase price was \$19.6 million and was funded from the sale proceeds of Series A convertible preferred stock and common stock of the Company. The results of operations of SkyePharma, Inc., are included in the consolidated financial statements of the Company from the Acquisition Date. The intangible assets acquired were core and developed technology, trademarks and trade names, and IPR&D. Purchased IPR&D totaling \$12.4 million was expensed upon the Acquisition because technological feasibility had not been established and no future alternative uses existed for the technology. The Company determined the estimated fair value of the developed technology, core technology and IPR&D based on a valuation that used the income method. Significant assumptions in the Company's analysis included discount rates of 68%, 55% and 63% for IPR&D, developed technology and core technology, respectively. The components of the purchase price allocation for SkyePharma, Inc. are as follows:

<b>Purchase consideration:</b>	
(in thousands)	
Cash paid to SkyePharma Holding, Inc.	\$ 19,632
Acquisition costs	1,355
Contingent purchase liability	2,042
Total purchase consideration	<u>\$ 23,029</u>
<b>Allocation of purchase price:</b>	
(in thousands)	
Acquired cash	\$ 175
Accounts receivable	850
Inventories	1,682
Prepaid expenses and other assets	626
Fixed assets	10,155
In-process research and development	12,400
Acquired intangible assets:	
Core technology	2,900
Developed technology	11,700
Trademarks and trade names	800
Liabilities assumed:	
Royalty interest obligation (see Note 10)	(13,000)
Unfavorable lease obligations	(3,300)
Other liabilities assumed	<u>(1,959)</u>
	<u>\$ 23,029</u>

The acquired intangibles consist of core technology, developed technology, and trademarks and trade names. As of the Acquisition Date, the core technology was comprised of the DepoFoam drug delivery technology and the developed technology was comprised of the DepoCyt(e) and DepoDur marketed products. The acquired trademarks and trade names include DepoCyt, DepoCyte, DepoDur and DepoFoam and related intellectual property. The amortization periods for the acquired intangibles are seven to nine years.

At the Acquisition Date, the Company determined that the lease rates associated with the assumed facilities leases were above market rates resulting in a \$3.3 million unfavorable lease accrual as of the Acquisition Date. The unfavorable lease accrual, which is recorded in other long-term liabilities in the Company's consolidated balance sheets, is amortized over the remaining terms of the leases.

In addition to the initial \$19.6 million purchase price, the Company entered into an earn-out agreement with SkyePharma Holding, Inc. as additional purchase price which was based on Pacira reaching certain revenue



**Pacira Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements—(continued)**

milestones following the Acquisition. According to this agreement, Pacira would pay SkyePharma Holding, Inc. certain milestone and royalty payments based on the net revenues of EXPAREL and certain other products from the future yet-to-be-developed biologics product line. Additionally, we agreed to pay to SkyePharma Holding, Inc. a 3% royalty of our sales of EXPAREL in the United States, Japan, the United Kingdom, France, Germany, Italy and Spain. The fair value of this contingent obligation was \$13.9 million on the Acquisition Date. For business combinations involving contingent consideration (that is, a combination that might result in the acquiring enterprise recognizing additional purchase price in a future period (also referred to as “contingent consideration”)), the acquiring enterprise is required to recognize, as if it were a liability, an amount equal to the lesser of: (1) the maximum amount of contingent consideration issuable, and (2) the total amount of negative goodwill. Accordingly, even though the fair value of the contingent consideration was \$13.9 million, the Company recognized only \$2.0 million as a contingent purchase liability as of the Acquisition Date. The carrying amount of the contingent purchase liability to SkyePharma Holding, Inc. was \$2.0 million as of December 31, 2009 and 2008. The Company has not paid any earn-out to SkyePharma Holding, Inc. for the years ended December 31, 2009, 2008 and 2007.

Had the Acquisition been completed as of the beginning of 2007, the Company’s pro forma results for 2007 would have been as follows:

<i>(in thousands, except per share data)</i>	<i>(Unaudited)</i>
Revenue	\$ 9,860
Net loss	\$ (48,165)
Basic and diluted net loss per common share	\$ (9.63)
Basic and diluted weighted average shares	5,000,000

**5. FAIR VALUE MEASUREMENTS**

Financial assets and financial liabilities are required to be measured and reported on a fair value basis using the following three categories for classification and disclosure purposes:

*Level 1:* Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

*Level 2:* Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

*Level 3:* Unobservable inputs that are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company also considers counterparty credit risk in its assessment of fair value.

The carrying value of financial instruments including cash and cash equivalents, restricted cash, accounts receivable, note receivable, and accounts payable approximate their respective fair values due to the short-term maturities of these instruments and debts. The fair value of the Company’s convertible notes (see Note 10) and promissory notes (see Note 10) cannot be practicably determined due to their related party nature.

**Pacira Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements—(continued)**

**6. INVENTORIES**

The components of inventories were as follows:

	December 31,	
	2009	2008
	(in thousands)	
Raw materials	\$ 811	\$ 915
Work-in-process	48	13
Finished goods	965	1,281
	1,824	2,209
Less provision for excess and obsolete inventory	(95)	(181)
Inventory, net	<u>\$1,729</u>	<u>\$2,028</u>

**7. FIXED ASSETS**

Fixed assets, at cost, summarized by major category, consist of the following:

	December 31,	
	2009	2008
	(in thousands)	
Machinery and laboratory equipment	\$ 19,413	\$ 16,934
Computer equipment and software	765	760
Office furniture and equipment	167	167
Leasehold improvements	3,809	3,388
Total	24,154	21,249
Less accumulated depreciation	(4,594)	(3,212)
Fixed assets, net	<u>\$19,560</u>	<u>\$ 18,037</u>

Depreciation expense for the years ended December 31, 2009, 2008 and 2007 was \$1.9 million, \$2.0 million and \$1.5 million, respectively. Depreciation expenses associated with the Company's commercial products are included in cost of revenue. Depreciation expenses associated with the Company's products in development are included in research and development expenses. Depreciation expenses associated with general and administrative activities are included in selling, general and administrative expenses.

**Pacira Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements—(continued)**

**8. INTANGIBLE ASSETS**

Intangible assets consist of core technology, developed technology and trademarks and trade names acquired in the acquisition of SkyePharma, Inc. (see Note 4). Intangible assets are recorded at cost, net of accumulated amortization. Amortization of intangible assets is provided over their estimated useful lives on a straight-line basis.

Intangible assets are summarized as follows:

	December 31,		Estimated Useful Life
	2009	2008	
(In thousands)			
<b>Core Technology</b>			
Gross Amount	\$ 2,900	\$ 2,900	9 years
Accumulated amortization	(886)	(564)	
Net	<u>2,014</u>	<u>2,336</u>	
<b>Developed Technology</b>			
Gross Amount	11,700	11,700	7 years
Accumulated amortization	(4,596)	(2,925)	
Net	<u>7,104</u>	<u>8,775</u>	
<b>Trademarks and trade names</b>			
Gross Amount	500	500	7 years
Accumulated amortization	(176)	(100)	
Net	<u>324</u>	<u>400</u>	
<b>DepoDur Rights</b>			
Gross Amount	2,058	1,736	Remaining patent life
Accumulated amortization	(322)	(163)	ending November 2018
Net	<u>1,736</u>	<u>1,573</u>	
<b>Intangible assets, net</b>	<u>\$ 11,178</u>	<u>\$ 13,084</u>	

Amortization expense for intangibles was \$2.2 million, \$2.2 million and \$1.7 million for the years ended December 31, 2009, 2008 and 2007, respectively. Amortization expenses associated with the Company's commercial products and developed technology are included in cost of revenue. Amortization expenses associated with the Company's products in development are included in research and development expenses.

The approximate amortization expense for intangibles subject to amortization is as follows (in thousands):

	Core Technology	Developed Technology	Trademarks and Tradenames	DepoDur Rights	Total
2010	\$ 322	\$ 1,671	\$ 76	\$ 196	\$ 2,265
2011	322	1,671	76	196	2,265
2012	322	1,671	76	196	2,265
2013	322	1,671	76	196	2,265
2014	322	420	20	196	958
Thereafter	404	—	—	756	1,160
<b>Total</b>	<u>\$ 2,014</u>	<u>\$ 7,104</u>	<u>\$ 324</u>	<u>\$ 1,736</u>	<u>\$ 11,178</u>

**Pacira Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements—(continued)**

Intangibles are evaluated for potential impairment whenever events or circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recorded to the extent the asset's carrying value is in excess of the fair value of the asset. When fair values are not readily available, the Company estimates fair values using expected discounted future cash flows. During 2008, the Company recorded an impairment loss of \$125,000, primarily related to the Company's DepoDur trademark. The DepoDur trademark was determined to be impaired because the Company's revised estimates of future sales were significantly lower than its prior estimates. Such impairment losses are reflected in costs of revenue in the Company's consolidated statements of operations. No impairment loss was recorded in 2009 and 2007. The Company believes that this impairment will not have a material impact on its future operations and cash flows because (i) the cash flows from DepoDur are not material and (ii) the Company has already taken the impairment charge for this trademark.

#### 9. OTHER BALANCE SHEET DETAILS

Other current assets consist of the following:

	December 31,	
	2009	2008
	(in thousands)	
Prepaid expenses	\$ 761	\$ 868
Other	311	308
<b>Total</b>	<b>\$1,072</b>	<b>\$1,176</b>

Accrued expenses consist of the following:

	December 31,	
	2009	2008
	(in thousands)	
Compensation and benefits	\$ 518	\$1,085
Lease rent deferral - current portion	1,705	—
Other	1,255	648
	<b>\$ 3,478</b>	<b>\$ 1,733</b>

#### 10. DEBT AND FINANCING ARRANGEMENTS

The composition of the Company's debt and financing obligations, including accrued interest, is as follows:

	December 31,	
	2009	2008
	(in thousands)	
Related party debt, including accrued interest:		
Convertible notes payable	\$ 11,124	\$ —
Secured notes payable	11,049	—
	<u>22,173</u>	<u>—</u>
Financing obligations:		
Royalty interest obligation, current portion	1,599	1,443
Royalty interest obligation, long-term portion	3,647	3,618
	<u>5,246</u>	<u>5,061</u>
<b>Total debt and financing obligations</b>	<b>\$27,419</b>	<b>\$5,061</b>

**Pacira Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements—(continued)**

***Convertible Notes Payable***

In 2009, the Company sold \$10.63 million aggregate principal amount of unsecured convertible promissory notes, or the 2009 Convertible Notes. The 2009 Convertible Notes were issued with detachable warrants to purchase an aggregate of 1.7 million shares of the Company's common stock at an exercise price of \$0.25 per share. In recording the transaction, the Company allocated the proceeds of the 2009 Convertible Notes and the warrants based on their relative fair values. Fair value of the warrants was determined using the Black-Scholes valuation model and allocated to additional paid-in capital. It was also determined that the 2009 Convertible Notes contained a beneficial conversion feature since the fair value of the common stock issuable upon the conversion of the notes exceeded the value allocated to the notes. The Company recognized and measured the embedded beneficial conversion feature of each of the 2009 Convertible Notes by allocating a portion of the proceeds equal to the intrinsic value of that feature to additional paid-in capital. The intrinsic value of the beneficial conversion feature was calculated at the commitment date as the difference between the conversion price and the fair value of the securities into which the convertible instruments were convertible.

The 2009 Convertible Notes accrue interest at an annual rate of 5% payable at maturity or at the time of conversion. In connection with entering into the GECC Credit Facility in April 2010, as further described in Note 18, the maturity date was extended to the earliest of (1) a sale of the Company, (2) December 31, 2013 and (3) 91 days after the date that all obligations under the GECC Credit Facility are paid in full and the GECC Credit Facility is terminated. Also in connection with entering into the GECC Credit Facility, the holders of the 2009 Convertible Notes entered into (i) a subordination agreement with GECC pursuant to which the 2009 Convertible Notes were subordinated to the GECC Credit Facility and (ii) an inter-creditor agreement with the holders of the 2009 Secured Notes and the 2010 Secured Notes, as further described below, whereby the 2009 Convertible Notes were subordinated to the 2009 Secured Notes (described below) and 2010 Secured Notes (described in Note 18) and the holders of the 2009 Secured Notes agreed to share payments pro rata with the holders of the 2010 Secured Notes.

Upon the closing of a Qualified Financing (as defined below), unless the holders of a majority of the aggregate principal amount of all 2009 Convertible Notes have elected Optional Conversion of the 2009 Convertible Notes as described below, all outstanding principal and accrued interest under the 2009 Convertible Notes will automatically convert into shares of the same class and series of capital stock of the Company issued to investors in the Qualified Financing at a conversion price per share equal to the price per share paid by other investors in the Qualified Financing. A "Qualified Financing" means the next sale of preferred stock of the Company (i) with gross proceeds to the Company (including proceeds from any indebtedness of the Company that converts into equity in such financing) of at least \$10 million or (ii) that is designated as a "Qualified Financing" by the holders of a majority of the aggregate principal amount of all 2009 Convertible Notes. Additionally, the 2009 Convertible Notes and any unpaid interest may be converted to Series A convertible preferred stock upon the election by the holders of a majority of the aggregate principal amount of all 2009 Convertible Notes with a conversion price paid per share equal to the price per share of Series A convertible preferred stock at the time of conversion ("Optional Conversion"). The warrants have an exercise price per share of \$0.25 and will expire on January 21, 2014.

In the event of the completion of a merger or consolidation, sale of all the Company's assets or common stock or voluntary or involuntary liquidation, prior to full payment of the 2009 Convertible Notes or prior to the time when the 2009 Convertible Notes may be converted, the 2009 Convertible Notes will be due and payable with a control premium and the then outstanding principal and unpaid accrued interest and will be senior to all payments of Company common stock and Series A convertible preferred stock. Additionally, the 2009 Convertible Notes are due on demand in the event of default, litigation that threatens to materially and adversely affect the Company's business, operations, assets or results of operations, or bankruptcy by the Company.

**Pacira Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements—(continued)**

The value of the warrants has been recorded as a discount to the 2009 Convertible Notes and amortized as a component of interest expense over the original term of the notes. For the year ended December 31, 2009, the amortization of the discount was \$268,591 resulting in no remaining balance as of December 31, 2009.

The value of the beneficial conversion feature has been recorded as a discount to the 2009 Convertible Notes and amortized as a component of interest expense over the original term of the notes. For the year ended December 31, 2009, the amortization of the discount was \$268,591 resulting in no remaining balance as of December 31, 2009.

The outstanding principal and accrued interest on the 2009 Convertible Notes was \$10.6 million and \$0.5 million, respectively, as of December 31, 2009 and interest expense associated with these notes was \$0.5 million for the year ended December 31, 2009.

***Secured Promissory Notes***

In June 2009, the Company entered into an agreement with certain of its existing investors to issue \$10.63 million in aggregate principal amount of secured notes, or the 2009 Secured Notes. To secure the performance of the Company's obligations under purchase agreement for the 2009 Secured Notes, the Company granted a security interest in all of its assets except the assets that secure the Company's obligations under its agreement with Paul Capital to the investors. In connection with entering into the GECC Credit Facility in April 2010, as further described in Note 18, the holders of the 2009 Secured Notes entered into (i) a subordination agreement with GECC pursuant to which the 2009 Secured Notes were subordinated to the GECC Credit Facility, and (ii) an inter-creditor agreement with the holders of the 2009 Convertible Notes and the 2010 Secured Notes, as further described below, whereby the 2009 Convertible Notes were subordinated to the 2009 Secured Notes and 2010 Secured Notes and the holders of the 2009 Secured Notes agreed to share payments pro rata with the holders of the 2010 Secured Notes.

The 2009 Secured Notes have an interest rate of 12% per year and all principal and accrued and unpaid interest on the 2009 Secured Notes is due on December 31, 2010. In connection with entering into the GECC Credit Facility, the maturity date was extended to the earliest of (1) a sale of the Company, (2) December 16, 2013 and (3) 91 days after the date that all obligations under the GECC Credit Facility are paid in full and the GECC Credit Facility is terminated.

The outstanding principal and accrued interest on the 2009 Secured Notes was \$10.6 million and \$0.4 million, respectively, as of December 31, 2009 and interest expense associated with these promissory notes was \$0.4 million for the year ended December 31, 2009.

***Sale of Royalty Interests***

In 2000, PPI-California and SkyePharma PLC entered into a Royalty Interests Assignment Agreement ("PLC Royalty Agreement") with an affiliate of Paul Capital Advisors, LLC ("Paul Capital") to raise \$30 million. Under the PLC Royalty Agreement, Paul Capital had the right to receive a royalty interest in four of SkyePharma's product sales including product sales of and other payments related to DepoCyt(e) and DepoDur. Payments began for product sales realized on or after January 1, 2003 and continue through December 31, 2014.

In connection with the Acquisition, the PLC Royalty Agreement was amended ("Amended and Restated Royalty Interests Assignment Agreement"). As part of this amendment the responsibility to pay the royalty interest in product sales of DepoCyt(e) and DepoDur were transferred to the Company and the payment to Paul

**Pacira Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements—(continued)**

Capital in a “Purchase Option Event” of the Company, as described below, was defined. The net present value of royalties expected to be repaid to Paul Capital (the “royalty interest obligation”) was valued at \$13.0 million.

The Company recorded the royalty interest obligation as a liability in the Company’s consolidated balance sheets in accordance with ASC 470-10-25, Sales of Future Revenues. The Company imputes interest expense associated with this liability using the effective interest rate method. The effective interest rate may vary during the term of the agreement depending on a number of factors including the actual sales of DepoCyt(e) and DepoDur and a significant estimation, performed quarterly, of certain of the Company’s future cash flows related to these products during the remaining term of the Royalty Interests Assignment Agreement which terminates on December 31, 2014. Any adjustment to the estimates is reflected in the Company’s consolidated statements of operations as interest income (expense). In addition, such cash flows are subject to foreign exchange movements related to sales of DepoCyt(e) and DepoDur denominated in currencies other than U.S. dollars.

The PLC Royalty Agreement also includes a provision for a “Purchase Option Event.” The events include: (1) any change of control, a direct or indirect consequence of which is a material abatement of efforts to develop, market or sell any of the products or reformulated products; or (2) the transfer by the parent of all or substantially all of the parent’s consolidated assets; or (3) the transfer by the Company of all or any part of their respective interests in the products or reformulated products, or (4) bankruptcy or other breach or default under the agreement.

In the event a Purchase Option Event occurs, Paul Capital shall have the right, but not the obligation, exercisable within 90 days, to require the Company to repurchase from Paul Capital the Royalty Interests Assignment, for a repurchase price equal to 50% of the cumulative amount of all payments made during the preceding 24 months (calculated from the date of the Purchaser’s receipt of the notice from the Company of the Purchase Option Event) multiplied by the number of days from the date of Paul Capital’s exercise of such option until December 31, 2014, divided by 365.

The Company has no minimum payment obligations under the PLC Royalty Agreement. However, the repayment of the Paul Capital liability is supported through a jointly controlled lockbox, where all DepoCyt(e) and DepoDur supply revenue and royalties are received. Commencing April 1 of every year, the first \$2.5 million received in the lockbox is restricted and will be used to make quarterly payments due to Paul Capital, if any, under the agreement during the subsequent 12 month period. On March 31 of the subsequent year, the balance of cash in the lockbox, if any, is remitted to Pacira. The PLC Royalty Agreement terminates on December 31, 2014. The PLC Royalty Agreement pertains only to DepoCyt(e) and DepoDur, and does not include revenue related to EXPAREL or any other product candidates. As of December 31, 2009 and 2008, \$1.2 million was in the lockbox and included in restricted cash in the Company’s consolidated balance sheets.

## 11. STOCKHOLDERS’ EQUITY

### *Common Stock*

In connection with its formation, the Company issued in March 2007 an aggregate of five million shares of common stock for total aggregate consideration of \$50,000.

### *Series A Convertible Preferred Stock*

In March 2007, the Company entered into a Series A Preferred Stock Purchase Agreement pursuant to which the Company issued and sold an aggregate of 68 million shares of Series A convertible preferred stock in four separate closings held in March 2007, February 2008, July 2008 and October 2008, at a purchase price of \$1.25 per share. The aggregate consideration for the shares of Series A convertible preferred stock was \$85 million in cash.

**Pacira Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements—(continued)**

Each holder of Series A convertible preferred stock has the right, at the option of the holder at any time, to convert their shares of Series A convertible preferred stock into shares of common stock at a current conversion ratio of one-to-one, subject to adjustment for stock splits, certain capital reorganizations and dilutive stock issuances. Each share of the Company's Series A convertible preferred stock will automatically convert into shares of the Company's common stock, at the then effective applicable conversion ratio upon the earlier of: (i) the closing of the sale of the Company's common stock pursuant to a firmly underwritten public offering in which the Company receives gross proceeds of at least \$25 million or (ii) the consent of the holders of at least 66 2/3% of the then outstanding shares of Series A convertible preferred stock.

The holders of Series A convertible preferred stock are entitled to receive, when, as and if declared by the Company's board of directors out of legally available funds, non-cumulative dividends in an amount equal to any dividends declared, paid or set aside on shares of the Company's common stock. As of December 31, 2009, no dividends have been declared by the Company's board of directors.

In the event of any liquidation, dissolution or winding up of the Company, the holders of the Series A convertible preferred stock will be entitled to receive in preference to the holders of the Company's common stock, the amount of their original purchase price per share, plus declared and unpaid dividends, if any. If the assets and funds available to be distributed among the holders of the Series A convertible preferred stock are insufficient to permit the payment to such holders of the full preference, then the entire assets and funds legally available for distribution to such holders shall be distributed ratably based on the total due each holder of the Series A convertible preferred stock. Any remaining assets of the Company will be distributed ratably among the holders of its common stock.

Holders of the Series A convertible preferred stock are entitled to the number of votes they would have upon conversion of their Series A convertible preferred stock into common stock at the then-applicable conversion rate. The holders of Series A convertible preferred stock have been granted certain rights with regard to the election of board members and various other corporate actions.

***Warrants***

On January 22, 2009, the Company issued warrants in connection with the issuance of the 2009 Convertible Notes (see Note 10). The warrants are convertible into an aggregate of 1.7 million of shares of the Company's common stock at an exercise price of \$0.25 per share and will expire on January 21, 2014. The value of the warrants has been recorded as a discount to the 2009 Convertible Notes and amortized as a component of interest expense over the original term of the 2009 Convertible Notes. For the year ended December 31, 2009, the amortization of the discount was \$268,591 resulting in no remaining balance as of December 31, 2009.

In addition, on July 2, 2009 the Company issued warrants to the landlord of the Company's two San Diego facilities in connection with amendments to the respective lease agreements that deferred minimum annual rental obligations (see Note 13). The warrants are exercisable for an aggregate of 250,000 shares of Series A convertible preferred stock at a price of \$1.25 per share and will expire on the earlier of July 1, 2016 or the fifth anniversary of the consummation of the Company's initial public offering. The value of the warrants was recorded as prepaid interest and is being amortized as a component of interest expense over the deferred rental payment term. For the year ended December 31, 2009, the amortization of the interest was \$62,577 resulting in a balance of \$141,439 as of December 31, 2009.



**Pacira Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements—(continued)**

**Share-Based Compensation**

The Company recognized share-based compensation in its consolidated statements of operations for the years ended December 31, 2009, 2008 and 2007 as follows:

	Years Ended December 31,		
	2009	2008 (in thousands)	2007
Selling, general and administrative	\$ 349	\$ 126	\$ 25
Research and development	175	116	55
	<u>\$ 524</u>	<u>\$ 242</u>	<u>\$ 80</u>

**Pacira Stock Incentive Plan**

Employees and directors have been granted options to purchase common shares under the 2007 Stock Option/Stock Issuance Plan (the “2007 Plan”). The 2007 Plan provides for the grant of options to purchase up to seven million shares of the Company’s common stock. The 2007 Plan was amended in April 2008, to, among other things, increase the number of shares of common stock authorized for issuance under the 2007 Plan from seven million shares to 11.475 million shares (see Note 18). Options granted under the 2007 Plan generally expire no later than ten years from the date of grant. The exercise price of incentive stock options must be equal to at least the fair value of the Company’s common stock on the date of grant.

The following table summarizes the Company’s stock option activity and related information for the period from January 1, 2007 to December 31, 2009:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Term (years)
Outstanding at January 1, 2007			
Granted	6,026,500	\$ 0.15	
Exercised	—	—	
Forfeited	(22,296)	0.15	
Expired	(864)	0.15	
Outstanding at December 31, 2007	6,003,340	0.15	9.7
Granted	4,884,900	0.18	
Exercised	(1,153,725)	0.15	
Forfeited	(1,227,118)	0.15	
Expired	(16,668)	0.15	
Outstanding at December 31, 2008	8,490,729	0.17	9.1
Granted	8,000	0.25	
Exercised	(18,916)	0.15	
Forfeited	(7,048,958)	0.17	
Expired	(866,972)	0.15	
Outstanding at December 31, 2009	563,883	\$ 0.17	8.2
Exercisable at December 31, 2009	366,508	\$ 0.17	7.6
Vested and expected to vest at December 31, 2009	548,083	\$ 0.17	7.6

**Pacira Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements—(continued)**

The weighted average fair value of options granted for the years ended December 31, 2009, 2008 and 2007 were \$0.18, \$0.13 and \$0.10 per share, respectively. The total fair value of options which vested during 2009, 2008 and 2007 was approximately \$0.1 million, \$0.2 million and \$0.1 million, respectively.

As of December 31, 2009, 9,738,476 shares of common stock were reserved for future grant of stock options. As of December 31, 2009, \$39,000 of total unrecognized compensation cost related to non vested stock options is expected to be recognized over the respective vesting terms of each award. The weighted average term of the unrecognized share-based compensation is 2.3 years. As further described in Note 15, unexercised options to purchase an aggregate of 5,138,958 shares of common stock options were cancelled during 2009, which resulted in share-based compensation of \$0.5 million.

The fair values of each option grant in 2009, 2008 and 2007 were estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

	Years Ended December 31,		
	2009	2008	2007
Expected dividend yield	None	None	None
Risk free interest rate	2.1-2.7%	1.9-3.8%	3.6-4.9%
Expected volatility	82.0%	78.2%	75.1%
Expected life of options	6.25 years	6.25 years	6.25 years

**12. COST OF REVENUES**

Cost of revenue consists of the following:

	Years Ended December 31,		
	2009	2008	2007
Cost of supply revenue	\$ 9,828	(in thousands) \$ 14,467	\$ 8,788
Cost of royalties	401	567	382
Cost of collaborative licensing and development revenue	2,072	2,429	322
Total cost of revenues	<u>\$ 12,301</u>	<u>\$ 17,463</u>	<u>\$ 9,492</u>

Cost of supply revenue consists of the manufacturing and allocated overhead costs related to the Company's supply of DepoCyt(e) and DepoDur to its commercial partners. Cost of royalties consists of payments to Research Development Foundation ("RDF") for the use of DepoFoam technology. Cost of collaborative licensing and development revenues consists of the Company's expenses related to feasibility studies and development work for third parties who desire to utilize the Company's DepoFoam extended release drug delivery technology for their products.

**13. COMMITMENTS AND CONTINGENCIES****Leases**

The Company leases office, research and development, and manufacturing facilities in San Diego, California. The two facilities in San Diego are comprised of the Science Center location and the Torrey Pines location. The leases for both these facilities expire July 2015. Under these leases, the Company is required to pay certain maintenance expenses in addition to the monthly rent. Rent expense is recognized on a straight-line basis

**Pacira Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements—(continued)**

over the lease term for leases that have scheduled rent increases. During 2009, the Company entered into amendments to its real estate leases for the Science Center and Torrey Pines facilities. As part of the lease amendments, the property-owner agreed to defer a portion of the minimum annual rent obligation due from February 1, 2009 to March 31, 2010 in exchange for interest compounded at 10% per annum, and warrants to purchase 250,000 shares of Series A convertible preferred stock with values totaling \$141,000 and \$63,000 on the Science Center and Torrey Pines facilities, respectively. The total amount of rent deferred will be \$438,414 and \$2,109,101 for the Torrey Pines and Science Center facilities, respectively. The amounts are to be repaid from April 1, 2010 to September 1, 2011. The warrants are convertible into Series A convertible preferred stock with an exercise price of \$1.25 per share and will expire on the earlier of July 1, 2016 or the fifth anniversary of the consummation of the Company's initial public offering. The value of the warrants has been recorded as prepaid interest and is being amortized over the deferred rental payment term. As of December 31, 2009, the balance of the related prepaid interest was \$141,000. For the year ended December 31, 2009, the additional interest associated with the deferred payments and amortization of the warrants was \$102,000 and \$63,000, respectively.

The Company determined that its lease rates associated with the assumed the Torrey Pines and Science Center facilities' leases were in excess of market rates resulting in a \$3.3 million unfavorable lease accrual as of the Acquisition Date. The unfavorable lease accrual, which is recorded in other long-term liabilities in the Company's consolidated balance sheets, is amortized over the remaining terms of the leases. The balance of the unfavorable lease accrual as of December 31, 2009 and 2008 was \$2.2 million and \$2.6 million, respectively. The amortization of the unfavorable lease accrual for 2009, 2008 and 2007 was \$0.4 million, \$0.4 million and \$0.3 million, respectively.

As of December 31, 2009, annual minimum payments due under the Company's office and equipment lease obligations are as follows (in thousands):

2010	\$6,215
2011	5,827
2012	4,820
2013	4,968
2014	5,136
Thereafter	3,072
	<u>\$30,038</u>

Total rent expense, net of unfavorable lease obligation amortization, under all operating leases for years ended December 31, 2009, 2008 and 2007 was \$4.6 million, \$4.6 million and \$3.5 million, respectively. Deferred rent at December 31, 2009 and 2008 was \$1.2 million and \$0.9 million, respectively.

***Litigation***

The Company periodically becomes subject to legal proceedings and claims arising in connection with its business. The ultimate legal and financial liability of the Company in respect to all claims, lawsuits and proceedings cannot be estimated with any certainty. Any outcome, either individually or in the aggregate, is not expected to be material to the Company's consolidated financial position, results of operations, or cash flows.

**Pacira Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements—(continued)**

**14. INCOME TAXES**

A reconciliation of income taxes at the U.S. federal statutory rate to the provision for income taxes is as follows (in thousands):

	Year ended December 31,		
	2009	2008	2007
	(in thousands)		
Benefit at U.S. federal statutory rate	\$(10,901)	\$(14,887)	\$(12,785)
State taxes—deferred	(1,713)	(1,844)	(1,220)
Increase in valuation allowance	12,916	17,417	9,476
Tax credits	(498)	(1,319)	(377)
In-process research and development	—	—	4,340
Other	196	633	566
Provision for income taxes	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

Significant components of the Company's deferred tax assets are as follows:

	Year ended December 31,	
	2009	2008
	(in thousands)	
Deferred tax assets:		
Federal and state net operating loss carryforwards	\$ 32,321	\$ 21,752
Federal and state research credits	2,778	2,234
Depreciation and amortization	1,090	675
Accruals and reserves	8,632	9,125
Deferred revenue	9,302	7,749
Other	332	4
Total gross deferred tax assets	<u>54,455</u>	<u>41,539</u>
Less valuation allowance for deferred tax assets	<u>(54,455)</u>	<u>(41,539)</u>
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

The valuation allowance for deferred tax assets increased by approximately \$12.9 million, \$17.4 million and \$24.1 million during the years ended December 31, 2009, 2008 and 2007, respectively. Management believes the significant doubt regarding the realization of net deferred tax assets requires a full valuation allowance.

As a result of certain realization requirements of ASC 718, the table of deferred tax assets is required to be reduced by certain deferred tax assets at December 31, 2009 and 2008 that arose directly from tax deductions related to equity compensation in excess of compensation recognized for financial reporting. Through December 31, 2009, the amount of such reduction was not material.

As of December 31, 2009, the Company had federal and state net operating losses of approximately \$82.4 and \$59.0 million, respectively. The Company also had federal and state research and development tax credit carry-forwards of approximately \$2.2 and \$0.9 million, respectively. The net operating loss carry-forwards and tax credits will expire at various dates, beginning in 2016, through 2026, if not utilized.

Utilizations of net operating loss and research and development credit carry-forwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended, due to

**Pacira Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements—(continued)**

ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of net operating loss and research and development credit carry-forwards that can be utilized annually to offset future taxable income and tax, respectively. An ownership change occurred on March 24, 2007, as a result of the Acquisition. The Company has not conducted a review of whether a change of control has occurred since the Acquisition Date. There also could be additional ownership changes in the future which may result in additional limitations in the utilization of these credits.

As discussed in Note 2 “Summary of Significant Accounting Policies,” the Company adopted new accounting principles on accounting for uncertain tax positions in 2007. Under these principles, tax positions are evaluated in a two-step process. The Company first determines whether it is more-likely-than-not that a tax position will be sustained upon examination. If a tax position meets the more-likely-than-not recognition threshold it is then measured to determine the amount of benefit to be recognized in the financial statements. The tax position is measured as the largest amount of benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement.

At December 31, 2009, the total amount of gross unrecognized tax benefits was not considered significant.

The Company is currently open for audit by the United States Internal Revenue Service and state tax jurisdictions for 2006 through 2009.

**15. RETIREMENT PLANS AND OTHER EMPLOYEE BENEFITS**

***Savings Plan***

The Company sponsors a 401(k) savings plan. Under the plan, employees may make contributions to the plan, which are eligible for a discretionary percentage match as defined in the plan and determined by the board of directors. The Company’s compensation expense under this plan, representing its employer matching contributions, was \$0.3 million for the year ended December 31, 2007. There was no compensation expense under the plan for years ended December 31, 2009 and 2008.

***Incentive Bonus Plan***

In March 2009, the Company adopted a company sale bonus plan and in March 2010 the Company amended and restated the company sale bonus plan. The company sale bonus plan provides for a potential cash bonus payment to specified employees and consultants, including executive officers, and non-employee directors, in the event of a sale of the Company. Under the company sale bonus plan, upon the closing of a sale transaction that satisfies specified criteria, each participant in the company sale bonus plan would receive either a bonus in an amount equal to a portion of the sale proceeds multiplied by a specified percentage for that participant or a fixed bonus payment. The plan terminates upon the completion of the Company’s initial public offering. As a condition to becoming participants under the plan, most of the participants, including all of the Company’s executive officers and non-employee directors, agreed to have their existing option grants cancelled. As a result, unexercised options for an aggregate of 5.1 million shares of common stock were cancelled. In addition, certain employees were eligible to receive a retention bonus (equivalent to two weeks of base salary upon receipt of positive data on the EXPAREL Phase 3 clinical trials, or if the Company’s board of directors deemed related data to be positive) and a pre-determined percentage of salary in the event of a Company sale. In the fourth quarter of 2009, the Company received positive data on the EXPAREL Phase 3 clinical trials and, accordingly, recorded compensation expense and paid \$0.1 million of retention bonuses.

**Pacira Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements—(continued)**

In October 2010, the Company entered into employment agreements with its executive officers. Each of these agreements provides the executive officer with certain severance benefits in connection with certain terminations of the executive's employment both before and after a change of control.

**16. COMMERCIAL PARTNERS AND AGREEMENTS**

***Sigma -Tau***

In December 2002, the Company entered into a supply and distribution agreement with Enzon Pharmaceuticals Inc. regarding the sale of DepoCyt. Pursuant to the agreement, Enzon was appointed the exclusive distributor of DepoCyt in the United States and Canada. In January 2010, Sigma-Tau Pharmaceuticals, Inc., or Sigma-Tau, acquired the rights to sell DepoCyt from Enzon Pharmaceuticals for the United States and Canada. Under the supply and distribution agreement, the Company supplies unlabeled DepoCyt vials to Sigma-Tau for finished packaging by Sigma-Tau. Under these agreements, the Company receives a fixed payment for manufacturing the vials of DepoCyt and a double-digit royalty on sales by Sigma-Tau in the United States and Canada.

***Mundipharma International Holdings Limited***

In June 2003, the Company entered into an agreement granting Mundipharma International Holdings Limited, or Mundipharma, exclusive marketing and distribution rights to DepoCyt in the European Union and certain other European countries. Under the agreement, as amended, and a separate supply agreement, the Company receives a fixed payment for manufacturing the vials of DepoCyt and a double-digit royalty on sales in the applicable territories by Mundipharma.

***EKR Therapeutics Inc.***

In August 2007, the Company entered into a licensing, distribution and marketing agreement with EKR Therapeutics, Inc., or EKR, granting them exclusive distribution rights to DepoDur in North America, South America and Central America. Under this agreement, as amended, the Company receives a fixed payment for manufacturing the vials of DepoDur and a double-digit royalty on sales in the applicable territories by EKR.

***Flynn Pharmaceuticals Limited***

In September 2007, the Company entered into a marketing agreement with Flynn Pharma Limited, or Flynn, granting them exclusive distribution rights to DepoDur in the European Union, certain other European countries, South Africa and the Middle East. Under this agreement and a separate supply agreement with Flynn, the Company provides or procures DepoDur manufacturing supply of finished product for sale in the territories licensed by Flynn, and receives a fixed payment for manufacturing the vials of DepoDur and a double-digit royalty on sales in the applicable territories by Flynn.

***Amylin Pharmaceuticals Inc***

In March 2008, the Company entered into a development and licensing agreement with Amylin Pharmaceuticals, Inc., or Amylin. Under the development and licensing agreement, the Company provides Amylin with access to its proprietary DepoFoam drug delivery technology to conduct research, feasibility and formulation work, and for the manufacturing of pre-clinical and clinical material for various Amylin products. The Company is entitled to payments from Amylin for its work on the formulation and development of compounds with the DepoFoam technology, its achievement of certain clinical development milestones, its

**Pacira Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements—(continued)**

achievement of certain worldwide sales and a tiered royalty based upon sales. In April 2008, the Company received an up-front milestone payment from Amylin. The development and licensing agreement with Amylin remains effective, however, neither party is currently performing any activities under the agreement.

***Feasibility Study Agreements with Third Parties***

In the ordinary course of its business activities, the Company enters into feasibility study agreements with third parties who desire access to its proprietary DepoFoam extended release drug delivery technology to conduct research, feasibility and formulation work. Under these agreements, the Company is compensated to perform feasibility testing on a third party product to determine the likelihood of developing a successful formulation of that product using its proprietary DepoFoam extended release drug delivery technology. If successful in the feasibility stage, these programs can advance to a full development contract. Currently, the Company is actively engaged in two feasibility assessments for third parties.

**17. RELATED PARTY TRANSACTIONS**

During the year ended December 31, 2009, the Company entered into 2009 Convertible Note Agreements and 2009 Secured Note Agreements with certain investors in the Company (see Note 10). The composition of the balances due to these investors, totaling \$22.2 million, including accrued interest of \$0.9 million, as of December 31, 2009.

In February 2008, the Company entered into a services agreement with Stack Pharmaceuticals Inc., or SPI, an entity controlled by David Stack, the Company's chief executive officer. Pursuant to the agreement, SPI provides the Company with the use of SPI's office facilities which include the use of office space for the Company's employees, office furnishings, phone system, internet connections, printers and other related office amenities such as conference rooms. Pursuant to the agreement, the Company pays SPI \$10,500 each month during the term of the services agreement. In addition, during 2008 and 2009, SPI performed various projects for the Company. These projects included a business analysis and commercial recommendation for the Company's DepoDur product, a market research project related to the development of a DepoMethotrexate product, market research and forecasting in support of clinical development of EXPAREL for the potential additional indications of nerve block and epidural administration and reimbursement for access to Datamonitor reports for commercial analysis and partnering discussions regarding EXPAREL. The Company incurred expenses under the SPI agreement of \$210,000, \$258,000 and \$71,000 for the years ended December 31, 2009, 2008 and 2007, respectively. As of December 31, 2009 and 2008, the Company had no outstanding balance payable to SPI.

MPM Asset Management ("MPM"), an investor in the Company, provides clinical management and subscription services to the Company. The Company incurred expenses of \$316,000, \$30,000 and \$0 for the years ended December 31, 2009, 2008 and 2007, respectively. As of December 31, 2009, \$88,000 was payable to MPM. The Company had no outstanding balance payable to MPM as of December, 2008.

In April 2010, the Company signed a statement of work for a feasibility study with Rhythm Pharmaceuticals, Inc. The Company earned contract revenue from this statement of work during 2010. MPM and its affiliates are holders of the Company's capital stock. MPM and its affiliates are holders of capital stock of Rhythm Pharmaceuticals, Inc. and a managing director of MPM is a member of the board of directors of Rhythm Pharmaceuticals, Inc.

**Pacira Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements—(continued)**

**18. SUBSEQUENT EVENTS**

The Company has evaluated events through November 1, 2010, the date at which the consolidated financial statements were available to be issued.

***2010 Secured Notes***

In March 2010, the Company entered into an agreement with certain of its existing investors to issue \$15 million in aggregate principal amount of secured notes in a private placement (the “2010 Secured Notes”). To secure the performance of its obligations under the purchase agreement for the 2010 Secured Notes, the Company granted a subordinated security interest in substantially all of its assets, including its intellectual property assets, to the investors. The investors purchased the entire \$15 million of 2010 Secured Notes in three closings in March, June and September 2010.

The 2010 Secured Notes have an interest rate of 5% per year and all principal and accrued and unpaid interest is due on December 31, 2010. In connection with entering into the GECC Credit Facility as noted below, the maturity date was extended to the earliest of (1) a sale of the Company; (2) December 16, 2013; and, (3) 91 days after the date that all obligations under the GECC Credit Facility are paid in full and the GECC Credit Facility is terminated. Also in connection with entering into the GECC Credit Facility, the holders of the 2010 Secured Notes entered into (i) a subordination agreement with GECC pursuant to which the 2010 Secured Notes were subordinated to the GECC Credit Facility, and (ii) an inter-creditor agreement with the holders of the 2009 Convertible Notes and the 2009 Secured Notes whereby the 2009 Convertible Notes were subordinated to the 2010 Secured Notes and the 2009 Secured Notes, and the holders of the 2010 Secured Notes agreed to share payments pro rata with the holders of the 2009 Secured Notes.

***HBM Secured Notes***

On April 30, 2010, the Company entered into a subordinated secured note purchase agreement with entities affiliated with HBM BioVentures, or HBM, to issue \$3.75 million in aggregate principal amount of secured notes, or the HBM Secured Notes, in a private placement. Pursuant to the purchase agreement for the HBM Secured Notes, upon written notice delivered to HBM prior to September 30, 2010, HBM purchased an amount of secured notes set forth in the notice. HBM purchased the entire \$3.75 million of the HBM Secured Notes in three closings in April, June and September 2010. To secure the performance of its obligations under the purchase agreement for the HBM Secured Notes, the Company granted a subordinated security interest in substantially all of its assets, including its intellectual property assets, other than the assets that secure its obligations under its agreement with Paul Capital. The HBM Secured Notes carry an interest rate of approximately 10% per year. In addition, the HBM Secured Notes require a final payment fee if they are prepaid prior to the maturity date. The maturity date of the HBM Secured Notes is the earliest of (1) a sale of the Company, (2) December 16, 2013 and (3) 91 days after the date that all obligations under the GECC Credit Facility are paid in full and the GECC Credit Facility is terminated. On April 30, 2010, the holders of the HBM Secured Notes entered into a subordination agreement with GECC pursuant to which the HBM Secured Notes were subordinated to the GECC Credit Facility.

***Credit Facility***

In April 2010, The Company entered into a credit facility with General Electric Capital Corporation (the “GECC Credit Facility”), with \$11.25 million available for borrowing. The Company borrowed an aggregate principal amount of \$5.62 million at the closing, \$2.81 million on July 1, 2010 and the remaining \$2.81 million on September 2, 2010. Each of the term loans under the GECC Credit Facility carries a fixed interest rate of



**Pacira Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements—(continued)**

approximately 10% that is payable monthly. The GECC Credit Facility requires no payment of principal for the first year, and then equal principal payments over 24 months until the maturity dates of 3 years from the funding dates. The GECC Credit Facility is secured by a first priority lien on all of the Company's assets other than the assets that secure its obligations under its agreement with Paul Capital, and is guaranteed in full by certain majority investors of the Company (the "guarantors").

In connection with any prepayments of term loans under the GECC Credit Facility, the Company's required to pay, in addition to all principal and accrued and unpaid interest on such term loan, a final payment fee equal to (i) 0.45% of the original principal amount of such term loan if the prepayment is made or required before the one year anniversary of such term loan, (ii) 2.25% of the original principal amount of such term loan if the prepayment is made or required on or after the one year anniversary of such term loan but before the two year anniversary of such term loan, and (iii) 3.50% of the original principal amount of such term loan if the prepayment is made or required on or after the two year anniversary of such term loan.

The GECC Credit Facility is guaranteed by the Company and is secured by a first priority lien on all of the assets of both PPI-California and the guarantors, other than the assets that secure its obligations under its agreement with Paul Capital. In addition, the GECC Credit Facility is guaranteed by certain of the Company's investors (other than HBM) on a several and not joint basis which guarantee is limited to each investor's pro rata portion of the outstanding principal and accrued and unpaid interest under the GECC Credit Facility, but in no event to exceed \$11.250 million in the aggregate. The obligations of the investors under the guarantee is not triggered until the earlier to occur of (i) thirty days after written notice from the agent that the obligations under the GECC Credit Facility have been accelerated, and (ii) the occurrence of a bankruptcy or insolvency event with respect to the borrower, the Company or any of the investor guarantors. The guarantee by the Company's investors of the GECC Credit Facility also includes covenants that require each such investor to maintain at all times unfunded commitments from its investors in an amount equal to at least one and one-half times the maximum amount which the investor may be obligated for under the investor guarantee, and also includes certain control requirements with respect to such investors.

The GECC Loan and Security Agreement contains events of default including payment default, default arising from the breach of the provisions of the GECC Loan and Security Agreement and related documents or the inaccuracy of representations and warranties, attachment default, judgment default, bankruptcy and insolvency, cross-default provision with respect to other material indebtedness, default based on the unenforceability, invalidity or revocation of a the GECC Loan and Security Agreement or any other related documents (including any guarantee or applicable subordination agreement) or any security interests, the occurrence of a material adverse effect (as defined in the GECC Loan and Security Agreement) and certain changes in control, including if the chief executive officer or chief financial officer of the borrower cease to be involved in the daily operations or management of the business, if certain holders cease to own or control at least 51% of the outstanding capital stock of the Company, if the Company ceases to own or control all the economic and voting rights of the borrower and if the borrower ceases to own or control, directly or indirectly, all of the economic or voting rights of each of its subsidiaries.

The occurrence of an event of default under the GECC Credit Facility could trigger the acceleration of the obligations under the GECC Credit Facility or allow the agent or lenders to exercise other rights and remedies, including rights against the assets which secure the GECC Credit Facility and rights under guarantees provided to support the obligations under the GECC Credit Facility.

The GECC Loan and Security Agreement contains a number of affirmative and restrictive covenants including reporting requirements, compliance with laws, protection of intellectual property and other collateral

**Pacira Pharmaceuticals, Inc.**  
**Notes to Consolidated Financial Statements—(continued)**

covenants, and limitations, subject to certain exceptions set forth in the GECC Loan and Security Agreement, on liens and indebtedness, limitations on dispositions, limitations on mergers and acquisitions, limitations on restricted payments and investments, limitations on transactions with the Company's affiliates, limitations on changes in business, limitations on amendments and waivers of certain agreements, and limitations on waivers and amendments to certain agreements, including certain portions of the Paul Capital agreements, the Company's organizational documents, and documents relating to debt that is subordinate to the Company's obligations under the GECC Credit Facility.

**2007 Plan**

On September 2, 2010, the Company's board of directors amended its 2007 Plan to increase the number of authorized plan shares to from 11,475,000 to 18,600,750 shares of common stock. This increase was approved by the Company's stockholders in October 2010. Concurrent with the amendment of the 2007 Plan, in September 2010 the board of directors granted stock options to employees, non-employee board members and consultants for an aggregate of 15,577,000 shares of common stock. The stock options have an exercise price of \$0.15 per share. In establishing the exercise price, the board of directors relied on a valuation that concluded as of August 31, 2010 the value of the Company's common stock was \$0.15 per share.

These stock options may be exercised only upon the completion of an initial public offering prior to December 31, 2012. If an initial public offering is not completed prior to December 31, 2012, then the options automatically cancel. The stock options have a 10-year term, and the option shares vest according to one of the following four schedules:

- (i) 75% of the option shares vest on the date of grant, and the remaining 25% of the option shares vest in equal successive monthly installments upon the optionee's completion of each month of service over the 12 month period following the date of grant;
- (ii) 50% of the option shares vest on the date of grant, and the remaining 50% of the option shares vest in equal successive monthly installments upon the optionee's completion of each month of service over 24 month period following the date of grant;
- (iii) 25% of the option shares vest upon optionee's completion of one year of service to the Company measured from the date of grant, and the remaining 75% of the option shares vest in equal successive monthly installments upon the optionee's completion of each month of service over the 36 month period following the first anniversary of the date of grant; or
- (iv) 50% of the option shares vest on the first anniversary of the closing of the Company's initial public offering provided that the optionee remains in service to the Company for such first year and, the remaining 50% of the option shares vest on the second anniversary of the closing of the Company's initial public offering provided that the optionee remains in service to the Company over such second year. Upon a change in control of the Company, as defined in the 2007 Plan, 100% of the shares underlying each of these options shall become vested and exercisable immediately prior to such change in control.

**Pacira Pharmaceuticals, Inc.**  
**Condensed Consolidated Balance Sheets (Unaudited)**  
**As of September 30, 2010 and December 31, 2009**

	<u>September 30,</u> <u>2010</u>	<u>December 31,</u> <u>2009</u>
	<small>(In thousands, except share and per share amounts)</small>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 13,851	\$ 7,077
Restricted cash	2,079	1,216
Trade accounts receivable	2,531	1,455
Inventories, net	1,050	1,729
Prepaid expenses and other current assets	880	1,072
Total current assets	20,391	12,549
Fixed assets, net	21,773	19,560
Intangibles, net	9,479	11,178
Other assets, net	1,113	667
Total assets	<u>\$ 52,756</u>	<u>\$ 43,954</u>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 7,015	\$ 6,994
Accrued expenses	2,984	3,478
Current portion of royalty interest obligation	1,645	1,599
Current portion of deferred revenue	2,162	2,346
Total current liabilities	13,806	14,417
Related party debt, including accrued interest	42,652	22,173
Long-term debt	11,250	—
Royalty interest obligation, excluding current portion	3,410	3,647
Deferred revenue, excluding current portion	18,783	20,387
Contingent purchase liability	2,042	2,042
Deferred rent	1,319	1,177
Other long-term liabilities	2,532	3,060
Total liabilities	95,794	66,903
Commitments and Contingencies		
Stockholders' deficit:		
Preferred stock, par value \$0.001, 88,000,000 shares authorized, 68,000,000 issued and outstanding at September 30, 2010 and December 31, 2009 (liquidation preference \$85,000,000)	68	68
Common stock, par value \$0.001, 120,000,000 shares authorized, 6,183,213 shares issued and 6,171,755 shares outstanding at September 30, 2010; 6,172,641 shares issued and outstanding at December 31, 2009	6	6
Additional paid-in capital	86,757	86,739
Accumulated deficit	(129,867)	(109,762)
	(43,036)	(22,949)
Less: treasury stock, 11,458 shares at cost	(2)	—
Total stockholders' deficit	(43,038)	(22,949)
Total liabilities and stockholders' deficit	<u>\$ 52,756</u>	<u>\$ 43,954</u>

*See accompanying notes to condensed consolidated financial statements.*

**Pacira Pharmaceuticals, Inc.**  
**Condensed Consolidated Statements of Operations (Unaudited)**  
**Nine Months Ended September 30, 2010 and 2009**

	Nine Months Ended September 30,	
	2010	2009
(in thousands, except share and per share data)		
Revenues:		
Supply revenue	\$ 7,127	\$ 4,273
Royalties	2,693	2,906
Collaborative licensing and development revenue	2,551	3,543
Total revenues	<u>12,371</u>	<u>10,722</u>
Operating expenses:		
Cost of revenues	10,168	8,823
Research and development	14,954	18,717
Selling, general and administrative	3,941	3,920
Total operating expenses	<u>29,063</u>	<u>31,460</u>
Loss from operations	(16,692)	(20,738)
Other income	100	353
Interest:		
Interest income	112	46
Interest (expense)	(2,577)	(990)
Royalty interest obligation	(1,048)	(1,407)
Net loss	<u>\$ (20,105)</u>	<u>\$ (22,736)</u>
Net loss per common share:		
Basic and diluted net loss per share	\$ (3.26)	\$ (3.69)
Weighted average shares outstanding—basic and diluted	6,174,576	6,161,112

*See accompanying notes to condensed consolidated financial statements.*

**Pacira Pharmaceuticals, Inc.**  
**Condensed Consolidated Statement of Stockholders' Deficit (Unaudited)**  
**Nine Months Ended September 30, 2010**

	<u>Preferred Stock</u>		<u>Common Stock</u>		<u>Additional</u>	<u>Accumulated</u>	<u>Treasury</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Paid-In</u>			
					<u>Capital</u>	<u>Deficit</u>	<u>Stock</u>	
Balances, January 1, 2010	68,000	\$ 68	6,173	\$ 6	\$ 86,739	\$ (109,762)	\$ —	\$ (22,949)
Exercise of stock options			10		1			1
Share-based compensation					17			17
Purchase of treasury stock							(2)	(2)
Net loss						(20,105)		(20,105)
Balances, September 30, 2010	<u>68,000</u>	<u>\$ 68</u>	<u>6,183</u>	<u>\$ 6</u>	<u>\$ 86,757</u>	<u>\$ (129,867)</u>	<u>\$ (2)</u>	<u>\$ (43,038)</u>

*See accompanying notes to condensed consolidated financial statements.*

**Pacira Pharmaceuticals, Inc.**  
**Condensed Consolidated Statement of Cash Flows (Unaudited)**  
**Nine Months Ended September 30, 2010 and 2009**

	Nine Months Ended September 30,	
	2010	2009
	(in thousands)	
<b>Operating activities:</b>		
Net loss	\$ (20,105)	\$ (22,736)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,066	3,125
Amortization of other assets and unfavorable lease obligation	(58)	(268)
Amortization of note discounts and warrants	113	424
Share-based compensation	17	518
Change in royalty interest obligation	(191)	137
Changes in operating assets and liabilities:		
Restricted cash	(863)	(457)
Trade accounts receivable	(1,076)	882
Inventories	679	(273)
Other current assets	(159)	(122)
Accounts payable	264	(3,303)
Other liabilities	919	1,406
Deferred revenue	(1,788)	(1,262)
Deferred rent	142	252
Net cash used in operating activities	<u>(19,040)</u>	<u>(21,677)</u>
<b>Investing activities</b> —Purchase of fixed assets	<u>(3,822)</u>	<u>(5,109)</u>
<b>Financing activities:</b>		
Proceeds from exercise of stock options	1	2
Purchase of treasury stock	(2)	—
Proceeds from convertible notes	—	19,025
Proceeds from secured promissory notes	18,750	—
Proceeds from credit facility	11,250	—
Financing costs	(363)	(215)
Net cash provided by financing activities	<u>29,636</u>	<u>18,812</u>
Net increase (decrease) in cash and cash equivalents	6,774	(7,974)
Cash and cash equivalents, beginning of period	7,077	12,386
Cash and cash equivalents, end of period	<u>\$ 13,851</u>	<u>\$ 4,412</u>
Supplemental cash flow information:		
Cash paid for interest	\$ 1,787	\$ 1,291
Non-cash investing and financing activities:		
Accrued fixed asset purchases	\$ —	\$ 2,254

*See accompanying notes to condensed consolidated financial statements.*

**Pacira Pharmaceuticals Inc.**  
**Notes to Condensed Consolidated Financial Statements (Unaudited)**

**1. BUSINESS**

Pacira Pharmaceuticals Inc. and its subsidiaries (collectively, the “Company” or “Pacira”) is an emerging specialty pharmaceutical company focused on the development, commercialization and manufacture of proprietary pharmaceutical products, based on its proprietary DepoFoam drug delivery technology, for use in hospitals and ambulatory surgery centers.

The Company was incorporated in Delaware under the name Blue Acquisition Corp. in December 2006 and changed its name to Pacira, Inc. in June 2007. In October 2010, the Company changed its name to Pacira Pharmaceuticals, Inc. Pacira Pharmaceuticals, Inc. is the holding company for the Company’s California operating subsidiary of the same name, which we refer to as PPI-California. The consolidated financial statements include the Company’s wholly owned subsidiaries PPI-California and Pacira Limited.

***Risks and Uncertainties***

The Company is subject to risks common to companies in similar industries and stages of development, including, but not limited to, competition from larger companies, reliance on revenue from few customers and products, new technological innovations, dependence on key personnel, reliance on third-party service providers and vendors, protection of proprietary technology, and compliance with government regulations.

***Going Concern***

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has reported net losses of \$20.1 million, and \$22.7 million and negative cash flows from operating activities of \$19.0 million and \$21.7 million for the nine months ended September 30, 2010 and 2009, respectively. As of September 30, 2010, the Company had a stockholders’ deficit of \$43.0 million. The Company has incurred losses and negative operating cash flow since inception and future losses are anticipated. The Company’s continued operations will depend on its ability to raise additional funds through sources such as equity and debt financing and revenues from commercial sale of EXPAREL. Insufficient funds could require the Company to delay, scale back or eliminate one or more of its research and development programs. The ability of the Company to continue as a going concern is dependent on improving the Company’s profitability and cash flow and securing additional financing. While the Company believes in the viability of its strategy to increase revenues and profitability and in its ability to raise additional funds, and believes that the actions presently being taken by the Company provide the opportunity for it to continue as a going concern, there can be no assurance that such financing will be available on acceptable terms, or at all. These condensed consolidated financial statements do not include any adjustments related to the recoverability and classification of asset amounts or the amounts and classification of liabilities that might be necessary if the Company is unable to continue as a going concern.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

***Basis of Presentation and Principles of Consolidation***

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries PPI-California and Pacira Limited. Pacira Limited was incorporated in the United Kingdom and its functional currency is the U.S. dollar. Intercompany accounts and transactions have been eliminated in consolidation. The consolidated financial statements for the interim periods included herein are unaudited; however, they contain all adjustments (consisting of only normal recurring adjustments) which, in the opinion of

**Pacira Pharmaceuticals, Inc.**

**Notes to Condensed Consolidated Financial Statements (Unaudited)—(continued)**

management, are necessary to present fairly the consolidated financial position of the Company as of September 30, 2010, and the results of its operations and cash flows for the nine months ended September 30, 2010 and 2009. The results of operations for the interim periods are not necessarily indicative of results that may be expected for any other interim period or for the full year. These interim financial statements should be read in conjunction with the audited annual consolidated financial statements and notes thereto included elsewhere in the registration statement.

The consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP, in accordance with the rules and regulations of the Securities and Exchange Commission for interim reporting. Pursuant to such rules and regulations, certain information and footnote disclosures normally included in complete annual financial statements have been condensed or omitted. The accounts of all wholly-owned subsidiaries are included in the consolidated financial statements. All intercompany balances and transactions have been eliminated in consolidation. The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported and the disclosure of contingent assets and liabilities. Estimates are used for, among other things, the valuation of assets acquired, valuation of common and preferred stock and stock-based compensation, unbilled revenue, customer credits and the valuation of deferred taxes. Estimates are also used to determine the remaining economic lives and recoverability of fixed assets and intangible assets. Management evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors, including the current economic environment, which management believes to be reasonable under the circumstances. Actual results could differ from those estimates.

***Concentration of Major Customers***

The Company's customers are its commercial and collaborative and licensing partners. For the nine months September 30, 2010, the Company's four largest customers accounted for 52%, 21%, 11%, and 10%, individually, of the Company's net revenues. For the nine months ended September 30, 2009, the Company's three largest customers accounted for 39%, 25%, and 22%, respectively, of the Company's net revenues. No other individual customers accounted for more than 10% of net revenues. As of September 30, 2010, the Company's two largest customers accounted for 58% and 28%, respectively, of the Company's trade accounts receivable. As of December 31, 2009, the Company's three largest customers accounted for 56%, 26% and 13%, respectively, of the Company's trade accounts receivable. The Company is dependent on these commercial partners to market and sell DepoCyt(e) and DepoDur, from which a substantial portion of its revenues are derived; therefore, the Company's future revenues from these products are highly dependent on these collaboration and distribution arrangements.

Domestic net revenues for the nine months ended September 2010 and 2009 accounted for 45% and 56% of the Company's net revenues, respectively. Export revenues for the nine months ended September 2010 and 2009 accounted for 55% and 44% of the Company's net revenues, respectively.

***Per Share Data***

Net loss per share is determined in accordance with the two-class method. This method is used for computing basic net loss per share when companies have issued securities other than common stock that contractually entitle the holder to participate in dividends and earnings of the Company. Under the two-class method, net loss is allocated between common shares and other participating securities based on their participation rights in both distributed and undistributed earnings. The Company's Series A preferred stock are participating securities, since the stockholders are entitled to share in dividends declared by the board of directors with the common stock based on their equivalent common shares.



**Pacira Pharmaceuticals, Inc.**

**Notes to Condensed Consolidated Financial Statements (Unaudited)—(continued)**

Basic net loss per share is computed by dividing net loss available (attributable) to common stockholders by the weighted average number of shares of common stock outstanding during the period. Because the holders of the Series A Convertible Preferred Stock are not contractually required to share in the Company's losses, in applying the two-class method to compute basic net loss per common share no allocation to preferred stock was made for the nine-month periods ended September 30, 2010 and 2009.

Diluted net loss per share is calculated by dividing net loss available (attributable) to common stockholders as adjusted for the effect of dilutive securities, if any, by the weighted average number of common shares and dilutive common stock outstanding during the period. Potential common shares include the shares of common stock issuable upon the exercise of outstanding stock options and a warrant (using the treasury stock method) and the conversion of the shares of Series A convertible preferred stock (using the more dilutive of the (a) as converted method or (b) the two-class method). Potential common shares in the diluted net loss per share computation are excluded to the extent that they would be anti-dilutive. No potentially dilutive securities are included in the computation of any diluted per share amounts as the Company reported a net loss for all periods presented. Potentially dilutive securities that would be issued upon the conversion of convertible notes, conversion of preferred stock and the exercise of outstanding warrants and stock options, were 77.2 million at September 30, 2010 and 77.0 million at September 30, 2009.

**3. RECENT ACCOUNTING PRONOUNCEMENTS**

In October 2009, the FASB issued Accounting Standards Update No. 2009-13, "Multiple-Deliverable Revenue Arrangements" ("ASU 2009-13"). ASU 2009-13, amends existing revenue recognition accounting pronouncements that are currently within the scope of Accounting Standards Codification, or ASC, Subtopic 605-25. This authoritative guidance provides principles for allocation of consideration among its multiple-elements, allowing more flexibility in identifying and accounting for separate deliverables under an arrangement. ASU 2009-13 introduces an estimated selling price method for valuing the elements of a bundled arrangement if vendor-specific objective evidence or third-party evidence of selling price is not available, and significantly expands related disclosure requirements. This guidance is effective on a prospective basis for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Alternatively, adoption may be on a retrospective basis, and early application is permitted. The Company is currently evaluating the impact that the adoption of this guidance will have on its consolidated results of operations, financial position or cash flows.

In April 2010, the FASB issued Accounting Standards Update No. 2010-17, "Milestone Method of Revenue Recognition (Topic 605)" ("ASU 2010-17"). This update provides guidance on defining a milestone and determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. Authoritative guidance on the use of the milestone method did not previously exist. This guidance is effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. Alternatively, retrospective adoption is permitted for all prior periods. The Company is currently evaluating the impact that the adoption of this guidance will have on its consolidated results of operations, financial position or cash flows.

Other pronouncements issued by the FASB or other authoritative accounting standards groups with future effective dates are either not applicable or not significant to the consolidated financial statements of the Company.

**Pacira Pharmaceuticals, Inc.****Notes to Condensed Consolidated Financial Statements (Unaudited)—(continued)****4. FAIR VALUE MEASUREMENTS**

Financial assets and financial liabilities are required to be measured and reported on a fair value basis using the following three categories for classification and disclosure purposes:

*Level 1:* Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

*Level 2:* Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

*Level 3:* Unobservable inputs that are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company also considers counterparty credit risk in its assessment of fair value.

The carrying value of financial instruments including cash and cash equivalents, restricted cash, accounts receivable, note receivable, and accounts payable approximate their respective fair values due to the short-term maturities of these instruments and debts. The fair value of the Company's convertible notes (see Note 6) and promissory notes (see Note 6) cannot be practicably determined due to their related party nature. The carrying amount of our borrowings under the GECC Credit Facility (see Note 6) approximates fair value. Such borrowings occurred in April, July and September, 2010 and were repaid in November 2010 (see Note 8).

**5. INVENTORIES**

The components of inventories were as follows:

	<u>September 30,</u> <u>2010</u>	(in thousands)	<u>December 31,</u> <u>2009</u>
Raw materials	\$ 758		\$ 811
Work-in-process	85		48
Finished goods	<u>302</u>		<u>965</u>
	1,145		1,824
Less provision for excess and obsolete inventories	<u>(95)</u>		<u>(95)</u>
Inventories, net	<u>\$ 1,050</u>		<u>\$ 1,729</u>

**Pacira Pharmaceuticals, Inc.****Notes to Condensed Consolidated Financial Statements (Unaudited)—(continued)****6. DEBT AND FINANCING ARRANGEMENTS**

The composition of the Company's debt and financing obligations, including accrued interest, is as follows:

	<u>September 30,</u> <u>2010</u>	<u>December 31,</u> <u>2009</u>
	(in thousands)	
Related party debt, including accrued interest:		
Convertible notes	\$ 11,522	\$ 11,124
2009 secured notes	12,002	11,049
2010 secured notes	15,273	—
HBM secured notes	3,855	—
	<u>42,652</u>	<u>22,173</u>
Long-term debt:		
GECC credit facility	11,250	—
Financing obligations:		
Royalty interest obligation, current portion	1,645	1,599
Royalty interest obligation, long-term portion	3,410	3,647
	<u>5,055</u>	<u>5,246</u>
Total debt and financing obligations	<u>\$ 58,957</u>	<u>\$ 27,419</u>

**2010 Financings:**

**2010 Secured Notes** In March 2010, the Company entered into an agreement with certain of its existing investors to issue \$15.0 million in aggregate principal amount of secured notes in a private placement (the "2010 Secured Notes"). To secure the performance of its obligations under the purchase agreement for the 2010 Secured Notes, the Company granted a subordinated security interest in substantially all of its assets, including its intellectual property assets, to the investors. The investors purchased the entire \$15 million of 2010 Secured Notes in three closings in March, June and September 2010.

The 2010 Secured Notes have an interest rate of 5% per year and all principal and accrued and unpaid interest is due on December 31, 2010. In connection with entering into the GECC Credit Facility as noted below, the maturity date was extended to the earliest of (1) a sale of the Company; (2) December 16, 2013; and, (3) 91 days after the date that all obligations under the GECC Credit Facility are paid in full and the GECC Credit Facility is terminated. Also in connection with entering into the GECC Credit Facility, the holders of the 2010 Secured Notes entered into (i) a subordination agreement with GECC pursuant to which the 2010 Secured Notes were subordinated to the GECC Credit Facility, and (ii) an inter-creditor agreement with the holders of the 2009 Convertible Notes and the 2009 Secured Notes whereby the 2009 Convertible Notes were subordinated to the 2010 Secured Notes and the 2009 Secured Notes, and the 2010 Secured Notes agreed to share payments pro rata with the holders of the 2009 Secured Notes.

The outstanding principal and accrued interest on the 2010 Secured Notes was \$15.0 million and \$0.3 million, respectively, as of September 30, 2010, and interest expense associated with these notes was \$0.3 million for the nine months ended September 30, 2010.

**HBM Secured Notes** On April 30, 2010, the Company entered into a subordinated secured note purchase agreement with entities affiliated with HBM BioVentures, or HBM, to issue \$3.75 million in aggregate principal amount of secured notes, or the HBM Secured Notes, in a private placement. Pursuant to the purchase agreement for the HBM Secured Notes, upon written notice to HBM delivered to HBM prior to September 30, 2010, HBM

**Pacira Pharmaceuticals, Inc.**

**Notes to Condensed Consolidated Financial Statements (Unaudited)—(continued)**

purchased an amount of secured notes set forth in the notice. HBM purchased the entire \$3.75 million of the HBM Secured Notes in three closings in April, June and September 2010. To secure the performance of the Company's obligations under the purchase agreement for the HBM Secured Notes, the Company granted a subordinated security interest in substantially all of its assets, including its intellectual property assets, other than the assets that secure its obligations under its agreement with RST. The HBM Secured Notes carry an interest rate of approximately 10% per year. In addition, the HBM Secured Notes require a final payment fee if they are prepaid prior to the maturity date. The maturity date of the HBM Secured Notes is the earliest of (1) a sale of the Company, (2) December 16, 2013 and (3) 91 days after the date that all obligations under the GECC Credit Facility are paid in full and the GECC Credit Facility is terminated. On April 30, 2010, the holders of the HBM Secured Notes entered into a subordination agreement with GECC pursuant to which the HBM Secured Notes were subordinated to the GECC Credit Facility.

The outstanding principal and accrued interest on the credit facilities was \$3.75 million and \$0.10 million, respectively, as of September 30, 2010, and interest expense associated with these notes was \$0.10 million for the nine months ended September 30, 2010.

***Credit Facility***

In April 2010, the Company entered into a credit facility with General Electric Capital Corporation (the "GECC Credit Facility"), with \$11.25 million available for borrowing. The Company borrowed an aggregate principal amount of \$5.63 million at the closing, \$2.81 million on July 1, 2010 and the remaining \$2.81 million on September 2, 2010. Each of the term loans under the GECC Credit Facility carries a fixed interest rate of approximately 10% that is payable monthly. The GECC Credit Facility requires no payment of principal for a year, and then equal principal payments over 24 months until the maturity dates of three years from the funding dates. The GECC Credit Facility is secured by a first priority lien on all of the Company's assets other than the assets that secure its obligations under its agreement with RST, and is guaranteed in full by certain majority investors of the Company (the "guarantors").

In connection with any prepayments of term loans under the GECC Credit Facility, the Company is required to pay, in addition to all principal and accrued and unpaid interest on such term loan, a final payment fee equal to (i) 0.45% of the original principal amount of such term loan if the prepayment is made or required before the one year anniversary of such term loan, (ii) 2.25% of the original principal amount of such term loan if the prepayment is made or required on or after the one year anniversary of such term loan but before the two year anniversary of such term loan, and (iii) 3.50% of the original principal amount of such term loan if the prepayment is made or required on or after the two year anniversary of such term loan.

The GECC Credit Facility is guaranteed by the Company and is secured by a first priority lien on all of the assets of both PPI-California and the guarantors, other than the assets that secure its obligations under its agreement with RST. In addition, the GECC Credit Facility is guaranteed by certain of the Company's investors (other than HBM) on a several and not joint basis which guarantee is limited to each investor's pro rata portion of the outstanding principal and accrued and unpaid interest under the GECC Credit Facility, but in no event to exceed \$11.25 million in the aggregate. The obligations of the investors under the guarantee is not triggered until the earlier to occur of (i) thirty days after written notice from the agent that the obligations under the GECC Credit Facility have been accelerated, and (ii) the occurrence of a bankruptcy or insolvency event with respect to the borrower, the Company or any of the investor guarantors. The guarantee by the Company's investors of the GECC Credit Facility also includes covenants that require each such investor to maintain at all times unfunded commitments from its investors in an amount equal to at least one and one-half times the maximum amount which the investor may be obligated for under the investor guarantee, and also includes certain control requirements with respect to such investors.

**Pacira Pharmaceuticals, Inc.**

**Notes to Condensed Consolidated Financial Statements (Unaudited)—(continued)**

The GECC Loan and Security Agreement contains events of default including payment default, default arising from the breach of the provisions of the GECC Loan and Security Agreement and related documents or the inaccuracy of representations and warranties, attachment default, judgment default, bankruptcy and insolvency, cross-default provision with respect to other material indebtedness, default based on the unenforceability, invalidity or revocation of a the GECC Loan and Security Agreement or any other related documents (including any guarantee or applicable subordination agreement) or any security interests, the occurrence of a material adverse effect (as defined in the GECC Loan and Security Agreement) and certain changes in control, including if the chief executive officer or chief financial officer of the borrower cease to be involved in the daily operations or management of the business, if certain holders cease to own or control at least 51% of the outstanding capital stock of the Company, if the Company ceases to own or control all the economic and voting rights of the borrower and if the borrower ceases to own or control, directly or indirectly, all of the economic or voting rights of each of its subsidiaries.

The occurrence of an event of default under the GECC Credit Facility could trigger the acceleration of the obligations under the GECC Credit Facility or allow the agent or lenders to exercise other rights and remedies, including rights against the assets which secure the GECC Credit Facility and rights under guarantees provided to support the obligations under the GECC Credit Facility.

The GECC Loan and Security Agreement contains a number of affirmative and restrictive covenants including reporting requirements, compliance with laws, protection of intellectual property and other collateral covenants, and limitations, subject to certain exceptions set forth in the GECC Loan and Security Agreement, on liens and indebtedness, limitations on dispositions, limitations on mergers and acquisitions, limitations on restricted payments and investments, limitations on transactions with the Company's affiliates, limitations on changes in business, limitations on amendments and waivers of certain agreements, and limitations on waivers and amendments to certain agreements, including certain portions of the Paul Capital agreements, the Company's organizational documents, and documents relating to debt that is subordinate to our obligations under the GECC Credit Facility.

The outstanding principal and accrued interest on the GECC Credit Facility was \$11.25 million as of September 30, 2010, and interest expense associated with this facility was \$0.03 million for the nine months ended September 30, 2010.

**STOCKHOLDERS' EQUITY**

***Pacira Stock Incentive Plan***

On September 2, 2010, the Company's board of directors amended its 2007 Plan to increase the number of authorized plan shares from 11,475,000 to 18,600,750 shares of common stock. This increase was approved by the Company's stockholders in October 2010. Concurrent with the amendment of the 2007 Plan, in September 2010 the board of directors granted stock options to employees, non-employee board members and consultants for an aggregate of 15,577,000 shares of the Company's common stock. The stock options have an exercise price of \$0.15 per share. In establishing the exercise price, the board of directors relied partly on a valuation that concluded as of August 31, 2010 the value of the Company's common stock was \$0.15 per share.

These stock options may be exercised only upon the completion of an initial public offering prior to December 31, 2012. If the Company's initial public offering is not completed prior to December 31, 2012, then the options automatically cancel in accordance with their terms. The stock options have a 10-year term, and the option shares vest according to one of the following four schedules:

(i) 75% of the option shares vest on the date of grant, and the remaining 25% of the option shares vest in equal successive monthly installments upon the optionee's completion of each month of service over the 12 month period following the date of grant;

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(ii) 50% of the option shares vest on the date of grant, and the remaining 50% of the option shares vest in equal successive monthly installments upon the optionee's completion of each month of service over the 24 month period following the date of grant;

(iii) 25% of the option shares vest upon the optionee's completion of one year of service to the Company measured from the date of grant, and the remaining 75% of the option shares vest in equal successive monthly installments upon the optionee's completion of each month of service over the 36 month period following the first anniversary of the date of grant; or

(iv) 50% of the option shares vest on the first anniversary of the closing of the Company's initial public offering provided that the optionee remains in service to the Company for such first year and, the remaining 50% of the option shares vest on the second anniversary of the closing of the Company's initial public offering provided that the optionee remains in service to the Company over such second year. Upon a change in control of the Company, as defined in the 2007 Plan, 100% of the shares underlying each of these options shall become vested and exercisable immediately prior to such change in control.

The following table summarizes the Company's stock option activity and related information for the period from January 1, 2010 to September 30, 2010:

	Shares	Weighted Average Exercise Price
Outstanding at January 1, 2010	563,883	0.17
Granted	15,668,000	0.15
Exercised	(10,572)	0.17
Forfeited	(22,233)	0.18
Expired	(22,109)	0.17
Outstanding at September 30, 2010	<u>16,176,969</u>	<u>\$ 0.15</u>

As of September 30, 2010, \$1.7 million of total unrecognized compensation cost related to non-vested stock options is expected to be recognized over the respective vesting terms of each award. The expenses associated with the options granted in September 2010, as described above, have been deferred until the successful completion of the initial public offering. The weighted average term of the unrecognized share-based compensation is 2.9 years. The weighted average fair value of the options granted during the nine months ended September 30, 2010 was \$0.10 per share.

The fair values of each option grant in 2010 and 2009 were estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

	Nine months ended	
	September 30, 2010	September 30, 2009
Expected dividend yield	None	None
Risk free interest rate	1.7-2.8%	2.1-2.7%
Expected volatility	80.8%	82.0%
Expected life of options	5.50-6.25 years	6.25 years

## 7. RELATED PARTY TRANSACTIONS

During the nine months ended September 30, 2010 and 2009, the Company entered into debt arrangements with certain investors in the Company (see Note 6). The composition of the balances due to these investors totaling \$42.7 million and \$22.2 million, including accrued interest of \$2.7 million and \$0.9 million, as of September 30, 2010 and December 31, 2009.

Stack Pharmaceuticals, Inc ("SPI"), an entity controlled by David M. Stack, the Company's chief executive officer, provides the Company use of its office facilities, which includes the use of office space for our

**Pacira Pharmaceuticals, Inc.**

**Notes to Condensed Consolidated Financial Statements (Unaudited)—(continued)**

employees, office furnishings, phone system, internet connections, printers and other related office amenities such as conference rooms. In addition, SPI also provides market research services. Pursuant to a new agreement signed in August, 2010, SPI will provide consulting services and commercial leadership related to EXPAREL regarding the development of strategic plans and analyses for the commercialization of EXPAREL, support in the development of documents, data and materials for investor and commercial partner presentations and documents, and commercial leadership in support of the Company's website. The Company incurred expenses of \$210,000 and \$157,000 for the nine months ended September 30, 2010 and 2009, respectively. The Company had no outstanding balance payable to SPI as of September 30, 2010 and December 31, 2009.

MPM Asset Management ("MPM"), an investor in the Company, provides clinical management and subscription services to the Company. The Company incurred expenses of \$583,000 and \$219,000 for the nine months ended September 30, 2010 and 2009, respectively. The Company had outstanding balances payable to MPM of \$384,000 and \$88,000 as of September 30, 2010 and December 31, 2009, respectively.

In April 2010, the Company signed a statement of work for a feasibility study with Rhythm Pharmaceuticals, Inc. The Company earned contract revenue from this statement of work during 2010. MPM and its affiliates are holders of the Company's capital stock. MPM and its affiliates are holders of the capital stock of Rhythm Pharmaceuticals, Inc. and a managing director of MPM is a member of the board of directors of Rhythm Pharmaceuticals, Inc. The Company earned \$286,000 for the nine months ended September 30, 2010. As of September 30, 2010 an amount of \$152,000 was payable by Rhythm Pharmaceuticals, Inc.

**8. SUBSEQUENT EVENTS**

The Company has evaluated events through December 3, 2010, the date at which the interim unaudited condensed consolidated financial statements were available to be issued.

***Hercules Credit Facility***

On November 24, 2010, the Company entered into a \$26.25 million credit facility with Hercules Technology Growth Capital, Inc. and Hercules Technology III, L.P., as lenders (the "Hercules Credit Facility"). At the closing of the Hercules Credit Facility, the Company entered into a term loan in the aggregate principal amount of \$26.25 million, which was the full amount available under the Hercules Credit Facility. As of November 30, 2010, the entire term loan of \$26.25 million was outstanding. The term loan under the Hercules Credit Facility is comprised of two tranches, Tranche A and Tranche B. The Tranche A portion of the term loan is comprised of \$11.25 million in principal and carries a floating per annum interest rate equal to 10.25% plus the amount, if any, by which the prime rate exceeds 4.00%. Upon the release of the investors' guaranty (described below), the interest rate on the Tranche A portion of the term loan will increase to a floating per annum interest rate equal to 11.00% plus the amount, if any, by which the prime rate exceeds 4.00%. The Tranche B portion of the term loan is comprised of \$15.0 million in principal and carries a floating per annum interest rate equal to 12.65% plus the amount, if any, by which the prime rate exceeds 4.00%. As of November 30, 2010, the interest rate on the Tranche A portion was 10.25% and on the Tranche B portion was 12.65%. Interest on the term loan is payable monthly. If there is an event of default under the Hercules Credit Facility, the Company will be obligated to pay interest at a higher default rate. The proceeds of the term loan under the Hercules Credit Facility have been used to repay the GECC Credit Facility in full and will be used for other general corporate purposes.

As further consideration to the lenders to provide the term loan to the Company under the Hercules Credit Facility, the Company issued to the lenders a warrant to purchase 1,925,000 shares of the Company's Series A convertible preferred stock. If after the closing date of the Hercules Credit Facility and prior to the completion of the Company's proposed initial public offering, the Company issues equity securities in a private placement then

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the lenders may, at their option, exercise the warrant for the same class and type of equity securities that the Company issues in such private placement in lieu of Series A convertible preferred stock. The exercise price for the shares to be issued under the warrant is equal to \$1.25 per share or the price per share paid in the next private placement. The warrant shall be valid from the date of issuance until the earlier to occur of ten (10) years from the date of issuance or five (5) years following the effective date of the registration statement of which this prospectus is a part.

The Hercules Credit Facility provides for an “interest only period” when no principal amounts are due and payable. The interest only period runs initially from November 24, 2010 through August 31, 2011, but can be extended, at the Company’s request, to either November 30, 2011 or February 28, 2012 if certain conditions are satisfied. Following the end of the interest only period, the term loan is to be repaid in 33 equal monthly installments of principal and interest beginning on the first business day after the month in which the interest only period ends. Amounts repaid may not be re-borrowed. The Company can, at any time, prepay all or any part of the term loan provided that so long as the investors’ guaranty (as described below) is in effect, the Company cannot prepay any part of the Tranche A portion of the term loan without the lenders’ consent if any of the Tranche B portion is outstanding. If the investors’ guaranty is not in effect, then any prepayments are to be applied pro rata across the outstanding balance of both portions of the term loan. In connection with any prepayments of the term loan under the Hercules Credit Facility, the Company is required to pay, in addition to all principal and accrued and unpaid interest on such term loan, a prepayment charge equal to 1.25% of the principal amount being prepaid. In addition, there is an end of term charge that is payable to the lenders upon the earliest to occur of the maturity date, the prepayment in full of the Company’s obligations under the Hercules Credit Facility and the acceleration of the Company’s obligations under the Hercules Credit Facility.

The Hercules Credit Facility is secured by a first priority lien on all of the Company’s assets other than the assets that secure the Company’s obligations under the Amended and Restated Royalty Interests Assignment Agreement (as described below). In addition, the Hercules Credit Facility is guaranteed by certain of the Company’s investors (other than entities affiliated with HBM) on a several and not joint basis, which guarantee is limited to each investor’s pro rata portion of the outstanding principal and accrued and unpaid interest under the Hercules Credit Facility, but in no event exceeding \$11.25 million in the aggregate. The Hercules loan agreement, provides that upon the occurrence of certain circumstances and upon the Company’s request, the investors’ guarantee may be terminated and released.

The Hercules loan and security agreement also contains a provision that entitles the lenders to, subject to applicable securities laws and regulatory requirements, a limited right to participate in any equity financings that occur between the closing date of the Hercules Credit Facility and the completion of the Company’s proposed initial public offering.

The Hercules loan and security agreement contains events of default including payment default, default arising from the breach of the provisions of the Hercules loan and security agreement and related documents (including the occurrence of certain changes in control, including if the Company’s chief executive officer ceases under certain conditions to be involved in the daily operations or management of the business, or if certain holders of the Company’s capital stock cease to retain, after the consummation of certain corporate transactions, shares representing more than 50% of the surviving entity after such transactions (provided that the Company’s initial public offering shall not constitute such a change in control)) or the inaccuracy of representations and warranties contained in the loan and security agreement, attachment default, bankruptcy and insolvency, cross-default with respect to certain other indebtedness (including certain events under the Amended and Restated Royalty Interests Assignment Agreement), breach of the terms of any guarantee (including the investors’ guarantee) of the Hercules Credit Facility, the occurrence of a material adverse effect (as defined in the Hercules loan and security agreement).



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The occurrence of an event of default under the Hercules Credit Facility could trigger the acceleration of the Company's obligations under the Hercules Credit Facility or allow the lenders to exercise other rights and remedies, including rights against the Company's assets that secure the Hercules Credit Facility and rights under guarantees provided to support the obligations under the Hercules Credit Facility.

The Hercules loan and security agreement contains a number of affirmative and restrictive covenants, including reporting requirements and other collateral limitations, certain limitations on liens and indebtedness, dispositions, mergers and acquisitions, restricted payments and investments, corporate changes and waivers and amendments to certain agreements, the Company's organizational documents, and documents relating to debt that is subordinate to the Company's obligations under the Hercules Credit Facility.

In connection with entering into the Hercules Credit Facility, the maturity dates of the 2009 Convertible Notes, the 2009 Secured Notes and the 2010 Secured Notes were extended to the earliest of (1) a sale of the Company, (2) the date which is 30 days after the last day of the month that is 33 months after the expiration of the "interest only period" under the Hercules Credit Facility (as described above) and (3) 91 days after the date that all obligations under the Hercules Credit Facility are paid in full and the Hercules Credit Facility is terminated.

In connection with entering into the Hercules Credit Facility, the holders of the 2009 Convertible Notes entered into a subordination and intercreditor agreement with the lenders under the Hercules Credit Facility pursuant to which the 2009 Convertible Notes were subordinated to the Hercules Credit Facility. The holders of the 2009 Convertible Notes previously entered into a separate intercreditor agreement with the holders of the 2009 Secured Notes and the 2010 Secured Notes pursuant to which the 2009 Convertible Notes were subordinated to the 2009 Secured Notes and the 2010 Secured Notes, and the holders of the 2009 Secured Notes agreed to share payments pro rata with the holders of the 2010 Secured Notes.

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**Pacira Pharmaceuticals, Inc.**

**Notes to Condensed Consolidated Financial Statements (Unaudited)—(continued)**

## Shares



## Common Stock

Prospectus

**Barclays Capital**

**Piper Jaffray**

**Wedbush PacGrow Life Sciences**

**Brean Murray, Carret & Co.**

Until \_\_\_\_\_, which is the date 25 days after the date of this prospectus, all dealers that buy, sell or trade our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to unsold allotments or subscriptions.

**PART II**  
**INFORMATION NOT REQUIRED IN PROSPECTUS**

**Item 13. Other Expenses of Issuance and Distribution**

The following table indicates the expenses to be incurred in connection with the offering described in this Registration Statement, other than underwriting discounts and commissions, all of which will be paid by the Registrant. All amounts are estimated except the Securities and Exchange Commission registration fee and the FINRA filing fee.

	<u>Amount</u>
Securities and Exchange Commission registration fee	\$ 6,150
FINRA filing fee	9,125
The NASDAQ Global Market listing fee	100,000
Accountants' fees and expenses	*
Legal fees and expenses	*
Blue Sky fees and expenses	*
Transfer Agent's fees and expenses	*
Printing and engraving expenses	*
Miscellaneous	*
Total Expenses	<u>\$ *</u>

\* To be filed by amendment

**Item 14. Indemnification of Directors and Officers**

Section 102 of the General Corporation Law of the State of Delaware permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our restated certificate of incorporation that will become effective upon the completion of this offering provides that no director of the Registrant shall be personally liable to it or its stockholders for monetary damages for any breach of fiduciary duty as director, notwithstanding any provision of law imposing such liability, except to the extent that the General Corporation Law of the State of Delaware prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the General Corporation Law of the State of Delaware provides that a corporation has the power to indemnify a director, officer, employee, or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he is or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Our restated certificate of incorporation provides that we will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than an

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action by or in the right of Pacira) by reason of the fact that he or she is or was, or has agreed to become, a director or officer of Pacira, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. Our restated certificate of incorporation provides that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of Pacira to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, a director or officer of Pacira, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee or, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of Pacira, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by us against all expenses (including attorneys' fees) actually and reasonably incurred in connection therewith. Expenses must be advanced to an Indemnitee under certain circumstances.

We intend to enter into indemnification agreements with each of our directors and our executive officers. These indemnification agreements may require us, among other things, to indemnify our directors and executive officers for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of his service as one of our directors or executive officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request.

We maintain a general liability insurance policy that covers certain liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers.

In the underwriting agreement we enter into in connection with the sale of common stock being registered hereby, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us with the meaning of the Securities Act of 1933, as amended, against certain liabilities.

**Item 15. Recent Sales of Unregistered Securities.**

Set forth below is information regarding all securities sold by us within the past three years. Also included is the consideration, if any, received by us for such shares, options and warrants and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

(a) Issuances of Securities

In March 2007, in connection with the Acquisition, we issued a total of 5,000,000 shares of common stock at a price per share of \$0.01 to HBM BioVentures (Cayman) Ltd., entities affiliated with MPM Capital, entities affiliated with Orbimed Advisors and entities affiliated with Sanderling Ventures, for an aggregate purchase price of \$50,000.

In March 2007, February 2008, July 2008 and October 2008, we issued a total of 68,000,000 shares of Series A convertible preferred stock at a price per share of \$1.25 to HBM BioVentures (Cayman) Ltd., entities

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affiliated with MPM Capital, entities affiliated with Orbimed Advisors and entities affiliated with Sanderling Ventures, for an aggregate purchase price of \$85.0 million.

No underwriters were involved in the foregoing issuances of capital stock. The capital stock described in this section (a) of Item 15 was issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(2) under the Securities Act and, in certain cases, Regulation D promulgated thereunder, relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required.

(b) Issuances of Promissory Notes

In January 2009, we issued convertible promissory notes to the Foundation for Research, HBM BioVentures (Cayman) Ltd., entities affiliated with MPM Capital, entities affiliated with Orbimed Advisors and entities affiliated with Sanderling Ventures. The aggregate principal amount of the notes issued was \$10,625,000 and the notes had an annual interest rate of 5%.

In August, September and October 2009, we issued secured promissory notes to the Foundation for Research, HBM BioVentures (Cayman) Ltd., entities affiliated with MPM Capital, entities affiliated with Orbimed Advisors and entities affiliated with Sanderling Ventures. The aggregate principal amount of the notes issued was \$9,676,972 and the notes had an annual interest rate of 12%.

In March, June and September 2010, we issued secured promissory notes to HBM BioVentures (Cayman) Ltd., entities affiliated with MPM Capital, entities affiliated with Orbimed Advisors and entities affiliated with Sanderling Ventures. The aggregate principal amount of the notes issued was \$15,000,000 and the notes had an annual interest rate of 5%.

In April, June and September 2010, we issued subordinated secured promissory notes to HBM BioVentures (Cayman) Ltd. The aggregate principal amount of the notes issued was \$3,750,000 and the notes had annual interest rates between 9.05% and 9.24%.

In April 2010, we issued a secured promissory note to General Electric Capital Corporation. The principal amount of the note issued was \$11,250,000 and the note had an annual interest rate of 9.24%.

In November 2010, we issued a secured promissory note to Hercules Technology Growth Capital, Inc. and Hercules Technology III, L.P. The principal amount of the note issued was \$26,250,000 and the note had a variable interest rate.

No underwriters were involved in the foregoing issuances of promissory notes. The promissory notes described in this section (b) of Item 15 were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(2) under the Securities Act and, in certain cases, Regulation D promulgated thereunder, relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required.

(c) Stock Option Grants

Since inception, we have issued options to certain directors, employees and consultants to purchase an aggregate of 26,587,400 shares of common stock as of November 30, 2010. As of November 30, 2010, options to purchase 1,185,296 shares of common stock had been exercised and options to purchase 16,178,011 shares of common stock remained outstanding at a weighted average exercise price of \$0.15 per share.

The stock options and the common stock issuable upon the exercise of such options as described in this section (b) of Item 15 were issued pursuant to written compensatory plans or arrangements with the Registrant's directors, employees and consultants in reliance on the exemption provided by Rule 701 promulgated under the Securities Act. All recipients either received adequate information about the Registrant or had access, through employment or other relationships, to such information.

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(d) Issuances of Warrants

In January 2009, we issued to HBM BioVentures (Cayman) Ltd., entities affiliated with MPM Capital, entities affiliated with Orbimed Advisors and entities affiliated with Sanderling Ventures warrants to purchase 1,700,000 shares of common stock in connection with the 2009 Convertible Note Financing. The common stock warrants have an exercise price of \$0.25 per share.

In June 2009, we issued warrants for an aggregate of 250,000 shares of Series A convertible preferred stock to our landlord in connection with a rent deferral.

In November 2010, we issued to Hercules Technology Growth Capital, Inc. and Hercules Technology III, L.P. a warrant to purchase 1,925,000 shares of preferred stock in connection with the Hercules Credit Facility. The preferred stock warrant has an exercise price of \$1.25 per share, which expires upon the earlier to occur of (i) November 24, 2020 or (ii) five years following the effective date of this registration statement.

No underwriters were involved in the foregoing issuances of warrants. The warrants described in this section (d) of Item 15 were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(2) under the Securities Act, including Regulation D promulgated thereunder, relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required.

All of the foregoing securities are deemed restricted securities for purposes of the Securities Act. All certificates representing the issued shares of capital stock described in this Item 15 include appropriate legends setting forth that the securities had not been registered and the applicable restrictions on transfer.

**Item 16. Exhibits**

The exhibits to the registration statement are listed in the Exhibit Index to this registration statement and are incorporated by reference herein.

**Item 17. Undertakings**

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that, in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a

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form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For purposes of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) For the purpose of determining liability under the Securities Act of 1933 to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(4) For the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

- (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
- (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
- (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
- (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.





**EXHIBIT INDEX**

<u>Exhibit number</u>	<u>Description</u>
1.1*	Form of Underwriting Agreement
3.1†	Amended and Restated Certificate of Incorporation of the Registrant, as amended to date
3.2*	Form of Restated Certificate of Incorporation of the Registrant, to be effective upon the completion of the offering
3.3†	Bylaws of the Registrant
3.4*	Form of Amended and Restated Bylaws of the Registrant, to be effective upon the completion of the offering
4.1*	Specimen Certificate evidencing shares of common stock
5.1*	Opinion of Wilmer Cutler Pickering Hale and Dorr LLP
10.1†	Second Amended and Restated 2007 Stock Option/Stock Issuance Plan
10.2†	Form of Stock Option Agreement under the Second Amended and Restated 2007 Stock Option/Stock Issuance Plan
10.3†	Investors' Rights Agreement, dated March 23, 2007, among the Registrant and the parties named therein
10.4+	Assignment Agreement, dated February 9, 1994, amended April 15, 2004, between the Registrant and Research Development Foundation
10.5+	Stock Purchase Agreement, dated January 8, 2007, between SkyePharma, Inc. and the Registrant
10.6+	Amended and Restated Royalty Interests Assignment Agreement, dated March 23, 2007, as amended, between SkyePharma, Inc. and Royalty Securitization Trust I
10.7+	Amended and Restated Security Agreement (SKPI), dated March 23, 2007, between SkyePharma, Inc. and Royalty Securitization Trust I
10.8+	Supply Agreement, dated June 30, 2003, between SkyePharma, Inc. and Mundipharma Medical Company
10.9+	Distribution Agreement, dated June 30, 2003, between SkyePharma, Inc. and Mundipharma International Holdings Limited
10.10+	Distribution Agreement, dated July 27, 2005, between SkyePharma, Inc. and Mundipharma International Holdings Limited
10.11+	Co-development, Collaboration and License Agreement, dated January 2, 2003, among Enzon Pharmaceuticals, Inc., Jagotec, AG, SkyePharma, Inc. and SkyePharma PLC
10.12+	DepoCyt Supply and Distribution Agreement, dated December 31, 2002, between SkyePharma, Inc. and Enzon Pharmaceuticals, Inc.
10.13+	Amended and Restated Strategic Licensing, Distribution and Marketing Agreement, dated October 15, 2009, between the Registrant and EKR Therapeutics, Inc.
10.14+	Amended and Restated Supply Agreement, dated October 15, 2009, between the Registrant and EKR Therapeutics, Inc.
10.15+	Strategic Marketing Agreement, dated September 25, 2007, between the Registrant and Flynn Pharma Limited
10.16+	Supply Agreement, dated December 5, 2007, between the Registrant and Flynn Pharma Limited
10.17†	Lease Agreement, dated August 17, 1993, amended July 2, 2009, between Pacira Pharmaceuticals, Inc. and HCP TPSP, LLC

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<u>Exhibit number</u>	<u>Description</u>
10.18†	Lease Agreement, dated December 8, 1994, amended July 2, 2009, between Pacira Pharmaceuticals, Inc. and LASDK Limited Partnership
10.19	Services Agreement, dated October 28, 2010, between the Registrant, MPM Asset Management LLC and Gary Patou
10.20	Services Agreement, dated September 15, 2010, between Pacira Pharmaceuticals, Inc. and Stack Pharmaceuticals, Inc.
10.21	Employment Agreement between the Registrant and David Stack
10.22	Employment Agreement between the Registrant and James Scibetta
10.23	Employment Agreement between the Registrant and Mark Walters
10.24	Employment Agreement between the Registrant and William Lambert
10.25	Loan and Security Agreement, dated November 24, 2010, among the Registrant, Pacira Pharmaceuticals, Inc. (California), Hercules Technology Growth Capital, Inc. and Hercules Technology II, L.P.
10.26	Guaranty Agreement, dated November 24, 2010, between the Registrant, Hercules Technology Growth Capital, Inc., Hercules Technology II, L.P. and the parties named therein
10.27	Warrant to purchase preferred stock of the Registrant, dated November 24, 2010
10.28†	Form of Warrant to purchase Series A convertible preferred stock of the Registrant, dated July 2, 2009
10.29†	Form of Warrant to purchase common stock of the Registrant, dated January 22, 2009
21.1†	Subsidiaries of Registrant
23.1	Consent of J.H. Cohn LLP
23.2*	Consent of Wilmer Cutler Pickering Hale and Dorr LLP (included in Exhibit 5.1)
24.1†	Powers of Attorney

† Previously filed.

\* To be filed by amendment.

+ Confidential treatment requested as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

**ASSIGNMENT AGREEMENT**

This Assignment Agreement (hereinafter referred to as "Agreement") is made and entered into as of the 9<sup>th</sup> day of February, 1994, by and between RESEARCH DEVELOPMENT FOUNDATION (hereinafter referred to as "RDF"), a Nevada nonprofit corporation having its office at 402 North Division Street, Carson City, Nevada, 89703;

**AND**

DEPOTECH CORPORATION (hereinafter referred to as "DepoTech"), a California corporation, having an office at 11025 North Torrey Pines Road, Suite 100, La Jolla, California, 92037.

**WITNESSETH:**

WHEREAS, RDF is a nonprofit organization exempt from taxation under Section 501 (c)(3) of the Internal Revenue Code of 1986;

WHEREAS, RDF is the owner of certain inventions, discoveries, and know-how comprising certain Proprietary Property (as hereinafter defined) described in Exhibit 1 hereto;

WHEREAS, RDF is the owner of all the right, title and interest in and to said Proprietary Property and has determined that assignment thereof to Licensee is the only practicable manner in which the Proprietary Property can be utilized to benefit the public;

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WHEREAS, RDF has filed and intends to file for patents and/or other protection therefor in the countries listed in Exhibit 2 hereto (hereinafter referred to as “worldwide”) as provided herein; and

WHEREAS, DepoTech desires to obtain the exclusive worldwide rights to use, make, produce and sell methods, processes, or products of RDF’s Proprietary Property;

NOW, THEREFORE, in consideration of the above premises and the covenants herein, the parties agree as follows:

ARTICLE I

Definitions

As used in this Agreement, the following terms shall have the following respective meanings:

1.1 The term “Proprietary Property” shall mean and include developments, patent rights, copyrights, as well as all patent applications, techniques, methods, processes, apparatus, products, data, trade secrets, confidential information, improvements thereto, modifications thereof, and Know-How, whether patentable or not, related to the technology described in Exhibit 1 hereto;

1.2 The term “Patent Rights” or “Rights in Patents” shall mean any pending United States patent application, any pending foreign patent application, and/or any patent now or hereafter owned or controlled by, or assigned to, RDF and any divisions, continuations and continuations-in-part based thereon, any reissues, patents of addition or importation, or other extensions thereof, and includes any pending patent applications and patents issuing thereon during the term of this Agreement which cover improvements and modifications related to the foregoing technology.

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1.3 The term “Know-How” shall mean all information, data, specifications, techniques, software, methods of manufacture, and clinical, as well as diagnostic, information relating to RDF’s Proprietary Property which is known to RDF, which RDF is free to disseminate without accounting to others and which is not in the public domain (as defined in Article XIII, paragraphs [a]-[d]).

1.4 The term “Assigned Proprietary Property” shall mean and include the Proprietary Property, including the Patent Rights, Rights in Patents and Know-How, all of which are assigned hereunder to DepoTech.

1.5 The term “Assigned Applications” shall mean patent application rights included within Proprietary Property, and any division, continuation, extension or confirmation rights with respect to the filings thereof in the United States of America and foreign countries.

1.6 The term “Assigned Patents” shall mean, both individually and collectively, the United States of America and Foreign Patents included within Proprietary Property and any division, reissue, continuation or extension thereof.

1.7 The term “Product” shall mean a product or portion of a product that where made, used or sold “embodies an invention there claimed, or which is specifically intended to be used to practice a method or process there claimed, in an Assigned Patent (or a patent application if the resulting Letters Patent would constitute an “Assigned Patent” hereunder) and which is manufactured and sold by or for DepoTech (or its licensees).

1.8 The term “Improvements” shall mean any improvement and/or modification of the Assigned Proprietary Property that comes within the claims of the Assigned Patents.

1.9 The term “Subsidiaries” shall mean any present or future companies organized under the laws of any nation with respect to which (i) at least fifty percent (50%) in value or (ii)

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at least fifty percent (50%) of the total combined voting power of all classes of shares entitled to vote is directly or indirectly under the control of DepoTech. The term "DepoTech" wherever used herein shall include any Subsidiaries of DepoTech.

1.10 The term "Gross Revenues" shall mean charges actually collected by DepoTech from sales, rental, lease, licensing, maintenance, or production of a Product or from licensing or the use of Assigned Proprietary Property to a third party, less:

- (a) Usual trade and/or cash discounts actually allowed and taken;
- (b) Forwarding expenses, freight, special packaging charges, postage and duties actually paid or allowed and taxes imposed directly on the seller with respect to such sales and other transactions;
- (c) Credits for goods returned; and
- (d) Government-related retroactive price reductions or rebates.

No other allowance or deduction shall be made by whatever name known. Notwithstanding the foregoing, Gross Revenues shall not include payments and fees relating to research, development and/or regulatory approval contracts or the like.

1.11 The terms "commercialize" and "commercialization" shall mean the sale, licensing, or other use by DepoTech of the right to use the method and process or to manufacture and distribute for sale to the public the Assigned Proprietary Property under such circumstances as may be permitted by applicable international, federal, and state laws and regulations.

## ARTICLE II

### Assignment

2.1 RDF hereby assigns to DepoTech all right, title, and interest in the Assigned Proprietary Property such that DepoTech shall have the exclusive rights to produce, have

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produced, to make, have made, to manufacture, have manufactured for it, to use and/or to sell, rent or lease the apparatus, products, techniques, methods, processes, advances, developments, and inventions employing the Assigned Proprietary Property throughout the world. Except as provided herein, no other, further, or different property or rights are hereby assigned or granted, either expressly or by implication.

2.2 DepoTech shall give to RDF written notice of licenses to others, and RDF shall be a third party beneficiary of each such license.

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ARTICLE III

Improvements, Patents and Publication

3.1 DepoTech agrees, at DepoTech's expense, to timely file patent applications relating to the Proprietary Property in the territories listed on Exhibit 2 hereto (except to the extent such applications have previously been filed by RDF).

3.2 DepoTech further agrees to use its best efforts to prosecute such patent applications and to maintain any patents issued thereon. Notwithstanding the foregoing sentence, in the event that DepoTech reasonably determines that prosecution or maintenance of a patent in a particular territory is not economically viable, DepoTech shall promptly notify RDF of DepoTech's intention to abandon such patent application or patent. Upon receipt of such notice, RDF, in its sole discretion, may elect to assume responsibility (and to pay associated fees and expenses) with respect to a patent application or patent which DepoTech intends to abandon. If RDF elects to assume responsibility for a patent application or patent which DepoTech intends to abandon, DepoTech shall assign such patent application or patent to RDF. RDF may, in its sole discretion, abandon any patent application or patent for which it has previously assumed responsibility and will not be liable to DepoTech in any way for such abandonment.

3.3 Consistent with the definitions contained in Article I, RDF agrees to make available promptly to DepoTech during the term of this Agreement any Improvements now or hereafter found, owned, or controlled by RDF, and to submit to DepoTech all available Know-How pertaining thereto. Such Improvements in or to the Assigned Proprietary Property and the corresponding rights throughout the world in patents or copyrights shall be included in the Assigned Proprietary Property which is assigned to DepoTech pursuant to Article II upon the same terms and conditions set forth in this Agreement.



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3.4 DepoTech shall reasonably, promptly submit to RDF during the term of this Agreement all available information and Know-How on any Improvements, whether patentable, copyrightable or not, now or hereafter found, discovered, invented, owned, or controlled by DepoTech.

3.5 Any Improvements, whether patentable, copyrightable or not, now or hereafter made and conceived by agents or employees of DepoTech, either independently or jointly with others, shall to the extent of DepoTech's rights therein be considered as part of the Assigned Proprietary Property. The world-wide rights in the corresponding patents, patent applications, copyrights and/or Know-How shall be the property of DepoTech subject to all the terms and conditions of this Agreement. RDF shall reimburse DepoTech for the salaries, costs and expenses DepoTech incurs directly (excluding indirect overhead) in conceiving, developing and reducing to practice Improvements included in the Assigned Proprietary Property that are subject to this Section wherein ownership is vested in DepoTech. Said reimbursement shall be effectuated by DepoTech retaining [\*\*] percent ([\*\*]%) of the royalties and payments resulting from such Improvements due and payable to RDF pursuant to Article IV. The total amount to be reimbursed hereunder for all Improvements subject to this Section shall not exceed the amount of \$[\*\*].

3.6 If patentable or otherwise protectable Improvements are now or hereafter made and conceived by agents or employees of DepoTech or RDF, either independently or jointly with others, and DepoTech, at its sole discretion, considers it desirable to obtain patent, copyright, or other protection thereon, RDF agrees to cooperate fully and to do all proper things necessary or desirable to obtain and maintain patent, copyright or other protection therefor throughout the world, all at DepoTech's expense.

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3.7 Notwithstanding the provisions in Section 3.6 above, if DepoTech fails to file an application for patent or other protection therefor within six (6) months after receipt of a written request from RDF to do so, DepoTech shall be deemed to have consented to RDF obtaining and maintaining the necessary protection therefor at RDF's expense, in which event all right, title and interest in such Improvements shall be the property of RDF, subject to: (i) DepoTech's right to open negotiations with RDF for a license back to DepoTech of such Improvements, and (ii) a right of first refusal on the part of DepoTech. The right of first refusal provided by this Section is exercisable as follows: if a license of all or a part of RDF's interest in Improvements acquired under this Section is to be offered to any party not under the exclusive control of RDF (hereafter, a "third party"), or if RDF receives an offer from a third party for a license of such Improvements by RDF, then RDF shall notify DepoTech in writing of its intent to make or consider the offer and of the terms of the offer.

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DepoTech shall then have a period of ninety (90) days from its receipt of the notice to respond thereto with an offer of terms for the license of the Improvements to DepoTech, which offer will be considered with good business judgment by RDF. Any competing offer made by or to RDF prior to the expiration of the ninety (90) day period will not be available for acceptance until (a) the expiration of the ninety (90) day period, and (b) RDF's consideration of, and response to, any offer made by DepoTech. The filing and prosecuting of the United States patent applications by DepoTech or RDF, at DepoTech's expense, shall in no case go beyond an appeal to and a decision by the United States Patent and Trademark Board of Appeals or the highest administrative patent authority in any other territory, unless DepoTech specifically agrees to further proceedings in writing. RDF may pursue further proceedings at its expense without the written authorization of DepoTech.

3.8 If either DepoTech or RDF files patent applications or otherwise obtains patent rights or copyrights which relate to the Assigned Proprietary Property, such patent application, patent rights or copyrights shall be included in the Assigned Proprietary Property, and DepoTech shall have exclusive worldwide rights thereto under the terms and conditions as set forth in this Agreement.

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ARTICLE IV

Royalties

4.1 As consideration for granting of the assignment herein by RDF, DepoTech shall pay RDF during the term of this Agreement an earned royalty of [\*\*] percent ([\*\*]%) on Gross Revenues.

4.2 Only one royalty shall be payable on a Product, regardless of the number of Assigned Applications and Assigned Patents of the Assigned Proprietary Property under which such Product has been manufactured, used or sold. In those cases where a Product is sold as a part of an article which includes additional materials or components, the production of which does not use the inventions, processes or methods of the Assigned Proprietary Property, the Gross Revenues shall be based on the sales price at which DepoTech would sell the Product or services with respect to Product independently of such other materials or components in an arm's length transaction.

4.3 Royalty payments, as provided in Section 4.1 of this Agreement, to be paid hereunder, shall be paid for a period extending from the first commercial revenue actually collected by DepoTech for the life of the last to expire of the patents or patent applications, of the Assigned Proprietary Property. Royalty payments shall cease for any patent which has been declared invalid by a final determination or judgment, or if this Agreement is terminated as hereinafter specified and provided.

4.4 DepoTech will pay to RDF [\*\*] percent ([\*\*]%) of the royalties or other consideration received from licensees with respect to the license of the Assigned Proprietary Property or the amount of royalty DepoTech would have owed pursuant to Section 4.1 had it engaged in the same conduct as said licensees, whichever is greater.

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4.5 Wherever this Agreement provides that DepoTech may deduct expenses, payments or other amounts from royalties payable to RDF, (a) such deduction shall be applied only against royalties received from the territory with respect to which such deduction arose, and (b) such deduction shall be prorated over such time as is necessary to assure that the royalties payable to RDF from such territory in any period shall not be reduced by more than [\*\*] percent ([\*\*]%).

ARTICLE V

Payment and Reports

5.1 DepoTech shall notify RDF, in writing, within thirty (30) days of the date of the first commercial making, use, sale, or production employing the Assigned Proprietary Property.

5.2 DepoTech agrees that beginning with the date of the first commercial making, use, sale, or production of the Assigned Proprietary Property, RDF shall receive within sixty (60) days after the end of each of the first three fiscal quarters and within ninety (90) days after the fiscal year end:

- (a) Payment of earned royalties; and
- (b) A report showing the information and basis on which the earned royalties have been calculated.

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5.3 All royalties payable by DepoTech shall be paid in U.S. Dollars. Conversion from currencies other than U.S. Dollars shall be at the rate of exchange used by DepoTech for its general accounting purposes, consistent with generally accepted accounting principles.

5.4 Until such time as royalties become payable pursuant to this Agreement, DepoTech agrees to make an annual report to RDF each April covering DepoTech's progress during the previous calendar year with respect to research, development and commercialization of the Assigned Proprietary Property.

5.5 DepoTech also agrees to make a written report to RDF within ninety (90) days after the termination of this Agreement, stating in such report the royalties payable hereunder, the basis therefor, and the reason not previously reported and paid to RDF. DepoTech shall also continue to make annual reports pursuant to the provisions of this Agreement covering sales, uses, or production and the applicable earned royalties hereunder for Assigned Proprietary Property and Products produced, during the term of this Agreement, but not sold or used until after termination thereof, until such time as all such reportable sales, uses, making, or production shall have terminated. Concurrent with the submittal of each post-termination report, DepoTech shall pay RDF all applicable royalties.

5.6 DepoTech shall keep full, true, clear and accurate records and books of account with respect to the Assigned Proprietary Property subject to royalty. Said records and books of account shall be kept by DepoTech at the usual places where their like records and books are kept and shall be retained for a period of five (5) years following the end of the calendar year to which they pertain. RDF shall have the right through its designated representatives to examine and audit, at a reasonable time, all such records and books of account and such other records and accounts as may under recognized accounting practices contain information bearing upon the

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amount of royalty payable to it under this Agreement. Prompt adjustment shall be made by the proper party to compensate for any errors or omissions disclosed by such examination or audit. Neither such right to examine and audit nor the right to receive such adjustment shall be affected by any statement to the contrary appearing on checks or otherwise, unless such statements appear in a letter, signed by the party having such right and delivered to the other party, expressly waiving such right. Notwithstanding the foregoing, RDF may require DepoTech to furnish any other information reasonably requested to enable RDF to evaluate DepoTech's performance under this Agreement. Information obtained by RDF or its designated representative, pursuant to this paragraph 5.6, shall be treated as confidential and not disclosed to third parties, except to the extent necessary to enforce this Agreement or to prepare accounting and financial records and reports of RDF.

5.7 Royalty payments provided for in this Agreement shall, when overdue, bear interest at the then existing prime rate at Citibank of New York plus [\*\*] percent ([\*\*]%) per annum until paid, but in no event shall such interest exceed the usury limit as it exists from time to time in the State of Nevada.

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ARTICLE VI

Effort to Commercialize

6.1 DepoTech shall undertake to use its best efforts with regard to commercialization of the Assigned Proprietary Property. DepoTech shall be considered to have utilized its best efforts if it pays to RDF within ninety (90) days after calendar year end the amounts specified below. Such payments shall begin with the calendar year in which occurs the date (the "Beginning Date") of the earlier of (a) FDA approval of the Product, or (b) the first commercial sale by DepoTech or a licensee of the Product:

- (a) For calendar year of Beginning Date, at least \$[\*\*].
- (b) For first calendar year after Beginning Date, at least \$[\*\*].
- (c) For second calendar year after Beginning Date, at least \$[\*\*].
- (d) For each succeeding calendar year, at least \$[\*\*].

The amounts paid may be earned royalties, payments attributable to licensing, or advances to be credited against future royalties payable by DepoTech to RDF.

6.2 In the event DepoTech shall fail to meet the requirements for commercialization set forth in Section 6.1 of this Article, RDF, in its sole discretion, may either convert this Agreement into a non-exclusive license agreement or terminate this Agreement pursuant to the provisions of Article IX.



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ARTICLE VII

Protection of Patents

7.1 DepoTech agrees where economically justified and within reasonable limits to protect the patent and/or Know-How of the Assigned Proprietary Property from infringement or misappropriation by third parties and to prosecute such infringers or defendants, but the decision to undertake such protection shall be in the sole discretion of DepoTech. DepoTech shall be entitled to deduct all its non-reimbursed expenses, including costs and legal fees incurred in bringing and prosecuting such infringement or misappropriation action, from royalties due RDF after commencement of such infringement or misappropriation action. In the event DepoTech desires to settle or compromise such suit or action in a manner that adversely impacts RDF or the Assigned Proprietary Property, DepoTech shall not so settle or compromise such suit or action without the written consent of RDF. In the event that DepoTech shall recover profits and/or damages from said infringer or defendant, DepoTech agrees to turn over to RDF [\*\*] percent (\*\*)% of any amounts paid to it by said infringer or defendant after deducting any of its expenses, including costs and legal fees incurred in such litigation, which DepoTech has not previously deducted from royalties payable to RDF.

7.2 RDF and DepoTech shall each give immediate written notice to the other of any infringement of a patent or misappropriation of Know-How of the Assigned Proprietary Property by any third party as may come to its knowledge. Notwithstanding Section 7.1, if DepoTech has not within six (6) months from the date on which it is notified or otherwise becomes aware of an infringement or misappropriation either terminated such infringement or initiated legal action against the infringer or defendant, it shall, upon written request of RDF, grant to RDF the right to prosecute an action against the infringer or defendant. DepoTech agrees, in the event that RDF

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cannot prosecute such infringement or misappropriation in its own name, to sign and give to RDF, as soon as practicable, all necessary documents in order for RDF to prosecute in the name of DepoTech, such infringement or misappropriation. In the event RDF shall recover profits and/or damages from said infringer or defendant, RDF agrees to turn over to DepoTech [\*\*] percent ([\*\*]%) of any amounts paid to it by said infringer or defendant after deducting any of its expenses, including costs and legal fees, incurred in such litigation.

7.3 DepoTech shall promptly advise RDF in writing of any notice or claim of any infringement and of the commencement against it of any suit or action for infringement of a third party patent made or brought against DepoTech and based upon the use hereunder by DepoTech of the Assigned Proprietary Property. RDF shall have the right either to:

- (a) Request that DepoTech enter into negotiations with such third party to obtain rights under the third party patent; or
- (b) Request that DepoTech defend such suit or action at DepoTech's expense.

7.4 DepoTech is neither obligated to enter into negotiations with such third party to obtain rights under the third party patent nor obligated to defend such suit or action. If DepoTech, at its sole discretion, elects to enter into negotiations with such third party to obtain rights under the third party patent, or if DepoTech, at its sole discretion, elects to undertake at its own expense the defense of any such suit or action to the extent that the alleged infringement is based upon such use hereunder of the Assigned Proprietary Property, RDF shall render DepoTech all reasonable assistance that may be required by DepoTech in the negotiations or in the defense of such suit or action. DepoTech has the primary right to control the defense of any such suit or action by counsel of its own choice, and RDF shall have the right, at its own expense, to be represented in any such suit or action in respect of which RDF is a defendant by

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counsel of its own choice, subject to DepoTech's right of control. Notwithstanding the foregoing, if DepoTech has not within ninety (90) days (or such lesser period of time as is necessary to avoid entry of a default judgment against DepoTech or RDF) from the date of receipt of a request from RDF under Section 7.3 either entered into negotiations with such third party to obtain rights under the third party patent or initiated legal action to defend such suit, it shall, upon written request of RDF, grant to RDF the right to enter such negotiations or defend such suit. DepoTech shall be entitled to deduct all its expenses, including costs and legal fees, incurred in entering into such negotiations or defending such suit from royalties due RDF after commencement of such action. In the event DepoTech desires to settle or compromise any such suit or action in a manner that adversely impacts RDF or the Assigned Proprietary Property, DepoTech shall not settle or compromise any such suit or action without the written consent of RDF, which consent shall not be unreasonably withheld.

7.5 In negotiating with such third party to obtain rights under such third party patents, and if, in obtaining such rights, DepoTech is required to make any payment to such third party, DepoTech shall be entitled to deduct such payment from the royalty payable to RDF.

## ARTICLE VIII

### Disclaimer of Liability and/or Warranty

8.1 Notwithstanding provisions in Article VII of this Agreement, nothing in this Agreement shall be construed as:

- (a) a warranty or representation by RDF as to the validity or scope of any Assigned Proprietary Property; or
- (b) a warranty or representation that anything sold, used, produced or otherwise disposed of under any assignment or license granted in this Agreement is or will be free from infringement of patents, copyrights, and/or trademarks of third parties; or

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(c) an express or implied warranty of merchantability or fitness for a particular purpose.

8.2 RDF shall exercise reasonable care in verifying the accuracy of information provided under this Agreement, but RDF shall not be liable for any damages arising out of or resulting from any information made available hereunder or of the use thereof, nor shall it be liable to DepoTech for consequential damages under any circumstances.

8.3 RDF shall have no responsibility for the ability of DepoTech to use such information, the quality or performance of any process or any product produced by DepoTech with the aid of such information or with respect to claims of third parties arising from DepoTech's use of such information.

8.4 DepoTech shall assume all responsibility and liability for the sale, use, production, and/or commercialization of the Assigned Proprietary Property, including, but not limited to, the safety, effectiveness, and reliability of the process and/or products produced pursuant to this Agreement. DepoTech further agrees to defend, indemnify, and hold RDF, its trustees, directors, officers, employees, agents, representatives, successors, assigns and affiliated entities, harmless from and against any and all liability, demands, damages, expenses and losses for death, personal injury, illness, or property damage, including the cost of defense against same, which may be asserted, or any claims which may arise from the sale, use, production, commercialization, or other disposition of the Assigned Proprietary Property. DepoTech acknowledges that the Assigned Proprietary Property hereby is experimental and agrees to take all reasonable precautions to prevent death, personal injury, illness, and property damage.

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8.5 DepoTech agrees to purchase and/or maintain insurance coverage sufficient, taking into account its other assets, to establish the ability of DepoTech to honor the indemnity made in Section 8.4 and shall name RDF as an additional named insured on such policy.

ARTICLE IX

Term and Termination

9.1 The term of this Agreement shall be for the life of the last to expire of the patents or patent applications of the Assigned Proprietary Property, whichever is later, unless sooner terminated as herein provided.

9.2 If DepoTech shall determine that it intends to declare itself insolvent or file for bankruptcy or reorganization, it shall give ten (10) days' written notice to RDF. Notwithstanding the above, if DepoTech shall become bankrupt or insolvent; if the business or any assets or property of DepoTech shall be placed in the hands of a receiver, assignee or trustee, whether by the voluntary act of DepoTech or otherwise; if DepoTech institutes or suffers to be instituted any procedure in bankruptcy court for reorganization or rearrangement of its financial affairs; or if DepoTech makes a general assignment for the benefit of creditors, this Agreement shall immediately terminate, and DepoTech shall reassign to RDF all right, title, and interest in the Assigned Proprietary Property, unless such bankruptcy, insolvency, receivership or assignment for the benefit of creditors shall have been cured within thirty (30) days of such event occurring. Upon occurrence of any of the foregoing events, DepoTech shall give immediate written notice thereof to RDF.

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9.3 Upon any material breach or material default under this Agreement by DepoTech, RDF may give written notice thereof to DepoTech, and DepoTech shall have ninety (90) days after such notice to cure such breach or default. If such breach or default is not so cured, RDF may then in its sole discretion and option (a) convert this Agreement into a non-exclusive license agreement, or (b) terminate this Agreement whereupon DepoTech shall reassign to RDF the Assigned Proprietary Property or (c) seek such other relief as may be provided by law in such circumstances by giving written notice thereof to DepoTech.

9.4 If DepoTech contests or assists another in contesting the validity of any of the patents assigned hereunder in a court of competent jurisdiction, RDF shall have the right to terminate this Agreement, whereupon DepoTech shall reassign to RDF the Assigned Proprietary Property.

9.5 Upon termination of this Agreement by reason of any breach or default of DepoTech, DepoTech agrees to discontinue the commercialization of the Assigned Proprietary Property, except for the sale of goods on hand.

9.6 Upon termination hereof for any reason, the licenses to third parties by DepoTech under the terms and conditions herein set forth shall remain in effect in accordance with the terms thereof, and DepoTech shall assign such Agreements to RDF.

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ARTICLE X

Representations and Warranties

10.1 RDF represents and warrants that it owns the Assigned Proprietary Property and has the legal power and authority to extend the rights granted to DepoTech pursuant to this Agreement and has not assigned, licensed, pledged or compromised the Assigned Proprietary Property or made any commitments or offers inconsistent with or in derogation of the rights created by this Agreement.

10.2 RDF represents and warrants that it has no knowledge of any information likely to have a material effect on the validity or enforceability of any Assigned Patent or any claim thereof which was not disclosed to the Patent Office at the time that the Patent Applications for the technology set forth on Exhibit 1 hereto were filed or during the pendency of said applications.

10.3 DepoTech represents and warrants that it has full power and authority to enter into this Agreement and to carry out the transactions contemplated hereby.

10.4 DepoTech represents and warrants that it has no knowledge of any third party patent that would present a question of infringement with respect to Products.

ARTICLE XI

Agency/Partnership

11.1 Neither party shall be deemed to be an agent of the other party as a result of any transaction under or related to this Agreement, and shall not in any way pledge the other party's credit or incur any obligations on behalf of the other party.

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11.2 This Agreement shall not constitute either a partnership or a joint venture, and neither party may be bound by the other to any contract, arrangement or understanding except as specifically stated herein.

11.3 Except as required by state or federal law, and subject to an exception for private and confidential discussions between DepoTech and potential corporate partners or licensees, DepoTech (including any affiliate or licensee of DepoTech) shall not, without prior written consent obtained from RDF, use for purposes of sales, advertising, marketing, marking of goods, promotion to investors, press releases or other publicity, etc.: (i) the name of (or any other information which would identify) RDF or any corporation which is controlled by the same persons who control RDF (“controlled corporation”); (ii) the names of trustees, directors, officers, or employees of RDF or a controlled corporation; or (iii) any trademarks (or adaptations thereof) of RDF or a controlled corporation.

## ARTICLE XII

### Marking

DepoTech agrees to apply or have applied to all articles where practical and to all containers containing products manufactured by it under this Agreement such patent notices as may be required by the laws of the territories where manufactured or as may reasonably be requested by RDF.



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ARTICLE XIII

Nondisclosure of Confidential Information

13.1 All Proprietary Property and confidential scientific and technical information communicated by either party to the other under this Agreement, including information contained in patent applications, shall be kept confidential by each party, who shall not disclose it to anyone without first receiving the written consent of the other party to do so. Notwithstanding the foregoing, each party shall be relieved of the confidentiality obligations herein and not be prevented by this Agreement from utilizing any information received by it from the other party if:

- (a) The information was previously known to such party, but not including what was previously known to the inventors of the Proprietary Property;
- (b) The information is or becomes generally available to the public through no fault of such party, including as a result of publications and/or laying open to inspection of any patent applications that RDF may file corresponding to such U.S. or foreign patent applications;
- (c) The information is acquired in good faith in the future by such party from a third party who is not under an obligation of confidence to the other party in respect to such information;
- (d) The disclosure of such information is essential for the commercial exploitation of the Proprietary Property under this Agreement.

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13.2 The agreement of DepoTech to maintain the Proprietary Property as confidential shall survive termination of this Agreement, regardless of the reason for its termination.

ARTICLE XIV

Miscellaneous

14.1 The captions herein are for convenience only and shall not be deemed to limit or otherwise affect the construction hereof.

14.2 All written notices, payments, reports and the like required or permitted hereunder shall be deemed to be given when mailed, postage prepaid, by registered or certified mail, if to RDF to:

Research Development Foundation  
c/o Andrew MacKenzie, Esq.  
402 North Division Street  
Carson City, Nevada 89703  
Attn: C. W. Wellen, President  
cc: James F. Weiler, Esq.

and if to DepoTech to:

DepoTech Corporation  
11025 North Torrey Pines Road  
Suite 100  
La Jolla, California 92037  
Attn: Edward L. Erickson, President

or to such other person or by such other means as to which the parties may from time to time agree.

14.3 This Agreement, in whole or in part, shall not be assignable by either party without prior written consent of the other (unless to a successor entity to the assigning party by merger, acquisition or other reorganization), which consent will not be unreasonably withheld, and any attempted assignment without such consent shall be void.

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14.4 The failure of either party to enforce at any time any of the provisions of this Agreement, or any rights in respect thereto, or to exercise any election herein provided, shall in no way be considered to be a waiver of such provisions, rights, or elections, or in any way to affect the validity of this Agreement. The exercise by either party of any of its rights herein or any of its elections under the terms or covenants herein shall not preclude either party from exercising the same or any other rights it may have under this Agreement, irrespective of any previous action or proceeding taken by either party hereunder.

14.5 This Agreement shall be governed and construed in accordance with the laws of the State of Nevada, U.S.A.

14.6 If any provision of this Agreement is judicially determined to be void or unenforceable, such provision shall be construed to be severable from the other provisions of this Agreement which shall retain full force and effect.

14.7 The parties hereto agree promptly to execute, forward, or otherwise provide all documents and material necessary or desirable to effectuate this Agreement.

14.8 The terms and conditions herein contained constitute the entire agreement between the parties and shall supersede all previous communications, either oral or written, between the parties hereto with respect to the subject matter hereof. No agreement or understanding bearing on the same shall be binding upon either party hereto unless it shall be in writing and signed by the duly authorized officer or representative of each of the parties and shall expressly refer to this Agreement.

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14.9 This Agreement shall be binding on and shall inure to the benefit of the parties hereto, and their respective successors and assigns.

14.10 Mention is made that by an agreement between the parties dated August 3, 1993, providing for the assignment of the Proprietary Property to DepoTech from RDF, DepoTech agreed to reimburse RDF for costs and expenses incurred to the date of the assignment in obtaining and maintaining patent protection for the Proprietary Property (approximately \$[\*\*]) reduced by costs and expenses incurred to the date of the assignment by DepoTech in connection with the patenting of the Proprietary Property (approximately \$[\*\*]). In lieu of a cash payment for such reimbursement, DepoTech agreed to give RDF a credit note for such amount which can be applied at the option of RDF against:

(a) the "Exercise Price" to be paid by RDF upon exercise of warrants to purchase DepoTech shares pursuant to the Warrant Agreement between the parties dated August 14, 1990; or

(b) royalties earned and payable on Improvements which would otherwise be credited to DepoTech under Section 3.5 of this Agreement; provided that, at any time after three (3) years from the date of this Agreement, RDF, at its option, may require that DepoTech elect to either: (i) pay off the remaining balance of the credit note in cash, or (ii) assign the Proprietary Property back to RDF (subject to an exclusive license back to DepoTech).

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed in multiple originals by their duly authorized representatives.

RESEARCH DEVELOPMENT FOUNDATION

By: /s/ Andrew MacKenzie  
Name: Andrew MacKenzie  
Title: Vice President

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DEPOTECH CORPORATION

By: /s/ Edward L. Erickson, President  
Edward L. Erickson, President

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EXHIBIT 1

Proprietary Property

The technology of “[\*\*],” “[\*\*],” “[\*\*],” and “[\*\*],” including without limitation U.S. patent application Nos. [\*\*]; and [\*\*]; [\*\*]; U.S. Patent No. [\*\*], respectively, and all divisional, continuation, continuation-in-part, renewal, extension and reissue applications; all foreign counterpart applications and patents; and all U.S. and foreign Patens issuing on said applications.

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EXHIBIT 2

Proprietary Property

“[\*\*]”

List of Countries

Australia  
Canada  
Denmark  
EPC \*  
Finland  
Ireland  
Israel  
Japan  
Korea  
New Zealand  
Norway  
Portugal  
South Africa  
Taiwan  
U.S.A.

\* European patent application (EPC) designating as contracting states:

Austria, Belgium, France, West Germany, Greece, Italy, Luxembourg, Netherlands, Spain, Sweden, Switzerland, United Kingdom

“[\*\*]”

List of Countries

Australia  
Canada  
EPC \*  
Finland  
Ireland  
Israel  
Japan  
Korea  
Kuwait  
New Zealand  
Norway  
Peoples Republic of China  
Portugal  
Russian Federation  
Saudi Arabia  
South Africa  
Taiwan  
U.S.A.

\* European patent application (EPC) designating as contracting states:

Austria, Belgium, Denmark, France, Germany, Greece, Italy, Liechtenstein, Luxembourg, Netherlands, Spain, Sweden, Switzerland, United Kingdom

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DATED 15 April 2004

(1) SKYEPHARMA, INC,

(2) SkyePharma PLC, ( solely in connection with issue of shares)

and

(2) RESEARCH DEVELOPMENT FOUNDATION

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AMENDMENT AGREEMENT

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AMENDMENT AGREEMENT

**THIS AGREEMENT** is made and entered into effective the 15th day of April 2004 (the "Effective Date")

**BETWEEN:**

- (1) **SKYEPHARMA INC**, (formerly known as Depotech Corporation) a company incorporated in California whose principal place of business is 10450 Sciences Center Drive, San Diego, California 92121 USA ("Skye"); and
- (2) solely with respect to Article 3, **SKYEPHARMA PLC**, a corporation organised and existing under the laws of United Kingdom, having offices located at 105 Piccadilly, London W1V 9FN (Parent); and
- (3) **RESEARCH DEVELOPMENT FOUNDATION** a Nevada nonprofit corporation having its office at 402 North Division Street, Carson City, Nevada, 89703 ("RDF").

**Whereas:**

- (A) Skye (then trading as Depotech) and RDF are the parties to the Assignment Agreement dated 9<sup>th</sup> February 1994 ("the "1994 Agreement") and the Letter Agreement dated 10<sup>th</sup> December 1997 hereinafter collectively called the ("Assignment Agreement");
- (B) The parties wish to clarify and revise the terms of the Assignment Agreement;

**THE PARTIES HEREBY AGREE** as follows:

**Article 1. Interpretation**

In this Agreement, except as otherwise provided below, words and phrases shall bear the same meaning as in the Assignment Agreement, except that the following words and phrases shall have the following meanings:

1.1 "Gross Revenues" shall mean charges actually collected by Skye from sales, rental, lease, licensing, maintenance, or production of a Product or from licensing or the use of Proprietary Property by Skye or a third party, less:

- (a) usual trade and/or cash discounts actually allowed and taken;

- 
- (b) forwarding expenses, freight, special packaging charges, postage and duties actually paid or allowed and taxes imposed directly on the seller with respect to such sales and other transactions;
  - c) credits for goods returned; and
  - (d) government-related retroactive price reductions or rebates.

No other allowance or deduction shall be made by whatever name known. Notwithstanding the foregoing, Gross Revenues shall not include payments and fees as defined in Article 1.5 "Other Consideration".

1.2 "Current Agreements" shall mean:

- a) those Agreements specified in Appendix 1
- b) the agreements entered into prior to the date of this Agreement in relation to the Proprietary Property between Skye and GeneMedix, Astralis, Kirin Brewing Company, Pfizer, Amgen and Chugai and the feasibility agreements between Skye and Cognetix, Zealand and Eyetech.

1.3 "Future Agreements" shall mean all agreements entered into from the date of this Agreement by Skye that provide a license to (or other marketing arrangement) a third party to allow such third party to exploit the Proprietary Property'.

1.4 "Proprietary Property" shall mean Skye's multivesicular liposome DepoFoam technology which consists of [\*\*], [\*\*] [\*\*] composed of [\*\*] (the "DepoFoam Technology"). Such DepoFoam Technology shall include (a) the Assigned Proprietary Property or Improvements as defined under the 1994 Agreement, and/or (b) existing and future patent or proprietary rights of Skye in DepoFoam Technology whether or not covered by or subject to the Assignment Agreement. For purposes of Skye's payment, reporting, and indemnification obligations to RDF under the terms of the Assignment Agreement, as hereby amended, the parties agree that: (a) the scope of all relevant terms impacting such obligations contained in the Assignment Agreement (e.g., the definitions of Products, Assigned Proprietary Property, Assigned Applications, Assigned Patents, Improvements, etc.) shall be deemed to include all of the DepoFoam Technology, and (b) the term of the Assignment Agreement and Skye's payment, reporting, and indemnification obligations to RDF thereunder, as

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herein amended, are hereby extended for so long as Skye receives payments with respect to any of the DepoFoam Technology. For the avoidance of doubt the Proprietary Property shall exclude Skye's proprietary technology known as [\*\*], which consists of [\*\*].

1.5 "Other Consideration" shall mean all compensation and consideration actually collected by Skye or its affiliates (other than royalties or any other form of payment based on Gross Revenues as defined in Article 1.1) from a Licensee or marketing partner from the licensing or use of the Proprietary Property, Products or Improvements, whether in the form of signing fee, milestone payment, or other payment, less:

- (a) research and development costs directly related to the Products incurred by Skye to date
- (b) cost incurred to date by Skye in respect of regulatory approvals (including without limitation filing fees)
- (c) payments made by Skye to third parties in respect of the Proprietary Property, Products or Improvements. Such payments shall include but not be limited to payments made for the acquisition or re-acquisition of rights to the Proprietary Property, Products or Improvements.
- (d) payment made to Skye for the issue of SkyePharma equity, other than payments for equity at a price over and above the average of the daily closing share price of SkyePharma PLC common shares as quoted in the London edition of the Financial Times for the 20 days prior to the date of issue of such common shares.

## **Article 2. Payments**

Following good faith negotiations between the parties, the parties have agreed that

- 2.1 SkyePharma will pay to RDF [\*\*]% of Gross Revenues on all Current and Future Agreements
- 2.2 RDF hereby waives its rights to any and all payments specified in Article 4.4 of the 1994 Agreement, on all Current and Future Agreements except as set out in Article 2.3 and 2.4 of this Agreement

- 
- 2.3 In respect of Current Agreements it is agreed that the allowed deductions under Article 1.5 a) b) c) and d) shall be as shown in Appendix 1. For the avoidance of doubt the following examples are given:
- a) For the MundiPharma Agreement, if milestones received by Skye under the Mundipharma Distribution Agreement total \$[\*\*], allowable deductions pursuant to Article 1.5 will be \$[\*\*] and therefore Other Consideration will be \$[\*\*] of which RDF will be due [\*\*]%.
  - b) For Nippon Shinyaku, if milestones received by Skye under the Supply and Distribution Agreement are \$[\*\*], there will be no allowable deductions and therefore Other Consideration will be \$[\*\*] of which RDF will be due [\*\*]%.
  - c) For Endo and Medeus Pharmaceuticals, if milestones received by Skye under the Endo Development and Marketing Strategic Alliance Agreement and Medeus Strategic Marketing Agreement are \$[\*\*], allowable deductions will be \$[\*\*] and therefore Other Consideration will be \$[\*\*] of which RDF will be due [\*\*]%.
  - d) For Enzon, if milestones received by Skyepharm under the Supply and Distribution Agreement are \$[\*\*], allowable deductions will be \$[\*\*] and therefore Other Consideration will be \$[\*\*] of which RDF will be due [\*\*]%.
  - e) No Other Consideration is expected to be received pursuant to the agreements listed in Article 1.2 (b) and therefore, assuming none is received, no monies will be due to RDF pursuant to these agreements.
  - f) For all Current Agreements listed in Article 1.2 (a) if all \$[\*\*] contracted milestones are received, allowable deductions will be \$[\*\*] and therefore Other Consideration will be \$[\*\*] of which RDF will be due [\*\*]%.
- 2.4 In respect of Future Agreements Skye will pay to RDF [\*\*]% of “Other Consideration”. For the purposes of such calculation for Future Agreements, the deductions under Article 1.5 of this Agreement will not apply and the only allowable deduction will be for payments of research and development costs by a partner which directly relate to a Product and are paid over to a Contract Research Organisation or other such clinical trial organisation

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### Article 3. Shares

Within 30 days of the Effective Date of this Agreement, Parent will allot and issue to RDF, credited as fully paid, [\*\*] ordinary shares (the “Shares”) of [\*\*] each of parent (representing [\*\*] ADR’s) based on a price of \$[\*\*] per ADR, equivalent in value to \$[\*\*]. In the event that the price of the Parent’s ADRs exceeds as of the day prior to the Effective Date of this Agreement \$[\*\*] per ADR or is less than \$[\*\*] per ADR, both as quoted in the daily price activity report provided to Parent by the Bank of New York then in such event the number of issuable Shares shall be recomputed using instead of the price of \$[\*\*] per ADR the average of the daily closing share price of Parent’s ADRs as quoted in the daily price activity report provided to Parent by the Bank of New York for the 10 days prior to the Effective Date of this Agreement. The issued Shares will bear the legend shown in Appendix II to this Agreement. RDF hereby gives the following Reps and Warranties to Parent in respect to the issued Shares:

- 3.1 Selling Restrictions. RDF is acquiring the Shares for its own account for investment purposes only and not with a view to or for distributing or reselling such Shares or any part thereof or interest therein. RDF agrees that if in future it decides to sell or otherwise transfer the Shares, it will do so only in accordance with the terms of this Agreement and (A)(1) to a person whom RDF and any person acting on its behalf reasonably believe is a qualified institutional buyer within the meaning of Rule 144A under the U.S. Securities Act of 1933, as amended (the “Securities Act”) purchasing for its own account or for the account of a qualified institutional buyer in a transaction meeting the requirements of Rule 144A, (2) in an offshore transaction in accordance with Rule 903 or Rule 904 of Regulation S under the Securities Act, (3) pursuant to an exemption from registration under the Securities Act provided by Rule 144 thereunder (if available), or (4) pursuant to sales registered under the Securities Act, and (B) in each case, in accordance with all applicable securities laws of the states of the United States.
- 3.2 Institutional Accredited Investor. RDF is an institution which is an “accredited investor” as that term is defined in Rule 501(a)(3) of Regulation D under the Securities Act (an “Institutional Accredited Investor”) and is acquiring the shares for its own account.
- 3.3 Financial Knowledge, Sophistication and Experience. RDF, either alone or together with its representatives, has such knowledge, sophistication and experience in business and financial matters as to be capable of evaluating the merits and risks of the prospective investment in the shares, and has so evaluated the merits and risks of such investment.

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3.4 Ability of RDF to Bear Risk of Investment. RDF is aware that the purchase of the shares involves substantial risk and RDF is able to bear the economic risk of an investment in the shares and is able to afford a complete loss of such investment.

3.5 Access to Information. RDF acknowledges receipt of Parent's Annual Report on Form 20-F for the year ended December 31,2002, which was filed with the U.S. Securities and Exchange Commission (the "SEC") on June 27, 2003, and all of Parent's Reports on Form 6-K furnished to the SEC after such date and further acknowledges that it has been afforded (1) the opportunity to ask such questions as it has deemed necessary of, and to receive answers from, representatives of Parent; (2) access to information (other than material non-public information) about Parent and the Parent's financial condition, results of operations, business, properties, management and prospects that RDF deemed necessary to enable it to evaluate its investment in the shares; and (3) the opportunity to obtain such additional information (other than material non-public information) which Parent possesses or can acquire without unreasonable effort or expense that RDF deemed necessary to make an informed investment decision with respect to the shares.

3.6 Reliance. RDF understands and acknowledges that (1) the shares are being offered and sold to it without registration under the Securities Act and (2) the availability of such exemption depends in part on, and that Parent will rely upon the accuracy and truthfulness of, the foregoing representations and RDF hereby consents to such reliance.

#### **Article 4. Entire Agreement Modification and Waiver**

4.1 This Agreement (including the Appendices and attachments hereto) together with the Assignment Agreement (including the Appendices and attachments thereto) set out and constitute the entire understanding, warranties and agreement of the parties. The parties acknowledge that no reliance is placed on any prior agreement, representation or understanding whether written or oral relating to its subject matter. In the event of any conflict between the terms of this Agreement and the terms of the Assignment Agreement, the terms hereof shall control.

- 
- 4.2 No amendment or waiver of this Agreement or of any right herein shall be deemed effective unless made in writing and agreed to in writing by a duly authorised officer of each of the parties.
- 4.3 Without RDF's prior written consent, Skye shall not amend any of the Current Agreements in any manner which would adversely affect the amount of consideration to be received by RDF.

**Article 5. Governing Law and Jurisdiction**

This Agreement is governed by and shall be construed in all respects with the laws of the State of Nevada, U.S.A. applicable to contracts made in such State without regard to conflicts of law doctrines, and the parties agree that jurisdiction and venue for any dispute regarding this Agreement will be in such State.

IN WITNESS whereof the duly authorised representative of the parties have executed this Agreement effective as of the day and year first above written.

Signed by:

/s/ [Illegible]

duly authorised for and on behalf of

**SkyePharma Inc**

Title: DIRECTOR

Date: 15 APRIL 2004

Signed by:

/s/ [Illegible]

duly authorised for and on-behalf of

**Research Development Foundation**

Title: President

Date: April 15, 2004

**Current Agreements**

**Legend for Parent's Restricted Shares Issuable to RDF**

THE SHARES REPRESENTED HEREBY HAVE NOT BEEN AND WILL NOT BE REGISTERED UNDER THE UNITED STATES SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), OR WITH ANY SECURITIES REGULATORY AUTHORITY OF ANY STATE OR OTHER JURISDICTION OF THE UNITED STATES AND MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED EXCEPT (1) TO A PERSON WHOM THE SELLER AND ANY PERSON ACTING ON ITS BEHALF REASONABLY BELIEVE IS A QUALIFIED INSTITUTIONAL BUYER WITHIN THE MEANING OF RULE 144A UNDER THE SECURITIES ACT PURCHASING FOR ITS OWN ACCOUNT OR FOR THE ACCOUNT OF A QUALIFIED INSTITUTIONAL BUYER IN A TRANSACTION MEETING THE REQUIREMENTS OF RULE 144A, (2) IN AN OFFSHORE TRANSACTION IN ACCORDANCE WITH RULE 903 OR RULE 904 OF REGULATIONS UNDER THE SECURITIES ACT, OR (3) PURSUANT TO AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT PROVIDED BY RULE 144 THEREUNDER (IF AVAILABLE), IN EACH CASE IN ACCORDANCE WITH ANY APPLICABLE SECURITIES LAWS OF ANY STATE OR OTHER JURISDICTION OF THE UNITED STATES. NO REPRESENTATION CAN BE MADE AS TO THE AVAILABILITY OF THE EXEMPTION PROVIDED BY RULE 144 UNDER THE SECURITIES ACT FOR REALES OF THE ORDINARY SHARES REPRESENTED HEREBY. NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THE FOREGOING, THE SHARES MAY NOT BE DEPOSITED INTO ANY UNRESTRICTED DEPOSITORY RECEIPT FACILITY IN RESPECT OF ORDINARY SHARES ESTABLISHED



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OR MAINTAINED BY A DEPOSITORY BANK UNLESS SUCH SHARES MAY BE RESOLD PURSUANT TO RULE 144(K). EACH HOLDER REPRESENTS THAT IT UNDERSTANDS AND AGREES TO THE FOREGOING RESTRICTIONS.

**APPENDIX I – Current Agreements**

<u>KEY FINANCIAL TERMS</u>	<u>MILESTONES TO BE RECEIVED (1)</u>	<u>ALLOWABLE DEDUCTIONS (2)</u>
<b>Pharmis Biofarmaceutica Supply and Distribution Agreement (dated August 2003)</b>		
Approval for Solid Tumour	\$[**]	
<b>MundiPharma Distribution Agreement (30<sup>th</sup> June 2003)</b>		
On top 5 markets if ex-company price is €[**] per vials or greater - \$[**]	\$[**]	
On EMEA approval - \$[**]	\$[**]	
On EMEA approval in top 5 markets if ex-company price is €[**] Per vial or greater - \$[**]	\$[**]	
<b>Elan Acquisition Agreement (12th March 2003)</b>		
Return of rights to DepoCyt from Elan		
- Completion of enrolment for Phase IV - \$[**]		\$[**]
- EMEA Approval for Neoplastic Meningitis - \$[**]		\$[**]
<b>MundiPharma Total</b>	<u>\$[**]</u>	<u>\$[**]</u>

<u>KEY FINANCIAL TERMS</u>	<u>MILESTONES TO BE RECEIVED</u>	<u>ALLOWABLE DEDUCTIONS</u>
<b>Nippon Shinyaku Supply and Distribution Agreement (29<sup>th</sup> June 2001)</b>		
Submission of NDA for Japan \$[**]	\$[**]	
Supply of first product \$[**]	\$[**]	
Net Sales of \$[**] per year - \$[**]	\$[**]	
Net Sales of \$[**] per year - \$[**]	\$[**]	
Net Sales of \$[**] per year - \$[**]	\$[**]	
<b>Enzon Supply and Distribution Agreement (31<sup>st</sup> December 2002)</b>		
On sales reaching - \$[**] - \$[**]	\$[**]	
On sales reaching - \$[**] - \$[**]	\$[**]	
US Registration for neoplastic indication - before Dec 2006 - \$[**]	\$[**]	
- before Dec 2007 - \$[**]		
-afterDec 2007 - \$[**]		
<b>Research and Development expenses</b>		<u>\$[**]</u>
<b>Enzon Total</b>	<u>\$[**]</u>	<u>\$[**]</u>
<b>Endo Pharmaceuticals Inc Development and Marketing Strategic Alliance Agreement (31 December 2002)</b>		
FDA Approval	\$[**]	
First time annual Net Sales \$[**]	\$[**]	
First time annual Net Sales \$[**]	\$[**]	
<b>Total Endo</b>	<u>\$[**]</u>	

<u>KEY FINANCIAL TERMS</u>	<u>MILESTONES TO BE RECEIVED</u>	<u>ALLOWABLE DEDUCTIONS</u>
<b>Medeus Pharma Ltd Strategic Marketing Agreement</b>		
Signing	\$[**]	
1 <sup>st</sup> Marketing Authorisation	\$[**]	
2 <sup>nd</sup> country launched	\$[**]	
Annual sales €[**]	\$[**]	
Annual sales €[**]	\$[**]	
Annual sales €[**]	\$[**]	
Annual sales €[**]	\$[**]	
Annual sales €[**]	\$[**]	
Annual sales €[**]	\$[**]	
Annual sales €[**]	\$[**]	
Annual sales €[**]	\$[**]	
<b>Total Medeus</b>	<u>\$[**]</u>	
Historical Research and Development expenses		\$[**]
Future Research and Development commitment under Medeus Contract		<u>\$[**]</u>
<b>Total DepoMorphine</b>	<u>\$[**]</u>	<u>\$[**]</u>
<b>Total All Products</b>	<u>\$[**]</u>	<u>\$[**]</u>

- (1) As summarized in Appendix A to the memorandum from Thomas Brorby dated 10 March, 2004, less the \$[\*\*] milestone in respect of FDA filing of DepoMorphine which was received from Endo in 2003 plus \$[\*\*] milestones in Medeus contract announced 7 April (\$[\*\*] less \$[\*\*] plus \$[\*\*] = \$[\*\*]). N.B no net impact on draft proposal.
- (2) As summarized in Appendix II to memorandum from Donald Nicholson dated 22 August, 2003 plus \$[\*\*] clinical costs committed to under Medeus contract.

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

**EXECUTION COPY**

STOCK PURCHASE AGREEMENT

by and among

Blue Acquisition Corp. (“Buyer”),

SkyePharma Holding, Inc. (“Seller”),

and

SkyePharma, Inc. (the “Company”)

dated as of

January 8, 2007

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**STOCK PURCHASE AGREEMENT**

This Agreement (the "Agreement") is made and entered into as of January 8, 2007 by and among Blue Acquisition Corp., a Delaware corporation ( "Buyer"), SkyePharma Holding, Inc. ("Seller"), a Delaware corporation and a wholly owned subsidiary of SkyePharma PLC, a company incorporated under the laws of England and Wales ("Parent"), and SkyePharma, Inc., a California corporation and wholly owned subsidiary of Seller (the "Company").

Recitals

Seller is the direct owner of all issued and outstanding shares of capital stock of the Company (the "Shares"). Buyer desires to purchase, and Seller desires to sell, the Shares for the consideration set forth below, on the terms and subject to the conditions set forth in this Agreement.

In order to induce Buyer to enter into this Agreement and consummate the transactions contemplated hereunder, concurrently herewith, Parent has executed and delivered to Buyer a Parent Guaranty Agreement in the form attached hereto as Exhibit A (the "Parent Guaranty").

In order to induce Seller to enter into this Agreement and consummate the transactions contemplated hereunder, concurrently herewith, Buyer has delivered the Commitment Letters (defined below) naming Seller as a third party beneficiary thereto.

NOW, THEREFORE, in consideration of the premises, and the mutual representations, warranties, covenants and agreements set forth in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, Buyer, Seller and the Company hereby agree as follows:

**ARTICLE I  
PURCHASE AND SALE OF THE SHARES**

1.1. Purchase of the Shares from Seller. Upon the terms and subject to the conditions set forth in this Agreement, at the Closing, Seller shall sell, transfer, convey, assign and deliver to Buyer, and Buyer shall purchase, acquire and accept from Seller, all of the Shares, free and clear of all Encumbrances. At the Closing, Seller shall deliver to Buyer certificates evidencing all of the Shares duly endorsed in blank or with stock powers duly executed by Seller. Buyer acknowledges and agrees that in acquiring the Shares, Buyer is not acquiring any rights, title or interest in, to and under (i) the names "SkyePharma USA, Inc.," "SkyePharma, Inc.," "SkyePharma," "SkyePharma USA," "Skye, Inc." "Skye," "Skye USA," variations and derivatives thereof and any other logos or trademarks, trade names or service marks of the Company (collectively, the "Names") and (ii) the Excluded Assets (as defined below) of the Company that, pursuant to Section 5.11, are to be transferred from the Company to Seller and/or Affiliates of Seller (other than the Company) prior to the Closing.

1.2. Further Assurances. At any time and from time to time after the Closing, at Buyer's request and without further consideration, Seller shall (and shall cause each of its Affiliates and each of its Affiliates' respective directors, officers and employees to) promptly

execute and deliver such instruments of sale, transfer, conveyance, assignment and confirmation, and take all such other action as Buyer may reasonably request, to transfer, convey and assign to Buyer, and to confirm Buyer's title to, all of the Shares, to put Buyer (through the ownership of the Shares) in effective operating control of the assets, properties and business of the Company, to assist Buyer in exercising all rights with respect thereto, and otherwise to carry out the purpose and intent of this Agreement.

1.3. Purchase Price. The Base Purchase Price to be paid by Buyer to Seller shall be twenty million dollars (\$20,000,000), subject to adjustment pursuant to Section 1.5. The Base Purchase Price shall be payable in the manner described in Section 1.4.

1.4. Payment of Base Purchase Price. At the Closing, Buyer shall (a) pay to Seller the Base Purchase Price, minus the Escrow Amount, in cash, by wire transfer of immediately available funds to an account designated by Seller, and (b) deliver to the Escrow Agent the Escrow Amount for deposit into the Escrow Fund, such amount and fund to be held in accordance with the provisions of Sections 1.5 and 5.15 and Article VIII of this Agreement and the Escrow Agreement.

1.5. Post-Closing Adjustments. The Base Purchase Price shall be subject to adjustment after the Closing Date as follows:

(a) Set forth in Column X of the spreadsheet attached in Schedule 1.5(a)(i) is a statement compiling certain asset and liability accounts of the Company as of November 24, 2006 (the "Target Net Assets Statement"). The Target Net Assets Statement was prepared on the same basis as the Most Recent Net Assets Statement, with the eliminations and adjustments set forth in Schedule 6.12 and the further eliminations set forth in Schedule 1.5(a)(ii). The Target Net Assets Statement includes a "net assets value" of the Company of \$[\*\*] (the "Net Assets Target"). No later than 5 p.m. Pacific Standard Time on the tenth (10<sup>th</sup>) business day after the Closing Date, Seller shall deliver to Buyer a compilation of the same asset and liability accounts included in the Target Net Assets Statement, but prepared as of the Closing Date (the "Draft Closing Net Assets Statement"), which shall be prepared by Seller on the same basis as the Most Recent Net Assets Statement, applied on a basis consistent with the past accounting practices of the Company, with the eliminations and adjustment set forth in Schedule 6.12 and the further eliminations set forth in Schedule 1.5(a)(ii). Solely for the avoidance of doubt, neither the Draft Closing Net Assets Statement nor the Final Closing Net Assets Statement will reflect any writedown or fair value adjustment of assets or any provision for liabilities arising from the termination of the Endo Agreement.

(b) Buyer shall deliver to Seller, no later than 6 p.m. Pacific Standard Time on the Objection Deadline Date, either a notice indicating that Buyer accepts the Draft Closing Net Assets Statement or a statement in reasonable detail describing its objections (if any) to the Draft Closing Net Assets Statement and the grounds for such objections (an "Objection Statement"). If Buyer delivers to Seller a notice accepting the Draft Closing Net Assets Statement, or Buyer does not deliver a timely Objection Statement by 6 p.m. Pacific Standard Time on the Objection Deadline Date, then, effective as of either the date of delivery of such notice of acceptance or as of the close of business on the Objection Deadline Date, the Draft Closing Net Assets Statement shall be deemed to be the final compilation of the asset and liability accounts included in the Target Net Assets Statement, measured and calculated as of the Closing Date (the "Final Closing Net Assets Statement"). If Buyer timely objects to the Draft Closing Net Assets Statement, such objections shall be resolved as follows:

(i) Buyer and Seller shall seek in good faith to resolve such objections. Each Party shall provide the other Parties with reasonable access to its records, personnel and supporting documentation relating to the Draft Closing Net Assets Statements and the items giving rise to the Objection Statement until such time as the Final Closing Net Assets Statement is determined.

(ii) If Buyer and Seller do not reach a resolution of all objections set forth in Buyer's Objection Statement within thirty (30) days after delivery of such Objection Statement, Buyer and Seller shall, within thirty (30) days following the expiration of such 30-day period, engage the Accountant, pursuant to an engagement agreement executed by Buyer, Seller and the Accountant, to resolve the Unresolved Objections.

(iii) Buyer and Seller shall jointly submit to the Accountant, within ten (10) days after the date of the engagement of the Accountant (as evidenced by the date of the engagement agreement), a copy of the Draft Closing Net Assets Statement, a copy of the Objection Statement, and a statement setting forth the resolution of any objections agreed to by Buyer and Seller. Each of Buyer and Seller shall submit to the Accountant (with a copy delivered to the other Party on the same day), within thirty (30) days after the date of the engagement of the Accountant, a memorandum (which may include supporting exhibits) setting forth their respective positions on the Unresolved Objections. Each of Buyer and Seller may (but shall not be required to) submit to the Accountant (with a copy delivered to the other Party on the same day), within forty five (45) days after the date of the engagement of the Accountant, a memorandum responding to the initial memorandum submitted to the Accountant by the other Party. Unless requested by the Accountant in writing, neither Party may present any additional information or arguments to the Accountant, either orally or in writing.

(iv) Within ninety (90) days after the date of its engagement hereunder, the Accountant shall determine whether the objections raised by Buyer are appropriate and shall issue a ruling which shall include a compilation of the accounts included (or required to be included) in the Draft Closing Net Assets Statement as adjusted pursuant to any resolutions to objections agreed upon by Buyer and Seller and pursuant to the Accountant's resolution of the Unresolved Objections. Such statement shall be Final Closing Net Assets Statement.

(v) The resolution by the Accountant of the Unresolved Objections shall be conclusive and binding upon Buyer and Seller. Buyer and Seller agree that the procedure set forth in this Section 1.5(b) for resolving disputes with respect to the Draft Closing Net Assets Statement shall be the sole and exclusive method for resolving any such disputes; provided that this provision shall not prohibit either Party from instituting litigation to enforce the procedures and deadlines set forth herein or to enforce rulings of the Accountant.

(vi) Buyer and Seller shall share equally the fees and expenses of the Accountant.

(c) Immediately following the Objection Deadline Date, if a timely Objection Statement is not delivered, or upon notification by Buyer to Seller that no objection to the Draft Closing Net Assets Statement will be made, or immediately upon final resolution of any dispute in connection with the determination of the Final Closing Net Assets Statement pursuant to this Section 1.5, the Adjusted Purchase Price shall be determined as follows:

(d) If the “net assets value” as shown on the Final Closing Net Assets Statement is more than [\*\*] dollars (\$[\*\*]) less than “net assets value” as shown in the Target Net Assets Statement, the deficiency in excess of such \$[\*\*] amount shall be deducted from the Base Purchase Price to obtain the Adjusted Purchase Price, and shall be paid by Seller to Buyer from the following sources in the following manner and priority: first, by payment in cash to Buyer by the Escrow Agent from the Escrow Fund, to the extent funds are available in the Escrow Fund, and thereafter, by payment in cash to Buyer by Seller, from funds of Seller, to an account designated by Buyer, in each case by wire transfer of immediately available funds within two (2) business days after such determination.

(e) For purposes of implementing the provisions of Section 1.5 and Section 8.1(h), each Party shall have reasonable access, upon request, during normal business hours and with reasonable advance notice, to the books, records and personnel of the other Parties to the extent reasonably relevant to the determination either of the Draft Closing Net Assets Statement and the Final Closing Net Assets Statement and the resolution of any Objection Statement and Unresolved Objections (in the case of Section 1.5) or the Designated Amounts and the invoices submitted as relating thereto (in the case of Section 8.1(h)).

1.6. Escrow Account. The Escrow Amount shall be delivered to the Escrow Agent for deposit into a fund (the “Escrow Fund”) that shall be held by the Escrow Agent under the terms of the Escrow Agreement for the purpose of securing the indemnification obligations of Seller pursuant to Article VIII and Section 5.15, any adjustment to the Base Purchase Price pursuant to Section 1.5, and any reimbursement obligation of Parent or Seller with respect to payments under the Stay Incentive Agreements under Section 5.16. The Escrow Fund shall be held as a trust fund and shall not be subject to any lien, attachment, trustee process or any other judicial process of any creditor of any Party, and shall be held and disbursed solely for the purposes and in accordance with the terms of the Escrow Agreement.

1.7. Earn-Out. Following the Closing, the Company shall pay to Seller the amounts set forth in Schedule 1.7, minus any amounts determined to be due to Buyer pursuant to Section 1.5 or Section 5.16, or pursuant to Article VIII or Section 5.15 (only to the extent of the Cap set forth in Section 8.5), and not otherwise paid to Seller before any such amounts on Schedule 1.7 (if any) become payable pursuant to Schedule 1.7.

1.8. The Closing.

(a) The Closing shall take place at the offices of Wilmer Cutler Pickering Hale and Dorr LLP, 1117 California Avenue, Palo Alto, California commencing at 9:00 a.m. Pacific Standard Time on the date within two (2) business days after the satisfaction or waiver of all of the conditions to the obligations of the Parties to consummate the transactions contemplated hereby (excluding the delivery at the Closing of any of the documents set forth in Articles VI and VII), or such other date as may be mutually agreeable to the Parties. The transfer of the Shares by Seller to Buyer shall be deemed to occur at 9:00 a.m. Pacific Standard Time, on the Closing Date.

(b) At the Closing, the following actions shall take place:

(i) Seller shall deliver the agreements, consents, certificates, and other instruments and documents required to be delivered to Buyer pursuant to Article VI, and Buyer shall execute and deliver the agreements, certificates, and other instruments and documents required to be delivered to Seller pursuant to Article VII;

(ii) Seller shall then deliver to Buyer certificates evidencing all of the Shares duly endorsed in blank or with stock powers duly executed by Seller; and

(iii) Buyer shall then pay the amount set forth in Section 1.4(a), in the manner prescribed therein.

1.9. Allocation of Payments. The Adjusted Purchase Price and the “Milestone Payments” pursuant to Section 1.7 and Schedule 1.7 shall be paid as consideration for the Shares and the covenants not to compete set forth in Section 9.3(a)(ii) and Section 9.3(a)(iii); the “DepoBupivacaine Percentage Payments” pursuant to Section 1.7 and Schedule 1.7 shall be paid as consideration for the covenant not to compete set forth in Section 9.3(a)(i); and the “Biologics Products Percentage Payments” pursuant to Section 1.7 and Schedule 1.7 shall be paid as consideration for the covenant not to compete set forth in Section 9.3(a)(iv). The Adjusted Purchase Price and all such Percentage Payments shall be allocated among the Shares and such covenants not to compete in accordance with Schedule 1.9. Unless otherwise required by a Final Determination, the Parties shall report the transactions contemplated by this Agreement in a manner consistent with such allocations.

**ARTICLE II**  
**REPRESENTATIONS AND WARRANTIES OF SELLER**  
**REGARDING THE SHARES**

Seller represents and warrants to Buyer that the statements contained in this Article II are true and correct as of the date of this Agreement and will be true and correct as of the Closing as though made as of the Closing, except to the extent such representations and warranties are specifically made as of a particular date (in which case such representations and warranties will be true and correct as of such date).

2.1. Title. Seller has (and upon consummation of the purchase contemplated hereby, Buyer will acquire from Seller) good and marketable title to the Shares, free and clear of any and all Encumbrances. Section 2.1 of the Seller Disclosure Schedule sets forth a true and correct description of the Shares and all shares of capital stock and other securities of the Company owned, directly or indirectly through any other subsidiary or affiliate, by Seller or which Seller has the right to acquire.

2.2. **Authority.** Seller has the full right, power and authority to enter into this Agreement and to transfer, convey and sell to Buyer at the Closing the Shares and otherwise to perform and fulfill its obligations under this Agreement and the Ancillary Agreements to which Seller is a party. Each of this Agreement and the Ancillary Agreements to which Seller is party (including the Escrow Agreement) has been duly and validly executed and delivered by Seller and constitutes a valid and binding obligation of Seller, enforceable against Seller in accordance with its terms. The passing of resolutions (i) approving the Agreement by a majority of the shareholders of Parent (on show of hands) or of the number of shares held by the shareholders of Parent (on a duly convened poll), in each case present (on a poll, either in person or by proxy) and voting and (ii) approving matters related to a placing by at least 75% of the shareholders (on show of hands) or of the number of shares (on a duly convened poll), in each case present (on a poll, either in person or by proxy) and voting therewith at a validly convened and held EGM shall operate to approve the transactions contemplated by this Agreement and confer authority on the Parent to complete the transactions contemplated by this Agreement in accordance with the terms of this Agreement and to take all further actions as it may consider expedient for the purposes thereof and is the only approval of Parent's shareholders required for the consummation of the transactions contemplated by this Agreement.

2.3. **Regulatory Approvals.** Except as set forth in Section 2.3 of the Seller Disclosure Schedule, neither Seller nor Parent is a party to, subject to or bound by any agreement or any judgment, order, writ, prohibition, injunction or decree of any court or other governmental body which would prevent the execution or delivery of this Agreement or any of the Ancillary Agreements by Seller or the transfer, conveyance and sale of the Shares by Seller to Buyer pursuant to the terms hereof.

2.4. **Circular.** The Circular prepared pursuant to Section 5.3 shall not, either at the time posted or at the time of the EGM or at the Closing, contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein not misleading.

2.5. **Brokers.** Except for the fees payable in the amounts and to the recipients set forth in Section 2.5 of the Seller Disclosure Schedule (which shall be the sole liability, obligation and responsibility of Parent and Seller and for which neither the Company nor Buyer shall have any liability or obligation), none of Seller, Parent or the Company or any of their Affiliates has any liability or obligation to pay any fees or commissions to any broker, finder or agent with respect to the transactions contemplated by this Agreement.

**ARTICLE III  
REPRESENTATIONS AND WARRANTIES OF SELLER  
REGARDING THE COMPANY**

Seller hereby represents and warrants to Buyer that, except as set forth in the Seller Disclosure Schedule, the statements contained in this Article III are true and correct as of the date of this Agreement and will be true and correct as of the Closing as though made as of the Closing, except to the extent such representations and warranties are specifically made as of a particular date (in which case such representations and warranties will be true and correct as of such date). The Seller Disclosure Schedule shall be arranged in sections and subsections



corresponding to the numbered and lettered sections and subsections contained in Article II and this Article III. The disclosures in any section or subsection of the Seller Disclosure Schedule shall qualify only the corresponding section or subsection in this Agreement except to the extent that it is clear from a reading of the disclosure that such disclosure is applicable to such other sections or subsections.

3.1. Organization, Qualification and Corporate Power. The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of California. The Company is duly qualified to conduct business and is in corporate and tax good standing under the laws of each jurisdiction listed in Section 3.1 of the Seller Disclosure Schedule, which jurisdictions constitute the only jurisdictions in which the nature of the Company's businesses or the ownership or leasing of its properties requires such qualification, except where the failure to be so qualified or in good standing would not be material to the transactions contemplated by this Agreement. The Company has all requisite corporate power and authority to carry on the businesses in which it is engaged and to own and use the properties owned and used by it. The Company has furnished to Buyer complete and accurate copies of its Certificate of Incorporation and By-laws. The Company is not in default under or in violation of any provision of its Certificate of Incorporation or By-laws.

3.2. Capitalization.

(a) The authorized capital stock of the Company consists of one thousand (1,000) shares of Common Stock, of which one thousand (1,000) shares are issued and outstanding and no shares are held in the treasury of the Company. All of the issued and outstanding shares of capital stock of the Company have been and on the Closing Date will be duly authorized, validly issued, fully paid, nonassessable and free of all preemptive rights. All of the issued and outstanding shares of capital stock of the Company were issued in compliance with all applicable federal and state securities laws.

(b) There are no outstanding or authorized options, warrants, rights, calls, convertible instruments, agreements or commitments to which the Company is a party or which are binding upon the Company providing for the issuance, disposition or acquisition of any of its capital stock. There are no outstanding or authorized stock appreciation, phantom stock or similar rights with respect to the Company. There are no agreements, voting trusts, proxies or understandings with respect to the voting of any shares of capital stock of the Company.

3.3. Authorization of Transaction. Each of Seller and the Company has all requisite power and authority to execute and deliver this Agreement and to perform its obligations under this Agreement and the Ancillary Agreements to which it is a party. The execution and delivery by Seller and the Company of this Agreement and the Ancillary Agreements to which Seller or the Company is a party and the consummation by Seller and the Company of the transactions contemplated by this Agreement and the Ancillary Agreements to which Seller or the Company is a party have been duly and validly authorized by all necessary corporate action on the part of Seller and the Company and has been authorized and approved by Parent. This Agreement has been duly and validly executed and delivered by Seller and the Company and constitutes a valid and binding obligation of Seller and the Company, enforceable against Seller and the Company in accordance with its terms. The passing of a resolution approving the Agreement by a majority

of the shareholders (on show of hands) or of the number of shares (on a duly convened poll), in each case present (on a poll, either in person or by proxy) and voting at a validly convened and held extraordinary general meeting of the shareholders of Parent, shall operate to approve the transactions contemplated by this Agreement and confer authority on the Parent to complete the transactions contemplated by this Agreement in accordance with the terms of this Agreement and to take all further actions as it may consider expedient for the purposes thereof and is the only approval of Parent's shareholders required for the consummation of the transactions contemplated by this Agreement.

3.4. Noncontravention. Except as set forth in Section 3.4 of the Seller Disclosure Schedule, neither the execution and delivery by Seller and the Company of this Agreement or any of the Ancillary Agreements to which Seller or the Company is a party, nor the consummation by Seller and the Company of the transactions contemplated by this Agreement or any of the Ancillary Agreements, will (a) conflict with or violate any provision of the Certificate of Incorporation or By-laws or similar organizational documents of Seller, Parent or the Company, (b) require on the part of Seller, Parent or the Company any notice to or filing with, or any permit, authorization, consent or approval of, any Governmental Entity, (c) conflict with, result in a breach of, constitute (with or without due notice or lapse of time or both) a default under, result in the acceleration of obligations under, create in any party the right to terminate, modify or cancel, or require any notice, consent or waiver under, any Material Contract (as defined in Section 3.15) or instrument to which Seller, Parent or the Company is a party or by which Seller, Parent or the Company is bound or to which any of their respective assets is subject, (d) result in the imposition of any Encumbrance upon any assets of Seller, Parent or the Company or (e) violate any order, writ, injunction, decree, statute, rule or regulation that, to the knowledge of Seller and the Company, is applicable to Seller, Parent or the Company or any of their respective properties or assets.

3.5. Subsidiaries. The Company has no Subsidiaries, whether wholly or partially owned. The Company does not control directly or indirectly or have any direct or indirect equity participation or similar interest in any corporation, partnership, limited liability company, joint venture, trust or other business association or entity which is not a Subsidiary.

3.6. Financial Statements.

(a) Seller has provided the Financial Statements to Buyer. The items included in the Financial Statements were prepared on the same basis as was used in preparing the consolidation schedules of the Company used in preparing the consolidated financial statements of Parent as at December 31, 2005, which were prepared in accordance with IFRS on a consistent basis. The Financial Statements fairly present the financial condition of the Company as of the respective dates thereof (except as set forth in Section 3.6(a) of the Seller Disclosure Schedule), and are consistent with the books and records of the Company.

(b) Each of the Company and, to the extent their books and records relate to or affect the Company, Parent and its subsidiaries (including Seller) maintain books and records that accurately reflect, in all material respects, its respective assets and liabilities and maintain internal controls over financial reporting that provide assurance that, in all material respects, (i) transactions are executed with management's general or specific authorization, (ii) transactions

are recorded as necessary to permit preparation of financial statements of the Company and to maintain accountability for the assets of the Company, (iii) access to assets of the Company is permitted only in accordance with management's general or specific authorization, (iv) the reporting of assets of the Company is compared with existing assets at regular intervals, and (v) notes and other receivables and inventory are properly recorded, and proper and adequate procedures are implemented to effect the collection of such notes and receivables on a current and timely basis.

(c) The Target Net Assets Statement was, and the Draft Closing Net Assets Statement will be, prepared by Seller on the same basis as the Most Recent Net Assets Statement, with the eliminations and adjustment set forth in Schedule 6.12 and the further eliminations set forth in Schedule 1.5(a)(ii).

3.7. Absence of Certain Changes. Since the Most Recent Net Assets Statement Date, (a) there has occurred no event or development that, individually or in the aggregate, has had, or could reasonably be expected to have in the future, a Company Material Adverse Effect, and (b) except as contemplated by this Agreement, the Company has not taken any of the actions set forth in paragraphs (c), (d), (e), (f) or (k) of Section 5.4 (disregarding any time limitations set forth in such paragraphs).

3.8. Undisclosed Liabilities. Except as set forth in Section 3.8 of the Seller Disclosure Schedule, the Company has (and will, as of the Closing, have) no liability (whether known or unknown, whether absolute or contingent, whether liquidated or unliquidated, whether due or to become due), except (a) as of the date hereof, liabilities reflected in the Most Recent Net Assets Statement and liabilities incurred in the Ordinary Course of Business since the Most Recent Net Assets Statement Date and (b) as of the Closing, liabilities that will be reflected in the Final Closing Net Assets Statement.

3.9. Taxes.

(a) Except as set forth on Section 3.9 of the Seller Disclosure Schedule:

(i) The Company has (A) properly filed on a timely basis all Tax Returns for Income Taxes and all material Tax Returns for Taxes other than Income Taxes that it was required to file, and all such Tax Returns were true, correct and complete in all material respects, (B) paid on a timely basis all material Taxes that were due and payable, and (C) established on its Most Recent Net Assets Statement reserves that are adequate for the payment of all unpaid Taxes.

(ii) The Company has not been a member of a group of corporations with which it has filed (or been required to file) consolidated, combined or unitary Tax Returns other than any group the common parent of which is Seller.

(iii) Seller has (A) properly filed on a timely basis all Tax Returns for Income Taxes that it was required to file with respect to any Affiliated Period, and all such Tax Returns were true, correct and complete in all material respects, and (B) paid on a timely basis all material Taxes that were due and payable with respect to all Affiliated Periods.

(iv) Since the Most Recent Net Assets Statement Date, the Company has not incurred any liability for Taxes other than (x) in the Ordinary Course of its Business, or (y) in connection with the transactions contemplated by this Agreement, including the distribution of the Excluded Assets and the transactions referred to in Schedule 6.12.

(v) The Company is not a party to or bound by any Tax indemnity, Tax sharing, Tax allocation or similar agreement.

(vi) The Company has complied in all material respects with all applicable laws relating to the payment and withholding of Taxes and has, within the time and manner prescribed by law, paid over to the proper governmental authority all amounts required to be withheld and paid over under all applicable laws.

(vii) There are no liens for Taxes imposed on the assets of the Company except for (A) liens for Taxes not yet due and payable or (B) liens for Taxes being contested in good faith in appropriate proceedings and with respect to which adequate reserves have been established on the Most Recent Net Assets Statement in accordance with IFRS.

(viii) The Company does not have any liability for Taxes of another person as a transferee or successor (or under similar principles) or pursuant to any contractual obligation.

(ix) No examination or audit of any Tax Return of Parent, Seller or the Company is currently in progress or, to the knowledge of Seller and the Company, threatened or contemplated.

(x) Section 3.9(a)(x) of the Seller Disclosure Schedule sets forth (i) each jurisdiction (other than United States federal) in which the Company files a Tax Return, (ii) to the knowledge of Seller, each jurisdiction (other than United States federal) in which the Company is required or has been required to file a Tax Return, and (iii) each jurisdiction that has sent written notices requesting information relating to the Company's nexus with such jurisdiction.

(xi) The Company has not (i) waived any statute of limitations with respect to Taxes or agreed to extend the period for assessment or collection of any Taxes which period has not expired, (ii) requested any extension of time within which to file any Tax Return, which Tax Return has not yet been filed, or (iii) executed or filed any power of attorney with any Taxing Authority that is still outstanding.

(xii) There are no adjustments under Section 481 of the Code (or any similar adjustments under any provision of the Code or corresponding foreign, state or local Tax laws) that are required to be taken into account by the Company in any period ending after the Closing Date by reason of a change in method of accounting in any taxable period ending on or before the Closing Date.

(xiii) For the two year period ending on the date hereof, the Company has not been a “distributing corporation” or a “controlled corporation” in a distribution intended to qualify under Section 355(a) of the Code.

(xiv) The Company does not own any interest in any entity that is characterized as a partnership for U.S. federal income Tax purposes.

(xv) The Company has not entered into a gain recognition agreement under Section 367 of the Code.

(xvi) The Company will not be required to include any item of income in, or exclude any item of deduction from, taxable income for any period (or any portion thereof) ending after the Closing Date as a result of any (i) closing agreement as described in Section 7121 of the Code (or any corresponding or similar provision of state, local or foreign Tax law) executed on or prior to the Closing Date, (ii) installment sale or other open transaction disposition made on or prior to the Closing Date, or (iii) prepaid amount received on or prior to the Closing Date.

(xvii) The Company has not engaged in any “listed transaction” for purposes of Treasury Regulation sections 1.6011-4(b)(2) or 301.6111-2(b)(2) or any analogous provision of foreign, state or local law.

(b) Seller has delivered to Buyer or made available to Buyer (or will make available upon Buyer’s request): (i) complete and correct copies of all Tax Returns of the Company and any Affiliated Group (but in the case of any such Affiliated Group, only the portions of such Tax Returns relating solely to the Company), and (ii) complete and correct copies of all private letter rulings, revenue agent reports, information document requests, notices of proposed deficiencies, deficiency notices, protests, closing agreements and any other similar material documents, in each case, submitted by, received by, or agreed to by the Company and relating to Taxes of the Company for all prior Taxable periods for which the statute of limitations has not expired.

(c) The aggregate basis in the assets of the Company as of December 31, 2006 for federal Income Tax purposes was not less than [\*\*] dollars (\$[\*\*]).

Notwithstanding anything to the contrary contained in this Agreement, except as and to the extent provided in Section 3.22, this Section 3.9 is the only Section in this Agreement in which representations and warranties relating or attributable to Taxes and/or Tax Returns are made, including for purposes of any other Section in this Article III and Section 6.2.

3.10. Assets. The Company is the true and lawful owner, and has good title to, all of the assets (tangible or intangible) reflected in the Most Recent Net Assets Statement (other than leasehold interests) or otherwise purported to be owned by the Company, free and clear of all Encumbrances, including the assets listed or described in Schedule 3.10(a). The Company owns or leases all tangible assets sufficient for the conduct of its businesses as presently conducted. Each such tangible asset is free from material defects, has been maintained in accordance with normal industry practice, is in good operating condition and repair (subject to normal wear and tear) and is suitable for the purposes for which it presently is used.

3.11. Owned Real Property. The Company has no direct or indirect ownership interest in any Owned Real Property.

3.12. Real Property Leases. Section 3.12 of the Seller Disclosure Schedule lists all Leases. The Company has delivered to Buyer complete and accurate copies of the Leases. With respect to each Lease:

(a) such Lease is legal, valid, binding, enforceable and in full force and effect as against the Company and, to the knowledge of the Seller and the Company, each other party thereto;

(b) neither the Company nor, to the knowledge of Seller and the Company, any other party, is in breach or violation of, or default under, any such Lease, and no event has occurred, is pending or, to the knowledge of Seller and the Company, is threatened, which, after the giving of notice, with lapse of time, or otherwise, would constitute a breach or default by the Company or, to the knowledge of Seller and the Company, any other party under such Lease;

(c) to the knowledge of Seller and the Company, there are no disputes, oral agreements or forbearance programs in effect as to such Lease;

(d) the Company has not assigned, transferred, conveyed, mortgaged, deeded in trust or encumbered any interest in the leasehold or subleasehold;  
and

(e) to the knowledge of Seller and the Company, there is no Encumbrance applicable to the real property subject to such Lease which would reasonably be expected to materially impair the current uses or the occupancy by the Company of the property subject thereto.

3.13. Intellectual Property.

(a) For purposes of this Agreement (other than for purposes of Section 3.30, in the case of terms separately defined in Section 3.30):

(i) "Intellectual Property" shall mean, collectively, all U.S. and non-U.S. registered, unregistered and pending (A) trademarks, trade dress, Product and Product Candidate names, internet domain names, and all registrations and applications therefor (collectively, "Trademarks"), (B) copyrights (including those in computer software), database rights, and all grants, registrations and applications therefor (collectively, "Copyrights"), (C) patents, and all registrations and applications therefor (collectively, "Patents"), (D) inventions, invention disclosures, statutory invention registrations, trade secrets and confidential business information, know-how, manufacturing and product processes and techniques, research and development information, financial, marketing and business data, pricing and cost information, business and marketing plans and customer and supplier lists and information, whether patentable or nonpatentable (collectively, "Trade Secrets"), and (E) other proprietary rights relating to any of the foregoing.

(ii) "IP Contracts" shall mean, collectively, all license, assignment, distribution, collaboration, development or other agreements relating to any Company Intellectual Property, including (A) all licenses, covenants or other agreements pursuant to which the Company or any of its Affiliate has assigned, transferred, licensed, distributed or otherwise granted any right or access to any Person, or covenanted not to assert any right, with respect to any past, existing or future Company Intellectual Property, and (B) all agreements, contracts, assignments or other instruments pursuant to which the Company or any of its Affiliate has obtained any right or license, or any joint or sole ownership interest, in or to any item of Company Intellectual Property.

(iii) "Company Intellectual Property" shall mean all (A) Intellectual Property in which the Company has an ownership interest or will, pursuant to Section 5.11, acquire an ownership interest ("Company Owned Intellectual Property"), (B) all Intellectual Property in which any Affiliate of Company has an ownership interest which claims or covers a Product or Product Candidate (or developing, making, using and commercializing any Product or Product Candidate), or is used or is currently intended to be used, in the business of the Company as now conducted or as intended to be conducted, including in connection with the developing, making, using and commercializing of any Product or Product Candidate, and including all patents and patent applications relating to Biosphere technology or otherwise set forth in Schedule 5.11 ("Affiliate Owned Intellectual Property"), and together with the Company Owned Intellectual Property, "Group Owned Intellectual Property"), and (C) all Intellectual Property in which a third party has an ownership interest which claims or covers a Product or Product Candidate (or developing, making, using and commercializing any Product or Product Candidate), or is used or is currently intended to be used, in the business of the Company as now conducted or as intended to be conducted, including in connection with the developing, making, using and commercializing of any Product or Product Candidate ("Third Party Intellectual Property").

(iv) "Company Patents" shall mean (A) all Patents included in the Group Owned Intellectual Property, and (B) all Patents included in Third Party Intellectual Property which the Company has the right or responsibility to prosecute, maintain and/or enforce pursuant to any IP Contract.

(v) "Products" shall mean the products of the Company known as DepoCyt, DepoDur, and DepoBupivacaine, but, in each case, only the form of such products, and the formulation and specification thereof, (1) in existence as of the Closing, or (2) as contemplated by an authorization or approval filed by the Company with a Relevant Regulatory Authority on or before the Closing, including any supplements thereto, in each case as filed on or before the Closing Date.

(vi) "Product Candidates" shall mean those products currently under pre-clinical research and development by the Company, including all products that are based on or derived from the DepoFoam or Biosphere technologies, but in each case, only the form of such products, and the formulation and specification thereof, in existence as of the Closing Date.

(vii) “Product Intellectual Property” shall mean all Company Intellectual Property included in, covering or used in connection with the Products or Product Candidate, or their therapeutic use or manufacture.

(viii) “Registered Intellectual Property” shall mean any and all U.S. and non-U.S. (A) Patents, (B) Trademark, (C) copyright registrations and applications therefor, (D) internet domain names, and (E) any other Intellectual Property that is the subject matter of an application, certificate, filing, registration or other document issued by, filed with, or recorded by any Governmental Entity.

(ix) The phrases “intended to be used,” “intended to be conducted,” and “intended to be done” in this Section 3.13 shall mean and be limited to the intent of the Company’s management prior to Closing as demonstrated by written business plans provided to Buyer prior to Closing.

(x) As used in this Section 3.13 only, the term “Affiliate” shall mean any affiliate, as defined in Rule 12b-2 under the Securities Exchange Act of 1934, existing on or before the Closing Date.

(b) Section 3.13(b) of the Seller Disclosure Schedule sets forth a complete and accurate list of (i) each item of Registered Intellectual Property that is included in the Group Owned Intellectual Property, in each case, enumerating specifically whether it is Company Owned Intellectual Property or Affiliate Owned Intellectual Property, and the applicable filing or registration number, title, jurisdiction in which filing was made or from which registration issued, date of filing or issuance, names of all current applicant(s) and registered owners(s), as applicable, and (ii) each IP Contract, specifically indicating the parties to such IP Contract and, as applicable, each amendment to each original agreement included in each such IP Contract (excluding IP Contracts of currently available, off the shelf software programs licensed by the Company pursuant to “shrink wrap” licenses, the total fees associated with which are less than [\*\*] dollars (\$[\*\*]) in the aggregate). All assignments of Registered Intellectual Property listed in Section 3.13(b) of the Seller Disclosure Schedule to the Company or to the applicable Affiliate have been, or as of the Closing Date shall be, properly executed and recorded in the name of Company.

(c) Except as set forth in Section 3.13(c)(1) of the Seller Disclosure Schedule which identifies the joint owners of the Company Owned Intellectual Property, the Company is the sole and exclusive owner of each item of Company Owned Intellectual Property, free and clear of any Encumbrance. Section 3.13(c) of the Seller Disclosure Schedule sets forth a complete and accurate list of Affiliate Owned Intellectual Property and, in each case, each applicable Affiliate that has an ownership interest therein. Except as set forth in Section 3.13(c)(2) of the Seller Disclosure Schedule which identifies the joint owners of the Affiliate Owned Intellectual Property, each Affiliate so listed is the sole and exclusive owner of each such item of Affiliate Owned Intellectual Property, free and clear of any Encumbrance. Except as set forth in Section 3.13(c)(3) of the Seller Disclosure Schedule, the Company or an Affiliate of Company, as applicable, is listed in the records of the appropriate U.S. and/or non-U.S. Governmental Entity as the sole and exclusive owner of record for each item of Registered Intellectual Property as such owner is listed in Section 3.13(b) of the Seller Disclosure Schedule or as a joint owner for each Company Owned Intellectual Property identified in Section 3.13 (c) of the Seller Disclosure Schedule. On or before the Closing, the Company will be the sole owner of all Group Owned Intellectual Property.



(d) Each item of Company Intellectual Property will be owned or available for use by the Company immediately following the Closing on identical terms and conditions as it was immediately prior to the Closing. Neither Company nor any of its Affiliates is, or will as a result of the consummation of the transactions contemplated by this Agreement be, in breach in any material respect of any IP Contract.

(e) Except for the Trademarks and Patents identified in Section 3.13(b) of Seller Disclosure Schedule as abandoned, to the knowledge of Company and Seller, no act has been done or omitted to be done by the Company or any of its Affiliates, or by any direct or indirect licensee, distributor or collaborator of the Company or any Affiliate, or any Person or Governmental Entity with which the Company or any Affiliate is a co-owner of any Group Owned Intellectual Property, which has, had or is reasonably likely to have the effect of canceling, forfeiting, abandoning or dedicating to the public, or entitling any U.S. or non-U.S. Governmental Entity or any other Person to cancel, forfeit, modify or consider abandoned, any Group Owned Intellectual Property, or give any Person or Governmental Entity any rights with respect thereto. Neither the Company nor the Seller has any knowledge of any facts or claims which cause or would cause any Group Owned Intellectual Property to be invalid or unenforceable. Neither the Company nor any Affiliate has received any written notice that any Person or Governmental Entity may bring a claim that would cause any Group Owned Intellectual Property to be invalid or unenforceable.

(f) With respect to the Company Patents: (i) all necessary registration, maintenance and renewal fees due and owing as of the Closing Date have been paid on or before the Closing and all necessary documents and certificates have been filed with the relevant Governmental Entities for the purpose of maintaining such Company Patents; (ii) there are no inventorship challenges or interferences declared or provoked with respect to such Company Patents; (iii) the Company and each applicable Affiliate has complied with their respective required duty of candor and good faith in dealing with the U.S. Patent and Trademark Office and similar Governmental Entities (collectively, "Patent Offices") with respect to the Company Patents, including the duty to disclose to the Patent Offices all information required to be disclosed under all applicable laws and regulations; and (iv) other than through an IP Contract listed in Section 3.13(b) of the Seller Disclosure Schedule, no third party, including any academic organization or Governmental Entity, possesses any rights or licenses to any Company Patent.

(g) The Company owns, free and clear of any Encumbrance, or otherwise has the right to use through an IP Contract listed in Section 3.13(b) of the Seller Disclosure Schedule, the terms of which have been fully disclosed to Buyer, all Company Intellectual Property (including all Product Intellectual Property), which, in each case, is either used in or currently intended to be used in, or is reasonably necessary for, the conduct of the business of the Company as now conducted or as intended to be conducted, including in connection with the developing, making, using and commercializing of all Products or Product Candidates. Except as set forth in Section 3.13(g) of the Seller Disclosure Schedule, the Company Owned

Intellectual Property, together with the Third Party Intellectual Property under which Company has rights under an IP Contract listed in Section 3.13(b) of the Seller Disclosure Schedule, constitutes all Intellectual Property necessary (i) to make, use and sell, as applicable, the Company Products and Product Candidates in the manner so done currently and intended to be done, and (ii) to conduct the business of the Company in all material respects in the manner currently conducted or intended to be conducted by the Company, including in connection with developing, making, using and commercializing of all Products and Product Candidates.

(h) To the knowledge of Seller and the Company, neither the Company, nor the business of the Company as previously conducted, as now conducted or as intended to be conducted, or any other activity, product or service of the Company (including the developing, making, using and commercializing of Products or Product Candidates), is in violation or infringement of, or has violated or infringed any rights or asserted rights of any other Person or Governmental Entity with respect to any Intellectual Property of such other Person or Governmental Entity. The Company has not (and no Affiliate of the Company has, with respect to the business of the Company), received any notice alleging any conflict with or violation or infringement of the Intellectual Property rights of any third party by the Company or any Affiliate of the Company. There are no Legal Proceedings pending, with respect to any such conflict, violation or infringement, nor have any such Legal Proceedings been instituted or asserted in writing against the Company or, with respect to the business of the Company or any Product or Product Candidate, any Affiliate of the Company, and, to the to the knowledge of Seller and the Company, no Legal Proceedings have been threatened against Company or any Affiliate of Company with respect to business of Company or any Product or Product Candidate, alleging any violation of any rights or asserted rights of any other Person or Governmental Entity with respect to any Intellectual Property of such other Person or Governmental Entity. To the knowledge of Seller and the Company, there is no valid basis for any such Legal Proceeding against the Company.

(i) Section 3.13(i) of the Seller Disclosure Schedule lists any and all written complaints, claims and notices, and threats of any of the foregoing (including any notification that a license under any patent is or may be required), received by the Company, or by any Affiliate of the Company alleging infringement, violation or misappropriation of any third party Intellectual Property and any request or demand for indemnification or defense received by the Company, or by any Affiliate of the Company with respect any alleged infringement, violation or misappropriation of any third party Intellectual Property from any reseller, distributor, customer, user or any other third party; and the Company and Seller have provided to Buyer copies of all such written complaints, claims, notices, requests, demands or threats, as well as any legal opinions, studies, market surveys and analyses relating to any such alleged infringement, violation or misappropriation.

(j) No Legal Proceedings in which the Company or any Affiliate alleges that any Person or Governmental Entity is infringing upon, or otherwise violating, any Group Owned Intellectual Property, are pending, and none have been served by, instituted or asserted by the Company or any Affiliate To the knowledge of Seller and the Company, there is no valid basis for any such proceeding or claim. The Company and Seller have provided to Buyer copies of all correspondence, legal opinions, or written complaints, claims, notices or threats concerning the infringement, violation or misappropriation of any Group Owned Intellectual Property.

(k) The Company has obtained from all individuals who are or have been involved in the development or invention of any Company Owned Intellectual Property (as employees of the Company, as consultants, as employees of consultants or otherwise) assignments of any and all rights of such individuals with respect thereto, and each Affiliate owner of Affiliate Owned Intellectual Property has obtained from all individuals who are or have been involved in the development or invention of any Affiliate Owned Intellectual Property (as employees of such Affiliate, as consultants, as employees of consultants or otherwise) assignments of any and all rights of such individuals with respect thereto. To the knowledge of Company and the Seller, no officer or employee of the Company is subject to any agreement with any other Person or Governmental Entity which requires such officer or employee to assign any interest in any Intellectual Property developed during such officer's or employee's employment with Company to such Person or Governmental Entity.

(l) The Company and, where applicable, each of its Affiliates, has taken all reasonable actions which are necessary or reasonable in order to protect the Company Intellectual Property in a manner consistent with prudent commercial practice in the biopharmaceuticals industry. To the knowledge of the Company, Company, and with respect to the business of the Company and Company Products, each of its Affiliates, has complied in all material respects with all applicable contractual and legal requirements pertaining to information privacy and security. No written complaint relating to an improper use or disclosure of, or a breach in the security of, any such information has been made or threatened against Company or, with respect to any business of the Company or Company Products, any Affiliate of the Company. There has been no: (i) to the knowledge of the Company, unauthorized disclosure of any third party proprietary or confidential information in the possession, custody or control of Company, or (ii) material breach of Company's security procedures as a result of which confidential information has been disclosed to a third person. The Company, and each applicable Affiliate of the Company, has use commercially reasonable efforts to police the quality of all goods and services sold, distributed or marketed under each of trademark relating to any Product, and has use commercially reasonable efforts to enforce adequate quality control measures to ensure that no trademarks relating to any Product that it has licensed to others shall be deemed to be abandoned.

(m) The Company and its Affiliates has not sought, applied for nor received any support, funding, resources or assistance from any Governmental Entity in connection with the any Company Product or any facilities or equipment used in connection therewith.

3.14. Inventory. All inventory of the Company, taken as a whole, whether or not reflected on the Most Recent Net Assets Statement, is usable and saleable in the Ordinary Course of Business, except for obsolete items and items of below-standard quality, all of which have been written-off or written-down to the estimated net realizable value on the Most Recent Net Assets Statement. All inventories not written-off have been priced at the lower of cost or market on a first-in, first-out basis.

3.15. Contracts.

(a) Section 3.15 of the Seller Disclosure Schedule lists the following agreements (written or oral) to which the Company is a party or by which any asset or property of the Company is bound (including all amendments thereto and modifications thereof, waivers thereunder, and termination notices and agreements with respect thereto):

(i) all agreements with Mundipharma, Maruho, Endo Pharmaceuticals, Enzon, and/or Zeneus Pharmaceuticals, any portion of which is (or is claimed by any person to be) currently in effect;

(ii) any agreement (or group of related agreements) for the purchase or sale of products or for the furnishing or receipt of services (A) which calls for performance over a period of more than one year, or (B) which involves more than the sum of [\*\*] dollars (\$[\*\*]), or (C) in which the Company has granted manufacturing, marketing, sale or distribution rights, "most favored nation" pricing provisions or marketing or distribution rights relating to any product or territory, or (D) in which the Company has agreed to purchase a minimum quantity of goods or services or has agreed to purchase goods or services exclusively from a certain party;

(iii) any agreement concerning the establishment or operation of a partnership, joint venture or limited liability company;

(iv) any agreement (or group of related agreements) under which it has created, incurred, assumed or guaranteed (or may create, incur, assume or guarantee) indebtedness (including capitalized lease obligations) involving more than [\*\*] dollars (\$[\*\*]) or under which it has imposed (or may impose) an Encumbrance on any of its assets, tangible or intangible;

(v) any agreement for the disposition of any significant portion of the assets or business of the Company (other than sales of products in the Ordinary Course of Business) or any agreement for the acquisition of the assets or business of any other entity (other than purchases of inventory or components in the Ordinary Course of Business);

(vi) any agreement concerning confidentiality or noncompetition;

(vii) any employment, severance or consulting agreement;

(viii) any agreement involving any current or, to the knowledge of Seller and the Company, former officer, director or stockholder of the Company or, to the knowledge of Seller and the Company, any Affiliate thereof;

(ix) any agreement under which the consequences of a default or termination would reasonably be expected to have a Company Material Adverse Effect;

(x) any agreement which contains any provisions requiring the Company to indemnify any other party (excluding indemnities contained in agreements for the purchase, sale or license of products entered into in the Ordinary Course of Business);

(xi) any agreement (or group of related agreements) for the lease of personal property from or to third parties providing for lease payments in excess of [\*\*] dollars (\$[\*\*]) per annum or having a remaining term longer than three (3) months; and

(xii) any other agreement (or group of related agreements) either involving more than [\*\*] dollars (\$[\*\*]) or not entered into in the Ordinary Course of Business.

(b) The Company has delivered to Buyer a complete and accurate copy of each agreement required by the terms of Section 3.13 or 3.15 to be listed in Section 3.13 or Section 3.15 of the Seller Disclosure Schedule (each a “Material Contract” and collectively, the “Material Contracts”). With respect to each agreement so listed: (i) the agreement is legal, valid, binding and enforceable and in full force and effect as against the Company and, to the knowledge of Seller and the Company, each other party thereto; and (ii) neither the Company nor, to the knowledge of Seller and the Company, any other party, is in breach or violation of, or default under, any such agreement, and no event has occurred, is pending or, to the knowledge of Seller and the Company, is threatened, which, after the giving of notice, with lapse of time, or otherwise, would constitute a breach or default by the Company or, to the knowledge of Seller and the Company, any other party under such agreement. With respect to the termination of that certain license agreement with Endo Pharmaceuticals, Inc., the Company has no financial obligations to Endo Pharmaceuticals, Inc. other than as set forth in the Endo Termination Agreement.

3.16. Accounts Receivable. All accounts receivable of the Company reflected on the Most Recent Net Assets Statement (other than those paid since such date and other than accounts receivable to be eliminated pursuant to items “c” and “e” of Schedule 6.12) are valid receivables subject to no setoffs or counterclaims and are, to the knowledge of Seller and the Company, collectible within ninety (90) days after the date on which it first became due and payable consistent with the past practices of the Company, net of the applicable reserve for bad debts on the Most Recent Net Assets Statement. A complete and accurate list of the accounts receivable reflected on the Most Recent Net Assets Statement, showing the aging thereof, is included in Section 3.16 of the Seller Disclosure Schedule. All accounts receivable of the Company that have arisen since the Most Recent Net Assets Statement Date (other than accounts receivable to be eliminated pursuant to items “c” and “e” of Schedule 6.12) are valid receivables subject to no setoffs or counterclaims and are, to the knowledge of Seller and the Company, collectible within ninety (90) days after the date on which it first became (or becomes) due and payable consistent with the past practices of the Company net of the applicable reserve for bad debts in an amount proportionate to the reserve shown on the Most Recent Net Assets Statement. The Company has not received any written notice from an account debtor stating that any account receivable in an amount in excess of [\*\*] dollars (\$[\*\*]) is subject to any contest, claim or setoff by such account debtor.

3.17. Powers of Attorney. There are no outstanding powers of attorney executed on behalf of the Company.

3.18. Insurance. Section 3.18 of the Seller Disclosure Schedule lists and provides a summary of the material terms of each insurance policy (including fire, theft, casualty, comprehensive general liability, workers compensation, business interruption, environmental,

product liability and automobile insurance policies and bond and surety arrangements) which have been issued and delivered to the Company to which the Company is a party, all of which are in full force and effect. True and complete copies of each insurance policy held by the Company for the benefit of the Company and so identified in Section 3.18 of the Seller Disclosure Schedule have been provided to Buyer. There is no material claim pending under any such policy as to which coverage has been denied or, to the knowledge of Seller and the Company, questioned or disputed by the underwriter of such policy. All premiums due and payable under all such policies have been paid, the Company is not liable for retroactive premiums or similar payments, and the Company is otherwise in compliance in all material respects with the terms of such policies. To the knowledge of Seller and the Company, except as set forth in Section 3.18 of the Seller Disclosure Schedule, there has been no threatened termination of, or premium increase with respect to, any such policy.

3.19. Litigation. Except as set forth in Section 3.19 of the Seller Disclosure Schedule, there is no Legal Proceeding which is pending or has been threatened in writing against the Company which (a) seeks either damages in excess of [\*\*] dollars (\$[\*\*]) or equitable relief or (b) in any manner challenges or seeks to prevent, enjoin, alter or delay the transactions contemplated by this Agreement. Except as set forth in Section 3.19 of the Seller Disclosure Schedule, there are no judgments, orders or decrees outstanding against the Company, and there are no arbitration awards outstanding against the Company that have not been paid in full.

3.20. Warranties. No product or service manufactured, sold, leased, licensed or delivered by the Company is subject to any guaranty, warranty, right of return, right of credit or other indemnity other than (i) the applicable standard terms and conditions of sale of the Company, which are set forth in Section 3.20 of the Seller Disclosure Schedule and (ii) manufacturers' warranties for which the Company has no liability. Section 3.20 of the Seller Disclosure Schedule sets forth the aggregate expenses incurred by the Company in fulfilling their obligations under their guaranty, warranty, right of return and indemnity provisions during each of the fiscal years and the interim period covered by the Financial Statements; and neither Seller nor the Company knows of any reason why such expenses should significantly increase as a percentage of sales in the future.

3.21. Employees.

(a) Section 3.21 of the Seller Disclosure Schedule contains a list of all employees of the Company whose annual rate of compensation exceeds [\*\*] dollars (\$[\*\*]) per year, along with each such person's position. Seller has heretofore disclosed to Buyer the current annual rate of compensation of each such person. Each person who is or at any time since January 1, 2004 or, to the knowledge of Seller and the Company, since March 11, 1999 (inclusive) was or has been) an employee of the Company has entered into a confidentiality/assignment of inventions agreement with the Company, and a copy of the form of agreement has previously been delivered to Buyer. Section 3.21 of the Seller Disclosure Schedule contains a list of all employees of the Company who are a party to a non-competition agreement with the Company; copies of such agreements have previously been delivered to Buyer. All of the agreements referenced in the two preceding sentences will continue to be legal, valid, binding and enforceable and in full force and effect against the Company and, to the knowledge of Seller and the Company, against such employee immediately following the

Closing in accordance with the terms thereof as in effect immediately prior to the Closing. Section 3.21 of the Seller Disclosure Schedule contains a list of all employees of the Company who are not citizens of the United States. To the knowledge of Seller and the Company, no employee or group of employees whose departure could result in a Company Material Adverse Effect has any plans to terminate employment with the Company.

(b) The Company is not a party to or bound by any collective bargaining agreement, nor has any of them experienced any strikes, grievances, claims of unfair labor practices or other collective bargaining disputes. Neither Seller nor the Company has knowledge of any organizational effort made or threatened, either currently or within the past two years, by or on behalf of any labor union with respect to employees of the Company.

(c) The Company has (and after the Closing will have) no liability to any employee under any stock, option or similar plan or scheme of Seller. Seller is and will remain solely responsible, and the Company will have no liability or obligation, for the Company's Stay Incentive Program or any Stay Incentive Agreement or any other management retention plan, scheme, arrangement or agreement with or in favor of any Company executive or employee.

**3.22. Employee Benefits.**

(a) Section 3.22(a) of the Seller Disclosure Schedule contains a complete and accurate list of all Company Plans. Complete and accurate copies of (i) all Company Plans which have been reduced to writing, (ii) written summaries of all unwritten Company Plans, (iii) all related trust agreements, insurance contracts and summary plan descriptions, and (iv) all annual reports filed on IRS Form 5500, 5500C or 5500R and (for all funded plans) all plan financial statements for the last three (3) plan years for each Company Plan, have been delivered to Buyer.

(b) Each Company Plan has been administered in all material respects in accordance with its terms and each of the Company and the ERISA Affiliates has in all material respects met its obligations with respect to each Company Plan and has made all required contributions thereto. The Company, each ERISA Affiliate and each Company Plan are in compliance in all material respects with the currently applicable provisions of ERISA and the Code and the regulations thereunder (including Section 4980 B of the Code, Subtitle K, Chapter 100 of the Code and Sections 601 through 608 and Section 701 et seq. of ERISA). All filings and reports as to each Company Plan required to have been submitted to the Internal Revenue Service or to the United States Department of Labor have been duly submitted. No Company Plan that is qualified under Section 401(a) of the Code has assets that include securities issued by the Company or any ERISA Affiliate.

(c) There are no Legal Proceedings (except claims for benefits payable in the normal operation of the Company Plans and proceedings with respect to qualified domestic relations orders) against or involving any Company Plan or asserting any rights or claims to benefits under any Company Plan that could give rise to any material liability.

(d) All the Company Plans that are intended to be qualified under Section 401(a) of the Code have received determination letters, or opinion letters relating to prototype plans upon which the Company is entitled to rely, from the Internal Revenue Service to the effect that such Company Plans are qualified and the plans and the trusts related thereto are exempt from federal income taxes under Sections 401(a) and 501(a), respectively, of the Code, no such determination letter has been revoked and revocation has not been threatened, and no act or omission has occurred with respect to any such Company Plan, that would adversely affect its qualification or materially increase its cost. Each Company Plan which is required to satisfy Section 401(k)(3) or Section 401(m)(2) of the Code has been tested for compliance with, and satisfies the requirements of Section 401(k)(3) and Section 401(m)(2) of the Code for each plan year ending prior to the Closing Date.

(e) Neither the Company nor any ERISA Affiliate has ever maintained an Employee Benefit Plan subject to Section 412 of the Code or Title IV of ERISA.

(f) At no time has the Company or any ERISA Affiliate been obligated to contribute to any "multiemployer plan" (as defined in Section 4001(a)(3) of ERISA).

(g) There are no unfunded obligations under any Company Plan providing benefits after termination of employment to any employee of the Company (or to any beneficiary of any such employee), including but not limited to retiree health coverage and deferred compensation, but excluding continuation of health coverage required to be continued under Section 4980B of the Code or other applicable law and insurance conversion privileges under state law. The assets of each Company Plan which is funded are reported at their fair market value on the books and records of such Company Plan.

(h) No act or omission has occurred and no condition exists with respect to any Company Plan that would subject the Company or any ERISA Affiliate to (i) any material fine, penalty, tax or liability of any kind imposed under ERISA or the Code or (ii) any contractual indemnification or contribution obligation protecting any fiduciary, insurer or service provider with respect to any Company Plan.

(i) No Company Plan is funded by, associated with or related to a "voluntary employee's beneficiary association" within the meaning of Section 501(c)(9) of the Code.

(j) Each Company Plan is amendable and terminable unilaterally by the Company at any time without liability or expense to the Company or such Company Plan as a result thereof (other than for benefits accrued through the date of termination or amendment and reasonable administrative expenses related thereto) and no Company Plan, plan documentation or agreement, summary plan description or other written communication distributed generally to employees by its terms prohibits the Company from amending or terminating any such Company Plan.

(k) The Company has not made any payment, is not obligated to make any payment, and is not a party to any agreement that could obligate it to make any payment that may be treated as an "excess parachute payment" under Section 280G of the Code (without regard to Sections 280G(b)(4) and 280G(b)(5) of the Code) or that may be subject to the tax imposed by Section 4999 of the Code.



(l) Section 3.22(l) of the Seller Disclosure Schedule sets forth the policy of the Company with respect to accrued vacation, accrued sick time and earned time off and the amount of such liabilities as of the date of this Agreement.

(m) Each Company Employee Plan that is a “nonqualified deferred compensation plan” (as defined in Code Section 409A(d)(1)) has been operated since January 1, 2005 in good faith compliance with Code Section 409A and IRS Notice 2005-1. No Company Employee Plan that is a “nonqualified deferred compensation plan” has been materially modified (as determined under Notice 2005-1) after October 3, 2004. No event has occurred that would be treated by Code Section 409A(b) as a transfer of property for purposes of Code Section 83. No stock option or equity unit option granted under any Company Employee Plan has an exercise price that has been or may be less than the fair market value of the underlying stock or equity units (as the case may be) as of the date such option was granted or has any feature for the deferral of compensation other than the deferral of recognition of income until the later of exercise or disposition of such option.

3.23. Environmental Matters.

(a) Except as set forth in Section 3.23(a) of the Seller Disclosure Schedule, the Company has complied and currently is in compliance in all material respects with all applicable Environmental Laws. There is no pending or, to the knowledge of Seller and the Company, threatened civil or criminal litigation, notice of violation, noncompliance or penalty assessment, formal administrative proceeding, or investigation, inquiry or information request by any Governmental Entity, relating to any Environmental Law involving the Company. Except as set forth in Section 3.23(a) of the Seller Disclosure Schedule, the Company has not been the subject of any such litigation, proceeding, investigation, inquiry or information request, or received any such notice, within the last three (3) years.

(b) Except as set forth in Section 3.23(b) of the Seller Disclosure Schedule, the Company has no material liabilities or obligations arising from the release of any Materials of Environmental Concern into the environment.

(c) Except as set forth in Section 3.23(c) of the Seller Disclosure Schedule, the Company is not a party to or bound by any court order, administrative order, consent order or other agreement between the Company and any Governmental Entity entered into in connection with any legal obligation or liability arising under any Environmental Law.

(d) Set forth in Section 3.23(d) of the Seller Disclosure Schedule is a list of all documents (whether in hard copy or electronic form) that contain any environmental reports, notices of noncompliance, violation or penalty assessment, investigations and audits relating to premises currently or previously owned or operated by the Company (whether conducted by or on behalf of the Company or a third party, and whether done at the initiative of the Company or directed by a Governmental Entity or other third party) which were received by or issued to the Company since the acquisition of the Company by Parent or Seller and of which the Company has possession or to which the Company has access. A complete and accurate copy of each such document has been provided by Seller to Buyer.

(e) Section 3.23(e)(1) of the Seller Disclosure Schedule sets forth a list of all material Permits issued to or held by the Company pursuant to any Environmental Law. Except as set forth in Section 3.23(e)(2) of the Seller Disclosure Schedule, (i) the Permits listed in Section 3.23(e)(1) of the Seller Disclosure Schedule are the only material Permits pursuant to Environmental Laws that are required for the Company to conduct its business as presently conducted, (ii) each such listed Permit is in full force and effect, (iii) the Company is in compliance in all material respects with the terms of each Permit listed in Section 3.23(e)(1) of the Seller Disclosure Schedule, and (iv) to the knowledge of Seller and the Company, no suspension or cancellation of any Permit listed in Section 3.23(e)(1) of the Seller Disclosure Schedule is threatened and there is no basis for believing that any such Permit listed in Section 3.23(e)(1) of the Seller Disclosure Schedule will not be renewable upon expiration. A complete and accurate copy of each Permit listed in Section 3.23(e)(1) of the Seller Disclosure Schedule has been provided by Seller to Buyer.

(f) Neither Seller nor the Company has any knowledge of any material environmental liability of any solid or hazardous waste transporter or treatment, storage or disposal facility that has been used by the Company.

(g) The Company has installed equipment sufficient to discharge wastewater from each of the Company's facilities in connection with the business as presently conducted at each such facility in compliance with the conditions and limitations set forth in the current wastewater discharge permits issued by any Governmental Entity for each such facility.

3.24. Legal Compliance. The Company is currently conducting, and has at all times since the acquisition of the Company by Seller conducted, its businesses in compliance in all material respects with each applicable law (including rules and regulations thereunder) of any Governmental Entity. The Company has not received any written or, to the knowledge of Seller and the Company, other notice or communication from any Governmental Entity or qui tam relator alleging noncompliance in any material respect with any applicable law, rule or regulation.

3.25. Customers and Suppliers. Section 3.25 of the Seller Disclosure Schedule sets forth a list of (a) each customer that accounted for more than one percent (1%) of the revenues of the Company during the last full fiscal year or the interim period through the Most Recent Net Assets Statement Date and the amount of revenues accounted for by such customer during each such period and (b) each supplier that is the sole supplier of any significant product or service to the Company. No such customer or supplier has indicated within the past year that it will stop, or decrease the rate of, buying products or supplying products, as applicable, to the Company in any material amount. No unfilled customer order or commitment obligating the Company or to process, manufacture or deliver products or perform services will result in a loss to the Company upon completion of performance. No purchase order or commitment of the Company is in excess of normal requirements, nor are prices provided therein in excess of current market prices for the products or services to be provided thereunder.

3.26. Permits. Section 3.26 of the Seller Disclosure Schedule sets forth a list of all material Permits issued to or held by the Company. Such listed Permits are the only material Permits that are required for the Company to conduct its business as presently conducted. Each

such Permit is in full force and effect; the Company is in compliance in all material respects with the terms of each such Permit; and, to the knowledge of Seller and the Company, no suspension or cancellation of such Permit is threatened and there is no basis for believing that such Permit will not be renewable upon expiration.

3.27. Certain Business Relationships With Affiliates. Neither Seller nor any other Affiliate of the Company (a) owns any property or right, tangible or intangible, which is used in the business of the Company, (b) has any claim or cause of action against the Company, or (c) owes any money to, or is owed any money by, the Company. Section 3.27 of the Seller Disclosure Schedule describes any transactions or relationships between the Company and any Affiliate thereof which occurred or have existed since the beginning of the time period covered by the Financial Statements.

3.28. Books and Records. The minute books and other similar records of the Company contain complete and accurate records of all actions taken at any meetings of the Company's stockholders, Board of Directors or any committee thereof and of all written consents executed in lieu of the holding of any such meeting. The books and records of the Company accurately reflect in all material respects the business assets, liabilities, condition (financial or otherwise) and results of operations of the Company and have been maintained in accordance with good business and bookkeeping practices. Section 3.28 of the Seller Disclosure Schedule contains a list of all bank accounts and safe deposit boxes of the Company and the names of persons having signature authority with respect thereto or access thereto.

3.29. Projections. The projections set forth in the "SkyePharma, Inc. Business Plan 2007-2010" were prepared in good faith by the Company on the basis of assumptions believed by the Company at the time of such preparation to be reasonable and information believed by the Company at the time of such preparation to be reliable and represented the best estimate of the Company at the time of such preparation of the matters set forth therein. Such projections were prepared in or about summer of 2006 and were based on assumptions, information and estimates that may or may not still be operative. Buyer acknowledges and understands that neither such Business Plan nor the projections contained therein constitute a promise, guarantee or representation of the financial, product development, sales, marketing or other performance or prospects of the Company.

3.30. Regulation. Solely for purposes of this Section 3.30, (i) "Products" shall mean the products that the Company (or, for and on behalf of the Company) (A) currently manufactures, markets, sells or licenses, or (B) have in clinical development, including products known as DepoCyt, DepoDur, and DepoBupivacaine, and (ii) "Product Candidates" shall mean those products currently under pre-clinical research and development by the Company, including those products that are based on or derived from the DepoFoam or Biosphere technologies.

(a) Compliance with Applicable Laws and Regulations. The Company is, and has been, in compliance in all material respects with all laws, rules, regulations, guidances and orders applicable to the research and development, manufacturing, processing, distribution, labeling, storage, testing, specifications, advertising and promotion, adverse event reporting, sale or marketing of any Product or Product Candidate by or on behalf of the Company, including the U.S. Federal Food, Drug, and Cosmetic Act ("FDCA") and the Public Health Service Act

(“PHSA”) and their applicable implementing regulations, all comparable state laws, and all other laws enforced by the U.S. Food and Drug Administration (“FDA”) or Drug Enforcement Administration (“DEA”), any comparable state or local regulatory authority, the U.K. Medicines and Healthcare products Regulatory Agency (“MHPRRA”), the European Medicines Evaluation Agency (“EMEA”), Health Canada (“HC”), and other comparable governmental or regulatory authority in each jurisdiction where the Products and Product Candidates are (or are currently proposed to be) developed, processed, tested, manufactured, labeled, stored, distributed, sold, or marketed, as applicable, by or on behalf of the Company (each, a “Relevant Regulatory Authority,” and collectively, the “Relevant Regulatory Authorities”).

(b) Eligibility for Government Programs. The Company is not debarred, excluded or restricted in any manner from participation in, any government program related to drug and biological products or any government funded health care program and, to its knowledge, does not and has not employed or obtained products or services from any debarred or otherwise excluded or restricted individual.

(c) Manufacturing Operations. All manufacturing operations conducted by the Company have been and are being conducted in compliance, in all material respects, with the FDA’s or Relevant Regulatory Authorities’ current Good Manufacturing Practices regulations, policies, and requirements for drug and biological products. In addition, each of Seller and the Company is in material compliance with all applicable registration and listing requirements set forth in 21 U.S.C. §360 and 21 CFR Part 207 and all similar applicable laws and regulations. Except as disclosed in Section 3.30(c)(1) of the Seller Disclosure Schedule, there are no FDA Form 483 notices or similar notices with respect to alleged violation of, or non-compliance with, any laws or regulations in connection with the facilities where Company manufactures any Products or Product Candidates. Except as disclosed in Section 3.30(c)(2) of the Seller Disclosure Schedule, to the knowledge of Seller and the Company, no Third Party manufacturer of Products or Product Candidates or active pharmaceutical ingredient or excipient used in any Products or Product Candidates has received an FDA Form 483 notice or similar notice with respect to alleged violation of, or non-compliance with, any laws or regulations in connection with any facility where such Third Party manufacturer manufactures any Product or Product Candidate or active pharmaceutical ingredient or excipient used in any Product or Product Candidate.

(d) Preclinical Tests and Clinical Trials.

(i) To the knowledge of Seller and the Company, all clinical investigations and trials (including any post-marketing studies), animal studies and preclinical tests and investigations conducted or sponsored by the Company (or on behalf of the Company) (“Preclinical Tests and Clinical Trials”) relating to any Product or Product Candidate have been, and if still pending, are being, conducted in compliance in all material respects with all applicable laws, rules, and regulations, administered or issued by the FDA or any other Relevant Regulatory Authority where the Preclinical Tests and Clinical Trials are being conducted and the requirements and approvals of the applicable institutional review boards or similar entities, including the protocols and informed consents, as applicable, with respect to each Clinical Trial.

(ii) Neither Seller nor the Company has received any written notice from the FDA or any other Relevant Regulatory Authority where the Preclinical Tests or Clinical Trials are being conducted or any institutional review board or similar entity with jurisdiction over a particular Clinical Trial requiring the termination, suspension, clinical hold, or material modification of any animal study, preclinical study or clinical trial conducted or sponsored by or on behalf of the Company. The Company has not suspended, put on hold or terminated prior to completion any Preclinical Test or Clinical Trial due to adverse events or other safety or efficacy reasons reported during the conduct of such Preclinical Test or Clinical Trial.

(e) Status of Applications. Except as disclosed in Section 3.30(e) of the Seller Disclosure Schedule, the Company has not received any information from the FDA or any other Relevant Regulatory Authority that states or would reasonably be interpreted to mean that any application or supplemental application for marketing approval of any Product or Product Candidate currently pending before the FDA or any other Relevant Regulatory Authority may not receive approval.

(f) No Suspensions or Recalls. Neither Seller nor the Company nor any of their respective representatives, nor, to the knowledge of Seller and the Company, any licensee or assignee of any Product or Product Candidate has received any notice that the FDA or any other Relevant Regulatory Authority has initiated, or threatened to initiate, any action to suspend or otherwise restrict the manufacture, sale, or distribution of any Product or Product Candidate. Except as set forth in Section 3.30(f) of Seller Disclosure Schedule, the Company has not conducted any recalls of any Product. There are no pending or, to the knowledge of Seller and the Company, threatened civil, criminal or administrative actions, suits, demands, claims, hearings, investigations, proceedings, complaints, voluntary or involuntary market withdrawals, field corrective actions, safety alerts, destruction orders, seizures, injunctions, adverse letters concerning promotional materials, or other regulatory enforcement actions related to any Product. To the knowledge of Seller and the Company, there is no act, omission, event, or circumstance that would reasonably be expected to give rise to any such action. To the knowledge of Seller and the Company, there are no known material adverse effects from the use of any marketed Products which are not disclosed in the Products' labeling, and there are no known material adverse effects from the use of any investigational Products which have not been disclosed to the clinical investigators.

(g) No False Statements. Neither Seller nor the Company nor, to the knowledge of Seller and the Company, any of their respective officers, employees or agents acting for Seller or the Company is subject to any pending or, to the knowledge of Seller and the Company, threatened, investigation by (A) the FDA pursuant to its "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" policy set forth in 56 Fed. Reg. 46191 (September 10, 1991) or any amendments thereto, (B) the Department of Health and Human Services Office of Inspector General, Department of Justice, or other Governmental Entity pursuant to the Federal Anti-Kickback Statute (42 U.S.C. §1320a-7(b)), or the Federal False Claims Act, or similar state or foreign law. To the knowledge of Seller and the Company, Seller and the Company have not and none of their respective officers, employees or agents acting for Seller or the Company has committed any act, made any statement or failed to make any statement that would reasonably be expected to provide a basis for action under any of the statutes, regulations,

and policy referred to in the foregoing statement. Seller and the Company have not and none of their respective officers, employees or agents acting for Seller or the Company has been convicted of any crime or engaged in any conduct that, to the knowledge of Seller and the Company, would reasonably be expected to result in (A) debarment under 21 U.S.C. §335a or any similar state or foreign law or (B) exclusion under 42 U.S.C. §1320a-7 or any similar state or foreign law.

(h) Correspondence and Reports. Seller has delivered or made available to Buyer (by deposit into the online and physical data room maintained by Seller in connection with the transactions contemplated by this Agreement followed by written notice of such deposit to Buyer) true, correct and complete copies of:

(i) all notices of inspectional observations, establishment inspection reports and any other documents received from the FDA or any other Relevant Regulatory Authority, that indicate a lack of compliance with the regulatory requirements of the FDA or any other Relevant Regulatory Authority, including any regulatory or warning letters or notice under 21 U.S.C. § 335 with respect to any Product or Product Candidate;

(ii) all written correspondence or reports to or from the FDA and each Relevant Regulatory Authority, all written summaries of meetings, with the FDA and each Relevant Regulatory Authority, and all other written records relating to material contacts between Seller, the Company or any of their representatives, on the one hand, and the FDA or any other Relevant Regulatory Authority, on the other hand, relating to the Company or any Product or Product Candidate;

(iii) each New Drug Application (“NDA”) and each Investigational New Drug Application (“IND”), and each similar state or foreign regulatory submission made by or on behalf of the Company, including all supplements and amendments thereto which relates to any Product or Product Candidate.

(i) No Proceedings. To the knowledge of Seller and the Company, there are no proceedings pending with respect to any violation or alleged violation by Seller or the Company of the FDCA, FDA regulations adopted thereunder, the Controlled Substance Act or any other legislation or regulation promulgated by any other Governmental Entity.

(j) Certain Claims and Payments.

(i) To the knowledge of Seller and the Company, the Company has not (i) solicited, received, paid or offered to pay any remuneration, directly or indirectly, overtly or covertly, in cash or kind, for the purpose of making or receiving any referral, purchase, lease, order, or recommendation of a purchase, lease, or order, which violated any applicable anti-kickback or similar law, including the Anti-Kickback Statute, or any applicable state anti-kickback law, or (ii) submitted or caused to be submitted any claim for payment to any payment program in violation of any laws relating to false claims or fraud, including the Federal False Claims Act, 31 U.S.C. § 3729 and 18 U.S.C. § 287 (the “Federal False Claims Act”); the Program Fraud Civil Remedies Act, 31 U.S.C. § 3802 (the “Program Fraud Civil Remedies Act”); or any applicable state false claim or fraud law.

(ii) The Company has complied with all applicable data security and privacy standards, laws, and regulations regarding health information, including without limitation all applicable privacy, data security, and data security breach notification laws or regulations, and contractual obligations undertaken by the Company pursuant to such laws or regulations.

(iii) Section 3.30(j) of the Seller Disclosure Schedule lists all written claims or statements (including all material correspondence) received from Governmental Entities during the three year period prior to the Closing which alleges (i) any material violation of any applicable rule, regulation, policy or requirement of any federal or state government funded healthcare program with respect to any activity, practice or policy of the Company, including any claim for payment or reimbursement submitted or caused to be submitted by the Company or any payment or reimbursement paid to the Company. To the knowledge of Seller and the Company, the Company is not in material violation of any applicable rule, regulation, policy or requirement of any federal or state government funded healthcare program and there is no reasonable basis to anticipate any investigation or inquiry, or the assertion of any claim or demand by any Governmental Entities with respect to any of the activities, practices, policies or claims of the Company, or any payments or reimbursements claimed by the Company, in each case concerning or relating to any federal or state government funded health care program. The Company is not the subject of any outstanding audit by any Governmental Entities. To the knowledge of Seller and the Company, there are no reasonable grounds to anticipate any such audit, except such audits in the ordinary course of review.

(k) Compliance with Certain Statutes and Regulations.

(i) To the knowledge of Seller and the Company, the Company has not submitted or caused to be submitted any claim to any government-funded health care program in connection with any referrals that violated any applicable self-referral law, including the Federal Ethics in Patient Referrals Act, 42 U.S.C. § 1395nn (known as the “Stark Law”), or any applicable state self-referral law.

(ii) Neither the Company nor, to the knowledge of Seller and the Company, any of their respective officers, directors or employees, acting in their capacities as such, is or has been involved in any activities which are, or are alleged in writing by any qui tam relator or Governmental Entity to be, prohibited under the federal Medicare and Medicaid statutes, including 42 U.S.C. §§ 1320a-7, 1320a-7a, 1320a-7b, 1395nn, 31 U.S.C. § 3802, 18 U.S.C. § 1347, § 287, §1001, and § 1035, or the federal CHAMPUS/TRICARE statute, or the regulations promulgated pursuant to such federal statutes.

(l) Authorizations and Permits. To the knowledge of Seller and the Company, Seller and the Company have received approval from the FDA and all other applicable Relevant Regulatory Authorities of all registrations, applications, licenses, requests for exemptions, permits and other regulatory authorizations necessary to conduct the business of the Company as currently conducted (the “Material Permits”) and all such Material Permits are valid and in full force and effect. To the knowledge of Seller and the Company, any third party which is a manufacturer of any Product or Product Candidate, or active pharmaceutical ingredient or excipient thereof, for the Company is in compliance in all material respects with all

approvals, registrations, applications, licenses, requests for exemptions, permits and other regulatory authorizations of the FDA and other Relevant Regulatory Authorities insofar as the same pertain to the manufacture of any Product or Product Candidate, or active pharmaceutical ingredient or excipient thereof, for the Company. To the knowledge of Seller and the Company, no Relevant Regulatory Authority is considering revoking, withdrawing, suspending, canceling, terminating or modifying any Material Permit.

(m) Rights and Obligations Respecting Other Products, Product Candidates, and Regulatory Matters . Except as set forth in Section 3.30(m) of the Seller Disclosure Schedule, there are no NDAs, ANDAs, INDs, Drug Master Files (“DMF”), regulatory agent relationships, or other regulatory applications, dossiers, licenses, permits, or filings of any kind in any jurisdiction, for which the Company has any right, interest, ownership, obligation, or authority, other than those related to DepoCyt, DepoDur, DepoBupivacaine and products related to the Biosphere technology. To the knowledge of Seller and the Company, the Company has complied with all legal and regulatory requirements and obligations administered or enforced by all Relevant Regulatory Authorities in connection with the NDAs, ANDAs, INDs, DMFs, and regulatory agent relationships identified in Section 3.30(m) of the Seller Disclosure Schedule.

3.31. Disclosure. No representation or warranty by Seller contained in this Agreement or any Ancillary Agreement, and no statement contained in the Seller Disclosure Schedule or any other document, certificate or other instrument delivered or required to be delivered by or on behalf of Seller or the Company pursuant to this Agreement or any of the Ancillary Agreements, contains or will contain any untrue statement of a material fact or omits or will omit to state any material fact necessary, in light of the circumstances under which it was or will be made, in order to make the statements herein or therein not misleading. Seller and the Company have not failed to disclose to Buyer any agreement, commitment, obligation, regulatory inquiry or notice, legal claim or liability of the Company (whether absolute or contingent) that (a) is known to Seller or the Company or would be known to Seller or the Company after reasonable inquiry by them and (b) is not within the actual knowledge of Buyer and (c) would be reasonably considered to be material to the Company. Solely for purposes of this Section 3.31, it is agreed that Buyer shall be presumed to have actual knowledge of the following documents that Seller has delivered or made available to Buyer and its legal and accounting advisers: (i) documents included in electronic form on the Stringer Saul LLP “Project San Diego” CD’s dated November 2006 and delivered to Buyer and its legal and accounting advisers in November 2006; (ii) documents in paper form delivered to Buyer and its legal and accounting advisers since November 17, 2006; (iii) documents in the online and physical data rooms on November 22, 2006 that have been maintained by the Company in connection with the transactions contemplated by this Agreement and to which Buyer and its legal and accounting advisers were provided actual access (as listed in the indexes e-mailed to Buyer on November 22, 2006); and (iv) documents e-mailed to Buyer and its legal and accounting advisers after November 22, 2006, or deposited after November 22, 2006 into the online and physical data rooms followed by written notice (including notice by e-mail) of such deposit, listing the documents so deposited, to Buyer.



**ARTICLE IV  
REPRESENTATIONS AND WARRANTIES OF BUYER**

Buyer represents and warrants to Seller that the statements contained in this Article III are true and correct as of the date of this Agreement and will be true and correct as of the Closing as though made as of the Closing, except to the extent such representations and warranties are specifically made as of a particular date (in which case such representations and warranties will be true and correct as of such date).

4.1. Organization, Qualification and Corporate Power. Buyer is a corporation duly organized, validly existing and in good standing under the laws of the state of its incorporation. Buyer is duly qualified to conduct business and is in corporate and tax good standing under the laws of each jurisdiction in which the nature of its businesses or the ownership or leasing of its properties requires such qualification, except where the failure to be so qualified or in good standing would not have a Buyer Material Adverse Effect. Buyer has all requisite corporate power and authority to carry on the businesses in which it is engaged and to own and use the properties owned and used by it. Buyer has furnished or made available to Seller complete and accurate copies of its Certificate of Incorporation and By-laws.

4.2. Authorization of Transaction. Buyer has all requisite power and authority to execute and deliver this Agreement and the Ancillary Agreements and to perform its obligations hereunder and thereunder. The execution and delivery by Buyer of this Agreement and the Ancillary Agreements to which Buyer is a party and the consummation by Buyer of the transactions contemplated hereby and thereby have been duly and validly authorized by all necessary corporate action on the part of Buyer. This Agreement has been duly and validly executed and delivered by Buyer and constitutes a valid and binding obligation of Buyer, enforceable against it in accordance with its terms.

4.3. Noncontravention. Neither the execution and delivery by Buyer of this Agreement or the Ancillary Agreements to which it is a party, nor the consummation by Buyer of the transactions contemplated hereby or thereby, will (a) conflict with or violate any provision of the charter or By-laws of Buyer, (b) require on the part of Buyer any filing with, or permit, authorization, consent or approval of, any Governmental Entity, (c) conflict with, result in breach of, constitute (with or without due notice or lapse of time or both) a default under, result in the acceleration of obligations under, create in any party any right to terminate, modify or cancel, or require any notice, consent or waiver under, any contract or instrument to which Buyer is a party or by which it is bound or to which its assets are subject, except for (i) any conflict, breach, default, acceleration, termination, modification or cancellation which would not adversely affect the consummation of the transactions contemplated hereby or (ii) any notice, consent or waiver the absence of which would not adversely affect the consummation of the transactions contemplated hereby, or (d) violate any order, writ, injunction, decree, statute, rule or regulation applicable to Buyer or any of its properties or assets.

4.4. Brokers' Fees. Buyer has no liability or obligation to pay any fees or commissions to any broker, finder or agent with respect to the transactions contemplated by this Agreement or any of the Ancillary Agreements.

4.5. **Investment Representation.** Buyer is acquiring the Shares from Seller for its own account for investment and not with a view to, or for sale in connection with, any distribution thereof, nor with any present intention of distributing or selling the same; and, except as contemplated by this Agreement and the agreements contemplated herein, Buyer has no present or contemplated agreement, undertaking, arrangement, obligation, indebtedness or commitment providing for the disposition thereof.

4.6. **Funding.** Buyer has heretofore obtained equity commitment letters (the “**Commitment Letters**”) covering the funding expected to be required for the consummation of the transactions contemplated by this Agreement and naming Parent as a third party beneficiary, copies of which have heretofore been provided to Seller. Each such Commitment Letter is in full force and effect in the form heretofore provided to Seller. Buyer has no reason to believe that the Commitment Letters will not be fully performed in accordance with the terms thereof.

## **ARTICLE V COVENANTS**

5.1. **Closing Efforts.** Each of the Parties shall use its commercially reasonable efforts to take all actions and to do all things necessary, proper or advisable to consummate the transactions contemplated by this Agreement, including using its commercially reasonable efforts to procure that (i) its representations and warranties remain true and correct in all material respects through the Closing Date and (ii) the conditions to the obligations of the other Parties to consummate the transactions contemplated by this Agreement are satisfied.

### **5.2. Governmental and Third-Party Notices and Consents.**

(a) Each Party shall use its commercially reasonable efforts to obtain, at its expense, all waivers, permits, consents, approvals or other authorizations from Governmental Entities, and to effect all registrations, filings and notices with or to Governmental Entities, as may be required for such Party to consummate the transactions contemplated by this Agreement and the Ancillary Agreements and to otherwise comply with all applicable laws and regulations in connection with the consummation of the transactions contemplated by this Agreement and the Ancillary Agreements. Without limiting the generality of the foregoing, each Party shall use its commercially reasonable efforts to make all necessary filings, and thereafter make any other required submissions, with respect to this Agreement and the transactions contemplated hereby, required under (i) the HSR Act and any other federal, state or foreign law designed to prohibit, restrict or regulate actions for the purpose or effect of monopolization or restraint of trade (collectively “**Antitrust Laws**”), and to respond to any government requests for information under any Antitrust Law. The Parties will consult and cooperate with one another, and consider in good faith the views of one another, in connection with any analyses, appearances, presentations, memoranda, briefs, arguments, opinions and proposals made or submitted by or on behalf of any Party hereto in connection with proceedings under or relating to any Antitrust Law. Notwithstanding anything to the contrary in this Agreement, neither Party shall be obligated (A) to institute or pursue litigation or (B) to sell or dispose of or hold separately (through a trust or otherwise) any assets or businesses. Buyer shall pay the filing fees of the notification reports required to be filed under the HSR Act.

(b) Seller and the Company shall, and shall procure that Parent shall, use their respective commercially reasonable efforts to obtain, at Seller's and Parent's expense, all such waivers, consents or approvals from third parties, and to give all such notices to third parties, as are required to be listed in the Seller Disclosure Schedule.

5.3. Parent Shareholder Approval. As promptly as practicable and (subject to receipt of approval by the UK listing authority) in no event more than ten (10) business days following the date of this Agreement (or, if later, three (3) business days after approval by the UK listing authority), Parent shall post a circular containing a notice calling an extraordinary general meeting of the shareholders of Parent ("EGM") to seek the requisite approval of Parent's shareholders (the "Circular"), such meeting to be held on a date as soon as practicable and in no event later than the thirtieth (30<sup>th</sup>) day following the posting of the Circular. Parent shall provide Buyer with reasonable opportunity to review and comment on the Circular, and no reference to Buyer or to the rights and obligations of the Parties under this Agreement or any of the Ancillary Agreements shall be made in the Circular without Buyer's consent, which shall not be unreasonably withheld by Buyer. To the fullest extent permitted by applicable law, (i) Parent and its Board of Directors shall recommend that Parent's shareholders vote to approve this Agreement and the transactions contemplated hereby and shall include such recommendation in the Circular, and (ii) neither Parent nor its Board of Directors nor any committee thereof shall withdraw or modify, or propose or resolve to withdraw or modify, in any manner adverse to Buyer, such recommendation; provided, that nothing in this Agreement shall prevent Parent's Board of Directors from withdrawing such recommendation prior to the EGM if in the exercise of their fiduciary obligations (determined in good faith by Parent's Board of Directors following consultation with outside counsel) the failure to take such action would result in a breach of their fiduciary obligations. Parent shall use its commercially reasonable efforts and take all action that is reasonable and lawful to solicit its shareholders to vote (or to deliver proxies) in favor of approval of this Agreement and the transactions contemplated hereby and shall take all other reasonable and lawful action necessary or advisable to secure the required approvals of Parent's shareholders. Without limiting the generality of the foregoing provisions, Dr. Argeris (Jerry) Karabelas, Frank Condella, Ken Cunningham, Peter Grant, Dr. David Ebsworth, R. Stephen Harris, and Alan Bray shall confirm in the Circular their intention to vote in favor of the resolutions put at the EGM in a form heretofore approved by Buyer and shall recommend in the Circular that Parent's shareholders do the same. Parent shall cause the Circular to include all information required by all applicable laws, including all required information regarding the terms of this Agreement and the transactions contemplated by this Agreement. To the extent subject thereto, the Circular will comply with applicable U.S. securities laws.

5.4. Operation of Business. Except as contemplated by this Agreement, during the period from the date of this Agreement to the Closing, the Company shall, and Seller shall cause the Company to, conduct its operations in the Ordinary Course of Business and in compliance with all applicable laws and regulations and, to the extent consistent therewith, use its commercially reasonable efforts to preserve intact its current business organization, keep its physical assets in good working condition, keep available the services of its current officers and employees and preserve its relationships with customers, suppliers and others having business dealings with it, and pay obligations incurred by it after the date of this Agreement and prior to the Closing (other than obligations disputed by the Company in good faith by appropriate

proceedings) either when due or otherwise substantially consistently with its past practices, to the end that its goodwill and ongoing business shall not be impaired in any material respect. Without limiting the generality of the foregoing, prior to the Closing, the Company shall not, and Seller shall cause the Company not to, take any of the following actions without the written consent of Buyer:

(a) issue or sell any stock or other securities of the Company or any options, warrants or rights to acquire any such stock or other securities (except pursuant to the conversion or exercise of preferred shares, options or warrants outstanding on the date hereof), or amend any of the terms of (including the vesting of) any options, warrants or restricted stock agreements, or repurchase or redeem any stock or other securities of the Company (except from former employees, directors or consultants in accordance with agreements providing for the repurchase of shares at their original issuance price in connection with any termination of employment with or services to the Company);

(b) split, combine or reclassify any shares of its capital stock; or declare, set aside or pay any dividend or other distribution (whether in cash, stock or property or any combination thereof) in respect of its capital stock;

(c) create, incur or assume any indebtedness (including obligations in respect of capital leases); assume, guarantee, endorse or otherwise become liable or responsible (whether directly, contingently or otherwise) for the obligations of any other person or entity; or make any loans, advances or capital contributions to, or investments in, any other person or entity;

(d) enter into, adopt or amend any Employee Benefit Plan or any employment or severance agreement or arrangement of the type described in Section 3.22(k) or (except for normal increases in the Ordinary Course of Business for employees who are not Affiliates) increase in any manner the compensation or fringe benefits of, or materially modify the employment terms of, its directors, officers or employees, generally or individually, or pay any bonus or other benefit to its directors, officers or employees (except for existing payment obligations listed in Section 3.22 of the Seller Disclosure Schedule) or hire any new officers or (except in the Ordinary Course of Business) any new employees;

(e) acquire, sell, lease, license or dispose of any assets or property (including any shares or other equity interests in or securities of any corporation, partnership, association or other business organization or division thereof), other than purchases and sales of assets in the Ordinary Course of Business and as otherwise required or expressly permitted by this Agreement;

(f) mortgage or pledge any of its property or assets or subject any such property or assets to any Encumbrance;

(g) discharge or satisfy any Encumbrance or pay any obligation or liability other than in the Ordinary Course of Business;

(h) amend its charter, by-laws or other organizational documents;

(i) change its accounting methods, principles or practices, except insofar as may be required by a generally applicable change in IFRS, or make any new elections, or changes to any current elections, with respect to Taxes, except as required by this Agreement;

(j) enter into, amend, terminate, take or omit to take any action that would constitute a violation of or default under, or waive any rights under, any contract or agreement of a nature required to be listed in Section 3.12, Section 3.13 or Section 3.15 of the Seller Disclosure Schedule;

(k) make or commit to make any capital expenditure in excess of [\*\*] dollars (\$[\*\*]) per item or [\*\*] dollars (\$[\*\*]) in the aggregate;

(l) institute or settle any Legal Proceeding in which the matter in controversy is more than [\*\*] dollars (\$[\*\*]) without Buyer's consent (which consent shall not be unreasonably withheld);

(m) take any action or fail to take any action permitted by this Agreement with the knowledge that such action or failure to take action would result in any of the representations and warranties of the Company set forth in this Agreement becoming untrue such that any of the conditions set forth in Article VI or Article VII would not be satisfied; or

(n) agree in writing or otherwise to take any of the foregoing actions.

5.5. Access to Information. From and after the date of this Agreement to the Closing Date:

(a) The Company shall permit representatives of Buyer to have full access (at all reasonable times, and in a manner so as not to interfere with the normal business operations of the Company) to all premises, properties, financial, tax and accounting records (including the work papers of the Company's independent accountants, subject to Buyer's entering into a separate agreement with such accountants to permit such access), contracts, other records and documents, and personnel, of or pertaining to the Company. Notwithstanding anything to the contrary contained in this Agreement, Buyer shall not be entitled to tax records relating to any Affiliated Group of which Seller is the common parent, other than records relating solely to the Company.

(b) Within fifteen (15) days after the end of each month ending prior to the Closing, beginning with the month of January 2007, the Company shall furnish to Buyer an unaudited income statement for such month and a balance sheet as of the end of such month, prepared on a basis consistent with the Financial Statements. Such financial statements shall present fairly the financial condition and results of operations of the Company as of the dates thereof and for the periods covered thereby (except as set forth in Section 3.6(a) of the Seller Disclosure Schedule), and shall be consistent with the books and records of the Company.

(c) Buyer (i) shall treat and hold as confidential any Confidential Information, (ii) shall not use any of the Confidential Information except in connection with this Agreement, and (iii) if this Agreement is terminated for any reason whatsoever, shall return to the Company all tangible embodiments (and all copies) thereof which are in its possession.

5.6. Notice of Breaches.

(a) From the date of this Agreement until the Closing, Seller and the Company shall promptly deliver to Buyer supplemental information concerning events or circumstances occurring subsequent to the date hereof which would render any representation, warranty or statement in this Agreement or the Seller Disclosure Schedule inaccurate or incomplete in any material respect at any time after the date of this Agreement until the Closing. No such supplemental information shall be deemed to avoid or cure any misrepresentation or breach of warranty or constitute an amendment of any representation, warranty or statement in this Agreement or the Seller Disclosure Schedule.

(b) From the date of this Agreement until the Closing, Buyer shall promptly deliver to the Company and Seller supplemental information concerning events or circumstances occurring subsequent to the date hereof which would render any representation or warranty in this Agreement inaccurate or incomplete in any material respect at any time after the date of this Agreement until the Closing. No such supplemental information shall be deemed to avoid or cure any misrepresentation or breach of warranty or constitute an amendment of any representation or warranty in this Agreement.

5.7. Exclusivity. Prior to the Closing:

(a) Neither Seller nor the Company shall directly or indirectly, through Parent or any Affiliate of Parent or through any officer, director, employee, representative, or agent of Seller, the Company, Parent or any Affiliate of Parent or otherwise, (i) initiate, solicit, encourage or otherwise facilitate any inquiry, proposal, offer or discussion with any third party (other than Buyer) concerning any merger, reorganization, consolidation, recapitalization, business combination, liquidation, dissolution, share exchange, sale of stock, sale of material assets or similar business transaction involving the Company, any subsidiary or any division of the Company, (ii) furnish any non-public information concerning the business, properties or assets of the Company, any subsidiary or any division of the Company to any third party (other than Buyer) or (iii) engage in discussions or negotiations with any third party (other than Buyer) concerning any such transaction.

(b) Seller and the Company shall (and represent and warrant that Parent will) immediately notify any party with which discussions or negotiations of the nature described in paragraph (a) above were pending that the Company is terminating such discussions or negotiations. If Parent, the Company or Seller receives any inquiry, proposal or offer of the nature described in paragraph (a) above, Seller shall, within two business days after such receipt, notify Buyer of such inquiry, proposal or offer, including the identity of the other party and the terms of such inquiry, proposal or offer.

5.8. Expenses. Except as set forth in Article VIII, Section 5.2 and the Escrow Agreement, Buyer shall bear its own costs and expenses (including legal and accounting fees and expenses) incurred in connection with this Agreement and the transactions contemplated hereby and Seller shall bear the costs and expenses (including legal and accounting fees and expenses) incurred by Seller, and/or the Company in connection with this Agreement and the transactions contemplated hereby.

5.9. Transition Services. Prior to the Closing, Buyer and Seller shall enter into a transition services agreement in substantially the form of Exhibit H hereto and otherwise in form reasonably acceptable to the Parties, pursuant to which Seller shall provide (or shall procure for Parent or an appropriate Affiliate of Parent to provide) to Buyer and Buyer shall provide to Seller the services described in Schedule 5.9 following the Closing (the "Transition Services Agreement").

5.10. License Agreement. Prior to the Closing, Seller shall arrange for Parent to enter into a license agreement with Buyer and the Company in substantially the form of Exhibit I hereto.

5.11. Assignment; Inter-Company Adjustments and Eliminations. After the date of this Agreement and prior to the Closing: (a) Seller shall assign or arrange to have assigned to the Company (i) the Biosphere Patents and all other patents and patent applications listed in Schedule 5.11(a)(i) hereto and (ii) all trademarks and tradenames containing the word "Biosphere" or any variations and derivatives thereof, and all other trademarks and servicemarks listed in Schedule 5.11(a)(ii) hereto, that have heretofore been registered in the name of Affiliates of the Company, in each case, pursuant to Assignments in substantially the forms of Exhibit G hereto (the "Biosphere Assets"); and (b) the Company shall distribute to Seller and its Affiliates the assets identified in Schedule 5.11(b) (the "Excluded Assets"), except for the investment for GeneMedix Plc. For the avoidance of doubt, Seller represents and warrants that the investment in GeneMedix is not owned by the Company and is not reflected in the Financial Statements, and Buyer acknowledges that such investment shall not be treated as an asset of the Company. Prior to the Closing, Seller shall take (and shall cause the Company to take) all action required to cause the Company's balance sheet as of the Closing to reflect the eliminations and adjustments described in Schedule 6.12, in accordance with the conditions set forth therein. After the Closing, if any payment is received by Buyer or the Company in respect of any receivable retained by or assigned to Seller pursuant to this Agreement, Buyer and the Company shall promptly deliver such payment to Seller, and if any payment is received by Seller or any of its Affiliates in respect of any receivable retained by or assigned to the Company or Buyer pursuant to this Agreement, Seller shall promptly deliver such payment to the Company or Buyer, as Buyer shall direct.

5.12. [Intentionally Omitted.]

5.13. Change of Company Name. Promptly following the Closing, Buyer shall change the name of the Company to a name that is not related to the Names and not likely to be confused with the Names. Buyer shall make all filings and/or notifications required by any applicable law to effect the change in name of the Company.

5.14. Sharing of Certain Data. Seller and its professional advisers shall have the right for a period of seven (7) years following the Closing Date to have reasonable access to such books, records and accounts, including financial and Tax information, correspondence,

production records, employment records and other records that are transferred to Buyer pursuant to the terms of this Agreement for the limited purposes of concluding its involvement in the business conducted by the Company prior to the Closing Date and for complying with its obligations under applicable financial reporting, securities, Tax, environmental, employment or other laws and regulations. Buyer and its professional advisers shall have the right for a period of seven (7) years following the Closing Date to have reasonable access to those books, records and accounts, including financial and accounting records (including the work papers of Seller's and Parent's independent accountants), Tax records of the Company, correspondence, production records, employment records and other records of the Company that are or may be retained by Seller or its Affiliates (including Parent) pursuant to the terms of this Agreement to the extent that any of the foregoing is needed by, or would be reasonably helpful to, Buyer for the purpose of conducting the business of the Company after the Closing or complying with its obligations or asserting its rights under applicable financial reporting, securities, Tax, environmental, employment or other laws and regulations. Neither Buyer nor Seller shall destroy (and Seller shall procure for Parent not to destroy) any such books, records or accounts retained by it without first providing the other Party with the opportunity to obtain or copy such books, records, or accounts at such other Party's expense. Notwithstanding anything to the contrary contained in this Agreement, Buyer shall not be entitled to Tax records relating to any Affiliated Group of which Seller is the common parent, other than records relating solely to the Company.

5.15. Certain Tax Matters.

(a) Preparation and Filing of Tax Returns.

(i) To the extent not previously filed, Seller shall prepare and timely file or shall cause to be prepared and timely filed (at its own cost and expense) (x) all Pre-Closing Tax Returns for any Income Taxes of the Company and (y) all other Pre-Closing Tax Returns of the Company required to be filed (taking into account extensions) prior to the Closing Date. If necessary under applicable law, Buyer shall cause the Company to execute any such Pre-Closing Tax Return or provide to Seller appropriate powers of attorney.

(ii) To the extent not previously filed, Buyer shall prepare and timely file or cause to be prepared and timely filed (at its own cost and expense) all Pre-Closing Tax Returns of the Company that are not described in Section 5.15(a)(i) and all Straddle Period Tax Returns of the Company. Buyer shall deliver or cause to be delivered drafts of each such Tax Return to Seller for its review at least thirty (30) days prior to the Due Date of such Tax Return and, in the case of a Straddle Period Tax Return, shall notify Seller of Buyer's calculation of Seller's share of the Taxes of the Company (determined in accordance with Section 5.15(d)) for such Straddle Period; provided, however, that such draft of such Straddle Period Tax Return or any Pre-Closing Tax Return to which this Section 5.15(a)(ii) applies, as the case may be, and, in the case of a Straddle Period Tax Return, the calculation of Seller's share of the Tax liability for such Straddle Period (determined in accordance with Section 5.15(d)), in each case, shall be subject to Seller's review and approval. If Seller disputes any item on any Tax Return to which this Section 5.15(a)(ii) applies, it shall notify Buyer of such disputed item (or items) and the basis for its objection. Buyer and Seller shall act in good faith to resolve any dispute as promptly as practicable. If Buyer and Seller cannot resolve any disputed item, the item in question shall be resolved in accordance with Article XI.



(iii) Transfer Taxes. Notwithstanding anything to the contrary contained in this Agreement, Buyer and Seller shall each be responsible for the payment of 50% of any transfer, sales, use, stamp, conveyance, value added, recording, registration, documentary, filing and other similar Taxes and administrative fees (including, without limitation, notary fees) arising in connection with the consummation of the transactions contemplated by this Agreement (“Transfer Taxes”). Buyer shall be responsible for preparing and filing all Tax Returns required to be filed in connection with Transfer Taxes, and Seller shall cooperate with Buyer in connection with the preparation of any such Tax Return relating to Transfer Taxes.

(b) Tax Indemnification by Seller. Seller shall indemnify and hold harmless Buyer and the Company in respect of and against (without duplication):

(i) all liabilities for Taxes imposed on the Company with respect to Pre-Closing Periods, and with respect to any Straddle Period, the portion of such Straddle Period ending on the Closing Date and as determined in the manner provided in Section 5.15(d);

(ii) all liabilities for Taxes imposed on the Company under Section 1.1502-6 of the Treasury Regulations (and corresponding provisions of state, local and foreign law) as a result of having been a member of any Affiliated Group for any taxable period ending on or before or that includes the Closing Date;

(iii) all Transfer Taxes for which Seller is liable pursuant to Section 5.15(a)(iii);

(iv) any breach of a representation set forth in Section 3.9; and

(v) all out-of-pocket expenses for advisors resulting from a breach of any obligation of Seller set forth in this Section 5.15;

provided, however, that Seller shall not be responsible for and shall not indemnify Buyer for (A) all Transfer Taxes for which Buyer is liable pursuant to Section 5.15(a)(iii), (B) an amount equal to the aggregate amount of Tax Reserves, (C) any and all Taxes imposed on the Company as a result of any election under Section 338 of the Code; and (D) any and all Taxes imposed on the Company as a result of any action taken by Buyer after the Closing that is not in the Ordinary Course of Business or that result from a breach of any of Buyer’s obligations pursuant to this Agreement (collectively, “Excluded Taxes”).

(c) Tax Indemnification by Buyer. Buyer shall indemnify and hold harmless Seller in respect of and against (without duplication):

(i) all Excluded Taxes;

(ii) all liabilities for Taxes imposed on the Company with respect to any period beginning after the Closing Date (a “Post-Closing Period”);

(iii) all liabilities for Taxes imposed on the Company with respect to a Straddle Period, but only with respect to the portion of such Straddle Period beginning after the Closing Date, as determined in accordance with the principles set forth in Section 5.15(d);

(iv) all Taxes and out-of-pocket expenses for advisors resulting from a breach of any obligation of Buyer set forth in this Section 5.15.

(d) Allocation of Certain Taxes.

(i) Buyer and Seller agree that if the Company is permitted but not required under applicable foreign, state or local Tax laws to treat the Closing Date as the last day of a taxable period, Buyer and Seller shall treat such day as the last day of a taxable period. Buyer and Seller agree that they will treat the Company as if it ceased to be part of the Affiliated Group of corporations of which the Company is a member within the meaning of Section 1504 of the Code, and, to the extent applicable, any comparable or similar provision of state, local or foreign laws or regulations, as of the close of business on the Closing Date.

(ii) The portion of any Taxes for a taxable period beginning before and ending after the Closing allocable to the portion of such period ending on the Closing Date shall be deemed to equal (A) in the case of Taxes that (x) are based upon or related to income or receipts or (y) imposed in connection with any sale or other transfer or assignment of property, other than Taxes described in Section 5.15(a)(iii), the amount which would be payable if the taxable year ended on (and included) the Closing Date, and (B) in the case of Taxes not described in Section 5.15(d)(ii)(A) (including Taxes imposed on a periodic basis (such as real property Taxes)), the amount of such Taxes for the entire period multiplied by a fraction the numerator of which is the number of calendar days in the period ending on (and including) the Closing Date and the denominator of which is the number of calendar days in the entire period. For purposes of this Agreement, transactions that occur on the Closing Date but after the Closing and that are not incurred in the Ordinary Course of Business of the Company shall be considered to be attributable to the period that commences on the day following the Closing Date. For purposes of Section 5.15(d)(ii)(A), any exemption, deduction, credit or other item that is calculated on an annual basis shall be allocated pro rata per day between the period ending on the Closing Date and the period beginning the day after the Closing Date.

(e) Refunds. Buyer shall pay to Seller (a) all Tax refunds and credits of Taxes (including any interest in respect thereof) received by any of Buyer or its Affiliates or the Company after the Closing Date and attributable to Taxes paid by the Company with respect to any Pre-Closing Period and (b) the portion of all refunds of Taxes or credits of Taxes (including any interest in respect thereof) received by any of Buyer or its Affiliates or the Company after the Closing Date and attributable to Taxes paid by the Company with respect to any Straddle Period (such portion to be allocated consistent with the principles set forth in Section 5.15(d)), Notwithstanding anything in this Section 5.15(e) to the contrary, Seller shall not be entitled to receive payment under this Section 5.15(e) to the extent such refunds or credits are (i) attributable to items of loss, deduction or credit which arise in any Post-Closing Period and that are carried back to a Pre-Closing Period or Straddle Period, or (ii) reflected as an asset of the Company on the Final Closing Net Assets Statement. Any such refunds or credits of Taxes required to be paid by Buyer to Seller shall be paid within five (5) business days of the receipt of such refunds or credits of Taxes by Buyer, its Affiliates or the Company.

(f) Cooperation. Buyer and Seller and their respective Affiliates shall cooperate in the preparation of all Tax Returns of or relating to the Company and the conduct of all Tax Audits or other administrative or judicial proceedings relating to the determination of any Tax of the Company for any Tax periods for which one Party could reasonably require the assistance of the other Party in obtaining any necessary information. Such cooperation shall include, but not be limited to, furnishing prior years' Tax Returns of the Company or return preparation packages to the extent related solely to the Company illustrating previous reporting practices or containing historical information relevant to the preparation of such Tax Returns of or relating to the Company, and furnishing such other information within such Party's possession requested by the Party filing such Tax Returns of or relating to the Company as is relevant to their preparation. Such cooperation and information also shall include without limitation provision by the Company to Seller of powers of attorney for the purpose of signing Tax Returns and defending audits and promptly forwarding copies of appropriate notices and forms or other communications received from or sent to any Taxing Authority which relate to the Company, and providing copies of all relevant Tax Returns to the extent related solely to the Company, together with accompanying schedules and related workpapers, documents relating to rulings received by the Company or other determinations by any Taxing Authority with respect to the Company and records concerning the ownership and Tax basis of property of the Company, which the requested Party may possess. Buyer and Seller and their respective Affiliates shall make their respective employees and facilities available on a mutually convenient basis to explain any documents or information provided hereunder. The obligations of Buyer and the Company under this Section 5.15(f) shall include the provision of information to Seller that is required by Seller to enable it to file any Tax Return of an Affiliated Group of which it is the common parent and the Company is or was a member.

(g) Tax Audits. Buyer shall deliver a written notice to Seller in writing promptly following any demand, claim, or notice of commencement of a claim, audit, proposed adjustment, assessment, examination or other administrative or court proceeding with respect to Taxes of the Company for which Seller may be liable pursuant to Section 5.15 ("Tax Contest") and shall describe in reasonable detail (to the extent known by Buyer or the Company) the facts constituting the basis for such Tax Contest, the nature of the relief sought, and the amount of the claimed Losses, if any (the "Tax Claim Notice"), provided, however, that no delay or failure on the part of Buyer to notify Seller pursuant to this Section 5.15(g) shall relieve Seller of any liability or obligations under Section 5.15 except to the extent that Seller is adversely prejudiced as a consequence of such failure.

(i) With respect to Tax Contests for Taxes of the Company for a Pre-Closing Period, Seller may elect to assume and control the defense of such Tax Contest by written notice to that effect to Buyer within twenty (20) days after delivery by Buyer to Seller of the Tax Claim Notice. If Seller elects to assume and control the defense of such Tax Contest, it (A) shall bear its own costs and expenses, (B) shall be entitled to engage its own counsel and (C) may (1) pursue or forego any and all administrative appeals, proceedings, hearings and conferences with any Tax authority, (2) either pay the Tax claimed or sue for refund where applicable law permits such refund suit or (3) contest, settle or compromise the Tax Contest in any permissible manner, provided, however, that Seller shall not enter into any settlement with respect to any such Tax Contest that relates to Taxes of the Company for a Pre-Closing Period without the prior written consent of Buyer, which consent shall not be unreasonably withheld or delayed, and Buyer shall (and shall cause its Affiliates) to cooperate with Seller in pursuing such

Tax Contest (including by providing appropriate powers of attorney). If Seller elects to assume the defense of any Tax Contest, (A) Seller shall keep Buyer reasonably informed of all material developments and events relating to such Tax Contest and (B) at its own cost and expense, Buyer shall have the right to participate in (but not control) the defense of such Tax Contest.

(ii) In connection with any Tax Contest that relates to Taxes of the Company for a Pre-Closing Period that Seller does not elect to control pursuant to Section 5.15(g)(i), such Tax Contest shall be controlled by Buyer and Seller agrees to cooperate with Buyer in pursuing such Tax Contest, provided, however, that none of Buyer or its Affiliates (including the Company) shall enter into any settlement with respect to any such Tax Contest that relates to Taxes of the Company for a Pre-Closing Period without the prior written consent of Seller, which consent shall not be unreasonably withheld or delayed. In connection with any Tax Contest that is described in this Section 5.15(g)(ii) and controlled by Buyer, Buyer shall keep Seller reasonably informed of all material developments and events relating to such Tax Contest and, at its own cost and expense, Seller shall have the right to participate in (but not control) the defense of such Tax Contest.

(iii) Buyer and Seller shall jointly control (at each Party's own cost and expense) all Tax Contests relating to Straddle Periods of the Company. The Parties agree to cooperate with each other in pursuing any such Tax Contest and neither Buyer nor Seller shall (or shall permit any of their Affiliates) to settle a Tax Contest relating to a Straddle Period of any Company without the other Party's prior written consent, which consent shall not be unreasonably withheld or delayed.

(h) Termination of Tax Sharing Agreements. All Tax sharing agreements or similar arrangements between the Company, on the one hand, and Seller or Parent, on the other hand, shall be terminated prior to the Closing Date and, after the Closing Date, Buyer and its Affiliates shall not be bound thereby or have any liability thereunder for amounts due in respect of periods ending on or before the Closing Date.

(i) Exclusivity; Conflicts. Notwithstanding anything to the contrary contained in this Agreement, (i) this Section 5.15 shall be the exclusive means by which a Party to this Agreement may seek indemnification relating or attributable to Taxes or Tax Returns, (ii) claims for indemnification pursuant to Sections 5.15(a) and (b) may be made by a Party at any time prior to the sixtieth (60<sup>th</sup>) day after the expiration of the statute of limitations applicable to the Tax matter to which the claim relates and (iii) to the extent there is any inconsistency between the terms of this Section 5.15 and any other provision of this Agreement, the provisions of this Section 5.15 shall govern and control, provided, however, that Sections 8.3(f), 8.5(c), 8.5(d) and 8.5(e) (or the principles of such Sections) shall apply to this Section 5.15.

(j) Treatment of Indemnification Payments. Any payments made to an Indemnified Party pursuant to this Section 5.15, Article VIII, or the Escrow Agreement shall be treated as an adjustment to the Adjusted Purchase Price for Tax purposes.

(k) FIRPTA Certificate. Prior to the Closing, Seller shall deliver to Buyer a certification that it is not a foreign person in accordance with the Treasury Regulations under Section 1445 of the Code. If Buyer does not receive the certification described above on or before the Closing Date, Buyer shall be permitted to withhold from the payments to be made pursuant to this Agreement any required withholding tax under Section 1445 of the Code.

(l) Taxes. Notwithstanding any other provision in this Agreement, except the last sentence of this Section 5.15(l), Buyer, the Company, and the Escrow Agent shall have the right to deduct and withhold Taxes from any payments to be made hereunder (including any payments to be made under the Escrow Agreement) if such withholding is required by law and to collect any necessary Tax forms, including Forms W-8 or W-9, as applicable, or any similar information, from Seller and any other recipients of payments hereunder. To the extent that amounts are so withheld, such withheld amounts shall be treated for all purposes of this Agreement as having been delivered and paid to Seller or any other recipient of payments in respect of which such deduction and withholding were made. Unless otherwise required by a change in law after the date hereof, Buyer shall not withhold any Taxes in respect of payments to be made to Seller for the covenants not to compete set forth in Section 9.3(a), as determined in accordance with Section 1.9 and Schedule 1.9.

(m) No Section 338 Election. None of Buyer or its Affiliates shall make any election pursuant to Section 338 of the Code (or any comparable provision of state, local or other Tax law) with respect to the Company.

(n) No Amendment. Neither Buyer nor the Company shall amend any Tax Return of the Company relating to a Pre-Closing Period or Straddle Period without the consent of Seller; provided, however, that Buyer or the Company shall be permitted to amend any such Tax return without the consent of Seller if Seller will not be adversely affected thereby, taking into account Seller's obligations under this Agreement.

(o) Certain Limitations. Notwithstanding anything to the contrary contained in this Agreement, neither Parent nor Seller (or any of their Affiliates) shall be required to indemnify or hold harmless Buyer and its subsidiaries (including after the Closing, the Company) and each Indemnified Buyer Party in respect of or against any and all Losses resulting from, relating or attributable to (i) Taxes or Tax Returns other than as set forth in Sections 5.15(b)(i), 5.15(b)(ii), 5.15(b)(iii), 5.15(b)(iv) (solely to the extent of Taxes of the Company for Pre-Closing Periods and Straddle Periods (determined in accordance with Section 5.15(d) and 5.15(b)(v)); provided, however, that the limitations imposed by this Section 5.15(o)(i) shall not apply to Losses resulting from a breach of Sections 3.9(a)(v), 3.9(a)(xii), 3.9(a)(xvi), 3.9(c), 3.22(h), 3.22(k), and 3.22(m) and (ii) any Tax attribute of the Company (other than resulting from a breach of Section 3.9(c)), including any net operating loss carryover or credit carryover, or the determination that any such carryover is subject to any limitation on its use under applicable law.

(p) Limitation on Actions. Subject to Section 5.15(g), neither Buyer nor any of its Affiliates (including after the Closing, the Company) shall take any action after the Closing relating or attributable to (or that would reasonably be expected to affect Taxes with respect to) a Pre-Closing Period or Straddle Period of the Company that would reasonably be expected to result in any increased Tax liability (or a reduction in a Tax refund or credit) in respect of a Pre-Closing Period of the Company or the portion of a Straddle Period of the Company ending on the Closing Date (determined in accordance with the principles of Section 5.15(d)). Subject to

Section 5.15(g), neither Seller nor any of its Affiliates shall take any action after the Closing relating or attributable to (or that would reasonably be expected to affect Taxes with respect to) a Post-Closing Period or Straddle Period of the Company that would reasonably be expected to result in any increased Tax liability (or a reduction in a Tax refund or credit) in respect of a Post-Closing Period of the Company or the portion of a Straddle Period of the Company beginning after the Closing Date (determined in accordance with the principles of Section 5.15(d)), provided, however, that all Pre-Closing Period Tax attributes of the Company (and any Tax attributes relating to the portion of any Straddle Period ending on the Closing Date determined in accordance with the principles of Section 5.15(d)), other than to the extent of the tax basis represented in Section 3.9(c), shall be ignored.

(q) Transfer of Biosphere Assets. Unless otherwise required by a Final Determination, the Parties shall (i) treat the transfer of the Biosphere Assets to the Company pursuant to Section 5.11(a) as a taxable transaction (and not as a transaction to which section 351 of the Code (or any comparable provision of any state, local or foreign tax jurisdiction) applies), and (ii) report such transfer as a taxable transaction for all Tax purposes and in a manner consistent with such assets having a fair market value as of the Closing Date equal to approximately [\*\*] dollars (\$[\*\*]).

(r) Unless otherwise required by a Final Determination or change in law after the date hereof, Seller shall not include in gross income on the Seller's 2007 U.S. consolidated Tax Return for Income Taxes and any comparable 2007 Tax Return for state or local Income Taxes (taking into account Section 108 of the Code and Section 1.1502-28 of the Treasury regulations promulgated under the Code, and any comparable provisions of state or local Tax law), any material amount of cancellation of indebtedness income that may result from Seller's assumption of the net debt owed by the Company to Parent and/or to any of its Affiliates (the "Company Debt") and Parent's and/or any of its Affiliates' novation of the Company liability under the Company Debt to Seller. The adjustments to the assets and liabilities of the Company set forth in Schedule 6.12 shall be effected in a manner that does not result, in any material respect, in any adverse Tax effect on the Company, other than the possible reduction of Tax attributes of the Company other than the tax basis represented in Section 3.9(c).

5.16. Employee Retention Arrangements. Seller shall pay (on behalf of the Company, when due), or shall reimburse the Company (promptly following payment by the Company and notice by the Company to Seller) for, all amounts due to be paid by the Company after the Most Recent Net Assets Statement Date to Company employees pursuant to the Company's Stay Incentive Plan and related Stay Incentive Agreements to the extent that such employees do not accept stock (or options to acquire stock) of Buyer or the Company (as determined by Buyer) in lieu of such cash amounts under the Stay Incentive Plan and Stay Incentive Agreements.

5.17. Transfer of Rights and Obligations Respecting Other Products, Product Candidates, and Regulatory Matters. Prior to the Closing, the Company will transfer to a third party(ies) acceptable to Buyer all rights, interest, ownership, obligations, and authority with respect to all NDAs, INDs, DMFs, regulatory agent relationships, and other regulatory applications, dossiers, licenses, permits, or filings other than those related to DepoCyt, DepoDur, DepoBupivacaine, and products related to the Biosphere technology.

**ARTICLE VI  
CONDITIONS TO OBLIGATIONS OF BUYER**

The obligations of Buyer under this Agreement are subject to the fulfillment, at the Closing Date, of the following conditions precedent, each of which may be waived (to the extent legally waivable) in writing in the sole discretion of Buyer:

6.1. Parent Shareholder Approval and Other Consents and Approvals. The requisite approval of Parent's shareholders as set forth in Sections 2.2, 3.3 and 5.3 shall have been obtained, and Parent, Seller and the Company shall have obtained at their own expense (and shall have provided copies thereof to Buyer) the consents and approvals described in Schedule 6.1 and all of the waivers, permits, consents, approvals or other authorizations, and effected all of the registrations, filings and notices, referred to in Section 5.2(a) which are required on the part of Seller, Holder and the Company.

6.2. Continued Accuracy of Representations and Warranties of Seller and the Company. The representations and warranties of Seller set forth in Article II, the first sentence of Section 3.1 and in Section 3.3 and any representations and warranties of Seller set forth in this Agreement that are qualified as to materiality shall be true and correct in all respects, and all other representations and warranties of Seller set forth in this Agreement shall be true and correct in all material respects, in each case as of the date of this Agreement and as of the Closing as though made as of the Closing, except to the extent such representations and warranties are specifically made as of a particular date (in which case such representations and warranties shall be true and correct as of such date);

6.3. Compliance with Covenants and Obligations. Seller and the Company shall have performed or complied with in all material respects their respective agreements and covenants required to be performed or complied with under this Agreement and Parent shall have performed or complied with in all material respects its agreements and covenants required to be performed or complied with in the Parent Guaranty as of or prior to the Closing Date.

6.4. Adverse Proceedings. No Legal Proceeding shall be pending or threatened against Parent, Seller or the Company or any of their Affiliates (a) seeking to prevent the consummation of any of the transactions contemplated by this Agreement or any of the Ancillary Agreements, (b) seeking to cause any of the transactions contemplated by this Agreement or any of the Ancillary Agreements to be rescinded, (c) wherein an adverse judgment would have, individually or in the aggregate, a Company Material Adverse Effect, and no such judgment, order, decree, stipulation or injunction shall be in effect.

6.5. Seller Compliance Certificate. Seller shall have delivered to Buyer the Seller Compliance Certificate.

6.6. Resignations. Buyer shall have received copies of the resignations, effective as of the Closing, of each director and officer of the Company (other than any such resignations which Buyer designates, by written notice to the Company, and other than the individual named in Section 6.10(j)).

6.7. Opinion of Counsel. Buyer shall have received from counsel to Parent, Seller and the Company an opinion with respect to the matters set forth in Exhibit C attached hereto, addressed to Buyer and dated as of the Closing Date.

6.8. Additional Closing Deliveries. Buyer shall have received such other certificates and instruments (including certificates of good standing of the Company in their jurisdiction of organization and the various foreign jurisdictions in which they are qualified, certified charter documents, certificates as to the incumbency of officers and the adoption of authorizing resolutions) as it shall reasonably request in connection with the Closing.

6.9. HSR Act. The waiting period applicable to the consummation of the transactions contemplated by this Agreement under the HSR Act shall have expired or been terminated.

6.10. Certain Agreements.

(a) Paul Capital. The Paul Capital Agreements shall have been amended as set forth in the Paul Capital Term Sheet annexed as Exhibit E hereto, and no other consent or waiver of Paul Capital shall be required for the execution or delivery of this Agreement or any of the Ancillary Agreement or the consummation of any of the transactions contemplated hereby or thereby (other than consents and waivers that shall heretofore have been obtained and delivered to Buyer and be in full force and effect).

(b) Endo. The Development and Marketing Strategic Alliance Agreement dated December 31, 2002 among Endo Pharmaceuticals, Inc., SkyePharma, Inc. and SkyePharma Canada Inc. shall have been terminated in accordance with the Termination Agreement with respect thereto substantially in the form of Exhibit F hereto and on the terms set forth Schedule 6.10(b) hereto.

(c) Parent Guaranty. Parent shall have executed and delivered to Buyer the Parent Guaranty, and the Parent Guaranty shall be in full force and effect.

(d) Release of Encumbrances, Upstream and Sister-Company Guarantees. The Company and its assets and properties shall have been fully, absolutely and unconditionally released from (i) all guarantees and obligations in respect of liabilities and obligations of Parent, Seller and their Affiliates and (ii) all Encumbrances (including liens in favor of General Electric Capital Corporation) other than liens in favor of equipment lessors with respect to equipment that is leased to the Company and will remain in the possession of the Company following the Closing.

(e) License Agreement. Seller shall have executed and delivered (and shall have procured for Parent and its Affiliates to execute and deliver) to Buyer a License Agreement in substantially the form of Exhibit I hereto with Buyer and the Company in form reasonably acceptable to Buyer and such License Agreement shall be in full force and effect.



(f) Patent and Trademark Assignments. Seller shall have executed and delivered (and shall have procured for Parent and its Affiliates, as applicable, to execute and deliver) to the Company a patent assignment with respect to the Biosphere Patents and all other patents and patent applications listed in Schedule 5.11(a)(i) hereto and a trademark assignment with respect to the name "Biosphere" and all trademarks and tradenames containing the word "Biosphere" or any variations and derivatives thereof, and all other trademarks and servicemarks listed in Schedule 5.11(a)(ii) hereto, in each case substantially in the forms of Exhibit G hereto, and each such assignment shall be in full force and effect.

(g) [Intentionally Omitted].

(h) Transition Service Agreement. Seller shall have executed and delivered (and shall have procured for Parent and its Affiliates to execute and deliver) to Buyer the Transition Services Agreement, and such agreement shall be in full force and effect.

(i) Escrow Agreement. The Escrow Agreement shall have been executed and delivered by all parties thereto and shall be in full force and effect.

6.11. No Material Adverse Effect. No Company Material Adverse Effect shall have occurred, and no circumstance shall exist and no event or occurrence shall have occurred, that would be reasonably likely to result in a Company Material Adverse Effect.

6.12. Balance Sheet. Seller and the Company shall have taken all action required to cause the Company's balance sheet as of the Closing to reflect the eliminations and adjustments described in Schedule 6.12.

6.13. 401(k) Contribution. Parent or Seller shall have paid in full (or shall have caused the Company to pay, out of funds provided by Parent or Seller, to the extent necessary) the 401(k) contribution to be made by the Company for 2006, in a total amount of \$[\*\*].

## **ARTICLE VII CONDITIONS TO OBLIGATIONS OF SELLER**

The obligations of Seller under this Agreement are subject to the fulfillment, at the Closing Date, of the following conditions precedent, each of which may be waived in writing (to the extent legally waivable) in the sole discretion of Seller:

7.1. Parent Shareholder Approval. The requisite approval of Parent's shareholders as set forth in Section 5.3 shall have been obtained.

7.2. Continued Accuracy of Representations and Warranties of Buyer. The representations and warranties of Buyer set forth in the first sentence of Section 4.1 and in Section 4.2 and any representations and warranties of Buyer set forth in this Agreement that are qualified as to materiality shall be true and correct in all respects, and all other representations and warranties of Buyer set forth in this Agreement shall be true and correct in all material respects, in each case as of the date of this Agreement and as of the Closing as though made as of the Closing, except to the extent such representations and warranties are specifically made as of a particular date (in which case such representations and warranties shall be true and correct as of such date).

7.3. Compliance with Covenants and Obligations. Buyer shall have performed or complied with in all material respects its agreements and covenants required to be performed or complied with under this Agreement as of or prior to the Closing Date.

7.4. Adverse Proceedings. No Legal Proceeding shall be pending or threatened in writing wherein an unfavorable judgment, order, decree, stipulation or injunction would (a) prevent consummation of any of the transactions contemplated by this Agreement, (b) cause any of the transactions contemplated by this Agreement to be rescinded following consummation or (c) have, individually or in the aggregate, a Buyer Material Adverse Effect, and no such judgment, order, decree, stipulation or injunction shall be in effect.

7.5. Buyer Compliance Certificate. Buyer shall have delivered to Seller the Buyer Compliance Certificate.

7.6. Opinion of Counsel. Seller shall have received from counsel to Buyer an opinion with respect to the matters set forth in Exhibit D attached hereto, addressed to Seller and dated as of the Closing Date.

7.7. Additional Closing Deliveries. Seller shall have received such other certificates and instruments (including certificates of good standing of Buyer in its jurisdiction of organization, certified charter documents, certificates as to the incumbency of officers and the adoption of authorizing resolutions) as Seller shall reasonably request in connection with the Closing.

7.8. HSR Act. The waiting period applicable to the consummation of the transactions contemplated by this Agreement under the HSR Act shall have expired or been terminated.

7.9. Transition Service Agreement. Buyer shall have executed and delivered to Seller the Transition Services Agreement, and such agreement shall be in full force and effect.

#### **ARTICLE VIII INDEMNIFICATION**

8.1. Indemnification by Seller. Seller shall indemnify Buyer and its subsidiaries (including, after the Closing, the Company) and their respective directors, offices, employees, agents and representatives (each an "Indemnified Buyer Party" and collectively the "Indemnified Buyer Parties") in respect of, and hold harmless each of the Indemnified Buyer Parties against, any and all Losses incurred or suffered by the Indemnified Buyer Parties resulting from, relating to or constituting:

(a) any breach of or inaccuracy in, as of the date of this Agreement or as of the Closing Date, of any representation or warranty of Seller or the Company contained in this Agreement, any of the Ancillary Agreements or any other agreement or instrument furnished by Seller or the Company to Buyer expressly pursuant to this Agreement, or any Third Party Claim alleging matters that would, if true, constitute such a breach or inaccuracy;

(b) any failure to perform any covenant or agreement of Seller or the Company contained in this Agreement, any of the Ancillary Agreements or any agreement or instrument furnished by Seller or the Company to Buyer expressly pursuant to this Agreement, or any Third Party Claim alleging matters that would, if true, constitute such a failure;

(c) any claim by Endo relating to DepoDur for any act or omission occurring or any circumstance existing prior to the Closing;

(d) any Losses arising out of conditions or events involving noncompliance with or violation of, prior to the Closing, any Permit or Environmental Law relating to wastewater discharge;

(e) any claim by Paul Capital Partners or any of its Affiliates for any breach after the Closing Date of any obligation of Parent, Seller or any of their Affiliates pursuant to any agreement between Parent, Seller or any of their Affiliates, on one hand, and Paul Capital Partners or any of its Affiliates, on the other hand;

(f) any of the claims identified in Schedule 8.1(f);

(g) the 401(k) contribution to be made by the Company for 2006, in a total amount of \$[\*\*], to the extent (if any) that such amount is not paid by Parent or Seller at or prior to the Closing; and/or

(h) any of the Designated Amounts; provided, that the indemnifiable Losses with respect to Designated Amounts shall be limited to the actual out-of-pocket amounts paid by Buyer and/or the Company (up to the actual amount invoiced (in the case of invoiced amounts) and up to the invoiced amount (or the portion thereof) that relates to the amount accrued on Schedule 12.1 (in the case of amounts listed on Schedule 12.1 as accruals and not yet invoiced as of the date hereof), plus any interest, late fee or similar charge for late payment, collection costs, and legal fees for which the Company is responsible or which the Company is obligated to bear, plus the actual reasonable legal fees and expenses incurred by Buyer and/or the Company in defending or responding to claims with respect to the designated Amounts).

8.2. Indemnification by Buyer. Buyer shall indemnify Seller and its subsidiaries and their respective directors, offices, employees, agents and representatives (each an "Indemnified Seller Party" and collectively the "Indemnified Seller Parties") in respect of, and hold each of the Indemnified Seller Parties harmless against, any and all Losses incurred or suffered by them resulting from, relating to or constituting:

(a) any breach, as of the date of this Agreement or as of the Closing Date, of any representation or warranty of Buyer contained in this Agreement or any other agreement or instrument furnished by Buyer to Seller expressly pursuant to this Agreement;

(b) any failure to perform any covenant or agreement of Buyer contained in this Agreement or any agreement or instrument furnished by Buyer to Seller expressly pursuant to this Agreement, or any Third Party Claim alleging matters that would, if true, constitute such a failure; and/or

(c) any claim by Paul Capital Partners or any of its Affiliates for any breach after the Closing Date of any post-Closing obligation of the Company pursuant to the agreement contemplated by the Paul Capital Term Sheet annexed hereto as Exhibit E to be entered into between Paul Capital Partners and the Company effective as of the Closing Date in connection with the transactions contemplated by this Agreement.

**8.3. Indemnification Claims.**

(a) An Indemnified Party shall give written notification to the Indemnifying Party of the service or receipt by the Indemnified Party of any Third Party Claim. Such notification shall be given within twenty (20) days after receipt by the Indemnified Party of the summons, complaint or other notice in writing of such Third Party Claim, and shall describe in reasonable detail (to the extent known by the Indemnified Party) the facts constituting the basis for such Third Party Claim, the nature of the relief sought, and the amount of the claimed damages (if any); provided, however, that no delay or failure on the part of the Indemnified Party in so notifying the Indemnifying Party shall relieve the Indemnifying Party of any liability or obligation hereunder except to the extent of any damage or liability caused by or arising out of such failure. Within twenty (20) days after delivery of such notification, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such Third Party Claim with counsel reasonably satisfactory to the Indemnified Party; provided that (i) the Indemnifying Party may only assume control of such defense if (A) it acknowledges in writing to the Indemnified Party that any Losses that the Indemnified Party may incur or sustain in connection with such Third Party Claim constitute Losses for which the Indemnified Party shall be indemnified pursuant to this Article VIII and (B) the *ad damnum* (when added to the total amount of all other claims for indemnification theretofore paid or then pending) is less than or equal to the amount of Losses for which the Indemnifying Party is liable under this Article VIII and (ii) the Indemnifying Party may not assume control of the defense of any Third Party Claim involving criminal liability or in which equitable relief or specific performance is sought against the Indemnified Party. If the Indemnifying Party does not, or is not permitted under the terms hereof to, so assume control of the defense of a Third Party Claim, the Indemnified Party shall control such defense. The Non-controlling Party may participate in such defense at its own expense. The Controlling Party shall keep the Non-controlling Party advised of the status of such Third Party Claim and the defense thereof and shall consider in good faith recommendations made by the Non-controlling Party with respect thereto. The Non-controlling Party shall furnish the Controlling Party with such information as it may have with respect to such Third Party Claim (including copies of any summons, complaint or other pleading which may have been served on such party and any written claim, demand, invoice, billing or other document evidencing or asserting the same) and shall otherwise cooperate with and assist the Controlling Party in the defense of such Third Party Claim. The fees and expenses of counsel to the Indemnified Party with respect to a Third Party Claim shall be considered Losses for purposes of this Agreement if (i) the Indemnified Party controls the defense of such Third Party Claim pursuant to the terms of this Section 8.3(a) or (ii) the Indemnifying Party assumes control of such defense and the Indemnified Party reasonably concludes that the Indemnifying Party and the Indemnified Party have conflicting interests or different defenses available with respect to such Third Party Claim. The Indemnifying Party shall not agree to any settlement of, or the entry of any judgment arising from, any Third Party Claim without the prior written consent of

the Indemnified Party, which shall not be unreasonably withheld, conditioned or delayed; provided that the consent of the Indemnified Party shall not be required if the Indemnifying Party unconditionally and absolutely agrees in writing to pay any amounts payable pursuant to such settlement or judgment and such settlement or judgment includes a complete release of the Indemnified Party from further liability and has no other adverse effect on the Indemnified Party. The Indemnified Party shall not agree to any settlement of, or the entry of any judgment arising from, any such Third Party Claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld, conditioned or delayed.

(b) In order to seek indemnification under this Article VIII, an Indemnified Party shall deliver a Claim Notice to the Indemnifying Party. If the Indemnified Party is Buyer and is seeking to enforce such claim pursuant to the Escrow Agreement, the Indemnifying Party shall deliver a copy of the Claim Notice to the Escrow Agent.

(c) Within twenty (20) days after delivery of a Claim Notice, the Indemnifying Party shall deliver to the Indemnified Party and the Escrow Agent a Response, in which the Indemnifying Party shall: (i) agree that the Indemnified Party is entitled to receive all of the Claimed Amount (in which case the Response shall be accompanied by a payment by the Indemnifying Party to the Indemnified Party of the Claimed Amount, by check or by wire transfer or, if the Indemnified Party is Buyer and is seeking to enforce such claim pursuant to the Escrow Agreement, a written authorization executed by Seller instructing the Escrow Agent to pay to Buyer an amount out of the Escrow Fund equal to the Claimed Amount); (ii) agree that the Indemnified Party is entitled to receive the Agreed Amount (in which case the Response shall be accompanied by a payment by the Indemnifying Party to the Indemnified Party of the Agreed Amount, by check or by wire transfer, or, if the Indemnified Party is Buyer and is seeking to enforce such claim pursuant to the Escrow Agreement, a written authorization executed by Seller instructing the Escrow Agent to pay to Buyer an amount out of the Escrow Fund equal to the Agreed Amount); or (iii) dispute that the Indemnified Party is entitled to receive any of the Claimed Amount.

(d) During the 30-day period following the delivery of a Response that reflects a Dispute, the Indemnifying Party and the Indemnified Party shall use good faith efforts to resolve the Dispute. If the Dispute is not resolved within such 30-day period, the Indemnifying Party and the Indemnified Party shall submit the Dispute to binding arbitration in accordance with the provisions of Section 8.3(e). If the Indemnified Party is Buyer and is seeking to enforce the claim that is the subject of the Dispute pursuant to the Escrow Agreement, the Indemnifying Party and the Indemnified Party shall deliver to the Escrow Agent, promptly following the resolution of the Dispute (whether by mutual agreement, arbitration, judicial decision or otherwise), a written notice executed by Buyer and Seller instructing the Escrow Agent as to what (if any) amount out of the Escrow Fund shall be paid to Buyer (which notice shall be consistent with the terms of the resolution of the Dispute).

(e) If, as set forth in Section 8.3(d), the Indemnified Party and the Indemnifying Party submit any Dispute to binding arbitration, the arbitration shall be conducted by a single arbitrator (the "Arbitrator") in accordance with the Commercial Rules in effect from time to time and the following provisions:

(i) In the event of any conflict between the Commercial Rules in effect from time to time and the provisions of this Agreement, the provisions of this Agreement shall prevail and be controlling.

(ii) The applicable Parties shall commence the arbitration by jointly filing a written submission with the New York, New York office of the AAA in accordance with Commercial Rule 5 (or any successor provision).

(iii) No depositions or other discovery shall be conducted in connection with the arbitration.

(iv) Not more than thirty (30) days after the conclusion of the arbitration hearing, the Arbitrator shall prepare and distribute to the Parties a writing setting forth the arbitral award and the Arbitrator's reasons therefor. Any award rendered by the Arbitrator shall be final, conclusive and binding upon the Parties, and judgment thereon may be entered and enforced in any court of competent jurisdiction; provided, that the Arbitrator shall have no power or authority to grant injunctive or equitable relief or specific performance.

(v) The Arbitrator shall have no power or authority, under the Commercial Rules or otherwise, to (x) modify or disregard any provision of this Agreement, including the provisions of this Section 8.3(e), or (y) address or resolve any issue not submitted by the Parties.

(vi) In connection with any arbitration proceeding pursuant to this Agreement, each party to such proceeding shall bear its own costs and expenses, except that the fees and costs of the AAA and the Arbitrator, the costs and expenses of obtaining the facility where the arbitration hearing is held, and such other costs and expenses as the Arbitrator may determine to be directly related to the conduct of the arbitration and appropriately borne equally by Buyer and Seller (which shall not include any Party's attorneys' fees or costs, witness fees (if any), costs of investigation and similar expenses) shall be shared equally by the Indemnified Party and the Indemnifying Party.

(f) If an Indemnified Buyer Party is entitled to indemnification from Seller, Buyer shall be entitled (but not required) to satisfy the amount of any indemnification entitlement by deduction from and offset and set-off against the amounts (if any) that Buyer would be obligated to pay to Seller pursuant to Section 1.7.

8.4. Survival. All representations and warranties, and all covenants and agreements (other than covenants and agreements that by their terms involve continuing or post-Closing obligations), that are covered by the indemnification provisions of Section 8.1(a) and (b) and Section 8.2 shall, except as provided in Section 5.15, (a) survive the Closing and (b) shall expire at 11:59 p.m. Pacific time on the date that is eighteen (18) months after the Closing Date (subject to extension as provided below, the "Expiration Date"), except that (i) the representations and warranties set forth in Sections 2.1, 2.2, and 2.5, Sections 3.1, 3.2, and 3.3 and Sections 4.1 and 4.2 shall survive the Closing without limitation and (ii) the representations and warranties set forth in Sections 3.13, 3.22, 3.23 and 3.30 shall survive until ninety (90) days following the date that would otherwise be the expiration of all statutes of limitation applicable to the matters

referred to therein. If an Indemnified Party delivers to an Indemnifying Party, before expiration of a representation or warranty, either a Claim Notice based upon a breach of or inaccuracy in such representation or warranty, or an Expected Claim Notice involving a breach or alleged breach of or inaccuracy or alleged inaccuracy in such representation or warranty, then the applicable representation or warranty shall survive, and the Expiration Date shall be extended, for purposes of the resolution of any claims arising from or related to the matter covered by such notice, until such resolution. If the legal proceeding or written claim with respect to which an Expected Claim Notice has been given is definitively withdrawn or resolved in favor of the Indemnified Party, the Indemnified Party shall promptly so notify the Indemnifying Party; and if the Indemnified Party has delivered a copy of the Expected Claim Notice to the Escrow Agent and a portion of the Escrow Fund has been retained in escrow after the Termination Date (as defined in the Escrow Agreement) with respect to such Expected Claim Notice, the Indemnifying Party and the Indemnified Party shall promptly deliver to the Escrow Agent a written notice executed by both Buyer and Seller instructing the Escrow Agent to distribute such retained portion of the Escrow Fund to Seller in accordance with the terms of the Escrow Agreement. If the legal proceeding or claim with respect to which an Expected Claim Notice has been given is resolved against an Indemnified Party, the Indemnified Party shall promptly so notify the Indemnifying Party and the Expected Claim Notice shall thereupon automatically be converted into and shall thenceforth be treated as a Claim Notice. The rights to indemnification set forth in this Article VIII shall not be affected by (i) any investigation conducted by or on behalf of an Indemnified Party or any knowledge acquired (or capable of being acquired) by an Indemnified Party, whether before or after the date of this Agreement or the Closing Date, with respect to the inaccuracy or noncompliance with any representation, warranty, covenant or obligation which is the subject of indemnification hereunder or (ii) any waiver by an Indemnified Party of any closing condition relating to the accuracy of representations and warranties or the performance of or compliance with agreements and covenants.

**8.5. Limitations.**

(a) Except as otherwise expressly set forth herein, Seller shall not be liable under this Article VIII unless and until the aggregate Losses for which Seller would otherwise be liable under this Article VIII exceed **[\*\*]** dollars (\$**[\*\*]**) (the "Threshold Amount") (at which point Seller shall become liable for all aggregate Losses subject to indemnification under this Article VIII, and not just amounts in excess of the Threshold Amount; provided that the limitation set forth in this sentence shall not apply to a claim pursuant to Section 8.1(a) relating to a breach of the representations and warranties set forth in Sections 2.1, 2.2 or 2.5 or Sections 3.1, 3.2, 3.3, 3.13, 3.23(g), or 3.30 or pursuant to Section 8.1(f) (as to which the Threshold Amount shall not apply), or to a claim pursuant to Section 8.1(d) with respect to matters disclosed in Schedule 8.1(d) (as to which the Threshold Amount shall be deemed to be **[\*\*]** dollars (\$**[\*\*]**)). For purposes solely of this Article VIII, all representations and warranties of Seller in Article II and Article III (other than Section 3.7 (Absence of Certain Changes) and Section 3.31 (Disclosure)) shall be construed without respect to any materiality limitation, materiality qualification or materiality basket, as if the term "material" and any reference to "Company Material Adverse Effect" (and variations thereof) were omitted from such representations and warranties.

(b) Notwithstanding anything to the contrary herein, Buyer shall not be liable under this Article VIII unless and until the aggregate Losses for which Buyer would otherwise be liable under this Article VIII exceed the Threshold Amount (at which point Buyer shall become liable for all aggregate Losses subject to indemnification under this Article VIII, and not just amounts in excess of the Threshold Amount); provided that the limitation set forth in this sentence shall not apply to a claim pursuant to Section 8.1(a) relating to a breach of the representations and warranties set forth in Sections 4.1, 4.2, 4.3, 4.4 or 4.6 or a claim for payment of any amount due pursuant to Article I. For purposes solely of this Article VIII, all representations and warranties (if any) of Buyer in Article IV with materiality limitations, qualifications or baskets shall be construed without respect to any materiality limitation, materiality qualification or materiality basket, as if the term “material” and any reference to “Buyer Material Adverse Effect” (and variations thereof) were omitted from such representations and warranties.

(c) The Escrow Agreement is intended to secure the indemnification obligations of Seller under Article VIII and Section 5.15, the adjustment obligations of Seller under Section 1.5, and the obligations of Parent under the Parent Guaranty. However, the rights of Buyer under this Article VIII, Section 5.15, and Section 1.5 shall not be limited to the Escrow Fund nor shall the Escrow Agreement be the exclusive means for Buyer to enforce such rights; provided that, except as otherwise expressly permitted by this Agreement, Buyer shall not attempt to collect any Losses directly from Seller pursuant to this Article VIII or Section 5.15 unless no remaining portion of the Escrow Fund is held in escrow pursuant to the Escrow Agreement and no portion of the Earn-Out is available to satisfy such Losses; and provided further that, notwithstanding anything to the contrary herein, in no event shall the aggregate liability of Seller pursuant to this Article VIII and Section 5.15 (and the aggregate liability of Parent pursuant to the Parent Guaranty insofar as such guaranty relates to the liabilities of Seller pursuant to this Article VIII), taken together, exceed the Cap.

(d) Except with respect to claims based on fraud or willful misrepresentation, after the Closing, the rights of the Indemnified Parties under this Article VIII, Section 5.15 and the Escrow Agreement, shall be the exclusive remedy of the Indemnified Parties with respect to claims resulting from or relating to any breach of or inaccuracy in any representation or warranty in this Agreement. For the avoidance of doubt, nothing in this Section 8.5(d) is intended to limit the Parties’ rights to recover purchase price adjustments pursuant to Section 1.5 or any rights of offset and set-off pursuant to Section 1.4 (b).

(e) Neither Seller nor any of its subsidiaries shall have any right of contribution against the Company with respect to any breach of or inaccuracy in any representation and warranty of the Company or any breach by the Company of any of its covenants or agreements.

(f) In the event that adjustment has been made pursuant to Section 1.5 for any item that also constitutes an indemnifiable Loss pursuant to this Article VIII arising out of a breach of Seller’s representations and warranties in Section 3.14 or Section 3.16, Buyer shall not be entitled to recover indemnification under this Article VIII for any amount that Buyer has theretofore recovered as an adjustment to the Base Purchase Price pursuant to Section 1.5.



**ARTICLE IX  
CERTAIN POST-CLOSING AGREEMENTS**

Seller agrees that from and after the Closing Date:

9.1. Proprietary Information.

(a) Seller shall (and shall cause each of its Affiliates to) hold in confidence and shall use its (and their) commercially reasonable efforts to have all officers, directors and personnel who continue after the Closing to be employed by Seller or any Affiliate of Seller to hold in confidence all knowledge and information of a secret or confidential nature with respect to the business of the Company and not to disclose, publish or make use of the same without the consent of Buyer, except as required by law (in which case Seller shall provide reasonable advance notice of such proposed disclosure and shall cooperate with Buyer and the Company, at their expense, in seeking an appropriate protective order or other confidentiality assurances) and except to the extent that such information shall have become public knowledge other than by breach of this Agreement by Seller.

(b) If (i) the employment of an officer, director or other employee of Seller or any Affiliate thereof, to whom secret or confidential knowledge or information concerning the business of the Company has been disclosed, is terminated and (ii) such individual is subject to an obligation to maintain such knowledge or information in confidence after such termination, Seller shall, upon request by Buyer, take all reasonable steps at their expense to enforce such confidentiality obligation in the event of an actual or threatened breach thereof. Any legal counsel retained by Seller in connection with any such enforcement or attempted enforcement shall be selected by Seller, but shall be subject to the approval of Buyer, which approval shall not be unreasonably withheld.

(c) Seller agrees that the remedy at law for any breach of this Section 9.1 would be inadequate and that Buyer shall be entitled to injunctive relief in addition to any other remedy it may have upon breach of any provision of this Section 9.1.

9.2. No Solicitation of Former Employees. Except as provided by law, for a period of [\*\*] ([\*\*]) years after the Closing Date, Seller shall not (and shall cause its subsidiaries and Affiliates not to) directly or indirectly solicit, induce or encourage any person who was an employee (other than secretarial and clerical staff) of either the Company on the date hereof or the Closing Date to terminate his employment with Buyer (or the Company, as the case may be) or to become an employee of Seller or any of its subsidiaries or Affiliates; provided, that nothing in this Section 9.2 shall be construed to prohibit Seller from placing advertisements in publications of general circulation that are not directly specifically at employees of Buyer or the Company.

9.3. Non-Competition Agreement.

(a) For a period of [\*\*] ([\*\*]) years after the Closing Date (the "Restricted Period"), neither Seller nor any of its subsidiaries or Affiliates shall (and Seller shall procure that Parent shall not), either directly or indirectly through any subsidiary or Affiliate, develop,

manufacture, market or sell, anywhere in the world (including anywhere in the United States or any country in North America, Japan or any country in Asia, Australia, New Zealand, England or any country in Europe), (i) any sustained-release bupivacaine-based product for use in pain management, or (ii) any sustained-release opioid-based product for use in pain management (other than the non-injectable sustained-release naproxen-hydrocodone combination products currently under development at the Company), or (iii) any sustained-release cytarabine-based product, or (iv) any sustained-release Biologics Product (as defined in Schedule 1.7). For purposes of this provision, "sustained-release" shall mean release such that the intended dosing or use is for more than twelve (12) hours. For a period of [\*\*] ([\*\*]) years after the Closing Date, Seller shall not, and shall procure that Parent and its Affiliates shall not, solicit any drug development business with respect to any of the substances listed in Column A of Schedule 9.3(a) from any of the entities named or otherwise identified opposite such substance in Column B thereof.

(b) Seller and Buyer agree that the market for the Company's products is worldwide, that development cycles for products such as the Company's products are lengthy, and that duration and geographic scope of the non-competition provision set forth in this Section 9.3 are reasonable. In the event that any court of competent jurisdiction determines that the duration or the geographic scope, or both, are unreasonable and that such provision is to that extent unenforceable, Seller and Buyer agree that the provision shall remain in full force and effect for the greatest time period and in the greatest area that would not render it unenforceable. Seller and Buyer intend that this non-competition provision shall be deemed to be a series of separate covenants, one for each and every county of each and every state of the United States of America and each and every country and political subdivision of each and every country outside the United States of America where this provision is intended to be effective. Seller agrees that damages are an inadequate remedy for any breach of this provision and that Buyer shall, whether or not it is pursuing any potential remedies at law, be entitled to equitable relief in the form of preliminary and permanent injunctions without bond or other security upon any actual or threatened breach of this non-competition provision.

(c) Notwithstanding the foregoing provisions: (i) nothing herein shall be construed to prevent or prohibit the acquisition of Parent as a whole by any unaffiliated acquiror or to subject the other operations of any such acquiror to the restrictions of this Section 9.3 (it being understood and agreed that the provisions of this Section 9.3 shall continue to apply to the operations of Seller and the entities that prior to the consummation of such an acquisition are Affiliates of Seller (including Parent and its Affiliates)); and (ii) in the event that Parent acquires a company whose assets and operations would violate the provisions of this Section 9.3, neither Parent nor Seller shall be deemed to be in violation of this Section 9.3 as long as Parent shall have divested, spun off or otherwise ceased to own or operate such assets and operations within one hundred eighty (180) days after the consummation of such acquisition.

9.4. Further Assurances. If at any time before the Closing or during the three (3) year period following the Closing any Omitted IP is discovered, Seller shall (and shall procure that Parent and its Affiliates shall), at Seller's sole expense, (a) assign, transfer and deliver all right, title and interest held by Seller (or by Parent or any of its Affiliates) in, to and under such Omitted IP to the Company at the Closing or as soon as reasonably practicable after the Closing,

but in any case, within thirty (30) days after such Omitted IP is discovered, and (b) take such further action reasonably requested by the Company or Buyer in order to more fully vest and record title in and to such Omitted IP the name of the Company. Subject to Seller's compliance with this Section 9.4, and provided that the omission of such Omitted IP is inadvertent, Buyer agrees and acknowledges that Buyer's rights under this Section 9.4 shall be its sole and exclusive remedy for a breach of the representations and warranties set forth in Section 3.13(g), where such breach arises solely from the failure of the Company to own such Omitted IP as of the Closing. Effective upon (and subject to) the assignment to the Company of any Licensed-Back Omitted IP in accordance with this Section 9.4, the Company hereby grants to Seller and its Affiliates a non-exclusive, royalty-free, perpetual, irrevocable, worldwide license, with the right to sublicense, under any and all such Licensed-Back Omitted IP for use by Seller and its Affiliates subject to the provisions of Section 9.3.

**ARTICLE X  
TERMINATION OF AGREEMENT**

10.1. Termination by Lapse of Time. This Agreement shall terminate at 5:00 p.m. Pacific Standard Time, on April 30, 2007, if the transactions contemplated hereby have not been consummated, unless such date is extended by the written consent of the Company, Buyer and Seller.

10.2. Termination by Agreement of the Parties. This Agreement may be terminated by the mutual written agreement of the Parties hereto. In the event of such termination by agreement, Buyer shall have no further obligation or liability to Seller or the Company under this Agreement, and Seller shall have no further obligation or liability to Buyer under this Agreement.

10.3. Termination by Reason of Breach.

(a) This Agreement may be terminated by Seller by giving written notice to Buyer in the event Buyer is in breach of any representation, warranty or covenant contained in this Agreement, and such breach, individually or in combination with any other such breach, (i) would cause the conditions set forth in Sections 7.2 or 7.3 not to be satisfied and (ii) is not cured within twenty (20) days following delivery by Seller to Buyer of written notice of such breach.

(b) This Agreement may be terminated by Buyer by giving written notice to Seller and the Company in the event that Seller or the Company are in breach of any representation, warranty or covenant contained in this Agreement, and such breach, individually or in combination with any other such breach, (i) would cause the conditions set forth in Sections 6.11 not to be satisfied and (ii) is not cured within twenty (20) days following delivery by Buyer of written notice of such breach.

10.4. Termination For Failure to Obtain Shareholder Approval. This Agreement may be terminated by either Party if the requisite approval of Seller's shareholders as set forth in Section 5.3 shall not have been obtained at the EGM (including adjournments thereof); provided, however, that no Party shall have the right to terminate this Agreement pursuant to this Section 10.4 if the failure to obtain the requisite approval of Seller's shareholders is attributable to a breach of that Party's obligations under this Agreement.

10.5. Effect of Termination. If any Party terminates this Agreement pursuant to Section 10.1 or 10.2, all obligations of the Parties hereunder shall terminate without any liability of any Party to any other Party and shall be null and void (except in each case for any liability of any Party for bad faith breaches of this Agreement). Notwithstanding the foregoing, (a) if this Agreement is terminated by any Party pursuant to Section 10.4, Seller shall promptly pay to Buyer the out-of-pocket expenses actually incurred by Buyer and its shareholders in connection with the negotiation of this Agreement and the Ancillary Agreements and the pursuit of the transactions contemplated hereby and thereby (the amount of which shall be disclosed by Buyer to Seller promptly following delivery by Seller to Buyer of a notice of intended termination requesting the same), up to a maximum of [\*\*] dollars (\$[\*\*]); and (b) if this Agreement is terminated (i) by Seller pursuant to Section 10.1 or Section 10.4, or (ii) by Buyer pursuant to Section 10.1 for breach by Seller of any of its obligations under Section 5.7, or (iii) by Buyer pursuant to Section 10.1 or 10.4, and if, in each case within the scope of the immediately preceding clauses (i), (ii) and (iii), after the date hereof and prior to such termination a competing offer, bid or indication or expression of interest (an “Acquisition Proposal”) shall have been made to acquire the Company or any material asset of the Company and such offer, bid or indication or expression of interest shall not have been definitively and unconditionally withdrawn a reasonable time before the EGM, and Seller, Seller, the Company or any of their subsidiaries enter into a definitive agreement with respect to an Acquisition Proposal within twelve (12) months after the date of such termination, then Seller shall, prior to and as a condition precedent to the effectiveness of any such termination and prior to or concurrently with the signing of such definitive agreement, pay to Buyer, by wire transfer of immediately available funds to an account to be designated by Buyer, the sum in cash of [\*\*] dollars (\$[\*\*]) plus the out-of-pocket expenses actually incurred by Buyer in connection with the negotiation of this Agreement and the Ancillary Agreements and the pursuit of the transactions contemplated hereby and thereby (the amount of which shall be disclosed by Buyer to Seller promptly following delivery by Seller to Buyer of a notice of intended termination requesting the same), which in no event shall be more than [\*\*] dollars (\$[\*\*]) in total (the “Termination Fee”). In the event that a payment is made pursuant to Section 10.5(b), no payment shall be made pursuant to Section 10.5(a), and in the event that a payment is made pursuant to Section 10.5(a), any subsequent payment pursuant to Section 10.5(b) shall be net of any amount paid pursuant to Section 10.5(a).

10.6. Election of Remedies; Liquidated Damages. If Seller wrongfully fails to close and complete the purchase and sale of the Shares contemplated by this Agreement, Buyer shall be entitled, at its election and in its sole discretion, to one (but not both) of the following remedies: (a) specific performance or other equitable relief to compel the consummation of the transactions contemplated by this Agreement or (b) payment by Buyer of liquidated damages in the amount of the Termination Fee, which (if paid by Seller within two (2) business days after receipt of notice of Buyer’s election of remedy) shall constitute full satisfaction of any and all claims that Buyer may have against Seller for breach of this Agreement; provided, that if Buyer elects the remedy provided by clause (a) of this Section 10.6, then the maximum amount of

damages recoverable by Seller against Buyer in respect of any claim or counterclaim of breach by Buyer of this Agreement shall be reciprocally limited to the amount of the Termination Fee, and if Buyer elects the remedy provided by clause (b) of this Section 10.6, then the damage remedies available to Seller against Buyer in respect of any claim or counterclaim of breach by Buyer of this Agreement shall not be limited to the amount of the Termination Fee.

**ARTICLE XI  
DISPUTE RESOLUTION**

11.1. General. In the event that any dispute should arise between Buyer and Seller after the Closing with respect to any matter covered by this Agreement (other than a dispute within the scope of Section 8.3(d) and 8.3(e)), including the Adjusted Purchase Price, Buyer and Seller shall resolve such dispute in accordance with the procedures set forth in this Article XI.

11.2. Consent of the Parties. Buyer and Seller shall first use their commercially reasonable efforts to resolve such dispute among themselves. If Buyer and Seller are unable to resolve the dispute within thirty (30) calendar days after the commencement of efforts to resolve the dispute, either Buyer or Seller may either (i) commence an action with respect to the matter in dispute in an appropriate court of competent jurisdiction in accordance with the provisions of Section 13.8, or (ii) submit the matter in dispute to arbitration in accordance with Section 11.3; provided, that if the other Party objects or is seeking relief that the arbitrator is not authorized or empowered to award, the matter in dispute shall not be submitted to arbitration but shall instead be determined in court in accordance with the provisions of Section 13.8.

11.3. Arbitration.

(a) Either Buyer or Seller may submit any matter referred to in Section 11.2 to arbitration by notifying the other Party (and, if the matter involves the Escrow Fund, the Escrow Agent), in writing, of such dispute. Within ten (10) days after receipt of such notice, Buyer and Seller shall designate in writing one arbitrator to resolve the dispute; provided, that if Buyer and Seller cannot agree on an arbitrator within such 10-day period, the arbitrator shall be selected by the AAA. The arbitrator so designated shall not be an employee, consultant, officer, director or stockholder of any Party hereto or any Affiliate of any Party to this Agreement.

(b) Within fifteen (15) days after the designation of the arbitrator, the arbitrator, Buyer and Seller shall meet, at which time Buyer and Seller shall be required to set forth in writing all disputed issues and a proposed ruling on each such issue.

(c) The arbitrator shall set a date for a hearing, which shall be no later than thirty (30) days after the submission of written proposals pursuant to paragraph (b) above, to discuss each of the issues identified by Buyer and Seller. Buyer and Seller shall each have the right to be represented by counsel. The arbitration shall be governed by the rules of the AAA; provided, that the arbitrator shall have sole discretion with regard to the admissibility of evidence.

(d) The arbitrator shall use his best efforts to rule on each disputed issue within thirty (30) days after the completion of the hearings described in paragraph (c) above.

The determination of the arbitrator as to the resolution of any dispute shall be binding and conclusive upon all Parties hereto. All rulings of the arbitrator shall be in writing and shall be delivered to the Parties hereto and, to the extent they involve the Escrow Fund, the Escrow Agent.

(e) The prevailing party in any arbitration shall be entitled to an award of reasonable attorneys' fees incurred in connection with the arbitration. The non-prevailing party shall pay such fees, together with the fees of the arbitrator and the costs and expenses of the arbitration.

(f) Any arbitration pursuant to this Section 11.3 shall be conducted in New York, New York.

(g) Notwithstanding any provision of this Article XI to the contrary, disputes that are within the scope of Section 8.3(d) and 8.3(e) shall be resolved in accordance with the provisions of Article VIII and not this Article XI.

## **ARTICLE XII DEFINITIONS**

12.1. Certain Definitions. For purposes of this Agreement, each of the following terms shall have the meaning set forth below.

"AAA" shall mean the American Arbitration Association.

"Adjusted Purchase Price" shall mean the Base Purchase Price as adjusted in accordance with Section 1.5(c).

"Affiliate" shall mean any affiliate, as defined in Rule 12b-2 under the Securities Exchange Act of 1934.

"Affiliated Group" shall mean a group of corporations with which the Company has filed (or was required to file) consolidated, combined, unitary or similar Tax Returns.

"Affiliate Owned Intellectual Property" shall have the meaning set forth in Section 3.13(a).

"Affiliated Period" shall mean any period in which the Company was a member of an Affiliated Group.

"Agreed Amount" shall mean part, but not all, of the Claimed Amount.

"Agreement" shall have the meaning set forth in the first paragraph.

"Ancillary Agreements" means the Parent Guaranty, the Escrow Agreement, the License Agreement, the Transition Services Agreement, the Assignment of Patents, and the Assignment of Trademarks.

“Anti-Kickback Statute” shall mean 42 U.S.C. § 1320a-7b(b).

“Antitrust Laws” shall have the meaning set forth in Section 5.2.

“Arbitrator” shall have the meaning set forth in Section 8.3(e).

“Base Purchase Price” shall mean the portion of the purchase price to be paid by Buyer at the Closing, as set forth in Section 1.3, subject to adjustment pursuant to Section 1.5.

“Biosphere Assets” shall have the meaning set forth in Section 5.11.

“Buyer” shall have the meaning set forth in the first paragraph of this Agreement.

“Buyer Compliance Certificate” shall mean a certificate to the effect that each of the conditions specified in Article VII is satisfied in all respects.

“Buyer Material Adverse Effect” shall mean any material adverse change, event, circumstance or development with respect to, or material adverse effect on, the business, assets, liabilities, capitalization, prospects, condition (financial or other), or results of operations of Buyer. For the avoidance of doubt, the Parties agree that the terms “material”, “materially” or “materiality” as used in this Agreement with an initial lower case “m” shall have their respective customary and ordinary meanings, without regard to the meaning ascribed to Buyer Material Adverse Effect.

“Cap” shall mean [\*\*] dollars (\$[\*\*]).

“CERCLA” shall mean the federal Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended.

“Circular” shall have the meaning set forth in Section 5.3.

“Claim Notice” shall mean written notification which contains (i) a description of the Losses incurred or reasonably expected to be incurred by the Indemnified Party and the Claimed Amount of such Losses, to the extent then known, (ii) a statement that the Indemnified Party is entitled to indemnification under Article VIII for such Losses and a reasonable explanation of the basis therefor, and (iii) a demand for payment in the amount of such Losses.

“Claimed Amount” shall mean the amount of any Losses incurred by the Indemnified Party or, in the case of Third-Party Claims, incurred or reasonably expected to be incurred by the Indemnified Party.

“Closing” shall mean the closing of the transactions contemplated by this Agreement.

“Closing Date” shall mean the date on which the actually closing occurs.

“Code” and “Internal Revenue Code” shall mean the Internal Revenue Code of 1986, as amended.

“Commercial Rules” shall mean the Commercial Arbitration Rules of the AAA.

“Commitment Letters” shall have the meaning set forth in Section 4.6.

“Common Stock” shall mean the shares of common stock, no par value per share, of the Company.

“Company” shall have the meaning set forth in the first paragraph of this Agreement.

“Company Debt” shall have the meaning set forth in Section 5.15(r).

“Company Intellectual Property” shall have the meaning set forth in Section 3.13(a).

“Company Material Adverse Effect” shall mean any material adverse change, event, circumstance or development with respect to, or material adverse effect on, the business, assets, liabilities, capitalization, employees, condition (financial or other), or results of operations of the Company. For the avoidance of doubt, the Parties agree that the terms “material,” “materially” or “materiality” as used in this Agreement with an initial lower case “m” shall have their respective customary and ordinary meanings, without regard to the meaning ascribed to Company Material Adverse Effect, and that the departure from the Company of material members of senior management (or the departure from the Company of a number of employees that is material to the operation of the business of the Company after the Closing and the transactions contemplated by this Agreement) may constitute a Company Material Adverse Effect.

“Company Owned Intellectual Property” shall have the meaning set forth in Section 3.13(a).

“Company Patents” shall have the meaning set forth in Section 3.13(a).

“Company Plan” shall mean any Employee Benefit Plan maintained, or contributed to, by the Company or any ERISA Affiliate for the benefit of any current or former employees of the Company.

“Confidential Information” shall mean any confidential or proprietary information of the Company that is furnished in writing to Buyer by the Company in connection with this Agreement and is labeled confidential or proprietary; provided, however, that it shall not include any information (A) which, at the time of disclosure, is available publicly, (B) which, after disclosure, becomes available publicly through no fault of Buyer, (C) which Buyer knew or to which Buyer had access prior to disclosure or (D) which Buyer rightfully obtains from a source other than the Company.

“Controlling Party” shall mean the party controlling the defense of any Third Party Claim.

“Copyrights” shall have the meaning set forth in Section 3.13(a).

“DEA” shall have the meaning set forth in Section 3.30.



“Designated Amounts” shall mean the items listed in Schedule 12.1.

“Dispute” shall mean the dispute resulting if the Indemnifying Party in a Response disputes its liability for all or part of the Claimed Amount.

“DMF” shall have the meaning set forth in Section 3.30(m).

“Draft Closing Net Assets Statement” shall have the meaning set forth in Section 1.5(a).

“Due Date” shall mean, with respect to any Tax Return, the date such Tax Return is required to be filed (taking into account all valid extensions).

“EGM” shall have the meaning set forth in Section 5.3.

“EMEA” shall have the meaning set forth in Section 3.30.

“Employee Benefit Plan” shall mean any “employee pension benefit plan” (as defined in Section 3(2) of ERISA), any “employee welfare benefit plan” (as defined in Section 3(1) of ERISA), and any other written or oral plan, agreement or arrangement involving direct or indirect compensation, including insurance coverage, severance benefits, disability benefits, deferred compensation, bonuses, stock options, stock purchase, phantom stock, stock appreciation or other forms of incentive compensation or post-retirement compensation.

“Encumbrance” means any and all Security Interests, covenants, conditions, restrictions, voting trust arrangements, liens, charges, encumbrances, rights of first offer or first refusal, options and adverse claims or rights whatsoever, provided, however, that Encumbrance shall not include a lien for Taxes (i) not yet due and payable, or (ii) being contested in good faith in appropriate proceedings and with respect to which adequate reserves have been established on the Most Recent Balance sheet in accordance with IFRS.

“Endo Agreement” means the Development and Marketing Strategic Alliance Agreement dated December 31, 2002 among Endo Pharmaceuticals, Inc., SkyePharma, Inc. and SkyePharma Canada Inc.

“Environmental Law” shall mean any federal, state or local law, statute, rule, order, directive, judgment, Permit or regulation or the common law relating to the environment, occupational health and safety, or exposure of persons or property to Materials of Environmental Concern, including any statute, regulation, administrative decision or order pertaining to: (i) the presence of or the treatment, storage, disposal, generation, transportation, handling, distribution, manufacture, processing, use, import, export, labeling, recycling, registration, investigation or remediation of Materials of Environmental Concern or documentation related to the foregoing; (ii) air, water and noise pollution; (iii) groundwater and soil contamination; (iv) the release, threatened release, or accidental release into the environment, the workplace or other areas of Materials of Environmental Concern, including emissions, discharges, injections, spills,

escapes or dumping of Materials of Environmental Concern; (v) transfer of interests in or control of real property which may be contaminated; (vi) community or worker right-to-know disclosures with respect to Materials of Environmental Concern; (vii) the protection of wild life, marine life and wetlands, and endangered and threatened species; (viii) storage tanks, vessels, containers, abandoned or discarded barrels and other closed receptacles; and (ix) health and safety of employees and other persons. As used above, the term “release” shall have the meaning set forth in CERCLA.

“ERISA” shall mean the Employee Retirement Income Security Act of 1974, as amended.

“ERISA Affiliate” shall mean any entity which is, or at any applicable time was, a member of (1) a controlled group of corporations (as defined in Section 414(b) of the Code), (2) a group of trades or businesses under common control (as defined in Section 414(c) of the Code), or (3) an affiliated service group (as defined under Section 414(m) of the Code or the regulations under Section 414(o) of the Code), any of which includes or included the Company.

“Escrow Agent” shall mean Boston Trust & Investment Management Company (or another escrow or depository agent designated by Buyer and reasonably acceptable Seller).

“Escrow Agreement” shall mean an escrow agreement in substantially the form attached hereto as Exhibit B.

“Escrow Amount” shall mean two million dollars (\$2,000,000).

“Escrow Fund” shall have the meaning set forth in Section 1.6.

“Excluded Assets” shall have the meaning set forth in Section 5.11.

“Excluded Taxes” shall have the meaning set forth in Section 5.15(b).

“Expected Claim Notice” shall mean a notice that, as a result of a legal proceeding instituted by or written claim made by a third party, an Indemnified Party reasonably expects to incur Losses for which it is entitled to indemnification under Article VIII.

“Expiration Date” shall have the meaning set forth in Section 8.4.

“FDA” shall have the meaning set forth in Section 3.30.

“FDCA” shall have the meaning set forth in Section 3.30.

“Federal False Claims Act” shall have the meaning set forth in Section 3.30.

“Final Closing Net Assets Statement” shall have the meaning set forth in Section 1.5(b).

“Final Determination” shall mean (i) a decision by a court of competent jurisdiction that is not subject to further judicial review, (ii) a closing agreement or other final resolution with the relevant Taxing Authority, or (iii) any other event that is a final and irrevocable determination of liability for Tax.

“Financial Statements” shall mean the balance sheet of the Company on a stand-alone basis as of October 27, 2006 and the Most Recent Net Assets Statement, each of which shall be prepared by Seller on a going-concern basis.

“Governmental Entity” shall mean (a) any nation (including but not limited to the United States of America), state, province, canton, county, city, district or other jurisdiction or political subdivision or unit of any nature; (b) any national, federal, state, provincial, cantonal, county, city, local, municipal or other government; (c) any branch or instrumentality of any government whether executive, legislative, judicial, administrative or other; (d) any administrative agency, administration or commission; (e) any court or tribunal; any quasi-governmental authority or body exercising or entitled to exercise any administrative, executive, judicial, legislative, police, regulatory, or taxing authority or power of any nature; and (f) any multi-national or supranational organization or body.

“Group Owned Intellectual Property” shall have the meaning set forth in Section 3.13(a).

“HC” shall have the meaning set forth in Section 3.30.

“HSR Act” shall mean the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

“IFRS” shall mean International Financial Reporting Standards.

“Income Tax(es)” shall mean any Tax(es) imposed upon or measured by net income and any franchise Tax(es).

“IND” shall have the meaning set forth in Section 3.30(h).

“Indemnified Buyer Party” shall have the meaning set forth in Section 8.1.

“Indemnified Party” shall mean a Person entitled, or seeking to assert rights, to indemnification under Article VIII.

“Indemnified Seller Party” shall have the meaning set forth in Section 8.2.

“Indemnifying Party” shall mean the party from whom indemnification is sought by the Indemnified Party.

“Intellectual Property” shall have the meaning set forth in Section 3.13(a).

“IP Contracts” shall have the meaning set forth in Section 3.13(a).

“Lease” shall mean any lease or sublease pursuant to which the Company leases or subleases from another party any real property.

“Legal Proceeding” shall mean any action, suit, proceeding, claim, arbitration or investigation before any Governmental Entity or before any arbitrator, except that the foregoing shall not apply to proceedings before the United States Patent and Trademark Office or similar entities in other jurisdiction with respect to patent prosecution conducted in the ordinary course of business.

“Licensed-Back Omitted IP” means Omitted IP that is (a) assigned by Seller or its Affiliates to the Company in accordance with Section 9.4, and (b) used by Seller or its Affiliates as of the Closing Date, other than in the business of the Company; provided, however, that “Licensed-Back Omitted IP” shall exclude any Product Intellectual Property and Intellectual Property solely comprising, claiming or covering the DepoFoam or Biosphere technologies.

“Losses” shall mean any and all debts, obligations and other liabilities (whether absolute, accrued, contingent, fixed or otherwise, or whether known or unknown, or due or to become due or otherwise), diminution in value, monetary damages, fines, fees, penalties, interest obligations, deficiencies, losses and expenses (including amounts paid in settlement, interest, court costs, costs of investigators, fees and expenses of attorneys, accountants, financial advisors and other experts, and other expenses of litigation), other than those costs and expenses of arbitration of a Dispute which are to be shared equally by the Indemnified Party and the Indemnifying Party as set forth in Section 8.3(e)(vi). The Losses recoverable by an Indemnified Party pursuant to Article VIII shall be net of any insurance proceeds actually received by the Indemnified Party without adverse impact on the continuation or increase in the cost of such insurance (it being understood and agreed that nothing herein shall be construed to impose any obligation to procure or maintain any insurance or to make or pursue any claim against any insurance that the Indemnified Party may possess).

“Material Contract” shall have the meaning set forth in Section 3.15.

“Material Permits” shall have the meaning set forth in Section 3.30.

“Materials of Environmental Concern” shall mean any: pollutants, contaminants or hazardous substances (as such terms are defined under CERCLA), pesticides (as such term is defined under the Federal Insecticide, Fungicide and Rodenticide Act), solid wastes and hazardous wastes (as such terms are defined under the Resource Conservation and Recovery Act), chemicals, other hazardous, radioactive or toxic materials, oil, petroleum and petroleum products (and fractions thereof), or any other material (or article containing such material) listed or subject to regulation under any law, statute, rule, regulation, order, Permit, or directive due to its potential, directly or indirectly, to harm the environment or the health of humans or other living beings.

“MHPRA” shall have the meaning set forth in Section 3.30.

“Most Recent Net Assets Statement” shall mean the unaudited asset and liability accounts of the Company as of the Most Recent Net Assets Statement Date, in the form set forth in Column D of the spreadsheet attached in Schedule 1.5(a)(i).

“Most Recent Net Assets Statement Date” shall mean November 24, 2006.

“Names” shall have the meaning set forth in Section 1.1.

“Net Assets Target” shall have the meaning set forth in Section 1.5(a).

“NDA” shall have the meaning set forth in Section 3.30(h).

“Non-controlling Party” shall mean the party not controlling the defense of any Third Party Claim.

“Objection Deadline Date” shall mean the date twenty (20) days after delivery by Seller to Buyer of the Draft Closing Net Assets Statement.

“Objection Statement” shall have the meaning set forth in Section 1.5(b).

“Omitted IP” means any Intellectual Property that is (i) owned by the Parent or any of its Affiliates (other than the Company) on the Closing Date, (ii) used by the Company as of the Closing Date or necessary for the conduct of its business in the manner conducted as of the Closing Date or intended to be conducted (as such phrase is defined in Section 3.13(a)(ix)) as of the Closing Date, and (iii) primarily used in the business of the Company (and not primarily being used in the business of the Parent or any of its Affiliates (other than the Company)) as of the Closing Date, including, without limitation, all such Intellectual Property satisfying subsections (i), (ii) and (iii) above and relating to, claiming or covering the development, making, using, selling or otherwise commercializing any Product or Product Candidate.

“Ordinary Course of Business” shall mean the ordinary course of business consistent with past custom and practice (including with respect to frequency and amount).

“Owned Real Property” shall mean each item of real property owned by the Company.

“Parent” shall have the meaning set forth in the second recital.

“Parent Guaranty” shall have the meaning set forth in the second recital.

“Parties” shall mean Buyer, Seller and the Company, and “Party” shall mean each of any of them, as appropriate in the context.

“Patents” shall have the meaning set forth in Section 3.13(a).

“Patent Office” shall have the meaning set forth in Section 3.13(f).

“Paul Capital Agreements” means (a) Royalty Interest Assignment Agreement, dated as of December 29, 2000, among SKPI, as seller, Jagotec, as seller, SKPP, as parent, and Paul Capital Royalty Acquisition Fund, L.P. (now known as Paul Royalty Fund, L.P., as purchaser, as transferred, conveyed and assigned by Paul Royalty Fund, L.P. to Royalty Financial Company LLC pursuant to Sale and Contribution Agreement dated as of December 9, 2004, between Paul Royalty Fund, L.P., as originator, and Royalty Financial Company LLC, as purchaser, as further transferred and assigned by Royalty Financial Company LLC to the Purchaser pursuant to Transfer and Servicing Agreement, dated as of December 9, 2004, among Royalty Financial Company LLC, as transferor, Paul Capital Advisors, L.L.C., as servicer, and the Purchaser, as issuer; (b) Security Agreement, dated as of December 29, 2000, among SKPI, as grantor, Jagotec, as grantor, and Paul Capital Royalty Acquisition Fund, L.P., as purchaser, as transferred, conveyed and assigned by Paul Royalty Fund, L.P. to Royalty Financial Company LLC pursuant to Sale and Contribution Agreement dated as of December 9, 2004, between Paul Royalty Fund, L.P., as originator, and Royalty Financial Company LLC, as purchaser, as further transferred and assigned by Royalty Financial Company LLC to the Purchaser pursuant to Transfer and Servicing Agreement, dated as of December 9, 2004, among Royalty Financial Company LLC, as transferor, Paul Capital Advisors, L.L.C., as servicer, and the Purchaser, as issuer; and (c) Lockbox Agreement, dated as of December 3, 2004, by and among SKPP, Jagotec, SKPI, Paul Royalty Fund, L.P. and JPMorgan Chase Bank, National Association, as assigned by Paul Royalty Fund, L.P. to Deutsche Bank Trust Company Americas, as Custodian, pursuant to Amended and Restated Custody Agreement dated as of December 9, 2004, between Paul Royalty Fund, L.P. and Deutsche Bank Trust Company Americas, as Custodian.

“Permits” shall mean all permits, licenses, registrations, certificates, orders, approvals, franchises, variances and similar rights issued by or obtained from any Governmental Entity (including those issued or required under Environmental Laws and those relating to the occupancy or use of owned or leased real property).

“Permitted Encumbrance” shall mean (i) mechanic’s, materialmen’s, and similar liens, (ii) liens arising under worker’s compensation, unemployment insurance, social security, retirement, and similar legislation and (iii) liens on goods in transit incurred pursuant to documentary letters of credit, in each case arising in the Ordinary Course of Business of the Company and not material to the Company.

“Person” means a natural person or entity, including a corporation, partnership, limited liability company, trust, or other entity.

“PHSA” shall have the meaning set forth in Section 3.30.

“Preclinical Tests and Clinical Trials” shall have the meaning set forth in Section 3.30.

“Pre-Closing Period” shall mean any taxable period ending on or before the Closing Date.

“Pre-Closing Tax Return” shall mean any Tax Return relating to a Pre-Closing Period.

“Products,” solely for purposes of Section 3.30, shall have the meaning set forth in Section 3.30, and, for all other purposes of this Agreement, shall have the meaning set forth in Section 3.13(a)(v).

“Product Candidates,” solely for purposes of Section 3.30, shall have the meaning set forth in Section 3.30, and, for all other purposes of this Agreement, shall have the meaning set forth in Section 3.13(a)(vi).

“Product Intellectual Property” shall have the meaning set forth in Section 3.13(a).

“Program Fraud Civil Remedies Act” shall have the meaning set forth in Section 3.30.

“Registered Intellectual Property” shall have the meaning set forth in Section 3.13(a).

“Relevant Regulatory Authority” shall have the meaning set forth in Section 3.30.

“Response” shall mean a written response containing the information provided for in Section 8.3(c).

“Restricted Period” shall have the meaning set forth in Section 9.3(a).

“Security Interest” shall mean any mortgage, pledge, security interest, encumbrance, charge or other lien (whether arising by contract or by operation of law).

“Seller” shall have the meaning set forth in the first paragraph.

“Seller Compliance Certificate” shall mean a certificate to the effect that each of the conditions specified in Article VI is satisfied in all respects.

“Seller Disclosure Schedule” shall mean the disclosure schedule provided by Seller and the Company to Buyer on the date hereof.

“Shares” shall have the meaning set forth in the first recital.

“Straddle Period” shall mean any taxable period beginning on or before and ending after the Closing Date.

“Straddle Period Tax Return” shall mean any Tax Return relating to a Straddle Period.

“Subsidiary” shall mean any corporation, partnership, trust, limited liability company or other non-corporate business enterprise in which the Company (or another Subsidiary) holds stock or other ownership interests representing (a) more than fifty percent (50%) of the voting power of all outstanding stock or ownership interests of such entity or (b) the right to receive more than fifty percent (50%) of the net assets of such entity available for distribution to the holders of outstanding stock or ownership interests upon a liquidation or dissolution of such entity.

“Target Net Assets Statement” shall have the meaning set forth in Section 1.5(a).

“Taxes” shall mean all taxes, charges, fees, levies or other similar assessments or liabilities in the nature of a tax, including income, gross receipts, ad valorem, premium, value-added, net-worth, capital stock, capital gains, documentary, recapture, alternative or add-on minimum, disability, estimated, registration, recording, excise, real property, personal property, sales, use, license, lease, service, service use, transfer, withholding, employment, unemployment, insurance, social security, business license, business organization, environmental, workers compensation, payroll, profits, severance, stamp, occupation, windfall profits, customs, duties, franchise and other taxes imposed by the United States of America or any state, local or foreign government, or any agency thereof, or other political subdivision of the United States of America or any such government, and any interest, fines, penalties, assessments or additions to tax resulting from, attributable to or incurred in connection with any tax or any contest or dispute thereof.

“Tax Claim Notice” shall have the meaning set forth in Section 5.15(g).

“Tax Contest” shall have the meaning set forth in Section 5.15(g).

“Tax Reserves” shall mean any reserves for Taxes reflected on the Final Closing Net Assets Statement.

“Tax Returns” shall mean all reports, returns, declarations, statements or other information required to be supplied to a taxing authority in connection with Taxes.

“Taxing Authority” shall mean a Governmental Entity responsible for the imposition or collection of Taxes.

“Transfer Taxes” shall have the meaning set forth in Section 5.15(a)(iii).

“Third Party Claim” shall mean any claim, suit or proceeding (including claims for or constituting Designated Amounts and suits and proceedings to collect Designated Amounts) by a person or entity other than a Party for which indemnification may be sought by a Party under Article VIII.

“Third Party Intellectual Property” shall have the meaning set forth in Section 3.13(a).

“Trademarks” shall have the meaning set forth in Section 3.13(a).

“Transition Services Agreement” shall have the meaning set forth in Section 5.9.

“Trade Secrets” shall have the meaning set forth in Section 3.13(a).

“Unresolved Objections” shall mean any objections set forth in an Objection Statement that remain unresolved thirty (30) days after delivery of such Objection Statement.



**12.2. Certain Rules of Construction.**

(a) The terms “law” and “laws” refer to each and every applicable U.S. and non-U.S. federal, national, state, provincial, local and municipal law, statute, rule, regulation and directive and each judgment, order, decree, permit, or order of each court and other Governmental Entity or Relevant Regulatory Authority of competent jurisdiction. Any reference to any federal, state, national provincial, local, municipal, foreign or other law shall be deemed also to refer to all rules and regulations promulgated thereunder (including rules and regulations of the Securities and Exchange Commission, state securities regulators, the NASD and its affiliates, and the FDA and other Relevant Regulatory Authorities), unless the context requires otherwise.

(b) Unless the context of this Agreement otherwise requires, (i) words of either gender or the neuter include the other gender and the neuter, (ii) words using the singular number also include the plural number and words using the plural number also include the singular number, (iii) the terms “hereof”, “herein”, “hereby” and derivative or similar words refer to this entire Agreement as a whole and not to any particular Article, Section or other subdivision, (iv) the terms “Article” or “Section” or other subdivision refer to the specified Article, Section or other subdivision of the body of this Agreement, (v) the word “include” shall be deemed to be followed by the phrase “but are not limited to”, the word “includes” shall be deemed to be followed by the phrase “but is not limited to”, and the word “including” shall be deemed to be followed by the phrase “but not limited to”, (vi) the phrase “materiality limitation”, with respect to a Party’s representations, warranties, covenants and agreements, includes all qualifications, limitations, thresholds and exceptions based on the concept of materiality, whether expressed by the word “material”, “materially”, “materiality”, “material adverse change”, or “material adverse effect”, (vii) when a reference is made in this Agreement to Exhibits, such reference shall be to an Exhibit to this Agreement unless otherwise indicated, (viii) when a statement herein with respect to a particular matter is qualified by the phrase “in all material respects”, materiality shall be determined solely by reference to, and solely within the context of, the specified matter and not with respect to the entirety of this Agreement or the entirety of the transactions contemplated hereby, and (ix) the terms “third party” or “third parties” refers to Persons other than Buyer, Seller, Parent, and the Company.

(c) When used herein, the phrases “to the knowledge of” any Person, “to the best knowledge of” any Person, “known to” any Person or any similar phrase, means (i) with respect to any Person who is an individual, the actual knowledge of such Person, (ii) with respect to any other Person (other than the Company), the actual knowledge of the directors and officers of such Person, and (iii) with respect to Seller and/or the Company, the directors and officers of Parent, Seller, and the Company and the individuals listed on Schedule 12.2(c), as well as any other knowledge which such executive directors, officers and individuals would have possessed had they made reasonable inquiry of appropriate employees and agents of the Company with respect to the matter in question.

(d) The language used in this Agreement shall be deemed to be the language chosen by the Parties to express their mutual intent, and no rule of strict construction shall be applied against any Party. The drafting and negotiation of the representations, warranties, covenants and conditions to the obligations of Buyer, Seller and the Company herein reflect compromises, and certain provisions may overlap with other provisions or may address the same

or similar subject matters in different ways or for different purposes. It is the intention of the Parties that, to the greatest extent possible, unless provisions are mutually exclusive and effect cannot be given to both or all such provisions, (i) the provisions of in this Agreement shall be construed to be cumulative; (ii) each provision of this Agreement shall be given full separate and independent effect; and (iii) no provision shall be limited by any other provision unless such limitation is expressly set forth.

**ARTICLE XIII  
MISCELLANEOUS**

13.1. Press Releases and Announcements. No Party shall issue any press release or public announcement relating to the subject matter of this Agreement without the prior written approval of the other Parties or referring to any other Party (or any stockholder of the Company or Buyer) without the prior written approval of the Party to whom reference is proposed to be made; provided, however, that any Party may make any public disclosure it believes in good faith is required by applicable law, regulation or stock market rule (in which case the disclosing Party shall use reasonable efforts to advise the other Parties and provide them with a copy of the proposed disclosure prior to making the disclosure).

13.2. Notices. Any notices or other communications required or permitted hereunder shall be sufficiently given if delivered personally or sent by telex, federal express, registered or certified mail, postage prepaid, addressed as follows or to such other address of which the Parties may have given notice:

To Buyer: Blue Acquisition Corp.  
c/o Wilmer Cutler Pickering Hale and Dorr LLP  
1117 California Avenue  
Palo Alto, CA 94304  
Fax: 650-858-6100  
Attention: Rod J. Howard, Esq.

With a copy to: Wilmer Cutler Pickering Hale and Dorr LLP  
1117 California Avenue  
Palo Alto, CA 94304  
Fax: 650-858-6100  
Attention: Rod J. Howard, Esq.

To Seller, or the Company: SkyePharma PLC  
105 Piccadilly  
London W1J 7NJ  
United Kingdom  
Fax: 011 44 (0) 207-491-3338  
Attention: Frank Condella, CEO  
and  
Fax: 011 44 (0) 207-491-3338  
Attention: John Murphy, General Counsel

With a copy to: Reed Smith LLP  
599 Lexington Avenue, 29th Floor  
New York, NY 10022  
Fax: 212-521-5450  
Attention: Herbert F. Kozlov, Esq.

Unless otherwise specified herein, such notices or other communications shall be deemed received (a) on the date delivered, if delivered personally, or (b) three (3) business days after being sent, if sent by registered or certified mail.

13.3. Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and assigns, except that Buyer, on the one hand, and Seller and the Company, on the other hand, may not assign their respective obligations hereunder without the prior written consent of the other Party; provided, however, that Buyer may assign this Agreement, and its rights and obligations hereunder, to a subsidiary or Affiliate of Buyer. Any assignment in contravention of this provision shall be void. No assignment shall release Buyer, Seller or the Company from any obligation or liability under this Agreement.

13.4. Entire Agreement; Amendments; Attachments. This Agreement, all Schedules and Exhibits hereto, and all agreements and instruments to be delivered by the Parties pursuant hereto represent the entire understanding and agreement between the Parties hereto with respect to the subject matter hereof and supersede all prior oral and written and all contemporaneous oral negotiations, commitments and understandings between such Parties. Buyer, by the consent of its Board of Directors or officers authorized by such Board, and Seller may amend or modify this Agreement, in such manner as may be agreed upon, by a written instrument executed by Buyer and Seller. If the provisions of any Schedule or Exhibit to this Agreement are inconsistent with the provisions of this Agreement, the provisions of the Agreement shall prevail. The Exhibits and Schedules attached hereto or to be attached hereafter are hereby incorporated as integral parts of this Agreement.

13.5. Severability. Any provision of this Agreement which is invalid, illegal or unenforceable in any jurisdiction shall, as to that jurisdiction, be ineffective to the extent of such invalidity, illegality or unenforceability, without affecting in any way the remaining provisions hereof in such jurisdiction or rendering that or any other provision of this Agreement invalid, illegal or unenforceable in any other jurisdiction.

13.6. No Third Party Beneficiaries. This Agreement shall not confer any rights or remedies upon any person other than the Parties and their respective successors and permitted assigns, the Indemnified Seller Parties, and the Indemnified Buyer Parties.

13.7. Governing Law. This Agreement (including the validity and applicability of the arbitration provisions of this Agreement, the conduct of any arbitration of a Dispute, the enforcement of any arbitral award made hereunder and any other questions of arbitration law or

procedure arising hereunder) shall be governed by and construed in accordance with the internal laws of the State of New York without giving effect to any choice or conflict of law provision or rule (whether of the State of New York or any other jurisdiction) that would cause the application of laws of any jurisdictions other than those of the State of New York.

13.8. Submission to Jurisdiction. Each Party (a) submits to the exclusive jurisdiction of U.S. District Court for the Southern District of New York (and the federal appellate courts with reviewing jurisdiction thereover) and, if such courts do not have subject matter jurisdiction of such matter, either the Supreme Court (Commercial Division) of the State of New York sitting in the City and County of New York (and the state appellate courts of the State of New York with reviewing jurisdiction thereover) or, at the election of Buyer, arbitration before a single arbitrator in accordance with the provisions of Article XI, in any action or proceeding arising out of or relating to this Agreement (including any action or proceeding for the enforcement of any arbitral award made in connection with any arbitration of a Dispute hereunder), (b) agrees that all claims in respect of such action or proceeding may be heard and determined in any such court, (c) waives any claim of inconvenient forum or other challenge to venue in such court, (d) agrees not to bring any action or proceeding arising out of or relating to this Agreement in any other court, and (e) waives any right it may have to a trial by jury with respect to any action or proceeding arising out of or relating to this Agreement; provided in each case that, solely with respect to any arbitration of a Dispute, the Arbitrator shall resolve all threshold issues relating to the validity and applicability of the arbitration provisions of this Agreement, contract validity, applicability of statutes of limitations and issue preclusion, and such threshold issues shall not be heard or determined by such court. Each Party agrees to accept service of any summons, complaint or other initial pleading made in the manner provided for the giving of notices in Section 13.2, provided that nothing in this Section 13.8 shall affect the right of any Party to serve such summons, complaint or other initial pleading in any other manner permitted by law.

13.9. Section Headings. The Article, Section and sub-Section headings are for the convenience of the Parties and in no way alter, modify, amend, limit, or restrict the contractual obligations of the Parties.

13.10. Counterparts and Facsimile Signature. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile signature.

IN WITNESS WHEREOF, this Agreement has been duly executed by the Parties hereto as of and on the date first above written.

**BLUE ACQUISITION CORP.**

By: /s/ Luke Evin  
Name: Luke Evin  
Title: Director

By: /s/ Carl L. Gordon  
Name: Carl L. Gordon  
Title: Director

By: /s/ Fred A. Middleton  
Name: Fred A. Middleton  
Title: Director

By: /s/ Andreas Wicki  
Name: Andreas Wicki  
Title: Director

IN WITNESS WHEREOF, this Agreement has been duly executed by the Parties hereto as of and on the date first above written.

**SKYEPHARMA HOLDING, INC.**

By: /s/ Steven Thornton

Name: Steven Thornton

Title: President

**SKYEPHARMA, INC.**

By: /s/ Steven Thornton

Name: Steven Thornton

Title: President

**Schedule 1.5(a)(ii)**

**Further Eliminations to be Applied in Preparing the Target Net Assets Statement, the Draft Closing Net Assets Statement and the Final Closing Net Assets Statement**

The following assets and liabilities (“Exclusions”) will be temporarily adjusted and will not be included in the Target Net Assets Statement, the Draft Closing Net Assets Statement and the Final Closing Net Assets Statement:

- a. Eliminate Paul Capital accounts
- b. Eliminate all intangible assets (including IP, software, goodwill etc)
- c. Eliminate cash held on trust in respect of employee medical obligations and the related liabilities
- d. Eliminate liabilities for management stay incentives
- e. Eliminate accounts receivable for sales of DepoCyt and DepoDur after December 31, 2006
- f. Eliminate all accumulated depreciation recorded from November 24, 2006 to the Closing Date
- g. Eliminate all prepaid amortization recorded from November 24, 2006 to the Closing Date
- h. Eliminate all deferred rent amortization recorded from November 24, 2006 to the Closing Date
- i. Eliminate all deferred revenue amortization recorded from November 24, 2006 to the Closing Date for sales recorded prior to November 25, 2006
- j. Eliminate the Designated Amounts
- k. Eliminate the Company’s liability for Company (employer) 401(k) contributions for 2006

**Schedule 1.7**

DepoBupivacaine  
Milestone Payments

- 1) One time payment of \$10,000,000 upon First Commercial Sale in the United States.
- 2) One time payment of \$4,000,000 upon First Commercial Sale in a Major EU Country.
- 3) \$8,000,000 when annual Net Sales in the Territory reach \$100,000,000.
- 4) \$8,000,000 when annual Net Sales in the Territory reach \$250,000,000.
- 5) \$32,000,000 when annual Net Sales in the Territory reach \$500,000,000.

DepoBupivacaine  
Percentage Payments

The Company will pay Seller a payment of 3% of Net Sales of DepoBupivacaine in the Territory

Biologics Products Percentage  
Payments

The Company will pay Seller a payment of 3% of Net Sales of Biologics Products (not to exceed 20% of royalty income to the Company) in the Territory

1.1 Certain Definitions. Solely for purposes of this Schedule 1.7, the following terms shall have the meanings set forth below. All other capitalized terms used in this Schedule 1.7 (other than names and proper nouns) shall have the meanings ascribed to such terms in the Stock Purchase Agreement to which this Schedule 1.7 is attached.

(a) "Biologics Products" means a pharmaceutical composition having one or more of the following active ingredients: follicle stimulating hormone, Biosphere-encapsulated human growth hormone, interferon-alpha, erythropoietin, and granulocyte colony stimulating factor.

(b) "DepoBupivacaine" means a pharmaceutical composition having bupivacaine as an active ingredient encapsulated with the Company's multivesicular liposomes technology to provide sustained release.

(c) "First Commercial Sale" means, with respect to a Product in a country in the Territory, the first day after the Closing Date when the Company (or any person or entity that after the Closing is an Affiliate or licensee of the Company) first sells or otherwise commercially disposes of such Product for use or consumption by the general public in a country in the Territory after receipt of Marketing Authorization for such country.

(d) "Force Majeure" means causes beyond the control of the Party asserting such causes as grounds for nonperformance, including, without limitation, acts of God; acts, regulations, or laws of any government adopted after the date of this Schedule 1.7 or subject to a new interpretation after the date of this Schedule 1.7 that render impossible or illegal performance by a Party of its obligations under this Schedule 1.7; war; civil commotion; destruction of production facilities or materials by fire, flood, earthquake, explosion or storm; epidemic; and failure of public utilities or common carriers.



(e) “Major EU Country” means United Kingdom, France, Germany, Italy and Spain or any of them.

(f) “Marketing Authorization” means, with respect to a country, all approvals, licenses, registrations and regulatory authorizations required to market and sell a Product in such country as granted by the Relevant Regulatory Authority. For countries where the Relevant Regulatory Authority approval is required for pricing or reimbursement for Product prior to undertaking sales or marketing, “Marketing Authorization” shall not be deemed to occur until such pricing or reimbursement approval is obtained.

(g) “Net Sales” means total gross sales of each Product invoiced and actually collected by the Company, its Affiliates or any licensee of the Company (or a further sublicense of such licensee) to unaffiliated third parties, less the following amounts actually deducted or allowed: (i) transport, freight and insurance costs; (ii) sales and excise taxes and duties; (iii) normal and customary trade, quantity and cash discounts and rebates; (iv) refunds and chargebacks; (v) actual rebates and credits or allowances allowed to customers in respect thereof; and (vi) amounts repaid or credited for actually returned or recalled Products. Notwithstanding anything else in Section 1.7 or this Schedule 1.7, the supply or other disposition of Products at no cost or charge to the recipient (x) as reasonable quantities of samples consistent with industry practices, (y) for use in non-clinical or clinical studies, or (z) for use in any tests or studies reasonably necessary to comply with any law, regulation or request by a regulatory or Relevant Governmental Authority, shall not be included within the computation of Net Sales. In the event a Product is sold in combination with, or contains, one or more other active ingredients which are not the subject of this Agreement (as used in this definition of Net Sales, a “Combination”), then the gross amount invoiced for that product shall be calculated by multiplying the gross amount invoiced for such Combination by the fraction  $A/(A+B)$ , where “A” is the gross amount invoiced for the Product sold separately and “B” is the gross amount invoiced for the other active ingredient(s) sold separately; provided, however, for the avoidance of doubt, in the case of DepoBupivacaine, a Product will not qualify as a “Combination” under this provision due to the use or inclusion of bupivacaine as another active ingredient in such product, regardless of the form or formulation that such bupivacaine may be included or otherwise found within DepoBupivacaine. In the event that the other active ingredient is not sold separately, then the gross amount invoiced for that product shall be calculated by multiplying the gross amount invoiced for the Combination by the fraction  $A/C$ , where “A” is the gross invoice amount for the Product, if sold separately, and “C” is the gross invoice amount for the Combination. In the event that no such separate sales are made, Net Sales for royalty determination shall be determined by the Parties in good faith.

(h) “Payment Period” has the meaning set forth for such term in Section 1.3 of this Schedule 1.7.

(i) “Product” means DepoBupivacaine or any of the Biologics Products.

(j) “Territory” means the United States of America, Japan and each Major EU Country.

(j) “Valid Claim” means a claim of any unexpired Patent of the Company existing as of the date of this Agreement (that will remain with the Company after the Closing) and issued in the Territory that shall not have been donated to the public, disclaimed, or held invalid or unenforceable against the other Party by a court of competent jurisdiction in an unappealed or unappealable decision.

1.2 Diligence; Non-Circumvention; Periodic Reports.

(a) During the Restricted Period, Buyer will cause the Company to use good faith efforts toward the development and commercialization of DepoBupivacaine in the United States and a Major EU Market Country; provided, however, that in all decisions related to such development and commercialization efforts the Company may take into account the factors of safety and efficacy, risk profile, profitability, product profile, competitive landscape, difficulty in developing or manufacturing the Product, competitiveness of alternative products, the patent or other proprietary position of the Product and/or third party products, the regulatory structure involved and the potential, and current corporate goals and priorities; and provided further that the Company may cease or reduce such development and commercialization efforts and funding for any reason other than for the sole or primary purpose of depriving Seller of payments it would otherwise be entitled to received under this Schedule 1.7 if the Board of Directors of the Company, in the exercise of its good faith business judgment, determines that it is in the best interests of the Company and its stockholders to do so.

(b) [\*\*] times each year until the end the Payment Period, as long as any of the DepoBupivacaine Milestone Payments remains unpaid and there is a reasonable expectation that such payment will become payable in the future, not later than the last day of the months of [\*\*], Buyer shall cause the Company to furnish Seller with a report summarizing the development status of DepoBupivacaine and the Biologics Products.

1.3 Payments.

(a) Beginning with the calendar quarter in which the First Commercial Sale of a Product is made in a country in the Territory and for each calendar quarter thereafter, on a country-by-country basis, until the expiration of the last Valid Claim covering the sale of such Product in such country (the “Payment Period”), the Company shall make the DepoBupivacaine Percentage Payments and Biologics Products Percentage Payments with respect to Net Sales of such Product in such country, as set forth in the table above (collectively, the “Percentage Payments”), as applicable, to Seller within ninety (90) days following the end of each calendar quarter. Each Percentage Payment shall be accompanied by a report, summarizing the total gross sales and total Net Sales (including an itemization of the deductions applied to the gross sales to derive such Net Sales), the number of units of Product sold (less damaged, rejected, returned or recalled Product) during the relevant calendar quarter and the calculation of the Percentage Payment, if any, due. Each such statement shall be accompanied by the payment of the Percentage Payment due to Seller. No invoice shall be required from Seller in this respect.

(b) All payments under this Schedule 1.7 shall, for sales made in the United States, be made in U.S. dollars, and shall, for all other sales worldwide, be made in Euros, in each case via wire transfer of immediately available funds or check as directed by Seller from time to time. Payments shall be without deduction of exchange, collection, transfer or other charges. Conversion into U.S. dollars and Euros, as appropriate, shall be made at the exchange rate on the applicable payment date as reported in The Wall Street Journal (East Coast edition) for the immediately preceding business day. Seller shall be entitled to interest on all late payments. Such interest shall be calculated from the date such amount was due until the date such amount is actually paid, at the prime rate of interest reported in The Wall Street Journal (East Coast Edition) for the date such amount was due plus [\*\*]%.

(c) The DepoBupivacaine Percentage Payments shall be made in consideration for the covenant not to compete set forth in Section 9.3(a)(i) and the Biologics Products Percentage Payments shall be made in consideration for the covenant not to compete set forth in Section 9.3(a)(iv).

(d) If after the expiration of the Restricted Period, Parent or any of its Affiliates engages in the development, manufacture, marketing or sale of any product within the scope of Section 9.3(a)(i), (ii) or (iii) anywhere in the world, the obligation to make payments under Section 1.7 and this Schedule 1.7 shall automatically and immediately cease. If after the expiration of the Restricted Period, Parent or any of its Affiliates engages in the development, manufacture, marketing or sale of any product within the scope of Section 9.3(a)(iv) anywhere in the world, and the Company is then selling or thereafter sells a Biologics Product, the obligation to make payments under Section 1.7 and this Schedule 1.7 shall automatically and immediately cease.

(e) Notwithstanding the foregoing, if during the Restricted Period the Company markets and sells a product as a substitute for DepoBupivacaine, the obligation to make DepoBupivacaine Percentage Payments under Section 1.7 and this Schedule 1.7 shall automatically and immediately cease and terminate and, in lieu thereof, the aggregate sales of such substitute product shall be counted toward the achievement of the thresholds for the DepoBupivacaine Milestone Payments.

(f) Until the end of the Payment Period, as long as there is a reasonable expectation that a payment pursuant to this Schedule 1.7 will become payable in the future, if the Company or any subsidiary or majority owner of the Company proposes to sell, assign or transfer substantially all rights to any of the Products to a third party, the Company shall, as a condition of such sale, assignment or transfer, require such third party to assume the obligations of the Company pursuant to this Schedule 1.7 with respect to such Product.

1.4 Records Retention. Commencing with the First Commercial Sale of a Product, Buyer shall keep, and shall require its relevant Affiliates to keep, and shall use commercially reasonable efforts to include terms in its licenses with licensees requiring its licensees to keep, complete and accurate records pertaining to the sale of Product for a period of three (3) calendar years after the year in which such sales occurred and in sufficient detail to permit Seller to confirm the accuracy of the Percentage Payments paid by Buyer pursuant to this Schedule 1.7.

**1.5 Audits.**

(a) At the request and expense of Seller, Buyer (and its Affiliates, if applicable) shall permit an independent, certified public accountant appointed by Seller and reasonably acceptable to Buyer, at reasonable times and upon reasonable written notice not more than once in each calendar year, to examine such records as may be necessary for the sole purpose of verifying the calculation and reporting of Net Sales and the correctness of any Percentage Payment or other payment made under this Schedule 1.7 for any period within the preceding [\*\*] ([\*\*]) calendar years. Said accountant shall not disclose to Seller or any other person any information, except that such accountant may disclose to Seller the fact of a deficiency, the lack of a deficiency or any overpayment, and the degree thereof, including the dollar amount. All results of any such examination shall be made available to Buyer.

(b) In the event that any audit reveals an overpayment or an underpayment in the amount of any payments that should have been paid by Buyer to Seller, then the overpayment or underpayment amount, as the case may be, shall be paid within thirty (30) days after receipt of the final audit report, plus interest thereon. Such interest shall be calculated in accordance with Section 1.3(b) of this Schedule 1.7. In addition, if the underpayment is in excess of [\*\*] percent ([\*\*]%) of the amount that actually should have been paid, then Buyer shall reimburse Seller for the reasonable cost of such audit. This Section 1.5(b) of this Schedule 1.7 sets forth the Parties' sole and exclusive liability for any such overpayment or underpayment.

(c) Except in the case of circumstances which would have prevented an error or anomaly from being disclosed during an audit performed under this Section 1.5 of this Schedule 1.7 such as fraud, misrepresentation or other willful misconduct or gross negligence to provide accurate information, upon the expiration of three (3) years following the end of any calendar year, the calculation of Percentage Payments payable with respect to such year will be binding and conclusive upon each Party and Buyer will be released from any liability or accountability with respect to Percentage Payments for such calendar year.

**1.6 Force Majeure.** Other than with respect to obligations for the payment of money, neither Party shall be held liable or responsible to the other Party nor be deemed to be in default under, or in breach of any provision of, this Schedule 1.7 for failure or delay in fulfilling or performing any obligation of this Schedule 1.7 when such failure or delay is due to Force Majeure. In such event, Seller or Buyer, as the case may be, shall immediately notify the other Party, with written notice to follow, of such inability and of the period for which such inability is expected to continue. The Party giving such notice shall thereupon be excused from such of its obligations under this Schedule 1.7 as it is thereby disabled from performing for so long as it is so disabled. Upon termination of a Force Majeure event, the performance of any suspended obligation or duty shall promptly recommence. To the extent possible, each Party shall use reasonable efforts to minimize the duration of any Force Majeure.

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**Schedule 1.9**

<u>Portion of —</u>	<u>Allocated to Shares</u>	<u>Allocated to Section 9.3(a)(i) Covenant Not to Compete</u>	<u>Allocated to Section 9.3(a)(ii) Covenant Not to Compete</u>	<u>Allocated to Section 9.3(a)(iii) Covenant Not to Compete</u>	<u>Allocated to Section 9.3(a)(iv) Covenant Not to Compete</u>
Adjusted Purchase Price	[**]	[**]	[**]	[**]	[**]
“Milestone Payments” pursuant to <u>Section 1.7</u> and <u>Schedule 1.7</u>	[**]	[**]	[**]	[**]	[**]
DepoBupivacaine Percentage Payments pursuant to <u>Section 1.7</u> and <u>Schedule 1.7</u>	[**]	[**]	[**]	[**]	[**]
“Biologics Products Percentage Payments” pursuant to <u>Section 1.7</u> and <u>Schedule 1.7</u>	[**]	[**]	[**]	[**]	[**]

**Schedule 3.10(a)**

**Certain Assets**

- 1) All physical assets of the Company (see attached print-out)
- 2) DepoDur and DepoCyt product rights and manufacturing/supply arrangements;
- 3) DepoBupivacaine product and development rights;
- 4) RDF licenses;
- 5) Biologics Products development programs and associated agreements;
- 6) Building and equipment leases;
- 7) Licenses related to the site and manufacturing of above products;
- 8) Employees; and
- 9) All other projects/third party feasibility agreements

**Schedule 5.9**

**Transition Services**

1. In respect of services that Seller or Parent (or an Affiliate of Seller) needs to provide to Company:

- customs clearance for DepoCyt in France (to the extent permitted by law);
- assistance with VAT returns in France (to the extent permitted by law);
- transitional insurance cover;
- packaging, labeling and release of DepoCyt for EU;
- transition, administration and wind-down (as requested by and at no cost to Buyer) of employee benefit plans maintained for Company employees by Parent or an Affiliate (Buyer to be responsible for any unpaid withholding taxes); and
- others to be discussed.

2. In respect of services that the Company needs to provide to Seller and/or its Affiliates:

- accounting and HR for Skye US Inc.;
- assistance with preparation and interface with PWC for 2006 Tax Return;
- access to records and data not physically transferred or removed;
- consultancy services regarding representation at FDA;
- transition, administration and wind-down (as requested by and at no cost to Seller) of employee benefit plans that heretofore have been administered by the Company for employees of other U.S. subsidiaries of Parent (Parent, Seller or such other U.S. subsidiary to be responsible for any unpaid withholding taxes); and
- others to be discussed.

**Schedule 5.11**

**(a)(i) Assigned Patents**

All patents and patent applications related to the “Biosphere” drug delivery system and technology of Parent and its Affiliates.

To the extent not already owned by the Company, all patents and patent applications set forth in Section 3.13(b) of the Seller Disclosure Schedule.

**(a)(ii) Assigned Trademarks**

Mark	Case Ref.	Status	Country	Application No.	Filing Date	Registration No.	Grant Date	Owner	International Classes
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]

All other trademarks and tradenames containing the word “Biosphere” or any variations and derivatives thereof, and other trademark registrations and applications used or held for use in the business of SkyePharma, Inc. but not held by SkyePharma, Inc.



**Schedule 5.11**

**(cont'd)**

**(b) Excluded Assets**

All right, title and interest in and to the outstanding promissory note and capital stock of GeneMedix, PLC pursuant to that certain August 2006 Deed of Waiver and Modification from the Company to GeneMedix, PLC

The other eliminations in items "c," "d," "e," "f," "g," and "h" of Schedule 6.12

**Schedule 6.1**

Term Loan Agreement, dated December 22, 2003, by and between Parent and General Electric Capital Corporation.

Industrial Real Estate Lease, dated December 8, 1994, by and between Company, as successor to Depotech Corporation, and Lankford & Associates, Inc. for property located at 10450 Science Center Drive, San Diego, California.

Industrial Real Estate Triple Net Lease, dated August 17, 1993 by and between Company, as successor to Depotech Corporation, and Slough TPSP, LLC, as successor to Equitable Life Assurance Society of the United States, for property located at 11011 N. Torrey Pines Road, La Jolla, California.

Supply Agreement, dated May 27, 2004, by and between Company and Sandoz GmbH/SkyePharma Inc.

Collaboration Agreement dated March 31, 1994 by and between Company, as successor to Depotech Corporation, and Chiron Corporation.

Master Technology Service Agreement dated January 30, 2006 between the Company and Medidata Solutions, Inc.

**Schedule 6.10(b)**

Endo Pharmaceuticals, Inc. ("Endo") shall have returned all rights with respect to DepoDur, DepoBupivacaine and DepoFoam technology to the Company, at no current or future cost to the Company (except as otherwise expressly set forth in the Agreement to terminate the Development and Strategic Alliance Agreement dated January \_\_, 2007 by and among Endo Pharmaceuticals, Inc., SkyePharma, Inc. and Jagotec AG (the "Termination Agreement") with respect to payments in consideration of services rendered by Endo after March 31, 2007 at the option and request of SkyePharma, Inc. after the Closing Date, and otherwise on terms consistent with the terms set forth below, and the Company shall be the sole holder of all such rights; and the Endo Agreement, shall have been terminated and such termination shall be in full force and effect; and the Company shall have no liability or obligation to Endo Pharmaceuticals, Inc., except as expressly set forth above with respect to the Termination Agreement.

**Schedule 6.12**

The following adjustments to the assets and liabilities of the Company will be effected by Parent, Seller and the Company prior to the Closing; the eliminated assets and liabilities will not be included in the assets and liabilities of the Company at the Closing; and the added assets will be included in the assets of the Company at the Closing. On a pro forma basis, had the adjustments described below taken place as at November 24, 2006, the assets and liabilities of the Company would have been substantially as set forth in Column Q of the spreadsheet attached in Schedule 1.5(a)(i).

- a. Transfer Biosphere IP to the Company from Jagotec in accordance with Section 5.11.
- b. Adjust for Paul Capital lock box receipts to allocate relevant cash received against specific receivables of the Company.
- c. Eliminate accounts receivable for sales and royalties receivable in respect of sales prior to January 1, 2007, of DepoCyt and DepoDur.
- d. Eliminate liabilities to Paul Capital for products (other than DepoDur and DepoCyt) pursuant to the amended agreement with Paul Capital.
- e. Eliminate all intra-group accounts with Parent and its Subsidiaries. Seller shall assume the Company Debt, and Parent and/or any of its Affiliates shall effect a novation of the Company liability under the Company Debt to Seller.
- f. Eliminate share based payment liabilities in respect of SkyePharma PLC and equity reserves by adjustment within equity.
- g. Eliminate FX equity reserves by adjustment within equity.
- h. Eliminate cash balance (except cash in account related to the employee 125S plan).

**Schedule 8.1(f)**

Claims by [\*\*] or [\*\*] for services provided or alleged to be provided to the Company.

The class action lawsuits and claims filed by the Action Alliance of Senior Citizens of Greater Philadelphia against Elan Corporation PLC and the Company under the Sherman Antitrust Act and various state statutes alleging, among other things, a contract in restraint of trade as well as an attempt to monopolize the market for Naprelan in violation of those laws[, as identified in Section 3.8 of the Seller Disclosure Schedule].

Section 9.3(a)

Column A

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Column B

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**Schedule 12.2(c)**

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Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

**EXECUTION VERSION**

AMENDED AND RESTATED  
ROYALTY INTERESTS ASSIGNMENT AGREEMENT

Dated as of March 23, 2007

between

SKYEPHARMA INC.,  
as Seller,

and

ROYALTY SECURITIZATION TRUST I  
as Purchaser

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## EXHIBITS AND SCHEDULES

### EXHIBITS

Exhibit A      Form of Bill of Sale

### SCHEDULES

Schedule A      Revenue Projections

Schedule B      Patents

Schedule 3.04    Ownership/Liens

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**AMENDED AND RESTATED  
ROYALTY INTERESTS ASSIGNMENT AGREEMENT**

**THIS AMENDED AND RESTATED ROYALTY INTERESTS ASSIGNMENT AGREEMENT** (as amended, supplemented or otherwise modified from time to time, this "*Agreement*") is made and entered into as of March 23, 2007 by and between **SKYEPHARMA INC.** (formerly known as Depotech Corporation), a California corporation (the "*Seller*"), and **ROYALTY SECURITIZATION TRUST I**, a Delaware statutory trust (the "*Purchaser*").

**WHEREAS**, the Seller has the right to receive revenues, royalties, net profits and/or other payments for the worldwide sales of DepoCyt and DepoDur (as each such term is hereinafter defined) and any reformulations thereof, pursuant to and subject to the terms and conditions of each of the Royalty Agreements (as hereinafter defined); and

**WHEREAS**, pursuant to the Original RIAA (as such term is hereinafter defined), the Seller sold, assigned, conveyed and transferred to the Purchaser's predecessor-in-interest, and the Purchaser's predecessor-in-interest purchased from the Seller, the Assigned Interests (as hereinafter defined), upon and subject to the terms and conditions set forth in the Original RIAA; and

**WHEREAS**, pursuant to the Master Modification Agreement (as such term is hereinafter defined), the Original RIAA has been terminated with respect to all parties other than the Seller and the Purchaser and the Seller and the Purchaser have agreed to amend and restate the Original RIAA as set forth in this Agreement;

**NOW, THEREFORE**, in consideration of the mutual covenants, agreements representations and warranties set forth herein, the parties hereto agree to amend and restate the Original RIAA to read as follows:

**ARTICLE I**

**DEFINITIONS**

**Section 1.01. Definitions.**

The following terms, as used herein, shall have the following meanings:

"*Additional Funds*" shall have the meaning set forth in Section 5.10(b).

"*Affiliate*" shall mean, with respect to any Person, any other Person which, directly or indirectly, controls, is controlled by, or is under common control with, such Person.

"*Agreement*" shall have the meaning set forth in the first paragraph hereof.

"*Applicable Percentage*" shall mean (A) [\*\*]% until such time as the cumulative payments to the Purchaser hereunder shall equal the Applicable Percentage Adjustment Amount, (B) [\*\*]% for the remainder of the calendar quarter in which the cumulative payments received by the Purchaser hereunder first equal the Applicable Percentage Adjustment Amount, and (C) [\*\*]%

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commencing in the calendar quarter following the calendar quarter in which cumulative payments to the Purchaser hereunder equal the Applicable Percentage Adjustment Amount. Notwithstanding the foregoing, the Applicable Percentage shall be (x) [\*\*]% in any calendar quarter following a calendar quarter in which the annualized DepoDur revenues are equal to or greater than [\*\*]% but less than [\*\*]% of the Revenue Projections, and (y) [\*\*]% in any calendar quarter following a calendar quarter in which the annualized DepoDur revenues are less than [\*\*]% of the Revenue Projections.

“**Applicable Percentage Adjustment Amount**” shall mean US\$[\*\*] of cumulative payments received by the Purchaser under this Agreement with respect to sales of the Products and any Reformulated Products occurring after December 31, 2006.

“**Assignment Documents**” shall mean, collectively, the Bill of Sale dated as of December 29, 2000 executed by the Seller and the Purchaser, and any other Bill of Sale executed by the Seller and the Purchaser in connection with any Future Agreement.

“**Assigned Interests**” shall mean the Applicable Percentage of the Royalty Payments.

“**Audit Costs**” shall mean, with respect to any audit, the cost of such audit, including, without limitation, all fees, costs and expenses incurred in connection therewith.

“**Audit Reports**” shall mean, with respect to a Licensee Audit, any and all reports, findings and other written information related to such Licensee Audit.

“**Bankruptcy Event**” shall mean:

(i) the Seller shall commence any case, proceeding or other action (A) under any existing or future law of any jurisdiction, domestic or foreign, relating to bankruptcy, insolvency, reorganization, relief of debtors or the like, seeking to have an order for relief entered with respect to it, or seeking to adjudicate it a bankrupt or insolvent, or seeking reorganization, arrangement, adjustment, winding-up, liquidation, dissolution, composition or other relief with respect to it or its debts, or (B) seeking appointment of a receiver, trustee, custodian or other similar official for it or for all or substantially all of its assets, or the Seller shall make a general assignment for the benefit of its creditors; or

(ii) there shall be commenced against the Seller any case, proceeding or other action of a nature referred to in clause (i) above which (A) results in the entry of an order for relief or any such adjudication or appointment, or (B) remains undismissed, undischarged or unbonded for a period of forty-five (45) days; or

(iii) there shall be commenced against the Seller any case, proceeding or other action seeking issuance of a warrant of attachment, execution, distraint or similar process against all or substantially all of its assets which results in the entry of an order for any such relief which shall not have been vacated, discharged, stayed, satisfied or bonded pending appeal within forty-five (45) days from the entry thereof; or

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(iv) the Seller shall take any action in furtherance of, or indicating its consent to, approval of, or acquiescence in, any of the acts set forth in clause (i), (ii) or (iii) above of this definition of “Bankruptcy Event”; or

(v) the Seller shall generally not, or shall be unable to, or shall admit in writing its inability to, pay its debts as they become due.

“**Bill of Sale**” shall mean a Bill of Sale pursuant to which the Seller shall assign all of the Seller’s rights and interests in and to the Assigned Interests to the Purchaser and shall be in the form of Exhibit A.

“**Business Day**” shall mean any day other than a Saturday, a Sunday, any day which is a legal holiday under the laws of the State of New York, or any day on which banking institutions located in the State of New York are required by law or other governmental action to close.

“**Change of Control**” shall mean any of (i) a sale of all or substantially all of the assets of the Seller to a single acquirer or group of affiliated acquirers (as used in this definition, an “Acquirer”), (ii) a sale of shares by the Seller to an Acquirer, or by the Purchasing Group to an Acquirer, where such shares constitute a majority of the shares of the Seller outstanding immediately after such sale, or (iii) merger in which the Seller is not the surviving or acquiring corporation, and, in each case:

(A) the Purchasing Group receives payment for, or a distribution in respect of, its shares of the Seller in such transaction, and

(B) such payment or distribution is, in aggregate, greater than the amount invested by the Purchasing Group in relation to the Seller.

“**Collateral**” shall have the meaning set forth in the Security Agreement.

“**Concentration Account**” shall mean a segregated account established and maintained at the Lockbox Bank pursuant to the terms of the Lockbox Agreement and this Agreement. The Concentration Account shall be the account into which the funds held in the Lockbox Account are swept by the Lockbox Bank and the account from which distribution to the Purchaser and the Seller shall be made in accordance with the terms of this Agreement and the Lockbox Agreement.

“**Confidential Information**” shall mean, as it relates solely to the Products and any Reformulated Products but not any other products of the Seller, technology, know-how, trade secrets, confidential business information (including ideas, research and development, know-how, formulas, schematics, compositions, technical data, specifications, customer and supplier lists, pricing and cost information, and business and marketing plans and proposals), inventory, ideas, algorithms, processes, computer software programs or applications (in both source code and object code form), client lists and tangible or intangible proprietary information or material. Notwithstanding the foregoing definition, Confidential Information shall not include information already in the public domain at the time such information is disclosed.

“**Delivery Media**” shall mean DepoFoam™.



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“**DepoCyt**” shall mean the product having a formulation of cytarabine that is sold by the Seller under the name “DepoCyt” and licensed by the Seller pursuant to the Enzon Royalty Agreement, the Mundipharma Royalty Agreement, the Mundipharma Supply Agreement, the Mundipharma Additional Territories Agreement, the Pharmis Biofarmaceutica Royalty Agreement, and any Future Agreement governing the licensing of such product.

“**DepoDur**” shall mean the injectable, sustained-release encapsulated formulation of DepoFoam™ morphine sulfate, also referred to as SKY0401, and previously known as DepoMorphine.

“**DepoDur Supply Agreement**” shall mean the DepoMorphine Supply Agreement by and between SkyePharma Inc. and Endo Pharmaceuticals Inc. dated as of December 31, 2002.

“**Deposit Accounts**” shall mean, collectively, the Lockbox Account and the Concentration Account established and maintained pursuant to the Lockbox Agreement.

“**Discrepancy Notice**” shall have the meaning set forth in Section 2.05(d).

“**Dollars**” or “**US\$**” shall mean the freely transferable lawful money of the United States.

“**Endo Royalty Agreement**” shall mean the Development and Marketing Strategic Alliance Agreement, dated December 31, 2002 among SkyePharma, Inc., SkyePharma Canada Inc. and Endo Pharmaceuticals Inc. incorporating the DepoDur Supply Agreement.

“**Enzon Royalty Agreement**” shall mean the Supply and Distribution Agreement, dated December 31, 2002, between SkyePharma, Inc. and Enzon Pharmaceuticals, Inc.

“**Excluded Liabilities and Obligations**” shall have the meaning set forth in Section 2.04.

“**Existing Royalty Agreements**” shall mean, collectively, the Endo Royalty Agreement (solely with respect to DepoDur and incorporating the DepoDur Supply Agreement), the Enzon Royalty Agreement, the Mundipharma Royalty Agreement, the Mundipharma Supply Agreement, the Mundipharma Additional Territories Agreement, the Orphan Australia Royalty Agreement, and the Pharmis Biofarmaceutica Royalty Agreement and any other existing license agreement entered into by SKPI as licensor on or before the date hereof with respect to the Products; each an “**Existing Royalty Agreement**”.

“**FDA**” shall mean the United States Food and Drug Administration.

“**Funding Termination Event**” shall mean:

(i) a Bankruptcy Event shall have occurred;

(ii) a breach of or default under any covenant or agreement hereunder or under any other Transaction Document by the Seller and (A) such breach or default is not capable of cure or, if capable of cure, has not been cured within thirty (30) days following receipt by the Seller of notice of such breach or default and (B) such breach or default, if not cured within such thirty day period, has a material and adverse effect on the Purchaser’s ability to substantially realize the economic benefits of the transactions contemplated by this Agreement; or

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(iii) a material and willful breach of any of Sections 5.02(c), 5.05, 5.06 or 5.10(a), (d), (e), (f) or (g), which breach has not been cured within thirty (30) days following receipt by the Seller of notice of such breach.

**“Future Agreement”** shall mean any licensing or similar agreement entered into by the Seller with any other Person after the date hereof relating to the marketing and/or distribution of any of the Products or the Reformulated Products, as the same may be amended, supplemented or otherwise modified from time to time, including any amendments, supplements or modifications to any of the Existing Royalty Agreements that relate to any Product and/or any Reformulated Product. For the avoidance of doubt, the term “Future Agreements” shall specifically include those agreements excluded from the definition of “Purchase Option Event” under clause (B) of the last paragraph of such definition; provided that nothing in such clause (B) will limit or modify any obligation of the Seller with respect to such Future Agreements under this Agreement, including, without limitation, the requirements set forth in the definition of **“Royalty Payments”**.

**“GAAP”** shall mean generally accepted accounting principles in the United States in effect from time to time.

**“Government Authority”** means any government, court, regulatory or administrative agency or commission, or other governmental authority, agency or instrumentality, whether federal, state or local (domestic or foreign), including, without limitation, the U.S. Patent and Trademark Office, the FDA and the U.S. National Institutes of Health.

**“Insolvency Proceedings”** shall have the meaning set forth in Section 9.03.

**“Intellectual Property”** shall mean, relating solely to the Products and/or the Reformulated Products and not any other products of the Seller or its Affiliates, all inventions (whether patentable or unpatentable and whether or not reduced to practice), all improvements thereto, and all patents, patent rights, patent applications and patent disclosures, together with all reissuance, continuations, continuations-in-part, revisions, extensions, and reexaminations thereof, all registered or unregistered trademarks, trade names, service marks, including all goodwill associated therewith, and copyrights and all applications and registrations for any of the foregoing, and all Confidential Information.

**“Knowledge”** shall mean, with respect to the Seller, that an executive officer of such Person shall have actual knowledge of a particular matter. Notwithstanding the foregoing, an executive officer charged with responsibility for the aspect of the business relevant or related to the matter at issue shall be deemed to have knowledge of a particular matter if, in the prudent exercise of his or her duties and responsibilities, such executive officer should have known of such matter.

**“Letter of Intent”** shall mean the letter dated December 20, 2006, among SkyePharma PLC, Paul Capital Advisors, L.L.C. and Blue Acquisition Corp.

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“**Licensee Audit**” shall have the meaning set forth in Section 5.06(b).

“**Licensees**” shall mean, collectively, the licensees under the Royalty Agreements; each a “**Licensee**”.

“**Licensee Remittance Date**” shall mean, with respect to each Royalty Agreement, a day on which any Licensee Royalty Payments become due and payable to the applicable Seller under such Royalty Agreement regardless of whether or not such payments (or any part thereof) has been paid.

“**Licensee Royalty Payments**” shall mean, with respect to any Existing Royalty Agreement, any amounts payable to the Seller with respect to Products or Reformulated Products pursuant to (i) Section 4.3 of the Endo Royalty Agreement, (ii) Section 10 of the DepoDur Supply Agreement, (iii) Section 8.1 of the Enzon Royalty Agreement, (iv) Section 6.7 or 6.8 of the Mundipharma Royalty Agreement, (v) Section 5 of the Orphan Australia Royalty Agreement, (vi) Section 7.1 of the Pharmis Biofarmaceutica Royalty Agreement, (vii) Section 2.2 of the Mundipharma Supply Agreement, (viii) Sections 5 and 6 of the Mundipharma Additional Territories Agreement; and (ix) with respect to any Future Royalty Agreement, any amounts payable to the Seller thereunder with respect to Products or Reformulated Products that are calculated on the basis of net sales, net profits or any similar basis.

“**Liens**” shall mean all liens, encumbrances, options, security interests, mortgages, charges, rights, privileges and adverse claims of any nature whatsoever,

“**Lockbox Account**” shall mean, collectively any lockbox and segregated lockbox account established and maintained at the Lockbox Bank pursuant to a Lockbox Agreement and this Agreement. The Lockbox Account shall be the account into which all payments payable by any Licensee to the Seller under a Royalty Agreement are to be remitted.

“**Lockbox Agreement**” shall mean the Amended and Restated Lockbox Agreement dated as of the date hereof, among the Seller, Deutsche Bank Trust Company Americas, as Custodian, and JPMorgan Chase Bank, N.A., as the same may be amended, supplemented or otherwise modified from time to time, and any replacement agreement entered into by a Lockbox Bank, the Seller and the Purchaser, in form and substance reasonably satisfactory to the parties thereto, pursuant to which, among other things, the Lockbox Account and Concentration Account shall continue to be maintained.

“**Lockbox Bank**” shall mean any bank or financial institution approved by the Purchaser and the Seller and is a party to any Lockbox Agreement.

“**Losses**” shall mean collectively, any and all claims, damages, losses, judgments, liabilities, costs and expenses (including, without limitation, reasonable expenses of investigation and reasonable attorneys’ fees and expenses in connection with any action, suit or proceeding).

“**Master Modification**” means the Master Modification Agreement (Skye I/PRF I) dated as of the date hereof, as the same may be amended, supplemented or otherwise modified from time to time.

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**“Material Adverse Effect”** shall mean (i) a material and adverse effect on the ability of the Seller to perform under Section 5.07 or (ii) a material and adverse effect on the Purchaser’s ability to substantially realize the economic benefits of the transactions contemplated by this Agreement.

**“Material Contracts”** shall mean, with respect to the Seller, any contract, agreement or other arrangement to which such Person is a party or any of such Person’s assets or properties are bound or committed (other than the Transaction Documents and the Royalty Agreements) for which breach, nonperformance, cancellation or failure to renew thereof would reasonably be expected to have a Material Adverse Effect. For purposes of the use of the term Material Contracts in Section 5.03, clause (i) contained in the definition of **“Material Adverse Effect”** shall not apply.

**“Mundipharma Additional Territories Agreement”** shall mean the Distribution Agreement, dated July 27, 2005, between SkyePharma Inc. and Mundipharma International Holdings Limited.

**“Mundipharma Royalty Agreement”** shall mean the Distribution Agreement, dated June 30, 2003, between SkyePharma, Inc. and Mundipharma International Holdings Limited.

**“Mundipharma Supply Agreement”** shall mean the Supply Agreement, dated June 30, 2003, between SkyePharma, Inc. and Mundipharma Medical Company.

**“Net Sales”** shall have the meanings ascribed thereto in the respective Existing Royalty Agreements and, with respect to Future Agreements, shall have the meanings ascribed therein to the term “Net Sales” or the correlative term, if any, used in such Future Agreements.

**“Notice of Election”** shall have the meaning set forth in Section 5.05(b).

**“Obligations”** shall mean any and all obligations of the Seller under this Agreement and the other Transaction Documents.

**“Offered Interests”** shall have the meaning set forth in Section 5.05(a).

**“Original RIAA”** means the Royalty Interest Assignment Agreement, dated as of December 29, 2000, entered into by and among Jagotec AG, the Seller, SkyePharma PLC and Paul Capital Royalty Acquisition Fund, L.P., as the same has been amended, supplemented or otherwise modified from time to time.

**“Orphan Australia Royalty Agreement”** shall mean the DepoDur Distribution Agreement Australia and New Zealand dated as of October 1, 2004 by and between SkyePharma, Inc. and Orphan Australia.

**“Other Interests”** shall have the meaning set forth in Section 5.05(a).

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**“Patent Office”** shall mean the respective patent office (foreign or domestic) for any Patent.

**“Patents”** shall mean, relating solely to the Products and/or the Reformulated Products and not any other products of the Seller or its Affiliates, all patents, patent applications and patent disclosures that are owned by the Seller or its Affiliates, together with all reissuance, continuations, continuations-in-part, revisions, extensions, and reexaminations thereof relating to the Products and/or the Reformulated Products, composition of matter, formulation, or methods of manufacture or use thereof, including, without limitation, those identified on Schedule B attached hereto.

**“Person”** means an individual, corporation, partnership, association, trust or other entity or organization, but not including a government or political subdivision or any agency or instrumentality of such government or political subdivision.

**“Pharmis Biofarmaceutica Royalty Agreement”** shall mean the DepoCyt Supply and Distribution Agreement dated as of July 18, 2003 by and between SkyePharma, Inc. and Pharmis Biofarmaceutica LDA.

**“PRF First Receipts Account”** shall have the meaning given to such term in the Lockbox Agreement.

**“Product”** shall mean each of DepoCyt and DepoDur; collectively the “**Products**”.

**“Proposed Transfer”** shall have the meaning set forth in Section 5.05(a).

**“Purchaser”** shall have the meaning set forth in the first paragraph hereof.

**“Purchaser Indemnified Party”** shall have the meaning set forth in Section 7.05(a).

**“Purchase Option Exercise Period”** shall have the meaning set forth in Section 5.07.

**“Purchase Option Event”** shall mean any one of the following events:

(i) any Change of Control a direct or indirect consequence of which is a material abatement of efforts to develop, market or sell any of the Products or Reformulated Products; or

(ii) the Transfer by the Seller of all or substantially all of the Seller’s consolidated assets; or

(iii) the Transfer by the Seller of all or any part of its interests in the Products or Reformulated Products; or

(iv) a Funding Termination Event shall have occurred.

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Notwithstanding clause (iii) of this definition of “**Purchase Option Event**” to the contrary, (A) in the event of a Transfer of any part of the Other Interests in accordance with Section 5.05, then such Transfer under such clause (iii) above shall not constitute a Purchase Option Event and (B) in the event of a Transfer of interests in the Products and/or the Reformulated Products in connection with bona fide development, manufacturing, distribution, marketing, promotion, collaboration, license and other similar transactions entered into in the ordinary course of the Seller’s business, then such Transfer shall not constitute a Purchase Option Event.

“**Purchaser’s Account**” shall mean an account maintained by the Purchaser at any financial institution and designated in writing by the Purchaser to the Seller, as the Purchaser may so designate from time to time. As of the date of this Agreement, the Purchaser has designated the “PRF Account” (as defined in the Lockbox Agreement) as Purchaser’s Account.

“**Purchaser’s Consultants**” shall mean, collectively, the Purchaser’s employees, officers, directors, agents or other authorized representatives.

“**Purchasing Group**” means the shareholders of Blue Acquisition Corp., a Delaware corporation, as of immediately after the “Closing”, as that term is defined in the Stock Purchase Agreement dated as of January 8, 2007 by and among SkyPharma Holding, Inc., Blue Acquisition Corp. and the Seller.

“**Quarterly Report**” shall mean, with respect to the relevant calendar quarter (or, if applicable, fiscal quarter) of the Seller, (i) a report showing all payments made by the Seller to the Purchaser under this Agreement during such quarter and showing in detail the basis for the calculation of such payments, (ii) a reconciliation of such report referred to in clause (i) above to all information and data delivered to the Seller by each Licensee, such report and reconciliation to be in form reasonably satisfactory to the Purchaser, and together with copies of any and all reports, materials and other written information related to any Royalty Agreement that was created or produced for the relevant calendar quarter, including any data and information delivered and produced by the Licensee to the Seller and (iii) a report that sets forth the monetary flows into and out of the Lockbox Account during such quarter, including information regarding monies held in the First Receipts Account and monies released to the PRF Account.

“**Regulatory Agency**” shall mean a regulatory agency with responsibility for the approval of the marketing and sale of drugs in any country.

“**Reformulated Product**” shall mean a subsequent version of a Product that represents an improvement, enhancement, refinement or modification of an existing Product and that incorporates, contains or combines (i) a Product, (ii) a Product and a Delivery Media, or (iii) a Product and a Delivery Media with one or more other components.

“**Repurchase Period**” shall have the meaning set forth in Section 5.07.

“**Repurchase Price**” shall have the meaning set forth in Section 5.07.

“**Revenue Adjustment Factor**” shall mean, with respect to any Reformulated Product, a fraction the numerator of which is the invoice price of the related Product, if sold separately, and the denominator of which is the sum of (x) the invoice price of the related Product, if sold separately, and (y) the total invoice price of any other components of such Reformulated Product, if sold separately. If the Product or other components of the Reformulated Product are not sold separately then the parties hereto will discuss and mutually agree on the appropriate values of the active and other components of the Reformulated Product.

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“**Revenue Projections**” shall mean for DepoDur for each calendar year the amount set forth opposite such calendar year on Schedule A attached hereto.

“**Royalty Agreements**” shall mean, collectively, the Existing Royalty Agreements and all Future Agreements; each, a “**Royalty Agreement**”.

“**Royalty Interest Period**” shall mean the period from and including January 1, 2007 through and including December 31, 2014.

“**Royalty Interests**” shall mean, collectively, all of the Seller’s respective rights under the Royalty Agreements to which the Seller is a party, including, without the limitation, all of the Seller’s respective rights to receive any Licensee Royalty Payments payable under such Royalty Agreements.

“**Royalty Overpayment**” shall have the meaning set forth in Section 2.02(c).

“**Royalty Payments**” shall mean:

(i) with respect to DepoCyt sales in the United States under any Existing Royalty Agreement, [\*\*]% of Net Sales (as defined in such Existing Royalty Agreement) during the Royalty Interest Period;

(ii) with respect to DepoCyt sales in Canada under any Existing Royalty Agreement, [\*\*]% of Net Sales (as defined in such Existing Royalty Agreement) during the Royalty Interest Period;

(iii) with respect to DepoCyt sales outside of the United States and Canada under any Existing Royalty Agreement, [\*\*]% of Net Sales (as defined in such Existing Royalty Agreement) during the Royalty Interest Period;

(iv)(A) with respect to Existing Royalty Agreements and Future Agreements relating to DepoDur, [\*\*]% of net sales (calculated in substantially the same manner as Net Sales are calculated in the Endo Royalty Agreement (solely with respect to DepoDur) and the Orphan Australia Royalty Agreement) of such Product during the Royalty Interest Period, and (B) in the case of Future Agreements relating to DepoCyt, [\*\*]% of net sales (calculated in substantially the same manner as Net Sales are calculated in the, the Enzon Royalty Agreement, the Mundipharma Royalty Agreement; the Mundipharma Supply Agreement, the Mundipharma Additional Territories Agreement, and the Pharmis Biofarmaceutica Royalty Agreement) during the Royalty Interest Period; and

(v) any milestone payment or similar payment payable to a Seller, in lieu of, or as a credit against, any of the foregoing fees, royalty payments or similar payments, in each case, without reference to any reductions in Royalty Payments or royalty rates resulting from any material breach or default by the Seller under the applicable Royalty Agreements.

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In the event that any payments under any Future Agreement relating to a Product and/or any Reformulated Product are calculated upon a basis different than the basis used under the Existing Royalty Agreements, the parties hereto will discuss and mutually agree on the basis of the appropriate payments to be made to the Purchaser in respect of any such Future Agreement and the manner of calculating such payments, which payments and manner of calculating payments will not be less advantageous to the Purchaser than are provided under the Existing Royalty Agreements.

Royalty Payments payable under any Future Agreement that are calculated in whole or in part by reference to royalty payments or royalty rates payable to the Seller shall be determined without reference to any reductions in such royalty payments or royalty rates resulting from (A) any offsets, credits, rebates or other similar reductions in respect of amounts payable to any of the Seller under such Royalty Agreements, or (B) any reductions or deferrals in Royalty Payments or royalty rates resulting from any alleged invalidity, defect in or impairment of the licenses granted by the Seller pursuant to the Royalty Agreements or the Intellectual Property licensed thereunder. Notwithstanding any changes in GAAP after the date hereof that would in any way modify accounting under GAAP for milestone or other similar payments, Royalty Payments shall be calculated under any Future Agreements in the same manner as that set forth above Existing Royalty Agreements, namely that milestone and similar payments will be excluded from the definition of Royalty Payments under Future Agreements unless they fall within subsection (v) of this definition of “**Royalty Payments**”.

With respect to Reformulated Products that represent reformulations of the Product, the multiple of (x) the Revenue Adjustment Factor and (y) the Royalty Payments specified pursuant to clauses (i) through and including (v) of this definition of “**Royalty Payments**”.

“**Security Agreement**” shall mean the Amended and Restated Security Agreement dated as of the date hereof by and between the Seller and the Purchaser providing for, among other things, the grant by the Seller in favor of the Purchaser a valid, continuing, perfected lien on and security interest in the Royalty Interests, the Assigned Interests and the other Collateral described therein.

“**Seller**” shall have the meaning set forth in the first paragraph hereof.

“**Seller’s Account**” shall mean an account maintained by the Seller at any financial institution and designated in writing by the Seller to the Purchaser, as the Seller may so designate from time to time.

“**Seller Indemnified Party**” shall have the meaning set forth in Section 7.05(b).

“**Seller Remittance Date**” shall have the meaning set forth in Section 2.05(a).

“**Threshold Amount**” shall have the meaning set forth in Section 7.05(d).

“**Transaction Documents**” shall mean, collectively, this Agreement, the Assignment Documents, the Security Agreement, and any Lockbox Agreement. For purposes of the representations and warranties contained in Article III, the term Transaction Documents shall not include any Assignment Document that is not dated on the date hereof and executed by the Seller and the Purchaser.



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“*Transfer*” or “*Transferred*” shall mean any sale, conveyance, assignment, disposition or transfer.

“*Transfer Notice*” shall have the meaning set forth in Section 5.05(a).

“*United States*” shall mean the United States of America.

“*UCC*” shall mean the Uniform Commercial Code (or any similar or equivalent legislation) as in effect in any applicable jurisdiction.

## ARTICLE II

### PURCHASE AND SALE OF ASSIGNED INTERESTS

#### **Section 2.01. Purchase and Sale.**

Upon the terms and subject to the conditions set forth in the Original RIAA, the Seller sold, assigned, transferred and conveyed to the Purchaser’s predecessor-in-interest, and the Purchaser’s predecessor-in-interest purchased from the Seller, all of the Seller’s rights and interests in and to the Assigned Interests.

#### **Section 2.02. Royalty Payments in Respect of the Assigned Interests.**

(a) Subject to Section 2.02(b) below, the Purchaser shall be entitled to receive the following amounts specified in such Section 2.02(b), payable from funds in the Concentration Account and, to the extent funds therein are insufficient to pay such amounts in full, payable to the Purchaser by the Seller pursuant to Section 2.05.

(b) Notwithstanding Section 2.02(a):

(i) the Purchaser shall be entitled to [\*\*]% of the first US\$[\*\*] of the Licensee Royalty Payments payable in respect of sales of Products and/or Reformulated Products earned for each calendar year during the Royalty Interest Period, which shall be deposited into the PRF First Receipts Account;

(ii) after payment in full of amounts payable in accordance with the preceding clause (i), the Seller shall not pay to the Purchaser any further amount until the Applicable Percentage of cumulative Royalty Payments received in respect of sales of Products and/or Reformulated Products earned for such calendar year equals US\$[\*\*];

(iii) no later than eighty (80) days following the end of a calendar quarter, the Seller shall instruct the Bank to transfer to the Purchaser that portion of amounts on deposit in the PRF First Receipts Account equal to the Applicable Percentage of the Royalty Payments received in respect of sales of Products and/or Reformulated Products earned for such calendar quarter as reflected in the applicable Quarterly Report. Any amount remaining on deposit in the

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PRF First Receipts Account on March 31 of each calendar year after the Bank has transferred an amount equal to the Applicable Percentage of cumulative Royalty Payments received in respect of sales of Products and/or Reformulated Products earned for the prior calendar year to the PRF Account, shall be released from the PRF First Receipts Account to the Seller as repayment of any applicable Royalty Overpayment.

(iv) after the Applicable Percentage of cumulative Royalty Payments received in respect of sales of Products and/or Reformulated Products earned for such calendar year equals US\$[\*\*], the Seller shall pay to the Purchaser the Applicable Percentage of each additional Royalty Payments received in respect of sales of Products and/or Reformulated Products earned for such calendar year;

(c) To the extent cumulative payments in respect of sales of Products and/or Reformulated Products earned for any calendar year made by the Seller to the Purchaser pursuant to subsection (b)(i) of this Section 2.02 exceed the aggregate of the product of (x) all Royalty Payments in respect of sales of Products and/or Reformulated Products earned for any calendar year and (y) the Applicable Percentage(s) applicable thereto (such excess, a “*Royalty Overpayment*”), such amount shall be rebated to the Seller in accordance with Section 2.02(b)(iii) above; provided, however, that if such Royalty Overpayment occurs in respect of the year ended December 31, 2014, then the Purchaser shall promptly repay to the Seller, within five (5) Business Days of receipt of notice of such Royalty Overpayment, an amount equal to such Royalty Overpayment. For the avoidance of doubt, the provisions of this Section 2.02(c) shall not apply to sales of Products and/or Reformulated Products earned prior to January 1, 2007.

**Section 2.03. Purchase Price.**

The Seller acknowledges that the Purchaser has paid all amounts payable by the Purchaser pursuant to Section 2.03 of the Original RIAA and that the Purchaser has no further obligation to pay any amount as “Purchase Price” (as such term is defined in the Original RIAA).

**Section 2.04. No Assumed Obligations.**

Notwithstanding any provision in this Agreement or any other writing to the contrary, the Purchaser acquired only the Assigned Interests and did not and is not assuming any liability or obligation of the Seller of whatever nature, whether previously in existence, presently in existence, or arising or asserted hereafter, whether under any Royalty Agreement, any license agreement or otherwise. All such liabilities and obligations shall be retained by and remain obligations and liabilities of the Seller (the “*Excluded Liabilities and Obligations*”).

**Section 2.05. Timing and Method of Payments by the Seller.**

(a) On the third (3rd) Business Day following each Licensee Remittance Date (each a “*Seller Remittance Date*”), the Seller shall pay, or cause to be paid, to the Purchaser from the funds then available in the Concentration Account such amounts as required pursuant to and in accordance with Section 2.02 based on the payments that become due and payable to the any of the Seller under any of the Royalty Agreements on such date.

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(b) If, for any reason, the amounts held in the Concentration Account are insufficient to pay to the Purchaser in full the amounts due to the Purchaser on a Seller Remittance Date, then the Seller shall, within ten (10) Business Days after such Seller Remittance Date, pay the difference between what was owing to the Purchaser on such Seller Remittance Date and the amount, if any, received by the Purchaser from the Concentration Account.

(c) Any payments to be made by the Seller to the Purchaser hereunder or any other Transaction Document shall be made by wire transfer of immediately available funds to the Purchaser's Account.

(d) Within one hundred-fifty (150) days following the end of each calendar year during the Royalty Interest Period, to the extent that either the Purchaser or the Seller has determined that there is a discrepancy as to the amounts paid to the Purchaser hereunder in respect of such calendar year, then such Person who has made such determination may notify the other in writing of such discrepancy indicating in reasonable detail its reasons for such determination (the "**Discrepancy Notice**"). In the event that the Purchaser or the Seller delivers to the other party a Discrepancy Notice, the Purchaser and the Seller shall discuss within ten (10) Business Days (or such other time as mutually agreed by the parties) after the receiving party has received a Discrepancy Notice to resolve in good faith such discrepancy. If the discrepancy has been resolved and, as a result thereof, it is determined that a payment is owing by the Purchaser to the Seller or by the Seller to the Purchaser, then the party owing such payment shall promptly pay such payment to the other party. For avoidance of doubt, this Section 2.05(d) is separate and not in lieu of Section 2.02(c).

### ARTICLE III

#### REPRESENTATIONS AND WARRANTIES OF SELLER

The Seller hereby represents and warrants to the Purchaser the following:

**Section 3.01. Organization.**

The Seller is a corporation duly incorporated, validly existing and in good standing under the laws of the State of California, and has all corporate powers and all licenses, authorizations, consents and approvals required to carry on its business as now conducted.

**Section 3.02. Corporate Authorization.**

The Seller has all necessary power and authority to enter into, execute and deliver this Agreement and the other Transaction Documents to which it is a party and to perform all of the obligations to be performed by it hereunder and thereunder and to consummate the transactions contemplated hereunder and thereunder. This Agreement and the other Transaction Documents have been duly authorized, executed and delivered by the Seller (to the extent a party thereto) and each of this Agreement and each other Transaction Document to which the Seller is a party constitutes the valid and binding obligation of the Seller, enforceable against the Seller in accordance with their respective terms subject, as to enforcement of remedies, to bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally or general equitable principles.

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**Section 3.03. Conflicts.**

Neither the execution and delivery of this Agreement or the other Transaction Documents nor the performance or consummation of the transactions contemplated hereby or thereby will: (i) contravene, conflict with, result in a breach or violation of, constitute a default under, or accelerate the performance provided by, in any material respects any provisions of: (A) any law, rule or regulation of any Government Authority, or any judgment, order, writ, decree, permit or license of any Government Authority, to which the Seller or any of its assets or properties may be subject or bound; or (B) any material contract, agreement, commitment or instrument to which the Seller is a party or by which the Seller or any of its assets or properties is bound or committed; (ii) contravene, conflict with, result in a breach or violation of, constitute a default under, or accelerate the performance provided by, in any respects any provisions of the certificate of incorporation or by-laws (or other organizational or constitutional documents) of the Seller; (iii) require any notification to, filing with, or consent of, any Person (including, without limitation, any party to the Royalty Agreements or any licensor of the Intellectual Property to the Seller) or Government Authority; (iv) constitute a breach of or default under any Royalty Agreement or give rise to any right of termination, cancellation or acceleration of any right or obligation of the Seller or any other Person or to a loss of any benefit relating to the Royalty Interests or Assigned Interests, or (v) result in the creation or imposition of any Lien on (1) the assets or properties of the Seller or (2) the Assigned Interests, Royalty Interests, any of the Royalty Agreements or any other Collateral, other than, with respect to clauses (1) and (2) above, pursuant to the Security Agreement.

**ARTICLE IV**

**REPRESENTATIONS AND WARRANTIES OF THE PURCHASER**

The Purchaser represents and warrants to the Seller the following:

**Section 4.01. Organization.**

The Purchaser is a statutory trust duly formed, validly existing and in good standing under the laws of the State of Delaware, and has all trust powers and all licenses, authorizations, consents and approvals required to carry on its business as now conducted.

**Section 4.02. Authorization.**

The Purchaser has all necessary power and authority to enter into, execute and deliver this Agreement and to perform all of the obligations to be performed by it hereunder. This Agreement has been duly authorized, executed and delivered by the Purchaser and constitutes its valid and binding obligation of the Purchaser, enforceable against the Purchaser in accordance with its terms, subject, as to enforcement of remedies, to bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally and general equitable principles.

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**Section 4.03. Conflicts.**

Neither the execution and delivery of this Agreement nor the performance or consummation of the transactions contemplated hereby will (i) conflict with, result in a breach or violation of, constitute a default under, or accelerate the performance provided by the terms of: (A) any law, any rule or regulation of any Government Authority or any judgment, order, writ, decree, permit or license of any court or other agency of any government to which the Purchaser may be subject; (B) any contract, agreement, commitment or instrument to which the Purchaser is a party or by which the Purchaser or any of its assets is bound or committed; or (C) the Purchaser's constituent partnership documents or other governing instruments, or (ii) require any notification to, filing with or consent of any Person or Government Authority.

**ARTICLE V**  
**COVENANTS**

During the term of this Agreement, each party hereto (as the case may be) agrees that:

**Section 5.01. Consents and Waivers.**

The Seller shall use commercially reasonable efforts to obtain any required consents, acknowledgements, certificates or waivers so that the transactions contemplated by this Agreement may be consummated and shall not result in any default or breach or termination of any of the Royalty Agreements.

**Section 5.02. Access; Books and Records.**

(a) Promptly after receipt by the Seller of any action, claim, investigation, proceeding (commenced or threatened), material notice, certificate, offer, proposal, correspondence or other written communication relating to the transactions contemplated by this Agreement, the Royalty Interests or any of the Royalty Agreements, the Seller shall inform the Purchaser of the receipt and substance of such action, claim, investigation, proceeding, notice, certificate, offer, proposal, correspondence or other written communication and, if in writing shall furnish the Purchaser with a copy of such action, claim, investigation, proceeding, notice, certificate, offer, proposal, correspondence or other written communication.

(b) The Seller shall keep and maintain, or cause to be kept and maintained, at all times accurate and complete books and records in accordance with GAAP. The Seller shall keep and maintain, or cause to be kept and maintained, at all times full and accurate books of account and records in accordance with GAAP adequate to correctly reflect all payments paid and/or payable under the Royalty Agreements, Assigned Interests and all deposits made into the applicable Deposit Accounts.

(c) The Purchaser and any of the Purchaser's Consultants shall have the right, from time to time, to visit the Seller's offices and properties where the Seller keeps and maintains its books and records relating or pertaining to the Assigned Interests, the Royalty Interests, the Royalty Agreements and the other Collateral for purposes of conducting an audit of such books and records, and to inspect, copy and audit such books and records, during normal business hours, and, upon two (2) Business Days notice given by the Purchaser to the Seller, the Seller will provide the Purchaser and any of the Purchaser's Consultants reasonable access to such books and records, and shall permit the Purchaser and any Purchaser's Consultants to discuss the business, operations, properties and financial and other condition of the Seller or any of its

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Affiliates relating or pertaining to the Assigned Interests, the Royalty Interests, the Royalty Agreements and the other Collateral with officers of such parties, and with their independent certified public accountants (to the extent such independent certified accountants agree to discuss such matters with the Purchaser).

(d) In the event any audit of the books and records of the Seller relating to the Royalty Interests, Assigned Interests, Royalty Agreements and the other Collateral by the Purchaser and/or any of the Purchaser's Consultants reveals that the amounts paid to the Purchaser hereunder for the period of such audit have been understated by more than [\*\*]% of the amounts determined to be due up to the time of such audit, then the Audit Costs in respect of such audit shall be borne by the Seller; and in all other cases, such Audit Costs shall be borne by the Purchaser.

**Section 5.03. Material Contracts.**

The Seller shall comply with, in its commercially reasonable judgment, all material terms and conditions of and fulfill all of its obligations under all the Material Contracts to which it is a party.

**Section 5.04. Confidentiality; Public Announcement.**

(a) All information furnished by the Purchaser to the Seller or by the Seller to the Purchaser in connection with this Agreement and the transactions contemplated hereby, as well as the terms, conditions and provisions of this Agreement, shall be kept confidential by the Seller and the Purchaser, and shall be used by the Seller and the Purchaser only in connection with this Agreement and the transactions contemplated hereby, except to the extent that such information (i) is already known by the party to whom the information is disclosed or is already in the public domain at the time the information is disclosed, (ii) thereafter becomes lawfully obtainable from other sources, (iii) is required to be disclosed in any document to be filed with any Government Authority, or (iv) is required to be disclosed under securities laws, rules and regulations applicable to the Seller or the Purchaser, as the case may be, or pursuant to the rules and regulations of the Nasdaq National Market or any other stock exchange or stock market on which securities of any of the Seller or the Purchaser may be listed for trading. Notwithstanding the foregoing, the Seller and the Purchaser may disclose such information to their partners, directors, employees, managers, officers, investors, bankers, advisors, trustees and representatives on a need-to-know basis, provided that such Persons shall be informed of the confidential nature of such information and shall be obligated to keep such information confidential pursuant to the terms of this Section 5.04(a).

(b) Except as required by law or the rules and regulations of any securities exchange or trading system or the FDA or any Government Authority with similar regulatory authority, or except with the prior written consent of the other party (which consent shall not be unreasonably withheld), neither party shall issue any press release or make any public statement with respect to the transactions contemplated by this Agreement.

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**Section 5.05. Right of First Refusal.**

(a) If the Seller at any time during the term of this Agreement proposes to Transfer any of the Royalty Interests (other than the Assigned Interests) (the “**Other Interests**”) (each, a “**Proposed Transfer**”), then the Seller shall, at least thirty (30) days prior to the closing of such Proposed Transfer, give written notice (the “**Transfer Notice**”) to the Purchaser setting forth (i) the Other Interests that are to be Transferred pursuant to such Proposed Transfer (the “**Offered Interests**”), (ii) the anticipated date of the closing of such Proposed Transfer, (iii) the names and addresses of the proposed transferees, and (iii) the material terms of such Proposed Transfer, including the cash and/or other consideration to be received in respect of such Proposed Transfer.

(b) Upon the receipt of any Transfer Notice, the Purchaser will have the option, but not the obligation, to purchase all, but not less than all, of all the Offered Interests, on the same terms as are specified in the Transfer Notice, provided, that the Purchaser will have the right to substitute cash in the amount of the fair market value of any non-cash consideration proposed to be received from the proposed transferee(s). Within twenty (20) days after the Purchaser’s receipt of the Transfer Notice, the Purchaser will give a written notice (a “**Notice of Election**”) to the Seller stating whether it elects to exercise such option.

(c) Failure by the Purchaser to give a Notice of Election within such time period specified in subsection (b) of this Section 5.05 will be deemed an election by the Purchaser not to exercise its option to purchase all the Offered Interests. The closing of the purchase and sale of the Offered Interests to the Purchaser will take place as soon as is reasonably practicable on such date and at such time and place, in each case as the Purchaser may reasonably determine but not later than twenty (20) days following the Seller’s receipt of the Notice of Election. If the Purchaser does not elect to purchase all of the Offered Interests hereunder, the Seller will thereafter be free for a period of 90 days after expiration of the twenty (20) day period referred to subsection (b) of this Section 5.05 to consummate the Proposed Transfer described in the Transfer Notice to the transferee(s) specified therein, at the price and on substantially identical terms set forth therein. However, if such Proposed Transfer is not consummated within such 90-day period, the Seller will not Transfer any of the Offered Interests as have not been purchased within such period without again complying with all of the provisions of this Section 5.05.

**Section 5.06. Licensee Audits; Audit Costs.**

(a) The Seller shall, promptly after the end of each calendar quarter of the Seller (or, if applicable fiscal quarter) (but in no event later than eighty (80) days following the end of such quarter), produce and deliver to the Purchaser a Quarterly Report for such quarter, together with a certificate of a senior officer of the Seller certifying that to the knowledge of such officer (i) such Quarterly Report is a true and complete copy and (ii) any statements and any data and information therein prepared by the Seller are true, correct and accurate in all respects.

(b) To the extent the Seller has the right to perform or cause to be performed inspections or audits under any of the Royalty Agreements regarding payments payable and/or paid to the Seller thereunder (each, a “**Licensee Audit**”), the Seller shall, at the reasonable request of the Purchaser made from time to time after January 1, 2003, cause such Licensee

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Audit to be promptly performed (it being understood that it shall not be a reasonable request if, in the good faith belief of the Seller, the requested Licensee Audit would impair the Seller's commercial relationship with the applicable Licensee). In conducting a Licensee Audit, the Seller may engage PricewaterhouseCoopers LLP or its then retained internationally recognized independent public accounting firm, or, if the Seller elects otherwise, such other internationally recognized independent public accounting firm reasonably acceptable to the Purchaser. Promptly after completion of any Licensee Audit (whether or not requested by the Purchaser), the Seller shall promptly deliver to the Purchaser an Audit Report in respect of such Licensee Audit. With respect to any Royalty Agreement under which the Seller has a right to perform or cause to be performed a Licensee Audit, in the event the Purchaser requests the Seller to perform a Licensee Audit and such Licensee Audit is in fact performed by or on behalf of the Seller, then if the results thereof reveal that the amounts paid to the Purchaser hereunder in respect of such Royalty Agreement for the period of such Licensee Audit have been understated by more than [\*\*]% of the amounts determined to be due up to the time of such Licensee Audit, then the Audit Costs incurred by the Seller in respect of such Licensee Audit shall be borne by the Seller. In all other cases the Audit Costs incurred by the Seller in respect of a Licensee Audit shall be borne by the Purchaser.

**Section 5.07. Purchase Option.**

In the event that a Purchase Option Event shall occur, and as a result of such event the Purchaser's ability to substantially realize the economic benefits of the transactions contemplated by this Agreement is materially and adversely affected, the Purchaser shall have the right, but not the obligation, exercisable by written notice to the Seller within ninety (90) days of the Purchaser's receipt of notice from the Seller of the Purchase Option Event (the "**Purchase Option Exercise Period**"), to require the Seller to repurchase from the Purchaser the Assigned Interests for a repurchase price equal to (i) [\*\*]% of the aggregate amount of payments made during the preceding [\*\*] months (calculated from the date of the Purchaser's receipt of the notice from the Seller of the Purchase Option Event) by SKPI to Purchaser with respect to DepoCyt and DepoDur and any related Reformulated Product (including, if and to the extent applicable, such payments made to the Purchaser with respect to DepoCyt and DepoDur and any related Reformulated Product prior to the date of this Agreement pursuant to the Original RIAA), multiplied by (ii) the number of days from the date of the Purchaser's exercise of such option until December 31, 2014, divided by 365 (the "**Repurchase Price**"). In the event that the Purchaser elects to exercise its right as provided in the immediately preceding sentence, then the Seller shall, within forty-five (45) days following the Seller's receipt of the Purchaser's repurchase election notice (the "**Repurchase Period**"), repurchase from the Purchaser the Assigned Interests at the Repurchase Price, the payment of which shall be made by wire transfer, in immediately available funds, to the Purchaser's Account designated by the Purchaser in such election notice.

**Section 5.08. Security Agreement.**

The Seller shall at all times until the Obligations of the Seller are paid and performed in full grant in favor of the Purchaser a valid, continuing, first perfected lien on and security interest in the Royalty Interests, the Assigned Interests and the other Collateral described therein.



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**Section 5.09. Commercially Reasonable Efforts; Further Assurance.**

(a) Subject to the terms and conditions of this Agreement, each party hereto will use its commercially reasonable efforts to take, or cause to be taken, all actions and to do, or cause to be done, all things necessary under applicable laws and regulations to consummate the transactions contemplated by this Agreement. The Purchaser and the Seller agree to execute and deliver such other documents, certificates, agreements and other writings (including any financing statement filings requested by the Purchaser) and to take such other actions as may be reasonably necessary in order to consummate or implement expeditiously the transactions contemplated by this Agreement and to vest in the Purchaser good, valid and marketable rights and interests in and to the Assigned Interests free and clear of all Liens, except those Liens created in favor of the Purchaser pursuant to the Security Agreement and any other Transaction Document.

(b) Each of the parties hereto shall execute and deliver such additional documents, certificates and instruments, and perform such additional acts, as may be reasonably requested and necessary or appropriate to carry out and effectuate all of the provisions of this Agreement and to consummate all of the transactions contemplated by this Agreement.

(c) The Seller and the Purchaser hereto shall cooperate and provide assistance as reasonably requested by the other party in connection with any litigation, arbitration or other proceeding (whether threatened, existing, initiated, or contemplated prior to, on or after the date hereof) to which any party hereto or any of its officers, directors, shareholders, agents or employees is or may become a party or is or may become otherwise directly or indirectly affected or as to which any such Persons have a direct or indirect interests, in each case relating to this Agreement, any Royalty Agreement, the Royalty Interests, the Assigned Interests or any other Collateral, or the transactions described herein or therein.

**Section 5.10. Remittance to Lockbox Account.**

(a) Any Lockbox Account and Concentration Account shall be held jointly by the Seller and the Purchaser. Funds deposited into the Lockbox Account shall be swept by the Lockbox Bank on a daily basis into the Concentration Account. Any funds held in the Concentration Account shall be disbursed in accordance with this Agreement and the Lockbox Agreement. Funds in the Concentration Account shall be invested at the Seller's discretion in permitted investments as set forth in the Lockbox Agreement.

(b) With respect to each Seller Remittance Date, if the Purchaser has received payment in full the amount due and owing the Purchaser on such Remittance Date and to the extent additional funds are available in the Concentration Account after such payment to the Purchaser has been made (the "*Additional Funds*"), then, subject to the immediately succeeding sentence, such Additional Funds shall be transferred into the Seller's Account on such Remittance Date. Notwithstanding anything contained in this Agreement to the contrary, if a Purchase Option Event shall have occurred and the Purchaser shall have exercised its rights under Section 5.07 and there exists no good faith dispute as to whether or not the Seller is obligated to pay the Repurchase Price, any and all funds held in the Concentration Account shall not be transferred out of the Concentration Account until the Seller has paid the Repurchase Price to the Purchaser pursuant to Section 5.07. Notwithstanding anything herein to the contrary, in the event a Bankruptcy Event shall have occurred, then any and all funds held in the Concentration Account shall not be transferred out of such account.

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(c) The Seller shall pay for all fees, expenses and charges of the Lockbox Bank, which such fees, expenses and charges may be paid by debiting any Additional Funds.

(d) The Seller shall cause all Licensee Royalty Payments to be made by the applicable Licensee to the Seller under the Royalty Agreements to which the Seller and Licensee is a party to be remitted directly by such Licensee into the Lockbox Account as provided in this Section 5.10. Without in any way limiting the foregoing, any and all Licensee Royalty Payments received by the Seller shall be deposited into the Lockbox Account within one Business Day of the Seller's receipt thereof.

(e) With respect to any Royalty Agreement entered into on or before December 31, 2006, the parties acknowledge that the Seller (i) to the extent not previously done so shall, instruct any Licensee under such Royalty Agreement to remit to the Lockbox Account when due all Licensee Royalty Payments that are due and payable to the Seller in respect of or derived from such Royalty Agreement for the Royalty Interest Period, and (ii) to the extent not previously done so shall deliver to the Purchaser evidence of such instruction and of such Licensee's agreement thereto in accordance with Section 5.12.

(f) With respect to any Future Agreement entered into by the Seller from and after January 1, 2007, such Seller (i) shall, at the time of the execution and delivery of such Future Agreement, instruct any Licensee under such Future Agreement to remit to the Lockbox Account when due all Licensee Royalty Payments that are due and payable to the Seller in respect of or derived from such Future Agreement for the calendar years commencing with and including the calendar year in which such Future Agreement was entered into and through and including 2014, and (ii) shall deliver to the Purchaser evidence of such instruction and of such Licensee's agreement thereto in accordance with Section 5.12.

(g) The Seller shall not have any right to terminate the Lockbox Bank without the Purchaser's prior written consent. Any such consent, if the Purchaser desires to give, shall be subject to the satisfactory of each of the following conditions to the satisfaction of the Purchaser:

(i) the successor Lockbox Bank shall be reasonably acceptable to the Purchaser;

(ii) the Purchaser, the Seller and the successor Lockbox Bank shall have entered into a lockbox agreement substantially in the form of the Lockbox Agreement initially entered into;

(iii) all funds and items in the accounts subject to the Lockbox Agreement to be terminated shall be transferred to the new accounts held at the successor Lockbox Bank prior to the termination of the then existing Lockbox Bank; and

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(iv) the Purchaser shall have received evidence that the Licensees under the Royalty Agreements have been instructed to remit all future Licensee Royalty Payments to the new accounts held at the successor Lockbox Bank.

**Section 5.11. Seller's Additional Covenants.**

(a) In the event that the Seller becomes aware that any Intellectual Property licensed by it to a licensee under any of the Royalty Agreements infringes or violates any third party Intellectual Property, the Seller shall promptly use commercially reasonable efforts to attempt to secure the right to use such Intellectual Property on behalf of itself and the affected Licensee and shall pay all costs and amounts associated with obtaining any such license, without any charge to the Licensee or any reduction in the Assigned Interests.

(b) The Seller shall duly perform and observe all of the Seller's covenants and obligations under each Royalty Agreement in all material respects. Upon the occurrence of a material breach of any of the Royalty Agreements by any other party thereto, which is not cured as provided therein, the Seller thereto shall in its commercially reasonable judgment, seek to enforce all of its rights and remedies thereunder.

(c) The Seller shall not, without the prior written consent of the Purchaser, which consent shall not be unreasonably withheld:

(i) Forgive, release or compromise any amount owed to the Seller and relating to the Assigned Interests;

(ii) Waive, amend, cancel or terminate, exercise or fail to exercise, any of its material rights constituting or relating to the Royalty Interests in a manner which could adversely affect the Assigned Interests;

(iii) Amend, modify, restate, cancel, supplement, terminate or waive any provision of any Royalty Agreement, or grant any consent thereunder, or agree to do any of the foregoing, including, without limitation, entering into any agreement with the Licensee under the provisions of such Royalty Agreement in each case which could reasonably be expected to have an adverse effect on any of the Royalty Interests or the Assigned Interests or any part thereof; provided, however, that the parties acknowledge and agree that this Section 5.11(c)(iii) shall not apply to the Endo Royalty Agreement, and that the Purchaser has consented to the termination of such agreement; or

(iv) Create, incur, assume or suffer to exist any Lien, or exercise any right of rescission, offset, counterclaim or defense, upon or with respect to the Royalty Interests, the Assigned Interests or the other Collateral, or agreeing to do or suffering to exist any of the foregoing, except for any Lien or agreements in favor of the Purchaser granted under or pursuant to this Agreement and the other Transaction Documents and except for the Liens set forth on Schedule 3.04.

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(d) The Seller shall provide the Purchaser with written notice as promptly as practicable (and in any event within five (5) Business Days) after becoming aware of any of the following:

(i) the occurrence of a Bankruptcy Event;

(ii) any breach of any provision of this Agreement or any other Transaction Document;

(iii) any representation or warranty made or deemed made by the Seller in any of the Transaction Documents to which it is a party or in any certificate delivered by the Seller to the Purchaser pursuant hereto shall prove to be untrue, inaccurate or incomplete in any material respect on the date as of which made or deemed made;

(iv) any breach or default by the Seller of a covenant or agreement hereunder or under any other Transaction Document that is not cured within the applicable cure period;

(v) the occurrence of a Purchase Option Event (other than a Funding Termination Event); or

(vi) any sublicense by a Licensee of any rights licensed pursuant to any Royalty Agreement.

(e) Promptly (but in no event later than five (5) Business Days) after (i) receiving oral or written notice from a Licensee (A) terminating or expressing any intention to terminate the related Royalty Agreement or (B) alleging any breach of or default under such Royalty Agreement by the Seller or (C) asserting the existence of any facts, circumstances or events which alone or together with other facts, circumstances or events could (with or without the giving of notice or passage of time or both) give rise to a breach of or default under or right to terminate such Royalty Agreement or (ii) otherwise the Seller having Knowledge of any fact, circumstance or event which alone or together with other facts, circumstances or events could (with or without the giving of notice or passage of time or both) give rise to a material breach of or default under such Royalty Agreement by the Seller or a right to terminate such Royalty Agreement by such Licensee, in each case, the Seller shall give a written notice to the Purchaser describing in reasonable detail the relevant breach, default or termination event, including a copy of any written notice received from such Licensee and, in the case of any breach or default or alleged breach or default by the Seller, describing any corrective action the Seller proposes to take.

(f) The Seller shall, at its sole expense, either directly or by causing the Licensee to do so, take any and all actions and prepare, execute, deliver and file any and all agreements, documents or instruments which are necessary or desirable to (A) diligently maintain the applicable licensed Intellectual Property and the Patents and (B) diligently defend such licensed Intellectual Property and such Patents against infringement or interference by any other Persons, and against any claims of invalidity or unenforceability, in any jurisdiction (including, without limitation, by bringing any legal action for infringement or defending any counterclaim of invalidity or action of a third party for declaratory judgment of non-infringement or non-interference). The Seller shall not, and shall use commercially reasonable efforts to cause the applicable Licensee not to, disclaim or abandon, or fail to take any action necessary or desirable to prevent the disclaimer or abandonment of, the applicable Patents.

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(g) The Seller shall use commercially reasonable efforts to secure and maintain, or, where a Licensee is required to do so under any Royalty Agreement, assist such Licensee in securing and maintaining, all regulatory and other governmental approvals, clearances, registrations and permits which may be required to manufacture, market and/or sell any and all of the Products and/or Reformulated Products.

(h) The Seller shall, to the extent required by the applicable Licensee, timely produce and deliver to the applicable Licensee invoices for payments owing to the Seller under the respective Royalty Agreement.

**Section 5.12. Future Agreements.**

(a) If the Seller, at any time and from time to time during the term of this Agreement, proposes to enter into a Future Agreement with a licensee, then the Seller shall, at least three (3) Business Days prior to the execution and delivery of such Future Agreement, give written notice to the Purchaser indicating that the Seller proposes to enter into such Future Agreement and the anticipated date of execution of such proposed Future Agreement.

(b) If the Seller enters into a Future Agreement, then the Seller shall, within three (3) Business Days after the date such Future Agreement was entered into by the parties thereto, deliver to the Purchaser the following:

(i) a fully executed duplicate copy of such Future Agreement, together correspondence of a senior officer of the Seller certifying that such Future Agreement is a true, correct and complete copy thereof;

(ii) an original Bill of Sale, fully executed by the Seller, pursuant to which the Seller shall assign, convey and transfer all of its rights and interests in and to the Assigned Interests relating to such Future Agreement free and clear of all Liens, except those Liens created in favor of the Purchaser pursuant to the Security Agreement and any other Transaction Document; and

(iii) a copy of (A) the written instruction of the Seller to the Licensee party to such Future Agreement that is required to be delivered by the Seller to the Licensee pursuant to Section 5.10 and (B) the Licensee's agreement to such instruction.

**Section 5.13. Funding Termination Event.**

Upon the occurrence and during the continuation of a Funding Termination Event, the Purchaser may exercise any rights and remedies available to it, including, without limitation, those rights and remedies available hereunder, under any Transaction Document and/or at law or in equity.

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**ARTICLE VI**  
**TERMINATION**

**Section 6.01. Termination Date.**

This Agreement shall terminate on December 31, 2014; provided, however, that if any payments are required to be made by one of the parties hereunder after that date, this Agreement shall remain in full force and effect until any and all such payments have been made in full, and solely for that purpose. In addition, this Agreement shall sooner terminate if the Purchaser shall have exercised its right under Section 5.07 to require the Seller to repurchase the Assigned Interests, with the termination date in that event being the date on which the Seller completes the repurchase of the Assigned Interests and pays in full in cash the Repurchase Price in accordance with the terms therein.

**Section 6.02. Effect of Termination.**

In the event of the termination of this Agreement pursuant to Section 6.01, this Agreement shall forthwith become void and have no effect without any liability on the part of any party hereto or its Affiliates, directors, officers or stockholders other than the provisions of this Section 6.02 and Sections 7.05 and 7.06 hereof. Nothing contained in this Section 6.02 shall relieve any party from liability for any breach of this Agreement.

**ARTICLE VII**  
**MISCELLANEOUS**

**Section 7.01. Survival.**

(a) All representations and warranties made herein and in any other Transaction Document, any certificates or in any other writing delivered pursuant hereto or in connection herewith shall survive the execution and delivery of this Agreement. Notwithstanding anything in this Agreement or implied by law to the contrary, all the agreements contained in Section 7.05 and 7.06 shall survive indefinitely following the execution and delivery of this Agreement and the termination of this Agreement.

(b) Any investigation or other examination that may have been made or may be made at any time by or on behalf of the party to whom representations and warranties are made shall not limit, diminish or in any way affect the representations and warranties in this Agreement and the other Transaction Documents, and the parties may rely on the representations and warranties in this Agreement and the other Transaction Documents irrespective of any information obtained by them by any investigation, examination or otherwise.

**Section 7.02. Specific Performance.**

Each of the parties hereto acknowledges that the other party will have no adequate remedy at law if it fails to perform any of its obligations under this Agreement or any of the Other Transaction Documents. In such event, each of the parties agrees that the other party shall have the right, in addition to any other rights it may have (whether at law or in equity), to specific performance of this Agreement.

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**Section 7.03. Notices.**

All notices, consents, waivers and communications hereunder given by any party to the other to be given hereunder shall be in writing (including facsimile transmission) and delivered personally, by telegraph, telecopy, telex or facsimile, by a recognized overnight courier, or by dispatching the same by certified or registered mail, return receipt requested, with postage prepaid, in each case addressed:

if to the Purchaser:

c/o Paul Capital Advisors, L.L.C.  
50 California Street  
Suite 3000  
San Francisco, California 94111  
Attention: Chief Financial Officer  
Facsimile No. (415) 283-4301

and

c/o Paul Capital Advisors, L.L.C.  
140 East 45th Street - 44<sup>th</sup> Floor  
New York, New York 10017  
Facsimile: (646) 264-1101  
Attention: Lionel Leventhal

with a copy to:

Chadbourne & Parke LLP  
30 Rockefeller Plaza  
New York, New York 10112  
Facsimile: (212) 541-5359  
Attention: Andrew C. Coronios, Esq.

with a copy to:

SkyePharma PLC  
105 Piccadilly  
London W1J 7NJ  
Facsimile: + 44 207 491 3338  
Attention: Finance Director

If Seller to:

SkyePharma, Inc.  
10450 Science Center Drive  
San Diego, California 92121  
U.S.A.  
Facsimile: (1) 858 625 2439  
Attention: Chief Executive Officer

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; or to such other address or addresses as the Purchaser or the Seller may from time to time designate by notice as provided herein, except that notices of changes of address shall be effective only upon receipt. All such notices consents, waivers and communications shall: (i) when posted by certified or registered mail, postage prepaid, return receipt requested, be effective three (3) Business Days after dispatch, unless such communication is sent trans-Atlantic, in which case shall be deemed effective five (5) Business Days after dispatch, (ii) when telegraphed, telexed or facsimiled, be effective upon receipt by the transmitting party of confirmation of complete transmission, (iii) when delivered by a recognized overnight courier or in person, be effective upon receipt when hand delivered.

**Section 7.04. Successors and Assigns.**

The provisions of this Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns; provided, however, that the Seller not shall be entitled to assign any of its obligations and rights hereunder or any other Transaction Documents without the prior written consent of the Purchaser. Without limiting the generality of the foregoing, nothing herein shall prohibit or restrict the Purchaser from assigning any of its rights and obligations hereunder other than its obligations under Section 2.03.

**Section 7.05. Indemnification.**

(a) The Seller hereby indemnifies and holds the Purchaser and its Affiliates and any of their respective partners, directors, managers, officers, employees and agents (each a "**Purchaser Indemnified Party**") harmless from and against any and all Losses incurred or suffered by any Purchaser Indemnified Party arising out of any breach of any representation, warranty or certification made by the Seller in any of the Transaction Documents or certificates given by the Seller in writing pursuant here to or thereto or any breach of or default under any covenant or agreement by the Seller pursuant to this Agreement or any Transaction Document, including any failure by the Seller to satisfy any of the Excluded Liabilities and Obligations.

(b) The Purchaser hereby indemnifies and holds the Seller and its Affiliates and any of their respective partners, directors, managers, officers, employees and agents (each a "**Seller Indemnified Party**") harmless from and against any and all Losses incurred or suffered by a Seller Indemnified Party arising out of any breach of any representation, warranty or certification made by the Purchaser in any of the Transaction Documents or certificates given by the Purchaser in writing pursuant here to or thereto or any breach of or default under any covenant or agreement by the Purchaser pursuant to this Agreement or any Transaction Document.

(c) If any claim, demand, action or proceeding (including any investigation by any Government Authority) shall be brought or alleged against an indemnified party in respect of which indemnity is to be sought against an indemnifying party pursuant to the preceding paragraphs, the indemnified party shall, promptly after receipt of notice of the commencement of any such claim, demand, action or proceeding, notify the indemnifying party in writing of the commencement of such claim, demand, action or proceeding, enclosing a copy of all papers



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served, if any; provided, that, the omission to so notify such indemnifying party will not relieve the indemnifying party from any liability that it may have to any indemnified party under the foregoing provisions of this Section 7.05 unless, and only to the extent that, such omission results in the forfeiture of substantive rights or defenses by the indemnifying party. In case any such action is brought against an indemnified party and it notifies the indemnifying party of the commencement thereof, the indemnifying party will be entitled to participate therein and, to the extent that it may wish, jointly with any other indemnifying party similarly notified, to assume the defense thereof, with counsel reasonably satisfactory to such indemnified party (who shall not, except with the consent of the indemnified party, be counsel to the indemnifying party), and after notice from the indemnifying party to such indemnified party of its election so to assume the defense thereof, the indemnifying party will not be liable to such indemnified party under this Section 7.05 for any legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof other than reasonable costs of investigation. In any such proceeding, an indemnified party shall have the right to retain its own counsel, but the reasonable fees and expenses of such counsel shall be at the expense of such indemnified party unless (i) the indemnifying party and the indemnified party shall have mutually agreed to the retention of such counsel, (ii) the indemnifying party has assumed the defense of such proceeding and has failed within a reasonable time to retain counsel reasonably satisfactory to such indemnified party or (iii) the named parties to any such proceeding (including any impleaded parties) include both the indemnifying party and the indemnified party and representation of both parties by the same counsel would be inappropriate due to actual or potential conflicts of interests between them. It is agreed that the indemnifying party shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable fees and expenses of more than one separate law firm (in addition to local counsel where necessary) for all such indemnified parties. The indemnifying party shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party from and against any loss or liability by reason of such settlement or judgment. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement of any pending or threatened proceeding in respect of which any indemnified party is or could have been a party and indemnity could have been sought hereunder by such indemnified party, unless such settlement includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such proceeding.

(d) An indemnified party shall not be permitted to enforce any claim under this Section 7.05 until the aggregate of all such claims of such indemnified party exceeds US\$[\*\*] (the "**Threshold Amount**"), and then only to the extent that the claims in the aggregate exceed the Threshold Amount.

**Section 7.06. Expenses.**

Each party hereto will pay all of its own fees and expenses in connection with entering into and consummating the transactions contemplated by this Agreement.

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**Section 7.07. Independent Nature of Relationship.**

(a) The relationship between the Seller, on one hand, and the Purchaser, on the other hand, is solely that of seller and purchaser, and neither the Purchaser, on one hand, nor the Seller, on the other hand, have any fiduciary or other special relationship with the other or any of its Affiliates. Nothing contained herein or in any other Transaction Document shall be deemed to constitute the Seller, on one hand, and the Purchaser, on the other hand, as a partnership, an association, a joint venture or other kind of entity or legal form.

(b) No officer or employee of the Purchaser will be located at the premises of the Seller or any of its Affiliates, except in connection with an audit performed pursuant to Section 5.02. No officer or employee of the Purchaser shall engage in any commercial activity with the Seller or any of its Affiliates other than as contemplated herein and in the other Transaction Documents.

(c) The Seller and/or any of its Affiliates shall not at any time obligate the Purchaser, or impose on the Purchaser any obligation, in any manner or respect to any Person not a party hereto.

**Section 7.08. Entire Agreement.**

This Agreement, together with the Exhibits and Schedules hereto (which are incorporated herein by reference), and the other Transaction Documents constitute the entire agreement between the parties with respect to the subject matter hereof and supersede all prior agreements (including the Letter of Intent), understandings and negotiations, both written and oral, between the parties with respect to the subject matter of this Agreement. No representation, inducement, promise, understanding, condition or warranty not set forth herein has been made or relied upon by either party hereto. None of this Agreement, nor any provision hereof, is intended to confer upon any Person other than the parties hereto any rights or remedies hereunder.

**Section 7.09. Amendments; No Waivers.**

(a) This Agreement or any term or provision hereof may not be amended, changed or modified except with the written consent of the parties hereto. No waiver of any right hereunder shall be effective unless such waiver is signed in writing by the party against whom such waiver is sought to be enforced.

(b) No failure or delay by either party in exercising any right, power or privilege hereunder shall operate as a waiver thereof nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege. The rights and remedies herein provided shall be cumulative and not exclusive of any rights or remedies provided by law.

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**Section 7.10. Interpretation.**

When a reference is made in this Agreement to Articles, Sections, Schedules or Exhibits, such reference shall be to an Article, Section, Schedule or Exhibit to this Agreement unless otherwise indicated. The words “include,” “includes” and “including” when used herein shall be deemed in each case to be followed by the words “without limitation.” The definitions of terms herein shall apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun shall include the corresponding masculine, feminine and neuter forms. Unless the context requires otherwise (a) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (b) any reference herein to any Person shall be construed to include such Person’s successors and assigns (subject to any restrictions on such assignments set forth herein), (c) the words “herein”, “hereof and “hereunder”, and words of similar import shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof, and (d) any reference to any law, rule or regulation shall be construed to mean that law, rule or regulation as amended and in effect from time to time. Neither party hereto shall be or be deemed to be the drafter of this Agreement for the purposes of construing this Agreement against one party or the other.

**Section 7.11. Headings and Captions.**

The headings and captions in this Agreement are for convenience and reference purposes only and shall not be considered a part of or affect the construction or interpretation of any provision of this Agreement.

**Section 7.12. Counterparts: Effectiveness.**

This Agreement may be executed in two or more counterparts, each of which shall be an original, but all of which together shall constitute one and the same instrument. This Agreement shall become effective when each party hereto shall have received a counterpart hereof signed by the other party hereto.

**Section 7.13. Severability.**

If any provision of this Agreement is held to be invalid or unenforceable, the remaining provisions shall nevertheless be given full force and effect.

**Section 7.14. Governing Law; Jurisdiction.**

(a) THIS AGREEMENT SHALL BE GOVERNED BY, AND CONSTRUED, INTERPRETED AND ENFORCED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK, WITHOUT GIVING EFFECT TO THE PRINCIPLES OF CONFLICTS OF LAW THEREOF OTHER THAN SECTION 5-1401 OF THE GENERAL OBLIGATIONS LAW OF THE STATE OF NEW YORK

(b) ANY LEGAL ACTION OR PROCEEDING WITH RESPECT TO THIS AGREEMENT OR ANY OTHER TRANSACTION DOCUMENT MAY BE BROUGHT IN ANY STATE OR FEDERAL COURT OF COMPETENT JURISDICTION IN THE STATE,

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COUNTY AND CITY OF NEW YORK BY EXECUTION AND DELIVERY OF THIS AGREEMENT, EACH PARTY HERETO HEREBY IRREVOCABLY CONSENTS TO AND ACCEPTS, FOR ITSELF AND IN RESPECT OF ITS PROPERTY, GENERALLY AND UNCONDITIONALLY THE NON-EXCLUSIVE JURISDICTION OF SUCH COURTS. EACH PARTY HERETO HEREBY FURTHER IRREVOCABLY WAIVES ANY OBJECTION, INCLUDING ANY OBJECTION TO THE LAYING OF VENUE OR BASED ON THE GROUNDS OF FORUM NON CONVENIENS, WHICH IT MAY NOW OR HEREAFTER HAVE TO THE BRINGING OF ANY ACTION OR PROCEEDING IN SUCH JURISDICTION IN RESPECT OF THIS AGREEMENT OR ANY OTHER TRANSACTION DOCUMENT.

(c) EACH PARTY HERETO HEREBY IRREVOCABLY CONSENTS TO THE SERVICE OF PROCESS OUT OF ANY OF THE COURTS REFERRED TO IN SUBSECTION (b) ABOVE OF THIS SECTION 7.14 IN ANY SUCH SUIT, ACTION OR PROCEEDING BY THE MAILING OF COPIES THEREOF BY REGISTERED OR CERTIFIED MAIL, POSTAGE PREPAID, TO IT AT ITS ADDRESS SET FORTH IN THIS AGREEMENT. EACH PARTY HERETO HEREBY IRREVOCABLY WAIVES ANY OBJECTION TO SUCH SERVICE OF PROCESS AND FURTHER IRREVOCABLY WAIVES AND AGREES NOT TO PLEAD OR CLAIM IN ANY SUIT, ACTION OR PROCEEDING COMMENCED HEREUNDER OR UNDER ANY OTHER TRANSACTION DOCUMENT THAT SERVICE OF PROCESS WAS IN ANY WAY INVALID OR INEFFECTIVE NOTHING HEREIN SHALL AFFECT THE RIGHT OF A PARTY TO SERVE PROCESS ON THE OTHER PARTY IN ANY OTHER MANNER PERMITTED BY LAW.

**Section 7.15. Waiver of Jury Trial**

EACH PARTY HERETO HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING, CLAIM OR COUNTERCLAIM ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY OTHER TRANSACTION DOCUMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY. THIS WAIVER SHALL APPLY TO ANY SUBSEQUENT AMENDMENTS, RENEWALS, SUPPLEMENTS OR MODIFICATIONS TO THIS AGREEMENT OR ANY OTHER TRANSACTION DOCUMENT.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK; SIGNATURE PAGES FOLLOW]

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SIGNATURE PAGE To AMENDED AND RESTATED  
ROYALTY INTERESTS ASSIGNMENT AGREEMENT

**IN WITNESS WHEREOF**, the parties hereto have caused this Agreement to be duly executed by their respective authorized officers as of the date first above written.

SELLER:

**SKYEPHARMA INC.**

By: /s/ S. Thornton

Name: S. Thornton

Title: President

By: /s/ Thomas M. Zech

Name: Thomas M. Zech

Title: Secretary

---

SIGNATURE PAGE To AMENDED AND RESTATED  
ROYALTY INTERESTS ASSIGNMENT AGREEMENT

PURCHASER:

**ROYALTY SECURITIZATION TRUST I**

By: Deutsche Bank Trust Company  
Delaware, not in its individual capacity,  
but solely as Owner Trustee

By: /s/ Elizabeth B. Ferry

\_\_\_\_\_  
Name: Elizabeth B. Ferry  
Title: Assistant Vice President

By: /s/ David Dwyer

\_\_\_\_\_  
Name: David Dwyer  
Title: Vice President

**EXHIBIT A TO  
AMENDED AND RESTATED ROYALTY INTEREST  
ASSIGNMENT AGREEMENT**

**FORM OF BILL OF SALE**

THIS **BILL OF SALE** (this "**Bill of Sale**"), dated as of [\_\_\_\_\_, 200\_\_] is made and entered into by and between [Name of Seller], a \_\_\_\_\_ ("**Seller**"), and [Name of Purchaser], a \_\_\_\_\_ ("**Purchaser**"). All capitalized terms used herein and not defined shall have the meanings ascribed to them in the Assignment Agreement (as defined below).

WHEREAS, Seller, Purchaser and the other Seller Parties party thereto are parties to that certain Amended and Restated Royalty Interests Assignment Agreement, dated as of March 23, 2007 (as amended, supplemented or otherwise modified from time to time, the "Assignment Agreement"), pursuant to which, among other things, Seller sells, assigns, transfers and conveys to the Purchaser, and the Purchaser purchases from Seller, all of Seller's rights and interests in and to the Assigned Interests under the Royalty Agreements to which such Seller is a party (the "Purchased Assets"), for consideration in the amount and on the terms and conditions provided therein; and

**WHEREAS**, the parties now desire to carry out the purposes of the Assignment Agreement by the execution and delivery of this instrument evidencing the purchase, acquisition, acceptance and vesting in Purchaser of the Purchased Assets;

**NOW, THEREFORE**, in consideration of the premises and of other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

1. **Sale and Assignment of Purchased Assets**. Seller hereby grants, transfers, sells, conveys, assigns, releases and delivers to Purchaser, its successors and assigns, free and clear of all Liens, all of Seller's rights and interests in and to all of the Purchased Assets, except Liens pursuant to the Security Agreement and otherwise as set forth in the Assignment Agreement or the schedules thereto.

2. **No Assumption of Obligations**. The parties hereby acknowledge that Purchaser is not assuming any debt, liability or obligation of Seller, known or unknown, fixed or contingent, in connection with the Purchased Assets, including, without limitation the Excluded Liabilities and Obligations in respect thereof.

3. **Further Assurances**. Each party hereto shall execute, acknowledge and deliver to the other party any and all documents or instruments, and shall take any and all actions, reasonably required by such other party from time to time, to confirm or effect the matters set forth herein, or otherwise to carry out the purposes of the Assignment Agreement and this Bill of Sale and the transaction contemplated thereby and hereby.

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4. **Purchase Agreement**. This Bill of Sale is entered into pursuant to and is subject in all respects to all of the terms, provisions and conditions of the Assignment Agreement, and nothing herein shall be deemed to modify any of the representations, warranties, covenants and obligations of the parties thereunder.

5. **Interpretation**. In the event of any conflict or inconsistency between the terms, provisions and conditions of this Bill of Sale and the Assignment Agreement, the terms, provisions and conditions of the Assignment Agreement shall govern.

6. **Governing Law**. This Bill of Sale will be construed and enforced in accordance with, and governed by, the laws of the State of New York applicable to contracts made and to be performed entirely within such State.

7. **Counterparts**. This Bill of Sale may be executed in counterparts, each of which shall be deemed to be an original but all of which together shall constitute a single agreement.

[Signature Page To Follow]



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**IN WITNESS WHEREOF**, Seller and Purchaser have caused this Bill of Sale to be duly executed as of the date first above written.

**[SELLER]**, as Seller

By: \_\_\_\_\_  
Name:  
Title:

**[PURCHASER]**, as Purchaser

By: \_\_\_\_\_  
Name:  
Title:

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**SCHEDULE A TO  
AMENDED AND RESTATED ROYALTY INTEREST  
ASSIGNMENT AGREEMENT**

**Schedule of DepoDur Revenue Projections**

<u>Calendar Year</u>	<u>Revenue Projection</u>	<u>50% of Revenue Projection</u>
2007	US\$[**]	US\$[**]
2008	US\$[**]	US\$[**]
2009	US\$[**]	US\$[**]
2010	US\$[**]	US\$[**]
2011	US\$[**]	US\$[**]
2012	US\$[**]	US\$[**]
2013	US\$[**]	US\$[**]
2014	US\$[**]	US\$[**]

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**SCHEDULE B TO  
AMENDED AND RESTATED ROYALTY INTEREST  
ASSIGNMENT AGREEMENT**

Schedule of Patents



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Schedule B

**	**	**	**	**	**	**	**	**
**	**	**	**	**	**	**	**	**

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Schedule B

**[\*\*]Related Product: Depocyt**  
**Owner: SkyePharma Inc.**

<u>SkyePharma Ref:</u>	<u>Attorneys' Ref:</u>	<u>Country</u>	<u>Application date</u>	<u>Application no.</u>	<u>Patent/ Publication no.</u>	<u>Grant date</u>	<u>Expiry date</u>	<u>Status</u>
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
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Schedule B

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[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]





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Schedule B

[\*\*]Owner: SkyePharma Inc.

<u>SkyePharma Ref:</u>	<u>Attorneys' Ref:</u>	<u>Country</u>	<u>Application date</u>	<u>Application no.</u>	<u>Patent/ Publication no.</u>	<u>Grant date</u>	<u>Expiry date</u>	<u>Status</u>
[**]	[**]	[**]	[**]	[**]				[**]





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Schedule B

**[\*\*]Related Product: Depodur**  
**Owner: SkyePharma Inc.**

<u>SkyePharma Ref:</u>	<u>Attorneys' Ref:</u>	<u>Country</u>	<u>Application date</u>	<u>Application no.</u>	<u>Patent/ Publication no.</u>	<u>Grant date</u>	<u>Expiry date</u>	<u>Status</u>
[**]	[**]	[**]	[**]	[**]				[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]

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Schedule B

**[\*\*]Related Product: Depodur**  
**Owner: SkyePharma Inc.**

<u>SkyePharma Ref:</u>	<u>Attorneys' Ref:</u>	<u>Country</u>	<u>Application date</u>	<u>Application no.</u>	<u>Patent/ Publication no.</u>	<u>Grant date</u>	<u>Expiry date</u>	<u>Status</u>
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]

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Schedule B

**[\*\*]Related Product: Depocyt/Depodur**  
**Owner: SkyePharma Inc.**

<u>SkyePharma Ref:</u>	<u>Attorneys' Ref:</u>	<u>Country</u>	<u>Application date</u>	<u>Application no.</u>	<u>Patent/ Publication no.</u>	<u>Grant date</u>	<u>Expiry date</u>	<u>Status</u>
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]

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Schedule B

**[\*\*]Related Product: Depocyt/Depodur**  
**Owner: SkyePharma Inc.**

<u>SkyePharma Ref:</u>	<u>Attorneys' Ref:</u>	<u>Country</u>	<u>Application date</u>	<u>Application no.</u>	<u>Patent/ Publication no.</u>	<u>Grant date</u>	<u>Expiry date</u>	<u>Status</u>
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]





Schedule B

**[\*\*]Related Product: Depocyt/Depodur**  
**Owner: SkyePharma Inc.**

<u>SkyePharma Ref:</u>	<u>Attorneys' Ref:</u>	<u>Country</u>	<u>Application date</u>	<u>Application no.</u>	<u>Patent/ Publication no.</u>	<u>Grant date</u>	<u>Expiry date</u>	<u>Status</u>
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Schedule B

Title	Country	Status	Application No.	Filing Date	Registration no.	Grant Date	Owner	International Classes
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
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[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]

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Schedule B

Title	Country	Status	Application No.	Filing Date	Registration no.	Grant Date	Owner	International Classes
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]

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**Schedule 3.04**  
**OWNERSHIP/LIENS**

Under an Assignment Agreement between Research Development Foundation (“RDF”) and SkyePharma Inc dated February 9, 1994, as amended by a letter agreement dated December 10, 1997 and an amendment agreement dated April 15, 2004 RDF assigned world-wide rights under certain assigned proprietary property, including patents and other intellectual property, to SkyePharma Inc and in return SkyePharma Inc agreed to pay to RDF [\*\*]% of world-wide revenues from the products (as defined in the Assignment Agreement and amendments thereto) developed from the assigned proprietary property, The products developed from the assigned proprietary property include DepoCyt and DepoDur.

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

EXECUTION VERSION

**AMENDED AND RESTATED SECURITY AGREEMENT (SKPI)**

Dated as of March 23, 2007

between

SKYEPHARMA INC.,  
as Grantor,

and

ROYALTY SECURITIZATION TRUST I,  
as Purchaser

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Schedules

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- Schedule II - Offices For Filing Financing Statements
- Schedule III - Deposit Accounts
- Schedule 3.1 - Names and Corporate Reorganizations and Mergers



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**AMENDED AND RESTATED SECURITY AGREEMENT (SKPI)**

THIS AMENDED AND RESTATED SECURITY AGREEMENT (SKPI) (as amended, supplemented or otherwise modified from time to time, this "Security Agreement"), is dated as of March 23, 2007 and entered into between **SKYEPHARMA INC.**, a California corporation (the "Grantor") and **ROYALTY SECURITIZATION TRUST I**, a Delaware statutory trust (the "Purchaser").

**RECITALS**

WHEREAS, the Grantor and the Purchaser have entered into the Amended and Restated Royalty Interests Assignment Agreement, dated as of March 23, 2007 (as amended, supplemented or otherwise modified from time to time, the "Assignment Agreement"); and

WHEREAS, it is a condition precedent to the execution and delivery of the Assignment Agreement that the Grantor shall have granted the security interests contemplated by this Security Agreement.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Grantor hereby agrees, for the benefit of the Purchaser, as follows:

**ARTICLE I**

**DEFINITIONS**

Section 1.1. Certain Terms.

The following terms (whether or not underscored) when used in this Security Agreement, including its preamble and recitals, shall have the following meanings:

"Account" shall have the meaning as provided in the UCC.

"Assignment Agreement" shall have the meaning set forth in the recitals hereto.

"Collateral" shall have the meaning set forth in Section 2.1.

"Deposit Accounts" shall mean all "Deposit Accounts" as defined and designated in the Assignment Agreement, including those set forth on Schedule III hereto.

"Event of Default" shall mean a Funding Termination Event.

"General Intangible" shall have the meaning as provided in the UCC.

"Grantor" shall have the meaning set forth in the preamble hereto.

"Instrument" shall have the meaning as provided in the UCC.

"Obligations" shall have the meaning set forth in the Assignment Agreement.

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“Proceeds” shall have the meaning as provided in the UCC.

“Receivables” mean the Royalty Interests and the Related Receivables.

“Related Receivables” shall have the meaning set forth in Section 2.1(c).

“Security Agreement” shall have the meaning set forth in the preamble hereto.

“UCC” shall mean the Uniform Commercial Code as in effect on the date hereof in the State of New York, as amended from time to time, and any successor statute; provided that if by reason of mandatory provision of law, the perfection or the effect of perfection or non-perfection of the security interest in the Collateral is governed by the Uniform Commercial Code of another jurisdiction or a similar or equivalent legislation as enacted in a relevant foreign jurisdiction, “UCC” means the Uniform Commercial Code or such legislation as in effect in such other jurisdiction for purposes of the provision hereof relating to such perfection or effect of perfection or non-perfection.

Section 1.2. Assignment Agreement Definitions.

Unless otherwise defined herein or the context otherwise requires, terms used in this Security Agreement, including its preamble and recitals, have the meanings provided in the Assignment Agreement.

Section 1.3. UCC Definitions.

Unless otherwise defined herein or the context otherwise requires, terms for which meanings are provided in the UCC in the State of New York are used in this Security Agreement, including its preamble and recitals, with such meanings.

Section 1.4. Other Interpretive Provisions.

(a) The meanings of defined terms are equally applicable to the singular and plural forms of the defined terms.

(b) The words “hereof”, “herein”, “hereunder” and similar words refer to this Security Agreement as a whole and not to any particular provision of this Security Agreement; and subsection, Section, Schedule, and Exhibit references are to this Security Agreement unless otherwise specified.

(c)(i) The term “documents” includes any and all instruments, documents, agreements, certificates, indentures, notices and other writings, however evidenced.

(ii) The term “including” is not limiting and means “including without limitation”.

(iii) The term “property” includes any kind of property or asset, personal or mixed, tangible or intangible, other than real property.

---

(d) Unless otherwise expressly provided herein, (i) references to agreements (including this Security Agreement) and other contractual instruments shall be deemed to include all subsequent amendments and other modifications thereto, but only to the extent such amendments and other modifications are not prohibited by the terms of any Transaction Document, and (ii) references to any statute or regulation are to be construed as including all statutory and regulatory provisions consolidating, amending, replacing, supplementing, or interpreting the statute or regulation.

(e) The captions and headings of this Security Agreement are for convenience of reference only and shall not affect the interpretation of this Security Agreement.

## ARTICLE II SECURITY INTEREST

### Section 2.1. Grant of Security.

As collateral security for the prompt and complete payment and performance when due of the Obligations, the Grantor has, and hereby confirms and ratifies that it has, assigned and granted to the Purchaser a security interest in all of the Grantor's right, title, and interest in and to the following property, whether now owned or hereafter existing or acquired (the "Collateral"):

(a) all Royalty Interests;

(b) all Assigned Interests;

(c) all Accounts, contract rights, payment intangibles, Instruments, and General Intangibles, in each case, constituting, comprising, evidencing or otherwise relating to any of the foregoing in this Section 2.1 (any and all such Accounts, contract rights, payments intangibles, Instruments, and General Intangibles being the "Related Receivables");

(d) all Deposit Accounts; and

(e) all products and Proceeds of and from any and all of the foregoing Collateral, all proceeds which constitute property of the types described in clauses (a) through (c) and, to the extent not otherwise included, all payments under insurance (whether or not the Purchaser is the loss payee thereof), including return premiums with respect thereto, or any indemnity, warranty, or guaranty payable by reason of loss or damage to or otherwise with respect to any of the foregoing Collateral; provided, however, that the term "Collateral" shall not include, and the Grantor shall not be deemed to have granted a security interest in, any of the Grantor's right, title or interest in, or any rights under, (i) any contract or other agreement existing on December 29, 2000 to the extent that such grant would result in a breach of a term of such contract or agreement prohibiting such grant without the consent of the other party thereto, other than to the extent that any such term would be rendered ineffective pursuant to Section 9-318 of the Uniform Commercial Code of any relevant jurisdiction and (ii) any Intellectual Property of the Grantor.

---

Section 2.2. Continuing Security Interest; Transfer of Notes.

This Security Agreement shall create a continuing security interest in the Collateral and shall:

- (a) remain in full force and effect until the payment and performance in full of all the Obligations,
- (b) be binding upon the Grantor and its successors, transferees and assigns, and
- (c) inure, together with the rights and remedies of the Purchaser, to the benefit of the Purchaser and its successors and assigns.

Upon the payment and performance in full of the Obligations, the security interest granted herein shall terminate and all rights to the Collateral shall revert to the Grantor. Upon any such termination, the Purchaser will promptly execute and deliver to the Grantor such instruments and documents necessary and as the Grantor shall reasonably request to evidence such termination.

Section 2.3. Grantor Remains Liable.

Anything herein to the contrary notwithstanding:

(a) the Grantor shall remain liable under the contracts and agreements to which it is a party included in the Collateral to the extent set forth therein and shall perform all of its duties and obligations under such contracts and agreements to the same extent as if this Security Agreement had not been executed,

(b) the exercise by the Purchaser of any of its rights and remedies hereunder shall not release the Grantor from any of its duties or obligations under any such contracts or agreements included in the Collateral, and

(c) the Purchaser shall have no obligation or liability under any such contracts or agreements included in the Collateral by reason of this Security Agreement, and the Purchaser shall not be obligated to perform any of the obligations or duties of the Grantor thereunder or to take any action to collect or enforce any claim for payment assigned hereunder.

---

**ARTICLE III**

**REPRESENTATIONS AND WARRANTIES**

The Grantor acknowledges that, pursuant to the Security Agreement dated as of December 29, 2000 by and among Jagotec AG, the Grantor, and the Purchaser, the Grantor represented and warranted to the Purchaser as follows in each case as of December 29, 2000:

Section 3.1. Location of Collateral, etc.

(a) On the date hereof, the place(s) of business and chief executive office of the Grantor and the office(s) where the Grantor keeps its records concerning the Receivables are located at the addresses set forth on Schedule I.

(b) The Grantor does not have trade name.

(c) Except as set forth on Schedule 3.1 hereto, the Grantor has not been known by any name different from the one set forth on the signature page hereto, and, within the last five years, the Grantor has not been the subject of any merger or other corporate reorganization.

(d) None of the Receivables is evidenced by a promissory note or other instrument.

Section 3.2. Ownership; No Liens.

The Grantor owns the Collateral free and clear of any Lien except for the security interest created by this Security Agreement. No effective financing statement or other instrument similar in effect covering all or any part of the Collateral is on file in any recording office, except such as may have been filed in favor of the Purchaser relating to this Security Agreement.

Section 3.3. Validity.

This Security Agreement creates a valid security interest in the Collateral securing the payment and performance in full of the Obligations. Upon the filing of appropriate financing statements in the applicable filing offices in the jurisdictions listed in Schedule II, all filings, registrations and recordings necessary or appropriate to create, preserve, protect and perfect the security interest granted by the Grantor to the Purchaser in the Collateral will have been accomplished and will create a perfected security interest therein prior to the rights of all other Persons therein and subject to no other Liens, except as otherwise set forth in the Assignment Agreement.

Section 3.4. Authorization, Approval.

No authorization, approval, or other action by, and no notice to or filing with, any Government Authority or other Person is required either:

(a) for the grant by the Grantor of the security interest granted hereby or for the execution, delivery, and performance of this Security Agreement by the Grantor, or

(b) for the exercise by the Purchaser of its rights and remedies hereunder.

---

## ARTICLE IV

### COVENANTS

The Grantor hereby covenants and agrees that, so long as any Obligations remains unpaid, unperformed or outstanding, the Grantor agrees to the following:

Section 4.1. As to Receivables.

(a) The Grantor shall keep its place(s) of business and its chief executive office and the office(s) where it keeps its books and records (including those concerning the Receivables) and all original copies of the Royalty Agreements located, in each case, at its address specified in Schedule I, or, upon 30 days' prior written notice to the Purchaser, at such other locations in a jurisdiction where all actions required by the first sentence of Section 4.3 shall have been taken with respect to the Receivables and the Royalty Agreements; not change its name or its state or place of incorporation or organization except upon 30 days' prior written notice to the Purchaser; and hold and preserve such books and records.

(b) Except as otherwise provided in this subsection (b), until an Event of Default has occurred and is continuing, the Grantor shall, subject to Section 5.11 of the Assignment Agreement, continue to collect, at its own expense, all amounts due or to become due the Grantor under the Royalty Agreements to which it is a party. In connection with such collections, provided no Event of Default shall have occurred and be continuing, the Grantor may, subject to Section 5.11 of the Assignment Agreement, take (and, at the Purchaser's direction, shall take) such action as the Grantor may deem necessary or advisable to enforce collection of the applicable Royalty Agreement. At any time after an Event of Default has occurred and is continuing, the Purchaser shall have the right to notify the account debtors or obligors under any Receivables of the assignment of such Receivables to the Purchaser and to direct such account debtors or obligors to make payment to the Purchaser or any amounts due or to become due thereunder and enforce collection of any or the Receivables by suit or otherwise and surrender, release or exchange all or any part thereof, or adjust, settle or compromise or extend or renew for any period (whether or not longer than the original period) any indebtedness thereunder or evidenced thereby. If an Event of Default has occurred and is continuing, upon the request of the Purchaser, the Grantor will, at its own expense, notify any parties obligated on any of the Receivables to make payment to the Purchaser of any amounts due or to become due thereunder, and in such event, the Purchaser is authorized to endorse, in the name of the Grantor, any item representing any payment on or other proceeds of any of the Receivables.

(c) After delivery to the Grantor by the Purchaser of a notice that an Event of Default has occurred and is continuing: (i) all amounts and proceeds (including Instruments) received by the Grantor in respect of any Receivables shall be received in trust for the benefit of the Purchaser hereunder, shall be segregated from other funds of the Grantor, and shall be forthwith paid over to the Purchaser in the same form as so received (with any necessary endorsements) to be held as cash collateral and applied as provided by this Security Agreement; and (ii) subject to Section 5.11 of the Assignment Agreement, the Grantor shall not adjust, settle, or compromise the amount or payment of any Receivable, or release wholly or partly any account debtor or obligor thereof, or allow any credit or discount thereon.

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(d) After the occurrence and during the continuance of an Event of Default, (A) the Purchaser may in its own name or in the name of others communicate with account debtors in order to verify with them to the Purchaser's reasonable satisfaction the existence, amount and terms of any Receivables and (B) the Purchaser shall have the right, at the Grantor's expense, to make test verifications of the Receivables in any reasonable manner and through any medium that it considers advisable, and the Grantor agrees to furnish all such assistance as the Purchaser may reasonably require in connection therewith.

Section 4.2. Transfers and Other Liens.

The Grantor shall not without the prior written consent of the Purchaser sell, assign (by operation of law or otherwise) or otherwise dispose of any of the (Collateral, except as expressly permitted by the Assignment Agreement.

Section 4.3. Further Assurances.

The Grantor agrees that, from time to time at its own expense, the Grantor will promptly execute and deliver all further instruments, assignments, agreements and documents, and take all further action, that may be necessary or desirable, or that the Purchaser may reasonably request, in order to perfect, preserve, and protect any security interest granted or purported to be granted hereby and the priority thereof or to enable the Purchaser to exercise and enforce its rights and remedies hereunder with respect to any Collateral. Without limiting the generality of the foregoing the Grantor will:

(a) if any Collateral shall be evidenced by a promissory note or other instrument or negotiable document, deliver and pledge to the Purchaser hereunder such promissory note, instrument or negotiable document duly endorsed and accompanied by duly executed instruments of transfer or assignment, all in form and substance reasonably satisfactory to the Purchaser;

(b) execute and file such financing or continuation statements, or amendments thereto, and such other instruments, assignments or notices, as may be necessary or desirable, or as the Purchaser may reasonably request, in order to perfect and preserve the security interests and other rights granted or purported to be granted to the Purchaser;

(c) furnish to the Purchaser, from time to time, statements and schedules further identifying and describing the Collateral and such other reports in connection with the Collateral as the Purchaser may reasonably request, and all in reasonable detail and in accordance with the terms of the Assignment Agreement.

With respect to the foregoing and the grant of the security interest hereunder, the Grantor hereby authorizes the Purchaser to file one or more financing or continuation statements, and amendments thereto, relative to all or any part of the Collateral without the signature of the Grantor where permitted by law. A carbon, photographic, or other reproduction of this Security Agreement or any financing statement covering the Collateral or any part thereof shall be sufficient as a financing statement where permitted by law.

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Section 4.4. General Covenants.

Without limiting any of the foregoing covenants, the Grantor agrees (a) not to use or permit any Collateral to be used unlawfully or in material violation of any provision of the Assignment Agreement, this Security Agreement, any other Transaction Document, or any applicable statute, regulation or ordinance or any policy of insurance covering the Collateral; and (b) to pay promptly when due all taxes, assessments, charges, encumbrances and Liens now or hereafter imposed upon or affecting any Collateral.

**ARTICLE V**

**RIGHTS AND DUTIES OF THE PURCHASER**

Section 5.1. Purchaser Appointed Attorney-in-Fact.

The Grantor hereby irrevocably appoints the Purchaser the Grantor's attorney-in-fact, with full authority in the place and stead of the Grantor and in the name of the Grantor or otherwise, from time to time in the Purchaser's discretion when an Event of Default has occurred and is continuing, to take any appropriate action and to execute any instrument that the Purchaser may deem necessary or advisable to accomplish the purposes of this Security Agreement (but the Purchaser shall not be obligated to and shall have no liability to the Grantor or any third party for failure so to do) including, without limitation:

(a) to ask, demand, collect, sue for, recover, compromise, receive, and give acquittance and receipts for moneys due and to become due under or in respect of any of the Collateral;

(b) to receive, endorse, and collect any drafts or other instruments, documents, and chattel paper in connection with clause (a) above;

(c) to file any claims or take any action or institute any proceedings that the Purchaser may deem necessary or desirable for the collection of any of the Collateral or otherwise to enforce the rights of the Purchaser with respect to any of the Collateral;

(d) to perform the affirmative obligations of the Grantor hereunder (including all obligations of the Grantor pursuant to Section 4.3);

(e) to execute and deliver for and on behalf of the Grantor any and all instruments, documents, agreements, and other writings necessary or advisable for the exercise on behalf of the Grantor of any rights, benefits or options created or existing under or pursuant to the Collateral; and

(f) to execute endorsements, assignments, or other instruments of conveyance and transfer.

The Grantor hereby acknowledges, consents and agrees that the power of attorney granted pursuant to this Section 5.1 is irrevocable and coupled with an interest.



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Section 5.2. Purchaser May Perform.

If the Grantor fails to perform any agreement contained herein, the Purchaser may itself perform, or cause performance of such agreement, provided that the Purchaser shall in any event first have given the Grantor written notice of its intent to do the same and the Grantor shall not have, within 30 days of such notice (or such shorter period as the Purchaser may reasonably determine is necessary in order to preserve the benefits of this Security Agreement with respect to any material portion of the Collateral), paid such claim or obtained to the Purchaser's satisfaction the release of the claim or Lien to which such notice relates. The Grantor agrees to reimburse the Purchaser upon demand for any costs and expenses, including, without limitation, reasonable attorneys' fees, the Purchaser incurs while acting as the Grantor's attorney-in-fact hereunder, all of which costs and expenses are included in the Obligations secured hereby.

Section 5.3. Limitations on Duties of Purchaser.

The Purchaser shall be obligated to perform such duties and only such duties as are specifically set forth in this Security Agreement, and no implied covenants or obligations shall be read into this Security Agreement against the Purchaser. If an Event of Default has occurred and is continuing, the Purchaser shall exercise the rights and powers vested in it by this Security Agreement, and shall not be liable (except for its gross negligence or willful misconduct) with respect to any action taken by it, or omitted to be taken by it, in accordance with, and subject to the limitations contained in, the Assignment Agreement.

Section 5.4. Reasonable Care.

It is understood and agreed between the parties hereto that the Purchaser's duty with respect to the custody, safekeeping, and physical preservation of the Collateral in its possession should be to deal with it in the same manner as the Purchaser deals with similar property for its own account; provided, however, that the Purchaser shall not be required to make any presentment, demand, or protest, or give any notice, and need not take any action to preserve any rights against any other Person with respect to the Collateral.

Section 5.5. Indemnification

The Grantor agrees to and shall indemnify and hold harmless each Purchaser Indemnified Party from and against any and all Losses of any kind whatsoever which may at any time be imposed on, assessed against or incurred by any Purchaser Indemnified Party: (1) in any way relating to or arising out of this Agreement or any documents contemplated by or referred to herein or the transactions contemplated hereby or any action taken or omitted to be taken by the Purchaser or its agents, officers and employees with respect to the foregoing to the extent that the same shall occur on or after the date hereof; or (2) in any manner resulting from any action taken or omitted to be taken by the Purchaser or its agents, officers and employees with respect to the Collateral on or after the date hereof; provided, however, that under no circumstance shall the Grantor be liable to a Purchaser Indemnified Party for any portion of any amount described in clause (1) or (2) above arising out of or resulting from the gross negligence or willful misconduct of such Purchaser Indemnified Party. The indemnification obligations of the Grantor under this Section 5.5 shall survive termination of this Security Agreement and payment and performance in full of the Obligations.

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## ARTICLE VI

### REMEDIES

#### Section 6.1. Certain Remedies.

If any Event of Default shall have occurred and is continuing:

(a) The Purchaser may exercise in respect of the Collateral, in addition to other rights available to it at law or in equity or otherwise, all the rights and remedies of a secured party on default under the UCC (whether or not the UCC applies to the affected Collateral) and also may (i) require the Grantor to, and the Grantor hereby agrees that it will, at its expense and upon request of the Purchaser forthwith, assemble all or part of the Collateral as directed by the Purchaser and make it available to the Purchaser at the place to be designated by the Purchaser that is reasonably convenient to both parties, (ii) exercise any and all rights and remedies of the Grantor under or in connection with the Collateral, (iii) foreclose or otherwise enforce the Purchaser's security interest in any manner permitted by law or provided for in this Security Agreement, (iv) without notice except as specified below, sell the Collateral or any part thereof in one or more parcels at public or private sale, at any place or places for cash, on credit, or for future delivery, and upon such other terms as the Purchaser may reasonably determine, (v) recover from the Grantor all costs and expenses, including, without limitation, reasonable attorneys' fees, incurred or paid by the Purchaser in exercising any right, power privilege or remedy provided by this Security Agreement or by law, (vi) enter into property where any Collateral or books and records relating thereto are located and take possession thereof, and (vii) prior to the disposition of the Collateral, prepare it for disposition in any manner and to the extent the Purchaser deems appropriate; provided, however, that notwithstanding the foregoing to the contrary, the Purchaser may sell or otherwise dispose the Collateral or any portion thereof in its then condition without any preparation or processing. The Grantor agrees that, to the extent notice of sale shall be required by law, at least ten (10) days' prior notice to the Grantor of the time and place of any public sale or the time after which any private sale is to be made shall constitute reasonable notification. The Purchaser shall not be obligated to make any sale of Collateral regardless of notice of sale having been given. The Purchaser may adjourn any public or private sale from time to time by announcement at the time and place fixed therefore, and such sale may, without further notice, be made at the time and place to which it was so adjourned. Upon any sale or other disposition pursuant to this Security Agreement, the Purchaser shall have the right to deliver, assign and transfer to the purchaser thereof the Collateral or portion thereof and transfer to the purchaser thereof the Collateral or portion thereof so sold or disposed of. Each purchaser at any such sale or other disposition (including the Purchaser) shall hold the Collateral free from any claim or right of whatever kind, including any equity or right of redemption of the Grantor and the Grantor specifically waives (to the extent permitted by law) all rights of redemption, stay or appraisal which it has or may have under any rule of law or statute now existing or hereafter adopted.

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(b) All cash proceeds received by the Purchaser in respect of any sale of, collection from, or other realization upon all or any part of the Collateral shall be applied to the Obligations. If any non-cash proceeds are received in connection with any sale of Collateral, the Purchaser shall not apply such non-cash proceeds to the Obligations unless and until such proceeds are converted to cash; provided, however, that if such non-cash proceeds are not expected on the date of receipt thereof to be converted to cash within one year after such date, the Purchaser shall nonetheless use commercially reasonable efforts to convert such non-cash proceeds to cash within such one-year period. Any surplus of such cash or cash proceeds held by the Purchaser after payment in full of all the Obligations shall be paid over to the Grantor or to whomsoever may be lawfully entitled to receive such surplus.

## ARTICLE VII

### MISCELLANEOUS PROVISIONS

#### Section 7.1. Amendments.

No amendment to or waiver of any provision of this Security Agreement and no consent to any departure by the Grantor herefrom shall in any event be effective unless the same shall be in writing and signed by the Purchaser, and then such waiver or consent shall be effective only in the specific instance and for the specific purpose for which given.

#### Section 7.2. Release of Collateral.

If any of the Collateral shall be sold, transferred, or otherwise disposed of by the Grantor in a transaction not expressly prohibited by the Assignment Agreement, then the Purchaser shall, at the Grantor's written request, promptly execute and deliver to the Grantor (at the sole cost and expense of the Grantor) such instruments or documents necessary and as the Grantor shall reasonably request to release the Liens created hereby on such Collateral, including any necessary UCC amendment, termination statement or partial termination statement.

#### Section 7.3. Notices.

All notices and other communications shall be given as set forth in Section 7.03 of the Assignment Agreement.

#### Section 7.4. Waiver; Cumulative Remedies.

(a) No failure to exercise and no delay in exercising, on the part of the Purchaser, any right, remedy, power, or privilege hereunder, shall operate as a waiver thereof; nor shall any single or partial exercise of any right, remedy, power or privilege hereunder preclude any other or further exercise thereof, or the exercise of any other right, remedy, power or privilege.

(b) The Grantor waives any right to require the Purchaser to proceed against any Person or to exhaust any Collateral or to pursue any remedy in such Purchaser's power.

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(c) The rights, powers and remedies of the Purchaser under this Security Agreement shall be in addition to all rights, powers and remedies given to the Purchaser by virtue of any statute or rule of law, the Assignment Agreement or any other agreement, all of which rights, powers and remedies shall be cumulative and may be exercised successively or concurrently without impairing the Purchaser's security interest in the Collateral.

Section 7.5. Successors and Assigns.

The provisions of this Security Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns, except that the Grantor may not assign or transfer any of its rights or obligations under this Security Agreement without the prior written consent of the Purchaser.

Section 7.6. Counterparts.

The Security Agreement may be executed in any number of separate counterparts, each of which, when so executed, shall be deemed an original, and all of said counterparts taken together shall be deemed to constitute but one and the same instrument.

Section 7.7. Severability.

The illegality or unenforceability of any provision of this Security Agreement any instrument or agreement required hereunder shall not in any way affect or impair the legality or enforceability of the remaining provisions of this Security Agreement or any instrument or agreement required hereunder.

Section 7.8. Governing Law and Jurisdiction.

(a) THIS SECURITY AGREEMENT SHALL BE GOVERNED BY, AND CONSTRUED, INTERPRETED AND ENFORCED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK, WITHOUT GIVING EFFECT TO THE PRINCIPLES OF CONFLICTS OF LAW THEREOF OTHER THAN SECTION 5-1401 OF THE GENERAL OBLIGATIONS LAW OF THE STATE OF NEW YORK.

(b) ANY LEGAL ACTION OR PROCEEDING WITH RESPECT TO THIS SECURITY AGREEMENT MAY BE BROUGHT IN ANY STATE OR FEDERAL COURT OF COMPETENT JURISDICTION IN THE STATE, COUNTY AND CITY OF NEW YORK. BY EXECUTION AND DELIVERY OF THIS SECURITY AGREEMENT THE GRANTOR HEREBY IRREVOCABLY CONSENTS TO AND ACCEPTS, FOR ITSELF AND IN RESPECT OF ITS PROPERTY, GENERALLY AND UNCONDITIONALLY THE NON-EXCLUSIVE JURISDICTION OF SUCH COURTS. THE GRANTOR HEREBY FURTHER IRREVOCABLY WAIVES ANY OBJECTION, INCLUDING ANY OBJECTION TO THE LAYING OF VENUE OR BASED ON THE GROUNDS OF FORUM NON CONVENIENS, WHICH IT MAY NOW OR HEREAFTER HAVE TO THE BRINGING OF ANY ACTION OR PROCEEDING IN SUCH JURISDICTION IN RESPECT OF THIS SECURITY AGREEMENT OR ANY DOCUMENT RELATED HERETO.

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Section 7.9. Waiver of Jury Trial.

THE GRANTOR AND THE PURCHASER HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING, CLAIM OR COUNTERCLAIM ARISING OUT OF OR RELATING TO THIS SECURITY AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY. THIS WAIVER SHALL APPLY TO ANY SUBSEQUENT AMENDMENTS, RENEWALS, SUPPLEMENTS OR MODIFICATIONS TO THIS SECURITY AGREEMENT.

Section 7.10. Amendment and Restatement. This Security Agreement amends and restates in its entirety the Security Agreement dated as of December 29, 2000 among SkyePharma Inc., Jagotec AG and Paul Capital Royalty Acquisition Fund, L.P., as the same may have been amended, supplemented or otherwise modified prior to the effectiveness of this Security Agreement.

*[Remainder of page intentionally left blank; signature pages follow]*

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SIGNATURE PAGE TO AMENDED AND RESTATED SECURITY AGREEMENT (SKPI)

IN WITNESS WHEREOF, the Grantor and the Purchaser have caused this Security Agreement to be duly executed and delivered by their respective duly authorized officers as of the date first above written.

GRANTOR:

**SKYEPHARMA INC.**

By: /s/ S. Thornton

Name: S. Thornton

Title: President

By: /s/ Thomas M. Zech

Name: Thomas M. Zech

Title: Secretary

PURCHASER:

**ROYALTY SECURITIZATION TRUST I**

By: Deutsche Bank Trust Company  
Delaware, not in its individual capacity,  
but solely as Owner Trustee

By: /s/ Elizabeth B. Ferry

Name: Elizabeth B. Ferry

Title: Assistant Vice President

By: /s/ David Dwyer

Name: David Dwyer

Title: Vice President

LOCATION OF CERTAIN COLLATERAL

**Place of Business and Chief Executive Office of the Grantor :**

SkyePharma Inc.  
10450 Science Centre Drive  
San Diego, California 92121

**Address of the Property At Which the Grantor Maintains Records Relating To the Collateral :**

SkyePharma Inc.  
10450 Science Centre Drive  
San Diego, California 92121



OFFICES FOR FILING FINANCING STATEMENTS

For SkyePharma Inc.:

Secretary of State of the State of California

**DEPOSIT ACCOUNTS**

**Bank Name**

**Account Number (Name)**

JPMorgan Chase Bank, N.A.

[\*\*] (Dollar Concentration Account)

JPMorgan Chase AG Frankfurt  
A/C JPMorgan Chase Bank London.

[\*\*] (Euro Concentration Account)

Union Bank of Switzerland, Zurich  
A/C JP Morgan Chase Bank London

[\*\*] (Swiss Francs Concentration Account)

JPMorgan Chase Bank London  
A/C JPMorgan Chase Bank London

[\*\*] (Sterling Concentration Account)

JPMorgan Chase Bank, N.A.

[\*\*] (PRF First Receipts Account)

NAMES AND CORPORATE REORGANIZATIONS AND MERGERS

On June 28, 1999, DepoTech Corporation changed its name to SkyPharma Inc.

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

**DATED 30<sup>th</sup> JUNE 2003**

**SKYEPHARMA INC**

**and**

**MUNDIPHARMA MEDICAL COMPANY**

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**SUPPLY AGREEMENT**

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**THIS AGREEMENT** is made on 30<sup>th</sup> June 2003

**BETWEEN**

- (1) **SKYEPHARMA INC** a company incorporated in California whose principal place of business is 10450 Sciences Center Drive, San Diego, California 92121 USA (“Skye”); and
- (2) **MUNDIPHARMA MEDICAL COMPANY** whose principal place of business is Mundipharma House, 14 Par-la-Ville Road, P.O. Box HM 2332, Hamilton HM JX, Bermuda (“Mundipharma”).

**Recitals**

- (A) Skye has entered into a distribution agreement with Mundipharma’s Affiliate, Mundipharma International Holdings Limited, under which Mundipharma International Holdings Limited will distribute the Product (as defined below) in certain territories.
- (B) Mundipharma International Holdings Limited has designated Mundipharma to purchase the Product from Skye

**Operative Provisions**

**1. Definitions**

- 1.1. In this Agreement the following words and expressions shall have the following meanings:

**“Affiliate”** means any company, corporation, firm, individual, trust or other entity which controls, is controlled by or is under common control with a party to this Agreement, and for the purpose of this definition the term “control” means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such firm, person, trust or

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company, whether through the ownership of voting securities, by contract or otherwise, or the ownership either directly or indirectly, including the ownership by trusts with substantially the same beneficial interests, of 50% or more of the voting securities (or, in relation to any country where ownership of more than 50% of the voting securities is prohibited by law, the maximum percentage permitted, provided such percentage is no less than 30%) of such company, corporation, firm, individual, trust or other entity;

**“Approved Facilities”**

means the approved facilities located at 10450 Science Center Dr, San Diego, CA 92121, USA (“Manufacturing Facility”) and Zone Industrielle Chesnes Ouest, 55, rue de Montmurier, BP. 45, F 38291 Saint Quentin-Fallavier, France (“Packaging Facility”) or as may be changed pursuant to this Agreement comprising buildings and Equipment where Skye shall Manufacture and Quality Control and store or have Manufactured, Quality Controlled and stored the Product;

**“Certificate of Analysis”**

means a document setting out the results of analysis of a batch of Product together with the Specification and methods by which, the tests were performed;

**“Certificate of Conformance”**

means a document stating and confirming that the Product has been Manufactured and Quality Controlled in accordance with, and in all respects complies with, cGMP and the Marketing Authorisation;

**“cGMP”**

means current Good Manufacturing Practice as set out in European Directive 91/356/EEC or its local equivalent as amended from time to time;

**“Confidential Information”**

means all confidential information, data and materials

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in whatever form disclosed by one party to the other or received in connection with this Agreement including, without limitation, the terms of this Agreement, but excluding information:

- (a) which, at the time of disclosure by one party to the other, is in the public domain;
- (b) which, after disclosure by one party to the other, becomes part of the public domain by publication, except by breach of any obligation of confidentiality;
- (c) which the receiving party can establish by competent proof was already in its possession at the time of its receipt and was not acquired directly or indirectly from the other party;
- (d) which, after disclosure by one party to the other, was developed independently of the information received; or
- (e) received from third parties who were lawfully entitled to disclose such information;

**“Delivery”**

means Skye making available at the Packaging Facility the Product for collection by Mundipharma or its nominated carrier,

**“Delivery Date”**

means that date upon which the Product is available for collection from the Packaging Facility;

**“Distribution Agreement”**

means the distribution agreement in relation to the Product between Skye and Mundipharma International Holdings Limited;

**“EMEA”**

means the European Medicines Evaluation Agency or any successors thereto;

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<b>“Equipment”</b>	means the equipment used in the Manufacture, assembly, Packaging, analysis and testing of the Product;
<b>“Finished Product”</b>	means Product presented in Vials, packaged and labelled for sale to end users;
<b>“Intellectual Property”</b>	means patents, trade marks, service marks, logos, trade names, rights in designs, copyright, utility models, rights in Know-How and other intellectual property rights, in each case whether registered or unregistered and including applications for registration, and all rights or forms of protection having equivalent or similar effect anywhere in the world;
<b>“Manufacture”</b>	means all methods, processes, data and documentation used by Skye or its Third Party Manufacturer in relation to the manufacture Packaging and Quality Control of the Product and “Manufacturer” shall be construed accordingly;
<b>“Manufacturing Approval”</b>	means all necessary or appropriate approvals, licences, permits, registrations and authorisations in respect of the Manufacture and Quality Control of the Product;
<b>“Manufacturing Licence”</b>	means any licence as granted by the Regulatory Authority to Skye or the Third Party Manufacturer in the applicable territory to Manufacture the Product;
<b>“Manufacturing Technology”</b>	means all methods, processes, designs, data, procedures and other information relating to the Manufacture of the Product, including without limitation final quality assurance procedures, manufacturing procedures, product and raw material specifications, formulation data and other technology related thereto;
<b>“Marketing Authorisation”</b>	means the approval by the EMEA numbered



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**“Net Sales”**

EU/1/01/187/001 permitting the commercial marketing of the Product in certain of the countries licensed to Mundipharma International Holdings Limited under the Distribution Agreement for the licensed indication;

means total gross sales of Finished Product invoiced by Mundipharma International Holdings limited, its Affiliates, sub-distributors and sub-licensees to Third Parties, less:

- (a) transport, freight and insurance costs;
- (b) sales and excise taxes and duties;
- (c) normal and customary trade, quantity and cash discounts and rebates;
- (d) amounts repaid, discounted or credited by reason of (i) retroactive price reductions; (ii) discounts; or (iii) rebates which are, in any case, imposed upon Mundipharma International Holdings limited, its Affiliates, sub-licensees or sub-distributors by any governmental or non-governmental body with the authority to impose such price reductions, discounts or rebates;
- (e) billing errors; and
- (f) amounts repaid or credited (other than in respect of outdated goods) for rejected, returned or recalled goods;

**“Packaging”**

means all operations in the assembly, labelling, packaging and Quality Control of the Finished Product ready for sale or supply to a third party in any country licensed under the Distribution Agreement and “Packaged” shall be construed accordingly;

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<b>“Product”</b>	means the Depofoam formulation of cytarabine (a sustained release formulation of cytarabine (ara-C) a pyrimidine analogue (L01BC01)) made to the Specification;
<b>“Product Price”</b>	means [**] Euros per Vial of Finished Product;
<b>“Qualified Person”</b>	means a Qualified Person as defined in European Directive 2001/83/EC;
<b>“Quality Control”</b>	means the sampling, laboratory testing and inspection at the Approved Facilities of: (a) Raw Materials, in-process materials and Finished Product; and (b) the Finished Product as necessary for Release;
<b>“Quarter”</b>	means any three month period ending on the last day of March, June, September or December in any calendar year;
<b>“Raw Materials”</b>	means all raw materials required to produce the Product;
<b>“Regulatory Authority”</b>	means any competent regulatory authority or other governmental body (for example, but not by way of limitation, the EMEA) responsible for granting Manufacturing Licences and Manufacturing Approvals in any country licensed under the Distribution Agreement;
<b>“Release”</b>	means release of the Finished Product from the Packaging Facility to Mundipharma for sale;
<b>“Specification”</b>	means the specification of the Product as set out in the Appendix;

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<b>“Technical Agreement”</b>	means the technical agreement between the parties relating to the Manufacture of the Product to be agreed in good faith;
<b>“Term”</b>	means the term of this Agreement as set out in Clause 9;
<b>“Third Party Manufacturer”</b>	means a third party appointed by Skye to Manufacture the Product on its behalf; and
<b>“Vial”</b>	means a [**] vial containing the Product.

- 1.2. In this Agreement, unless the context requires otherwise:
  - 1.2.1. the headings are included for convenience only and shall not affect the construction of this Agreement;
  - 1.2.2. references to “persons” includes individuals, bodies corporate (wherever incorporated), unincorporated associations and partnerships;
  - 1.2.3. words denoting the singular shall include the plural and vice versa;
  - 1.2.4. words denoting one gender shall include each gender and all genders; and
  - 1.2.5. any reference to an enactment or statutory provision is a reference to it as it may have been, or may from time to time be amended, modified, consolidated or re enacted.
- 1.3. The Appendix comprises part of and shall be construed in accordance with the terms of this Agreement. In the event of any inconsistency between the Appendix and the terms of this Agreement, the terms of this Agreement shall prevail.

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## 2. Appointment of Manufacturer

- 2.1. In consideration of the Manufacture of the Product by Skye or by its Third Party Manufacturer, Mundipharma shall obtain supplies of the Finished Product only from Skye during the period of [\*\*] ([\*\*]) years from the date of this Agreement. Thereafter, Mundipharma shall obtain at least [\*\*]% of its requirements for Finished Product from Skye.
- 2.2. Mundipharma shall pay to Skye for Product supplied ex works (as defined in Incoterms 2000) Lyon:
  - 2.2.1. the Product Price; and
  - 2.2.2. in the event that [\*\*]% of the Net Sales in a Quarter is greater than the number of Vials sold (less rejected, returned or recalled Vials other than those rejected, returned or recalled in connection with the expiry of the shelf life of the Vials) in that Quarter multiplied by the Product Price in that Quarter, Mundipharma shall pay the difference to Skye within [\*\*] days of the end of the Quarter.
- 2.3. From the date of this Agreement, Skye shall Manufacture or have Manufactured by a Third Party Manufacturer and sell to Mundipharma, and Mundipharma or its designee shall purchase such quantities of the Product as are ordered by Mundipharma, in accordance with the terms hereof. Skye shall give Mundipharma reasonable notice of any proposal to appoint a Third Party Manufacturer and shall satisfy all legal and regulatory requirements relating to any variation of the Marketing Authorisation or any other regulatory approval relating to such appointment at its own cost and shall procure reasonable inspection and audit rights for Mundipharma in respect of the Third Party Manufacturer's site.

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### **3. Forecasting and Ordering**

- 3.1. Except as set out below, Mundipharma shall purchase Finished Product from Skye in whole lots, currently estimated to be not more than [\*\*] ([\*\*]) Vials or such other quantities up to [\*\*] ([\*\*]) Vials as may be specified by Skye. For the period from the date of this Agreement to the first [\*\*] months following the first Commercial Delivery by Mundipharma, Mundipharma shall be permitted to order Finished Product in 1A lot quantities not more than [\*\*] every [\*\*] months. In the next [\*\*] months, Mundipharma shall be permitted to order V4 lot quantities not more than [\*\*] per [\*\*]. Thereafter, Mundipharma shall order Finished Product in full lot quantities. In each case lots may be divided for Packaging for individual countries.
- 3.2. Mundipharma shall provide Quarterly to Skye a twelve month rolling forecasts of units of Finished Product (by country) estimated to be required by Mundipharma on a quarterly basis throughout the Term. Skye agrees to Deliver Mundipharma's requirement for initial launch stocks as soon as practicable. Thereafter, not later than ninety (90) days prior to the required Delivery Date in the immediately succeeding Quarter ("Q1"), Mundipharma shall place a firm commitment for quantities of the Product, in writing, for Q1 with notification of the required Delivery Date and simultaneously indicate its estimated requirements for each of the following three (3) Quarters ("Q2", "Q3" and "Q4", respectively).
- 3.3. Skye shall confirm receipt of Mundipharma's order(s) for Q1 and the Delivery Date within [\*\*] working days.

### **4. Supply, Delivery, Title and Payment**

- 4.1. Skye shall use its reasonable endeavours to Deliver to Mundipharma or its designee each of Mundipharma's orders for the Product on

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Mundipharma's specified Delivery Date. If Skye becomes aware that for any reason it will be unable to Deliver ordered Product on the due Delivery Date, Skye shall promptly advise Mundipharma of that fact, the reason for the delay and (if appropriate) give its best estimate of the likely date of delayed Delivery. Skye shall use its reasonable endeavours to minimise the delay. If Skye is unable to arrange Delivery of the Product when ordered in accordance with this Agreement within [\*\*] days of the due Delivery Date on [\*\*] or more occasions, Skye shall use all reasonable endeavours to:

- 4.1.1. secure alternative supplies of the Product from an Affiliate or a third party for the same Product Price and on substantially the same terms as under this Agreement; and
  - 4.1.2. shall provide Mundipharma all reasonable co-operation and assistance in order to ensure continuity of supply, including, if Mundipharma so requests, transferring the Manufacturing Technology to Mundipharma's designee and obtaining all necessary variations to the Marketing Authorisation or other relevant regulatory approvals to enable the designee to Manufacture.
- 4.2. Within thirty (30) days from the date of receipt of each shipment of the Finished Product, and prior to releasing such Finished Product for sale to customers, Mundipharma or its designee shall conduct (i) a visual inspection of the Finished Product for defects or damages and (ii) an inspection of all associated quality assurance documents, including, without limitation, the Certificate of Analysis and Certificate of Conformance. Mundipharma shall have the right to return any Finished Product to the extent Mundipharma determines that the Finished Product fails to conform with the Specification following such inspection. All or any part of any shipment may be held for Skye's disposition and at Skye's expense if found to be not in conformity with the Specification.

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- 4.3. All Finished Product Delivered to Mundipharma or its designee hereunder shall be deemed to materially conform with the Specification unless Skye receives from Mundipharma or its designee written notice, not later than [\*\*] ([\*\*]) days after Mundipharma's receipt of a given shipment, specifying the shipment, purchase order number and the exact nature of the failure of such shipment to conform, along with reasonable evidence of such non-conformity (including a sample of the Finished Product from the shipment tested); provided, however, that Mundipharma's failure to advise Skye in a timely manner that a shipment of the Product does not conform to the Specification shall not prejudice Mundipharma's right to reject or revoke acceptance of the Product if the defect or other non-conforming condition which justifies, rejection or revocation could not reasonably have been detected by Mundipharma's or its designee's inspection undertaken pursuant to Section 4.2.
- 4.4. If at any time Mundipharma does not accept, or revokes its acceptance of, all or any part of a shipment of the Finished Product, then the parties shall have [\*\*] ([\*\*]) days from the date of Skye's receipt of Mundipharma's notification to resolve any dispute regarding whether all or any part of such shipment of the Finished Product conforms with the Specification. Disputes between the parties as to whether all or any part of a shipment rejected by Mundipharma conforms with the Specification not resolved in the [\*\*] ([\*\*]) day period shall be resolved by an independent cGMP testing laboratory or consultant acceptable to both Mundipharma and Skye (the "Laboratory"). The determination of the Laboratory with respect to all or part of any shipment of Finished Product shall be final and binding upon the parties. The fees and expenses of the Laboratory making such determination shall be paid by the party against which the determination is made. If the Laboratory

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determines that the Finished Product is defective, Skye shall replace it free of charge (on the assumption that Mundipharma or its designee has already paid or will pay for the defective Finished Product) within [\*\*] days and shall use its reasonable endeavours to supply the replacement Finished Product earlier.

- 4.5. Legal title in the Finished Product shall pass from Skye to Mundipharma upon payment of the Product Price by Mundipharma or upon sale of the Finished Product by Mundipharma, whichever is earlier. Risk in, and responsibility for, any consignment of the Finished Product shall pass from Skye to Mundipharma upon Delivery of the Finished Product to the carrier.
- 4.6. Skye shall render an invoice in respect of the Product Price for each consignment of the Finished Product upon Delivery to Mundipharma or its nominee. Mundipharma shall pay amounts properly due under the relevant invoice within [\*\*] ([\*\*]) days from the date of receipt of the invoice. Unless otherwise agreed between the parties, the Product Price shall be invoiced and paid in Euros.
- 4.7. On Delivery, Finished Product shall have a remaining shelf-life:
  - 4.7.1. of at least [\*\*] ([\*\*]) months for Finished Products ordered up to the end of the first [\*\*] ([\*\*]) months following first Commercial Delivery by Mundipharma; and
  - 4.7.2. for Finished Products ordered thereafter of at least [\*\*] ([\*\*]) months on Delivery.

## **5. Project Management**

- 5.1. Each party shall from time to time by notice to the other nominate a Project Manager to co-ordinate relationships between the parties pursuant to this Agreement. The Project Manager shall be the first point of contact between the parties in relation to the placement of Finished Product orders, confirmation of Delivery Dates, issues relating to Manufacturing and Manufacturing Approvals.



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The Project Managers shall form a project team comprising relevant staff from both Skye and Mundipharma for the co-ordination of the supply of the Finished Product to Mundipharma.

- 5.2. Skye and Mundipharma shall diligently carry out the tasks assigned to them hereunder, and as subsequently agreed in writing during the Term. Each party shall co-operate with the other in good faith particularly with respect to problems or contingencies that arise during the Term and shall perform its obligations in good faith and in a commercially reasonable, diligent and workmanlike manner.

**6. Manufacture and Warranties**

- 6.1. Manufacture, Release and supply of the Product upon the terms hereof shall be subject to the Technical Agreement in force from time to time.
- 6.2. Skye shall not be obliged to Manufacture, Release or supply the Product unless the Technical Agreement has been agreed by the parties.
- 6.3. Skye shall:
- 6.3.1. not, without Mundipharma's prior written consent, not to be unreasonably withheld or delayed, change or allow to be changed the Approved Facilities, its manufacturing environment or the processes for the Manufacture of the Finished Product;
  - 6.3.2. retain or have retained file samples of the Finished Product and Raw Materials and maintain analytical and production records in respect of the Manufacture of the Product in accordance with cGMP;

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- 6.3.3. immediately report to Mundipharma any incident at the Approved Facilities which may give rise to delay in the Delivery of the Finished Product, and inspections by Regulatory Authorities relating to the Product; and
  - 6.3.4. inform and keep Mundipharma informed of all hazards, regulations and guidance (statutory or otherwise) which Skye knows or believes to be associated with the use, handling, storage, labelling, transport, treatment or disposal of the Product and Skye shall ensure that Finished Product is safely packaged and labelled so as to prevent any health risk to persons, property or the environment, and properly marked with the appropriate internationally recognised danger symbols and that, if appropriate, prominent hazard warnings appear on all packages and documents.
- 6.4. In the event that a Regulatory Authority imposes any change affecting the Marketing Authorisation, the Manufacturing Approval or the Manufacture of the Finished Product, the parties shall discuss in good faith with a view to reaching agreement on the actions and timing required to effect such change, any regulatory approval required, and including any pricing implications.
- 6.5. Skye represents and warrants that as at the date hereof:
- 6.5.1. the Approved Facilities comply in all material respects with all relevant and applicable laws, regulations, rules and standards and have all relevant regulatory permits and approvals including valid Manufacturing licences and Manufacturing Approvals and shall not operate the Approved Facilities other than in compliance therewith; and
  - 6.5.2. the Approved Facilities currently have, and Skye shall use commercially reasonable endeavours to maintain, the necessary

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Equipment and appropriately qualified personnel required for the Manufacture of the Product in compliance with the Marketing Authorisation or other regulatory approval in any country licensed under the Distribution Agreement.

- 6.6. Skye represents and warrants that:
- 6.6.1. each batch of the Finished Product supplied to Mundipharma under this Agreement shall:
- (a) meet the Specification and be Manufactured and tested in accordance with the Technical Agreement;
  - (b) be Manufactured and tested in strict compliance with the Marketing Authorisation or other applicable regulatory approval;
  - (c) be Manufactured in compliance with all applicable national and local laws, rules and regulations, including but not limited to those promulgated by any relevant Regulatory Authority, and relevant professional standards, relevant laws, standards and codes of conduct;
  - (d) be Manufactured in compliance with cGMP; and
  - (e) be sold with good title free from any security, interest, lien or encumbrance.
- 6.6.2. it or its Third Party Manufacturer has all necessary right, title or interest in any Intellectual Property rights used in the Manufacture of the Finished Product
- 6.7. Skye makes no warranties, express or implied, other than those expressly made herein with respect to the Product. All other warranties, express or implied, including but not limited to the implied warranties of merchantability, satisfactory quality and fitness for a particular purpose are hereby disclaimed by Skye.

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**7. Approvals, Audits and Inspections**

- 7.1. Mundipharma (or its representatives) shall be entitled at any time, but in any event no more than once in any twelve month period during the Term, upon 30 days advance notice in writing, to access the Approved Facilities in the company of a representative of Skye to review and audit the Approved Facilities or the Manufacture of the Finished Product.
- 7.2. Mundipharma shall be entitled to prepare and send to Skye observations and enquiries as a result of the audit and Skye shall use reasonable endeavours to respond promptly, fully and accurately to any such observations and enquiries (or any reasonable enquiries made by Mundipharma from time to time).
- 7.3. Skye shall use all reasonable endeavours to:
  - 7.3.1. obtain and maintain in force all the Manufacturing Licences in relation to the Manufacture of the Product, as may be required in the country of Manufacture of the Product; and
  - 7.3.2. ensure that the Approved Facilities maintain Manufacturing Approval to Manufacture the Product in respect of all countries licensed under the Distribution Agreement.

**8. Compliance with Specification**

- 8.1. Skye shall submit to Mundipharma with each batch of Product Manufactured by Skye a Certificate of Analysis and a Certificate of Conformance each signed by Skye's Qualified Person setting out the results of the analysis of that batch of the Product and confirming that the batch is Manufactured in conformity with the Specification, Marketing Authorisation and cGMP.

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- 8.2. If any Product is determined pursuant to clauses 4.2 to 4.4 not to conform to the Specification, upon Mundipharma's request Skye shall replace it free of charge (on the assumption that Mundipharma or its designee has already paid or will pay for the defective Finished Product) within [\*\*] days and shall use its reasonable endeavours to supply the replacement Finished Product earlier.

**9. Term and Termination**

- 9.1. This Agreement shall come into effect on signature and, subject to earlier termination pursuant to this Clause 9, shall continue for as long as the Distribution Agreement continues in force.

**10. Events on Termination**

- 10.1. Upon termination pursuant to Section 9 above Mundipharma shall accept Delivery of any orders placed prior to the date of such termination provided that Mundipharma is still permitted and able to sell such Finished Product in accordance with the Distribution Agreement.
- 10.2. Upon expiry or termination for any reason the provisions of Clauses 6, 10 and 12 shall continue in full force and effect in accordance with their respective terms and Skye shall retain pharmaceutical records and samples in accordance with cGMP.

**11. Assignment and Sub-Contracting**

Mundipharma shall be entitled to sub-licence, assign, license, transfer or delegate in whole or in part its rights and obligations under this Agreement to an Affiliate (for so long as such Affiliate remains an Affiliate). Neither party shall, nor shall it purport to, assign, transfer, sub-contract or charge any of its rights or obligations under this Agreement to a third party (other than an Affiliate) without the prior written consent of the other party.

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**12. Confidentiality**

- 12.1. Skye and Mundipharma undertake to each other to keep confidential, and to procure that their respective Affiliates, employees, directors, officers, contractors, lawyers and accountants (including those of their Affiliates) keep confidential, Confidential Information disclosed to it by or belonging to the other party, until it ceases to be Confidential Information.
- 12.2. Any Confidential Information received from the other party shall not be disclosed to any third party or used for any purpose other than as provided or specifically envisaged by this Agreement, unless it ceases to be Confidential Information.
- 12.3. The confidentiality and non-use obligations contained in this Agreement shall continue for the duration of this Agreement and for a period of [\*\*] years after termination for any reason of this Agreement.

**13. Force Majeure**

- 13.1. Neither Party shall be entitled to terminate this Agreement or shall be liable to the other under this Agreement for loss or damages attributable to any Force Majeure, provided the party affected shall give prompt notice thereof to the other party. Subject to Clause 13.2, the party giving such notice shall be excused from all affected obligations hereunder for so long as it continues to be affected by Force Majeure.
- 13.2. If such Force Majeure continues unabated for a period of at least [\*\*] days, the parties will meet to discuss in good faith what actions to take or what modifications should be made to this Agreement as a consequence of such Force Majeure in order to alleviate its consequences on the affected party.

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**14. Notices**

- 14.1. Any notice or other document given under this Agreement shall be in writing in the English language and shall be given by hand or sent by prepaid airmail, by fax transmission or e-mail to the address of the receiving Party as set out in Clauses 14.3 below unless a different address or fax number has been notified to the other in writing for this purpose.
- 14.2. Each such notice or document shall:
- 14.2.1. if sent by hand, be deemed to have been given when delivered at the relevant address;
  - 14.2.2. if sent by prepaid airmail, be deemed to have been given 7 days after posting; or
  - 14.2.3. if sent by fax transmission be deemed to have been given when transmitted provided that a confirmatory copy of such facsimile transmission shall have been sent by prepaid airmail within 24 hours of such transmission.
- 14.3. The address for services of notices and other documents on the parties shall be:

**To Mundipharma**

**Address:** Mundipharma House,  
14 Par-la-Ville Road,  
P.O. Box HM 2332,  
Hamilton, HM JX,  
Bermuda

**Fax:** 001 809 292 1472

Attention: General Manager

**Copy To: [\*\*]**

**Fax: [\*\*]**

**To Skye**

**Address:** 10450 Sciences Center  
Drive, San Diego,  
California 92121 USA

**Fax:** 001 858 623 0376

Attention: President

**Copy To:** Skye Legal Department,  
105 Piccadilly, London  
W1V9FN

**Fax:** +44 20 74913338

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**15. General Provisions**

- 15.1. Nothing in this Agreement is deemed to constitute a partnership between the parties nor constitute either party the agent of the other party for any purpose.
- 15.2. Each of the parties shall do execute and perform and shall procure to be done executed and performed all such further acts, deeds, documents and things as the other party may reasonably require from time to time to give full effect to the terms of this Agreement.
- 15.3. In performing any respective obligations under this agreement, each party shall comply with the Data Protection Act 1998, any notification requirements under the Data Protection Act 1998 and the Data Protection Principles specified in that Act, and any equivalent legislation in the Territory.
- 15.4. Each party shall pay its own costs, charges and expenses incurred in connection with the negotiation, preparation and completion of this Agreement.
- 15.5. This Agreement and the Distribution Agreement set out the entire agreement and understanding between the parties in respect of the subject matter of this Agreement. This Agreement supersedes any heads of agreement which shall cease to have any further force or effect. It is agreed that:
  - 15.5.1. no party has entered into this Agreement in reliance upon any representation, warranty or undertaking of the other party which is not expressly set out in this Agreement;



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- 15.5.2. no party shall have any remedy in respect of misrepresentation or untrue statement made by the other party or for any breach of warranty which is not contained in this Agreement;
- 15.5.3. this Clause shall not exclude any liability for, or remedy in respect of, fraudulent misrepresentation.
- 15.6. No variation of this Agreement shall be valid unless it is in writing and signed by or on behalf of both parties.
- 15.7. Unless expressly agreed, no variation shall constitute a general waiver of any provisions of this Agreement, nor shall it affect any rights, obligations or liabilities under or pursuant to this Agreement which have already accrued up to the date of variation, and the rights and obligations of the parties under or pursuant to this Agreement shall remain in full force and effect, except and only to the extent that they are so varied.
- 15.8. If and to the extent that any provision of this Agreement is held to be illegal, void or unenforceable, such provision shall be given no effect and shall be deemed not to be included in this Agreement but without invalidating any of the remaining provisions of this Agreement. In such event the parties shall negotiate with a view to finding the nearest permissible provision to that found to be illegal, void or unenforceable.
- 15.9. No failure or delay by either party in exercising any right or remedy provided by law under or pursuant to this Agreement shall impair such right or remedy or operate or be construed as a waiver or variation of it or preclude its exercise at any subsequent time and no single or partial exercise of any such right or remedy shall preclude any other or further exercise of it or the exercise of any other right or remedy.
- 15.10. The rights and remedies of each of the parties under or pursuant to this Agreement are cumulative, may be exercised as often as such party considers appropriate and are in addition to its rights and remedies under general law.

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- 15.11. This Agreement may be executed in any number of counterparts and by the parties on separate counterparts, each of which is an original but all of which together constitute one and the same instrument
  - 15.12. A person who is not a party to this Agreement, other than an Affiliate, shall have no right under the Contracts (Rights of Third Parties) Act 1999 to enforce any of its terms.
  - 15.13. This Agreement and the relationship between the parties shall be governed by, and interpreted in accordance with, English law.
  - 15.14. Each of the parties agree that the courts of England are to have exclusive jurisdiction to settle any dispute (including claims for set off and counterclaims) which may arise in connection with the creation, validity, effect, interpretation or performance of, or the legal relationships established by, this Agreement or otherwise arising in connection with this Agreement and for such purposes irrevocably submit to the jurisdiction of the English courts.

**AS WITNESS** the hands of the parties or their duly authorised representatives the day and the year first above written

SIGNED for and by behalf of  
**SKYEPHARMA INC**

) /s/ Michael R. D Ashton  
\_\_\_\_\_  
)  
)

**MICHAEL R. D ASHTON**

**Print Name**

SIGNED for and by behalf of  
**MUNDIPHARMA MEDICAL  
COMPANY**

) /s/ James M. Keyes  
\_\_\_\_\_  
)  
)

**JAMES M. KEYES**

**Print Name**

APPENDIX – THE SPECIFICATION

Product Release Specifications (Page 1 of 2)

Test	Release Specification at Time of Manufacture	Release Specification for Commercial Distribution	Test Method (005-) / Validation Report (024-)
Appearance	[**]	[**]	[**]
Identity by HPLC	[**]	[**]	[**]
Identity by UV	[**]	[**]	[**]
Total Cytarabine	[**]	[**]	[**]
% Free Cytarabine	[**]	[**]	[**]
Content Uniformity	[**]	[**]	[**]
pH	[**]	[**]	[**]
Particle Size	[**]	[**]	[**]
Uracil Arabinoside	[**]	[**]	[**]
Cytosine	[**]	[**]	[**]
Cytidine	[**]	[**]	[**]
Uridine	[**]	[**]	[**]
Uracil	[**]	[**]	[**]
Total Cytarabine Related Impurities (Excluding Uracil Arabinoside)	[**]	[**]	[**]
Cholesterol	[**]	[**]	[**]
Triolein	[**]	[**]	[**]
DPPG*	[**]	[**]	[**]
DOPC**	[**]	[**]	[**]
Lyso DOPC**	[**]	[**]	[**]
Sodium Chlorides	[**]	[**]	[**]

\* DPPG -1,2-Dipalmitoyl-*sn*-glycero-3-phospho-*rac*-(1 -glycerol)

\*\* DOPC - 1,2-Dioleoyl-*sn*-glycero-3-phosphocholine

LT Less than

MT More than

NMT Not more than

**Product Release Specifications (Page 2 of 2)**

Test	Release Specification at Time of Manufacture	Release Specification for Commercial Distribution	Test Method (005-) / Validation Report (024-)
Dextrose	[**]		[**]
L-Lysine	[**]		[**]
Residual Chloroform	[**]		[**]
Osmolality	[**]	[**]	[**]
Fill Volume	[**]		[**]
Particulates (foreign)	[**]	[**]	[**]
<i>In Vitro</i> Release Assay:			[**]
day-0			
day-1	[**]	[**]	
day-2	[**]	[**]	
day-3	[**]	[**]	
day-4	[**]	[**]	
Sterility	[**]		[**]
Bacterial Endotoxins	[**]		[**]
* DPPG -1,2-Dipalmitoyl- <i>sn</i> -glycero-3-phospho- <i>rac</i> -(1 -glycerol)			
** DOPC - 1,2-Dioleoyl- <i>sn</i> -glycero-3-phosphocholine			
LT Less than			
MT More than			
NMT Not more than			

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

**DATED 30<sup>th</sup> JUNE 2003**

**SKYEPHARMA INC**

**and**

**MUNDIPHARMA INTERNATIONAL HOLDINGS LIMITED**

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**DISTRIBUTION AGREEMENT**

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THIS AGREEMENT is made on 30<sup>th</sup> June 2003

BETWEEN

- (1) SKYEPHARMA INC a company incorporated in California whose principal place of business is 10450 Sciences Center Drive, San Diego, California 92121 USA (“Skye”); and
- (2) MUNDIPHARMA INTERNATIONAL HOLDINGS LIMITED a company incorporated in Bermuda whose principal place of business is Mundipharma House, 14 Par-la-Ville Road, P.O. Box HM 2332, Hamilton HM JX, Bermuda (“Mundipharma”).

**Recitals**

- (A) Skye is the owner of certain Skye Technology (as defined below) and possesses expertise relating to the Product (as defined below), which may be useful in the treatment of cancer.
- (B) Mundipharma has, among other things, specialist knowledge and expertise in relation to the marketing and sale of pharmaceutical products.
- (C) Skye desires to grant and Mundipharma desires to acquire the exclusive right to market the Finished Product (as defined below) in the Territory (as defined below).

**Operative Provisions**

**1 Definitions**

- 1.1 In this Agreement the following words and expressions have the following meanings:

**“Affiliate”** means any company, corporation, firm, individual, trust or other entity which controls, is controlled by or is under common control with a party to this Agreement, and for the purpose of this definition the term “control”

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means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such firm, person, trust or company, whether through the ownership of voting securities, by contract or otherwise, or the ownership either directly or indirectly, including the ownership by trusts with substantially the same beneficial interests, of 50% or more of the voting securities (or, in relation to any country where ownership of more than 50% of the voting securities is prohibited by law, the maximum percentage permitted, provided such percentage is no less than 30%) of such company, corporation, firm, individual, trust or other entity;

**“Applicable Laws”**

means all laws, rules, regulations and codes of practice regarding the representation, promotion and marketing of the Finished Products in any jurisdiction in the Territory;

**“Commercial Delivery”**

means the date of the first commercial sale to a Third Party customer for commercial use or onsale of Finished Product in any country within the Territory following Regulatory Approval;

**“Competing Product”**

means a product (other than the Finished Product) available in a country in the Territory in which the Finished Product is sold by Mundipharma or its distributors which is indicated for use in the Field;

**“Confidential Information”**

means all confidential information, data and materials in whatever form disclosed by one party to the other or received in connection with this Agreement including, without limitation, the terms of this Agreement, Mundipharma’s marketing plans and Mundipharma’s sales forecasts, but excluding information:

- (a) which, at the time of disclosure by one party to the other, is in the public domain;

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- (b) which, after disclosure by one party to the other, becomes part of the public domain by publication, except by breach of any obligation of confidentiality;
  - (c) which the receiving party can establish by competent proof was already in its possession at the time of its receipt and was not acquired directly or indirectly from the other party;
  - (d) which, after disclosure by one party to the other, was developed independently of the information received; or
  - (e) received from Third Parties who were lawfully entitled to disclose such information;

**“EEA”**

means the European Economic Area as at the Effective Date, together with any other countries joining the European Economic Area thereafter as from the date of their joining;

**“Effective Date”**

means the date of this Agreement;

**“EMA”**

means the European Medicines Evaluation Agency or any successors thereto;

**“FDA”**

means The Food and Drug Administration of the United States of America or any successor thereto;

**“Field”**

means the intrathecal treatment of malignant disease (including without limitation lymphomatous meningitis and, if an approved indication, the treatment of neoplastic meningitis);



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<b>“Finished Product”</b>	means Product presented in Vials, packaged and labelled for sale to end users;
<b>“Force Majeure”</b>	means in relation to either party, any cause affecting the performance of this Agreement or the Supply Agreement arising from or attributable to any acts, events, non happenings, omissions or accidents beyond the reasonable control of the party to perform and in particular but without limiting the generality thereof shall include strikes, lock outs, industrial action, civil commotion, riot, invasion, war, threat of or preparation for war, terrorist activity, fire, explosion, storm, flood, earthquake, subsidence, epidemic or other natural physical disaster, impossibility of the use of railways, shipping, aircraft, motor transport, or other means of public or private transport, failure or suspension of utilities, and political interference with the normal operation of either party;
<b>“Improvements”</b>	means any discovery, development, improvement, Know-How or Patent relating to the Product and/or the Field generated, conceived, reduced to practice or otherwise created during the Term by Skye (or any Affiliate or licensee of Skye);
<b>“Intellectual Property”</b>	means patents, trade marks, service marks, logos, trade names, rights in designs, copyright, utility models, rights in Know-How and other intellectual property rights, in each case whether registered or unregistered and including applications for registration, and all rights or forms of protection having equivalent or similar effect anywhere in the world;
<b>“Know-How”</b>	means all information, procedures, instructions, techniques, data, technical information, knowledge and experience (including, without limitation, toxicological,

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	pharmaceutical, clinical, non-clinical and medical data, health registration data and marketing data), designs, dossiers (including, without limitation, manufacturing assay and quality control dossiers) manufacturing formulae, processing specifications, sales and marketing materials and technology relating to or concerned with the Product and/or the Finished Product whether in written, electronic or other form including without limitation the Product Data and the Manufacturing Technology;
<b>“Manufacturing Technology”</b>	means all methods, processes, designs, data, procedures and other information relating to the manufacture of the Product, including without limitation final quality assurance procedures, manufacturing procedures, product and raw material specifications, formulation data and other technology related thereto;
<b>“Marketing Authorisation”</b>	means the approval by the EMEA numbered EU/1/01/187/001 permitting the commercial marketing of the Product in the countries of the Territory listed in Part A of Schedule VII for the intrathecal treatment of lymphomatous meningitis;
<b>“Marketing Plan”</b>	means the plan for the marketing, distribution and sale of the Finished Product in the Territory submitted to the Committee in accordance with Clause 4;
<b>“Milestone Event”</b>	means the event identified in Schedule III which triggers a one-off Milestone Payment;
<b>“Milestone Payment”</b>	means each one-off payment by Mundipharma to Skye identified in Schedule III which is triggered by a Milestone Event;
<b>“Neoplastic Indication”</b>	means the use of the Product for the treatment of neoplastic meningitis;

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**“Net Sales”**

means total gross sales of Finished Product invoiced by Mundipharma, its Affiliates, sub-distributors and sub-licensees to Third Parties, less:

- (a) transport, freight and insurance costs;
- (b) sales and excise taxes and duties;
- (c) normal and customary trade, quantity and cash discounts and rebates;
- (d) amounts repaid, discounted or credited by reason of (i) retroactive price reductions; (ii) discounts; or (iii) rebates which are, in any case, imposed upon Mundipharma, its Affiliates, sub-licensees or sub-distributors by any governmental or non-governmental body with the authority to impose such price reductions, discounts or rebates;
- (e) billing errors; and
- (f) amounts repaid or credited (other than in respect of outdated goods) for rejected, returned or recalled goods;

**“Patents”**

means any patent and patent application (including provisional and non-provisional applications) that may be issued or issue in any country, including all additions, divisions, confirmations, continuations-in-part, substitutions, re-issues, re-examinations, extensions, registrations, patent terms extensions, supplementary protection certificates and renewals of any of the above;

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<b>“Phase IV Trial”</b>	means the phase IV clinical trial entitled Skye 0101-010;
<b>“Pricing Approval”</b>	means grant of all necessary pricing and reimbursement approvals by a regulatory, governmental or non-governmental authority in any country of the Territory;
<b>“Product”</b>	means the Depofoam formulation of cytarabine (a sustained release formulation of cytarabine (ara-C) a pyrimidine analogue (L01BC01));
<b>“Product Data”</b>	means all data, information or results generated in the performance of any clinical studies, non-clinical studies (including pharmacological and toxicological studies) or chemistry and analytical studies in respect of the Product conducted by or on behalf of either party whether before or after the Effective Date;
<b>“Quarter”</b>	means a three month period ending on the last day of March, June, September or December in any Year;
<b>“Regulatory Approval”</b>	means the grant of all necessary regulatory and governmental approvals by a regulatory authority or other governmental body required to sell the Finished Product in any country of the Territory including, without limitation, the Marketing Authorisation but excluding Pricing Approval;
<b>“Regulatory Authority”</b>	means any competent regulatory authority or other governmental body (for example, but not by way of limitation, the EMEA) responsible for granting Regulatory Approval in the Territory;
<b>“Skye IP”</b>	means all Intellectual Property owned by or in the possession or control of Skye at any time during the Term relating to the Product or Finished Product (including any Improvements);

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<b>“Skye Patents”</b>	means those Patents set out in Schedule I and such other Patents as come into existence during the Term and relate to the Product or Finished Product (including any Improvements);
<b>“Skye Technology”</b>	means the Skye Patents and Skye IP;
<b>“Supply Agreement”</b>	means the agreement between Skye and Mundipharma Medical Company for the manufacture and supply of the Finished Product by Skye;
<b>“Term”</b>	means the term of this Agreement as set out in Clause 15;
<b>“Territory”</b>	means each of the countries and territories listed or referred to in Schedule VII;
<b>“Third Party”</b>	means any company, corporation, firm, individual or other entity but excluding a party to this Agreement or an Affiliate;
<b>“Trade Marks”</b>	means those trade marks registered or applied for set out in Schedule II and such other trade marks as are agreed between the parties from time to time;
<b>“Vial”</b>	means a [**] vial containing the Product; and
<b>“Year”</b>	means a calendar year.

1.2 In this Agreement, unless the context requires otherwise:

- 1.2.1 the headings are included for convenience only and shall not affect the construction of this Agreement;
- 1.2.2 references to “persons” includes individuals, bodies corporate (wherever incorporated), unincorporated associations and partnerships;

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- 1.2.3 words denoting the singular shall include the plural and vice versa;
  - 1.2.4 words denoting one gender shall include each gender and all genders; and
  - 1.2.5 any reference to an enactment or statutory provision is a reference to it as it may have been, or may from time to time be amended, modified, consolidated or re enacted.
- 1.3 The Schedules comprise part of and shall be construed in accordance with the terms of this Agreement. In the event of any inconsistency between the Schedules and the terms of this Agreement, the terms of this Agreement shall prevail.

## **2 Grant of Rights**

- 2.1 Subject to the terms of this Agreement, Skye hereby exclusively appoints Mundipharma in the Territory to use, import, warehouse, market, distribute, sell and dispose of the Finished Product in the Field.
- 2.2 Skye hereby grants Mundipharma an exclusive licence to use the Trade Marks in relation to the use, import, warehousing, marketing, distribution, sale and disposal of Finished Product in the Field in the Territory for the Term of this Agreement.
- 2.3 Skye hereby grants Mundipharma an exclusive license to use all other Skye Technology in relation to the use, import, warehousing, marketing, distribution, sale and disposal of Finished Product in the Field in the Territory for the Term of this Agreement.
- 2.4 The term “exclusive” means to the exclusion of all others, including Skye and its Affiliates, except to the extent necessary to enable Skye to perform its specific obligations under this Agreement.

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- 2.5 Skye shall not in the Territory during the Term:
- 2.5.1 grant any Third Party the right to use, import, warehouse, market, distribute, sell or dispose of the Product and/or Finished Product; or
  - 2.5.2 either itself or through or with any Affiliate or Third Party actively conduct or participate in any use, importation, warehousing, marketing, distribution, sale or disposal of the Product and/or Finished Product, except as specifically permitted by this Agreement.
- 2.6 During the Term, Mundipharma has an exclusive right to use, import, warehouse, market, distribute, sell and dispose of Improvements in the Product and/or the Field in the Territory at no additional cost to Mundipharma. Skye shall promptly disclose all Improvements to Mundipharma.
- 2.7 Mundipharma may describe itself as an “Authorised Distributor” of Skye for the Finished Product in the Territory but shall not hold itself out as Skye’s agent for sales of the Finished Product or otherwise as being entitled to bind Skye in any way.
- 2.8 Mundipharma shall be entitled to conduct clinical research in respect of the Product. The results of any such research shall be Mundipharma’s property.
- 2.9 Mundipharma shall be entitled to use Skye’s Confidential Information in any submission to any Regulatory Authority regarding pricing or reimbursement and in any submission to the National Institute of Clinical Excellence in the UK (or any equivalent body elsewhere in the Territory), in each case insofar as it may be relevant
- 2.10 Mundipharma may sell the Finished Products through its Affiliates. Mundipharma may also sell the Finished Products through Third Party sales agents or sub-distributors upon obtaining the express prior written

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permission of Skye. Notwithstanding any such permission that may be granted by Skye, Mundipharma shall be and remain responsible in all respects for the acts and omissions of any Affiliate, sales agent or sub-distributor and those acts and omissions shall for the purpose of this Agreement be deemed the acts and omissions of Mundipharma. Mundipharma or its Affiliate shall consolidate all orders from any Affiliates, sales agents or sub-distributors.

2.11 In relation to Italy, the parties agree as follows:

- 2.11.1 Italy is currently excluded from the Territory as it is subject to an option held by a Third Party (“Option Holder”). Skye shall immediately notify Mundipharma in writing if that option is not exercised, is waived or lapses. Upon receipt of such notice by Mundipharma, Italy shall be automatically included in the Territory under this Agreement. If such notice is received:
- (i) before [\*\*], Mundipharma shall pay [\*\*] Euros (€[\*\*]) to Skye within thirty (30) days of receipt of the notice;
  - (ii) after [\*\*] but before [\*\*] Mundipharma shall pay [\*\*] Euros (€[\*\*]) to Skye within thirty (30) days of receipt of the notice; and
  - (iii) if such notification is given on or after [\*\*] [\*\*] shall be due by Mundipharma to Skye in respect thereof.
- 2.11.2 Skye agrees not to offer the rights to Italy which would otherwise be licensed to Mundipharma under this Agreement to the Option Holder on terms which are in any material respect less favourable to Skye than the terms of this Agreement and



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the Supply Agreement, nor will Skye offer such rights to any other Third Party. For the avoidance of doubt, an offer shall be assessed on the basis of the Net Present Value (discounted at [\*\*]%) of the financial terms relating to the rights to be granted to the Product.

2.11.3 Skye shall indemnify and hold harmless Mundipharma and its Affiliates against any claim by the Option Holder arising out of or in connection with the matters covered by this Clause 2.11.1 and 2.11.2.

2.12 Skye agrees to enter into good faith discussions with Mundipharma regarding the possibility of licensing the Product to Mundipharma in other countries of the world outside the Territory (other than South America and Australasia in which outstanding offers currently exist) which are available for licensing to Mundipharma.

### **3 Obligations**

3.1 The Parties acknowledge that Skye is currently conducting the Phase IV Trial required by the FDA to maintain the lymphomatous meningitis indication. Skye shall, at its sole expense, use commercially reasonable efforts to:

- (a) conduct the Phase IV Trial, as may be amended by Skye from time to time in consultation with the FDA and EMEA, as may be applicable;
- (b) promptly prepare and submit any applications for Regulatory Approval with respect to the Neoplastic Indication with the EMEA provided the Phase IV Trial produces statistically significant results sufficient to support such a filing and is not terminated on safety grounds, and thereafter
- (c) maintain any such Regulatory Approvals.

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For the avoidance of doubt, Skye shall be under no other or further obligation to Mundipharma in relation to obtaining Regulatory Approval of the Product in any part of the Territory for the Neoplastic Indication.

3.2 Skye shall:

- 3.2.1 use commercially reasonable efforts to maintain in full force and effect any Regulatory Approvals for the Product granted or issued to it, and to comply with all conditions attaching to such Regulatory Approvals;
- 3.2.2 manufacture and supply, or procure the manufacture and supply of, the Product in accordance with the Supply Agreement;
- 3.2.3 promptly provide Mundipharma with all information in its possession or otherwise coming to its attention relating to the occurrence of a serious adverse event or an adverse event (in any jurisdiction throughout the world) in connection with the Product;
- 3.2.4 promptly provide Mundipharma with all Product Data and other Know How in its possession or which is or becomes available to it during the Term which it is entitled to disclose which is relevant or useful to Mundipharma in performing its obligations under this Agreement; and
- 3.2.5 not make any voluntary change to any Regulatory Approval without Mundipharma's prior written consent, not to be unreasonably withheld or delayed.
- 3.2.6 promptly provide Mundipharma with proofs of packaging and package inserts for the Finished Product and, subject to obtaining Mundipharma's comments and receipt of Mundipharma's artwork designs, promptly apply for Regulatory Approval of the same.

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3.3 The appointment of Mundipharma, the acceptance of forecasts and orders for the Finished Product, the supply of the Finished Product to Mundipharma and the resale and distribution thereof by Mundipharma shall at all times be conditional on the Regulatory Approval for the Product being in force in the Territory.

In addition, Mundipharma's obligations in respect of Clauses 3.4, 3.5 and 5.3 in any country in the Territory in any Marketing Year shall be subject to timely supply of Finished Product by Skye pursuant to the Supply Agreement and to Skye complying with its other material obligations under this Agreement in a timely way. In respect of any Marketing Year in any country of the Territory in which the exercise of any Third Party Intellectual Property rights materially prevents Mundipharma, its Affiliates, sub-licensees or sub-distributors from using, importing, warehousing, distributing, marketing, selling or disposing of Finished Product in that country of the Territory the parties shall agree in good faith a proportionate reduction in the minimum Net Sales in Clause 5.3 and, where relevant, an appropriate amendment to Mundipharma's obligations under Clauses 3.4 and 3.5. If the parties cannot agree, an expert shall be appointed to resolve the issue pursuant to the dispute resolution procedure in Schedule VIII

3.4 Mundipharma shall:

3.4.1 use its commercially reasonable efforts to diligently obtain pricing and reimbursement approval at a level satisfactory to Mundipharma as soon as reasonably practicable after the Effective Date in each country of the Territory;

3.4.2 launch and achieve Commercial Delivery of the Product in each country of the Territory no later than [\*\*] ([\*\*]) months following pricing and reimbursement approval in that country at a level satisfactory to Mundipharma;

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- 3.4.3 during the term of this Agreement, promote, market, sell and distribute the Finished Product to customers within the Territory and use its commercially reasonable efforts to satisfy the demand for the Finished Product throughout the Territory and to attempt to increase the demand for such Finished Product by, among other things, servicing customer accounts with reasonable frequency. Mundipharma shall be solely responsible for, and shall bear all costs associated with, all marketing activities related to the Finished Product in the Territory;
  - 3.4.4 maintain adequate warehouse facilities and employ or procure a sufficient number of experienced, trained and qualified sales and marketing personnel to promote the sale of the Finished Product in the Territory and perform, or procure the performance of the activities set forth in the Marketing Plan;
  - 3.4.5 maintain a reasonable inventory of Finished Product taking into account the shelf life of the Product to reasonably fulfil the requirements of its customers in the Territory;
  - 3.4.6 maintain adequate records concerning the sale of the Finished Product as required by any applicable Regulatory Authority in the Territory;
  - 3.4.7 submit advertising literature proposed to be used in connection with the sale of the Finished Product in the Territory to Skye at least [\*\*] ([\*\*]) business days in advance of its intended use of same to enable Skye to provide Mundipharma with comments within said [\*\*] ([\*\*]) business day period. Mundipharma shall ensure that all such advertising literature complies with all relevant codes of practice, regulations and laws and shall indemnify Skye in respect of any breach;

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- 3.4.8 promptly provide Skye with all information in its possession or otherwise coming to its attention relating to the occurrence of a serious adverse event or an adverse event (in any jurisdiction throughout the world) in connection with the Product, and promptly forward to Skye information concerning any and all charges, complaints or claims reportable to any Regulatory Authority relating to the Product that may come to Mundipharma's attention, and otherwise comply in all respects with the adverse drug event reporting and recall procedures set out or referred to in Schedule IV from time to time;
  - 3.4.9 obtain and maintain all necessary licenses, permits, records and authorizations required by law in respect of the marketing, distribution and sale of the Finished Product in the Territory and observe and comply with all Applicable Laws; and
  - 3.4.10 following receipt of Skye's proofs of packaging and package inserts for the Finished Product pursuant to Clause 3.2.6, promptly provide its comments and artwork designs.
- 3.5 In connection with the promotion and marketing of the Finished Product Mundipharma shall:
- 3.5.1 observe and comply with such storage, stock control and operational practices and procedures as may be legally required in the Territory and as reasonably specified in writing by Skye from time to time;
  - 3.5.2 market the Product throughout the Territory under the Trade Marks and all marketing materials for the Product shall display the Trade Marks. In addition, all packaging shall state that "Depocyte® is distributed by Mundipharma under an exclusive licence from SkyePharma Inc."

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- 3.6 Mundipharma shall not actively market distribute and/or sell the Finished Product outside the Territory but may respond to passive sales enquiries from within the EEA.
- 3.7 For [\*\*] ([\*\*]) years from the first Commercial Delivery in the EEA or during the Term, whichever is shorter, Mundipharma shall not market, distribute or sell a Competing Product in the Territory. Thereafter during the Term, Mundipharma shall purchase no less than [\*\*] per cent ([\*\*]%) of its total requirement (being the sum of Finished Product and Competing Product) from Skye.
- 3.8 If Mundipharma receives a request from a customer located both outside the EEA and outside the Territory for supply of the Product and/or Finished Product, Mundipharma shall forward such request to Skye.
- 3.9 Nothing in this Agreement shall entitle Mundipharma to any right or remedy against Skye if the Product is sold in the Territory by any person outside the Territory other than by Skye or with Skye's consent.
- 3.10 To the extent permissible by applicable law, Skye shall use commercially reasonable efforts to ensure that in the event that Skye grants exclusive marketing and distribution rights for the Finished Product to a Third Party outside the Territory, provisions having equivalent effect to those contained in Clauses 3.6 to 3.8 inclusive shall be included mutatis mutandis in any agreement for such grant of rights to such Third Party.

#### **4 Committee**

- 4.1 The Parties shall establish a committee ("Committee") consisting of 4 individuals ("Committee Members"); 2 of whom shall be nominated by

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Skye; and 2 of whom shall be nominated by Mundipharma. The Committee Members may be replaced by notice to the other Party and shall be appropriately qualified and experienced in order to make a meaningful contribution to Committee meetings.

- 4.2 The purpose of the Committee is to provide a forum for the Parties to share information and knowledge on the on-going development and marketing of the Product including, but not limited to, monitoring progress on clinical studies, reviewing clinical trial programmes, considering proposed marketing and promotional plans, reviewing market conditions and discussing any regulatory, technical, quality assurance or safety issues in relation to the Product. The Committee shall conduct its discussions in good faith with a view to operating to the mutual benefit of the Parties and in furtherance of the successful development and marketing of the Product.
- 4.3 The Committee shall meet as often as the Committee Members may determine, but in any event not less than 2 times per Year. The Committee may invite individuals with special skills to attend such meetings where considered to be relevant and appropriate. The quorum for Committee meetings shall be 2 Committee Members, comprising 1 Committee Member from each Party.
- 4.4 Mundipharma shall on or before 15 October of each Year thereafter provide the Committee with its Marketing Plan for the coming Year. Each Marketing Plan shall include, without limitation, Net Sales targets and projections with respect to sales force staffing levels, marketing research, physician education, marketing expenditure and advertising.

## **5 Product Supply**

- 5.1 In consideration of the manufacture, packaging and supply of the Finished Product, Mundipharma agrees that the supply price under the

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Supply Agreement shall be [\*\*] Euros (€[\*\*]) per Vial supplied to Mundipharma in any country of the Territory during the Term, subject to adjustment in accordance with the other terms of the Supply Agreement

- 5.2 Within 30 days of the end of each Quarter during the Term of this Agreement, Mundipharma shall send to Skye a statement setting out in respect of each country in the Territory in which Product is sold, details of Product sold during the previous Quarter itemised by presentation form, quantity, total gross receipts, itemised deductions which are applied to achieve the Net Sales figure and Net Sales of Product. The statement shall (where appropriate) show:
- 5.2.1 the total Net Sales for each country expressed both in local currency and in Euros and the conversion rate used; and
- 5.2.2 the total number of Vials sold in each country (less rejected, returned or recalled Vials other than those rejected, returned or recalled in connection with the expiry of the shelf life of the Vials).
- 5.3 Notwithstanding anything contained herein to the contrary, Mundipharma agrees that, by the end of the first period of 365 days following first Commercial Delivery of the Product (such period, and each subsequent 365 day period, being a “Marketing Year”), Mundipharma, together with its Affiliates, sub-licensees and sub-distributors, if any, shall achieve minimum Net Sales of Product in the Territory which, in the aggregate, shall not be less than [\*\*] Euros (€[\*\*]). In the next four Marketing Years, Mundipharma, together with its Affiliates, sub-licensees and sub-distributors, if any, shall achieve minimum aggregate Net Sales of Product in the Territory for each such Marketing Year of not less than the applicable amounts set out in Schedule V, depending on whether or not the Neoplastic Indication has been granted by the EMEA. In the



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event Mundipharma fails to achieve the minimum Net Sales requirements set forth in this Clause 5.3 during any Marketing Year, Mundipharma shall pay to Skye, within forty-five (45) days of the end of such Marketing Year, [\*\*]% of the difference between actual Net Sales in the Territory during the Marketing Year and the minimum Net Sales applicable in that Marketing Year. In addition to the foregoing but subject to Clause 3.3, in the event Mundipharma fails to achieve the minimum Net Sales requirements set forth in this Clause 5.3 in any two consecutive Marketing Years Skye, in addition to any other rights or remedies available hereunder, may terminate this Agreement pursuant to Clause 16.1.1.

5.4 For the avoidance of doubt, Skye shall be liable for any Third Party royalty obligations existing at the date hereof relating to the Skye Technology.

5.5 The supply price specified in Clause 5.1 is for Finished Product supplied ex-works (as defined in Incoterms 2000) Lyon.

## **6 Payments**

6.1 On signing, the non-creditable and non-refundable sum of [\*\*] Euros (€[\*\*]) in one lump sum shall become due from Mundipharma to Skye which shall be payable within ten (10) business days of the execution of this Agreement by the parties.

6.2 Upon occurrence of each Milestone Event, the corresponding non-creditable and non-refundable Milestone Payment shall become payable by Mundipharma to Skye. Mundipharma shall provide to Skye details of the basis of the calculation of Mundipharma's ex-company price referred to in Schedule III. The Milestone Event relating to the Marketing Authorisation for the sale of the Product for the Neoplastic Indication shall be deemed to have occurred upon the grant to Skye of

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EMA Regulatory Approval for the Neoplastic Indication with no materially adverse restrictions, conditions or warnings beyond those relating to the existing indication.

- 6.3 Each Milestone Payment shall be due once only upon the first occurrence of the given Milestone Event.
- 6.4 Milestone Payments due under this Clause 6 shall be paid within the later of:
- 6.4.1 [\*\*] ([\*\*]) days from identification of the occurrence of the Milestone Event by Mundipharma; or
- 6.4.2 in respect of the Milestone Event relating to the Regulatory Approval for the Neoplastic Indication, [\*\*] ([\*\*]) business days from receipt by Mundipharma of a copy of such approval by the EMA.
- 6.5 If the Marketing Authorisation is cancelled or permanently withdrawn, or if Mundipharma, its Affiliates, sub-licensees or sub-distributors are prevented from selling the Finished Product in any three of the following countries, UK, Germany, France, Spain and, if included within the Territory under this Agreement, Italy due to a final non-appealable judgment in respect of any infringement by the Skye Technology or the sale of Finished Product in accordance herewith of any Third Party Intellectual Property rights, no further Milestone Payments will be due and the sales minima and right to terminate this Agreement under Clause 5.3 shall cease to apply.
- 6.6 If (i) the Marketing Authorisation or other Regulatory Approval is suspended, temporarily withdrawn or materially varied; or (ii) any Third Party asserts any Third Party Intellectual Property rights which are reasonably likely to result in a court order; in either case, in a way which would have a material impact on Mundipharma's ability (itself

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or through its Affiliates, sub-licensees or sub-distributors) to achieve its sales forecasts, or if a Regulatory Approval (other than the Marketing Authorisation) is cancelled or withdrawn or if a body responsible for pricing issues or prescribing guidance makes an adverse assessment or decision concerning the Product, the parties shall discuss in good faith a proportionate reduction in future Milestone Payments and also in the minimum Net Sales in Clause 5.3. If the parties are unable to agree upon such reduction, the dispute shall be referred to an expert pursuant to Schedule VIII.

- 6.7 In addition to any amounts payable by Mundipharma or its Affiliate pursuant to Clause 5.1, Mundipharma shall pay a royalty of:
- 6.7.1 [\*\*] Euros (€[\*\*]) per Vial of Finished Product supplied to Mundipharma Medical Company pursuant to the Supply Agreement within [\*\*] days of the date of Skye's invoice to Mundipharma Medical Company for such Vials; and
- 6.7.2 in the event that [\*\*] per cent ([\*\*]%) of Net Sales in a Quarter is greater than the number of Vials sold (less rejected, returned or recalled Vials other than those rejected, returned or recalled in connection with the expiry of the shelf life of the Vials) in that Quarter multiplied by [\*\*] Euros (€[\*\*]) Mundipharma shall pay the difference to Skye within [\*\*] ([\*\*]) days of the end of the Quarter.
- 6.8 If aggregate Net Sales of Mundipharma, its Affiliates, sub-licensees and sub-distributors in the Territory in any Marketing Year during the Term exceed [\*\*] Euros (€[\*\*]), Mundipharma shall pay an additional royalty of [\*\*] per cent ([\*\*]%) of the amount by which aggregate Net Sales in each such year exceed [\*\*] Euros (€[\*\*]). Such royalty shall be paid by Mundipharma within [\*\*] ([\*\*]) days of the end of the Marketing Year, supported by a royalty statement showing how the royalty has been calculated.

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- 6.9 If at any time the continued performance of this Agreement ceases to be commercially profitable or would otherwise involve financial hardship for either party, the parties shall discuss in good faith ways of restructuring this Agreement with a view to restoring commercial profitability or removing the financial hardship.

**7 Payment, Accounting, Audit Rights**

- 7.1 Unless otherwise agreed between the parties, all payments to be made hereunder shall be made in Euros. Net Sales shall be determined in the currency in which the Product was sold and shall be converted into Euros using closing mid point published in the Financial Times for the last business day of the Quarter for which such payment is being determined.
- 7.2 Any amount payable under this Agreement shall be deemed to be exclusive of Value Added Tax, which shall be payable in addition, if applicable.
- 7.3 Mundipharma shall be entitled to deduct from its payments to Skye the amount of any withholding taxes required to be withheld and shall on Skye's request provide proof of payment of such taxes.
- 7.4 Mundipharma shall maintain and shall procure the maintenance of accurate and up to date records and books of account showing the quantity, description and value of the Products supplied in each country of the Territory during the previous 6 years as well as details of the basis of calculation of Mundipharma's ex-company price set out in Schedule III.
- 7.5 Mundipharma shall during business hours, on no less than 14 days' notice from Skye and not more than once in any Year, make available for inspection the records and books referred to in Clause 7.4. Such inspection shall be undertaken by an independent auditor appointed by

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Skye and reasonably acceptable to Mundipharma for the purpose of verifying the accuracy of any statement or report given by Mundipharma to Skye and/or the amount of royalties due.

- 7.6 Skye shall procure that any independent auditor appointed under Clause 7.5 shall maintain all information and materials received, directly or indirectly, by it from Mundipharma in strict confidence and shall not use or disclose the same to any Third Party, nor to Skye save for the sole purpose of reporting the results of the audit pursuant to this Clause.
- 7.7 In the event that an auditor appointed pursuant to this Clause concludes that there has been an underpayment or overpayment, Skye shall deliver to Mundipharma a copy of such auditor's report. Any deficit payable by Mundipharma or any excess refundable by Skye shall be payable within 30 days of Mundipharma's receipt of such report. The fees charged by such auditor shall be payable by Skye, provided that if the audit reveals that payments due to Skye for any Year have been understated by more than [\*\*]%, the fees charged by such auditor shall be payable by Mundipharma.
- 7.8 Should any amount not be paid pursuant to Clause 7.7 by either party on or before the due date for payment the non-payer shall pay to the other party in addition interest on such amount unpaid at the rate of [\*\*]% above the base rate from time to time of the National Westminster Bank Plc and such interest shall be calculated and payable in respect of the period from the date such amount is due until the date payment in full is received in cleared funds by the payee.

## **8 Intellectual Property and Trade Marks**

- 8.1 Except as set out in this Agreement, all right, title and interest in the Skye Technology shall belong to Skye and Mundipharma shall not have any right, title or interest in the Skye Technology.

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- 8.2 Mundipharma shall:
- 8.2.1 use the Trade Marks in a manner which conforms to the reasonable directions and standards notified to it by Skye from time to time; and
- 8.2.2 not do anything which could, in Skye's reasonable opinion, bring the Trade Marks or Skye into disrepute or otherwise damage the goodwill attaching to the Trade Marks.
- 8.3 Skye shall, at its own cost, take all steps required to maintain those registrations for the Trade Marks subsisting at the Effective Date, and prosecute any applications subsisting at the Effective Date for registration of the Trade Marks through to grant (including oppositions thereto) in the Territory.
- 8.4 Mundipharma may request that Skye use reasonable efforts to obtain trade mark registrations in respect of the Trade Marks, in classifications which cover the Finished Products, in any countries in the Territory. Skye shall promptly notify Mundipharma if it does not intend to make or pursue a trade mark registration in any of the countries in the Territory and Mundipharma shall thereafter be entitled to make applications for such trade mark registrations in its own name. For the avoidance of doubt this Clause shall not oblige Skye to obtain further trade mark registrations in Norway, Switzerland or at the Office for Harmonisation in the Internal Market, nor shall it oblige Skye to obtain trade mark registrations for the word "Depocyt".
- 8.5 Mundipharma shall have the right during the Term to register domain names specific to the countries comprised in the Territory that incorporate the Trade Mark.
- 8.6 In the event that the trade mark Depocyte® is unavailable for the Finished Product in any country of the Territory, the parties shall, via

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the Committee consider an appropriate alternative trade mark for registration in that country or territory. Upon registration, such trade marks shall comprise part of the Trade Marks hereunder.

**9 Representations and Warranties**

- 9.1 Each of the parties warrants and represents that:
  - 9.1.1 it has full power and authority and legal right to enter into this Agreement and perform the obligations under it;
  - 9.1.2 the execution of this Agreement has been duly authorised by all necessary actions;
  - 9.1.3 this Agreement is a legal and valid obligation, binding on each of the parties and enforceable in accordance with its terms; and
  - 9.1.4 entry into and exercise of the respective rights and obligations under this Agreement do not, and will not, violate any provision of any agreement or other instrument or document to which it is party or affect or be in conflict with or result in the breach of or constitute a default under any such agreement, instrument or document.
- 9.2 Skye represents and warrants that as at the Effective Date:
  - 9.2.1 to the best of its knowledge and belief the Skye Technology includes all Intellectual Property in the possession, custody or control of Skye which is reasonably necessary for the exploitation of the Product by Mundipharma in accordance with the terms of this Agreement;
  - 9.2.2 it is the owner of, or has exclusive rights (for at least as long as the term of this Agreement) to, all of the Skye Technology in existence at the Effective Date, and is exclusively entitled to grant the rights granted under this Agreement;

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- 9.2.3 to the best of its knowledge and belief there are no Third Party interests or rights in the Skye Technology that may prevent, encumber or restrict in any way the exercise by Mundipharma of the rights granted under this Agreement nor will Skye grant any such rights after the Effective Date;
- 9.2.4 to the best of its knowledge and belief no Third Party is infringing or has infringed the Intellectual Property rights in any of the Skye Technology;
- 9.2.5 at the date hereof, Skye has no notice, and is not aware, that the exercise of Mundipharma's rights granted under this Agreement infringes or conflicts with any Third Party Intellectual Property rights and to the best of its knowledge and belief the exercise of Mundipharma's rights granted under this Agreement will not infringe or conflict with any Third Party Intellectual Property rights and will not incur any obligation to any Third Party;
- 9.2.6 all renewal and maintenance fees and all steps necessary for the filing, prosecution and maintenance of the Skye Patents have been paid or taken;
- 9.2.7 at the Effective Date it is the holder of the Marketing Authorisation and to the best of its knowledge such Marketing Authorisation is not subject to any threatened or pending claim, challenge or review by any Third Party nor is there any pre-clinical or clinical data or correspondence with a Regulatory Authority which suggests that there may exist quality, toxicity, safety or efficacy concerns which may materially impair the utility or safety of the Product;
- 9.2.8 all information, data and Third Party notices in relation to adverse events, serious adverse events or recalls relating to or connected with the Product (in any jurisdiction throughout the



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world) and of which Skye is aware have been disclosed by Skye to Mundipharma; to the best of its knowledge and belief Skye has disclosed all information in its possession or control concerning the Products and the subject matter of this Agreement which would be material to a prudent distributor's decision to enter into this Agreement.

- 9.3 Skye confirms and agrees that where its representations and warranties in Clause 9.2 are subject to its knowledge, belief or awareness, Skye shall be deemed to have carried out due and careful enquiries into the subject matter of those representations and warranties.

## **10 Liability, Insurance and Indemnities**

- 10.1 Skye shall remain solely responsible for discharging creditors and for all Claims (as defined in this Clause 10) relating to the development, manufacture, sale and supply of the Product resulting from any act, default, transaction or circumstance occurring prior to the Effective Date (including claims or demands arising after the Effective Date to the extent they are based on events occurring prior to the Effective Date), and Skye shall indemnify and hold harmless Mundipharma and its Affiliates from and against any and all such Claims or part thereof arising in connection therewith.
- 10.2 Skye shall indemnify and hold harmless Mundipharma and its Affiliates from and against;
- 10.2.1 Claims arising from or in connection with Intellectual Property infringement proceedings with Third Parties in connection with the Skye Technology (except to the extent that the claim has arisen from Mundipharma's use of the Skye Technology other than in accordance with this Agreement); and

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- 10.2.2 Claims against Mundipharma arising from or in connection with death or personal injury except to the extent arising out of any breach of this Agreement or the Supply Agreement by Mundipharma or its Affiliates or out of any negligent act or omission of Mundipharma or its Affiliates or their employees in the course of their employment.
- 10.3 Mundipharma shall indemnify and hold harmless Skye from and against Claims arising from or in connection with:
- 10.3.1 the use, storage, marketing, distribution or sale of the Product by Mundipharma or its Affiliates to the extent that such Claims arise out of any breach of this Agreement or the Supply Agreement by Mundipharma or its Affiliates or out of any negligent act or omission of Mundipharma or its Affiliates or their employees in the course of their employment; and
- 10.3.2 death or personal injury to the extent arising out of any breach of this Agreement or the Supply Agreement by Mundipharma or its Affiliates or out of any negligent act or omission of Mundipharma or its Affiliates or their employees in the course of their employment.
- 10.4 Promptly after receipt by a party of any Claim or alleged claim or notice of the commencement of any action, administrative or legal proceeding, or investigation as to which an indemnity provided for in this Clause 10 may apply, the indemnified party shall give written notice to the indemnifying party of such fact. The indemnifying party shall have the option to assume the defence thereof by election in writing within thirty (30) days of receipt of such notice. If the indemnifying party fails to make such election, the indemnified party may assume such defence and the indemnifying party will be liable for reasonable legal and other expenses subsequently incurred in connection with such defence. The parties will co-operate in good

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faith in the conduct of any defence, provide such reasonable assistance as may be required to enable any Claim to be properly defended, and the party with conduct of the action shall provide promptly to the other party copies of all proceedings relating to such action.

- 10.5 Should the indemnifying party assume conduct of the defence:
- 10.5.1 the indemnified party may retain separate legal advisors in the event that it reasonably concludes that it may have defences available to it which are additional to, different from or inconsistent with those available to the indemnifying party, in which case the indemnifying party shall be liable for the indemnified party's reasonable costs and expenses so incurred; and
  - 10.5.2 the indemnifying party will not, except with the consent of the indemnified party (such consent not be unreasonably withheld or delayed), consent to the entry of any judgment or enter into any settlement (other than for the payment of damages by the indemnifying party, which includes as an unconditional term a release from the claimant to the indemnified party from all liability in respect of all claims).
- 10.6 The indemnified party shall not admit liability in respect of, or compromise or settle any such action without the prior written consent of the indemnifying party, such consent not to be unreasonably withheld or delayed.
- 10.7 Each party shall maintain, at its own cost, either
- 10.7.1 comprehensive product liability insurance and general commercial liability insurance. Such insurance shall be with a reputable insurance company and where reasonably possible (taking into account the availability of such insurance) shall be maintained for not less than 6 years following the expiry or termination of this Agreement; or

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- 10.7.2 a reasonable level of self-insurance.
- 10.8 Any and all liability of Skye to Mundipharma arising in respect of Clauses 9,10.1 and 10.2.2 of this Agreement, shall be limited (except for death or personal injury caused by negligence) to [\*\*] Euros (€[\*\*]).
- 10.9 Any and all liability of Mundipharma to Skye arising in respect of Clause 10.3 of this Agreement shall be limited (except for death or personal injury caused by negligence) to [\*\*] Euros (€[\*\*]).
- 10.10 Notwithstanding anything contained in this Agreement or the Supply Agreement in no circumstance shall either party be liable to the other in contract, tort (including negligence or breach of statutory duty) or otherwise howsoever, and whatever the cause thereof, for any special, indirect or consequential loss or damage of any nature whatsoever.
- 10.11 Nothing in this Clause shall be construed as excluding or limiting the liability of either party or any of its officers, employees and agents to the other party for death or personal injury of any person resulting from the negligence of such persons.
- 10.12 In this Clause 10, "Claims" shall mean any and all claims, actions and demands made or brought by Third Parties, and all judgements, losses, damages, settlements, costs and expenses in connection therewith, including reasonable legal and expert fees incurred in defending such claims, actions and demands.

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**11 Confidentiality, Press Releases and Publications**

- 11.1 Skye and Mundipharma undertake to each other to keep confidential, and to procure that their respective Affiliates, employees, directors, officers, contractors, lawyers and accountants (including those of their Affiliates) keep confidential, Confidential Information disclosed to it by or belonging to the other party, until it ceases to be Confidential Information.
- 11.2 Any Confidential Information received from the other party shall not be disclosed to any Third Party or used for any purpose other than as provided or specifically envisaged by this Agreement, unless it ceases to be Confidential Information.
- 11.3 The confidentiality and non-use obligations contained in this Agreement shall continue for the duration of this Agreement and for a period of [\*\*] years after termination for any reason of this Agreement.
- 11.4 The parties shall consult with each other, in advance, with regard to the terms of all proposed press releases, public announcements and other public statements with respect to the transactions contemplated under this Agreement. The press release to be issued by the parties on execution of this Agreement shall be substantially in the form of the document set out in Schedule VI of this Agreement.
- 11.5 The Confidential Information may be disclosed by the other parties to the extent that such disclosure has been ordered by a court of law or directed by a governmental authority, provided that, wherever practicable, the party disclosing the Confidential Information has given sufficient written notice in advance to the other party to enable it to seek protection or confidential treatment of such Confidential Information, and may be disclosed only to the extent that such disclosure has been so ordered or directed.

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**12 Patents**

12.1 Skye shall file, prosecute and maintain the Skye Patents, and meet all related costs and expenses.

**13 Infringement of Third Party Rights**

13.1 In the event of a party becoming aware that the exercise of either party's rights and obligations pursuant to this Agreement are infringing or may infringe the rights of a Third Party, it will promptly so notify the other party and provide it with such details of the Third Party rights and the extent of the infringement as are known to it. Skye shall be entitled at its discretion to contest any such Third Party claim or proceedings or otherwise to take such steps to terminate any infringement or remedy the position and where necessary enter any Third Party licence agreement provided in each case that Mundipharma will lawfully be able to practice fully the rights and licenses granted hereunder. No later than [\*\*] days from becoming aware of or receiving notification in relation to any infringement of the rights of a Third Party, Skye shall inform Mundipharma whether it intends to contest the claim or take such other steps necessary to terminate any infringement (including the negotiation of a Third Party licence agreement) and Mundipharma may thereafter contest any such Third Party claim or proceedings at its cost. If Skye does contest the claim or take steps to terminate any infringement it shall keep Mundipharma informed of its actions in this regard. If Skye enters into a Third Party licence agreement any Third Party royalties or licence fees incurred in this regard shall be borne by Skye.

13.2 Where Mundipharma has assumed responsibility for contesting any such Third Party claim or proceedings in accordance with Clause 13.1 (including the negotiation of a Third Party licence agreement), Mundipharma shall keep Skye reasonably informed of its actions in this regard and Skye will provide Mundipharma with all reasonable co-operation

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in connection with such actions. Without limitation this shall include Mundipharma furnishing Skye with drafts of any proposed Third Party licence agreement and Mundipharma seeking Skye's approval to the terms of any such agreement. Mundipharma shall not enter into any such Third Party licence agreement without the prior written approval of Skye to such agreement (which shall not be unreasonably withheld or delayed). Skye shall reimburse Mundipharma's reasonable costs in defending any such claim and any Third Party licence fees incurred in this regard and Mundipharma or its Affiliate shall be entitled to credit any Third Party royalties against payments due to Skye pursuant to Clauses 5 and 6 or under the Supply Agreement.

**14    Infringement of Skye Technology**

- 14.1    In the event that Mundipharma becomes aware of any actual or suspected infringement or misuse of the Skye Technology or an attack on its validity in the Territory it shall promptly notify Skye and provide it with all details thereof in its possession.
- 14.2    No later than [\*\*] days from becoming aware of or receiving notification of any actual or suspected infringement or misuse of the Skye Technology or attack on its validity in the Territory, Skye shall inform Mundipharma whether it intends to institute or defend proceedings against the infringer or attacker.
- 14.3    Skye shall be entitled at its discretion to take such action to seek an abatement of such infringement, or to defend such attack on validity, as it sees fit, which may include the institution or defence of proceedings against the infringer or attacker. Mundipharma shall provide all such assistance at Skye's cost and expense as Skye may reasonably require in the prosecution or defence of any such proceedings.

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14.4 Any damages, award or settlement monies actually received by Skye in respect to such infringement and paid in compensation for sales lost by Mundipharma shall belong to Mundipharma, subject to such payments being treated as Net Sales and Skye deducting therefrom any payment it would be due had Mundipharma achieved such Net Sales. Any damages, award or settlement monies actually received by Skye in respect to such infringement and not paid in compensation for sales lost by Mundipharma shall belong to Skye.

14.5 Should in accordance with Clause 14.2 Skye notify Mundipharma that it does not intend to pursue any such infringement, Mundipharma may thereafter pursue such infringement. Any damages, award or settlement monies actually received by Mundipharma in respect to such infringement and paid in compensation for sales lost by Mundipharma shall belong to Mundipharma, subject to such payments (net of reasonable costs of pursuing the infringement) being treated as Net Sales and Mundipharma paying to Skye therefrom any payment which would be due to Skye had Mundipharma achieved such Net Sales. Any damages, award or settlement monies actually received by Mundipharma in respect to such infringement and not paid in compensation for sales lost by Mundipharma shall belong to Skye, save that Mundipharma shall be entitled to set off its reasonable costs in pursuing such infringement against such damages, award or settlement actually received by Mundipharma.

**15 Term**

15.1 This Agreement commences on the Effective Date and, subject to earlier termination in accordance with the provisions of Clause 16, shall continue in force for a period of [\*\*] ([\*\*]) years and shall continue thereafter from year to year unless terminated by either party giving to the other no less than [\*\*] ([\*\*]) months prior written notice expiring on or after the [\*\*] anniversary of the Effective Date.



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**16 Termination**

- 16.1 Either party shall be entitled forthwith to terminate this Agreement by notice to the other if:
- 16.1.1 the other party commits a material or persistent breach of any obligation under this Agreement or the Supply Agreement, and in the case of a breach which is capable of remedy fails to remedy it within [\*\*] days of receipt of notice from the first party of such breach and of its intention to exercise its rights under this Clause; or
  - 16.1.2 a petition is presented, or a meeting is convened for the purpose of considering a resolution, or other steps are taken, for making an administration order against or for the winding up of the other party or an administration order or a winding up order is made against or a provisional liquidator is appointed with respect to the other party; or
  - 16.1.3 an encumbrancer takes possession of, or a trustee or administrative receiver or similar officer is appointed in respect of, all or any material part of the business or assets of the other party, or distress or any form of execution is levied or enforced upon or sued out against any such assets and is not discharged within [\*\*] days of being levied, enforced or sued out; or
  - 16.1.4 the other party is unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986 or becomes unable to pay its debts as they fall due or suspends or threatens to suspend making payments with respect to all or any class of its debts; or
  - 16.1.5 any voluntary arrangement is proposed under section 1 of the Insolvency Act 1986 in respect of the other party; or

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- 16.1.6 the other party proposes or makes any composition or arrangement or composition with, or any assignment for the benefit of, its creditors; or
- 16.1.7 anything analogous to any of the events described in Clauses 16.1.2 – 16.1.6, inclusive, occurs under the laws of any applicable jurisdiction; or
- 16.1.8 the other party ceases or threatens to cease to carry on the whole or any material part of its business.
- 16.2 Skye may terminate this Agreement with immediate effect if within [\*\*] months of Skye having secured the appropriate variation to the Marketing Authorisation naming Mundipharma as distributor of the Finished Product in UK and Germany and subject to Skye having made launch stocks available within [\*\*] ([\*\*]) months of such variation in response to an order properly placed by Mundipharma under the Supply Agreement, first Commercial Delivery has not occurred in both those countries,.
- 16.3 Mundipharma shall be entitled forthwith to terminate this Agreement in the event of the Marketing Authorisation being cancelled or withdrawn for a period likely to exceed [\*\*] ([\*\*]) months or in the event of Mundipharma, its Affiliates, sub-licensees or sub-distributors being prevented from selling the Product in any three of the following countries, UK, Germany, France, Spain and, if included within the Territory under this Agreement, Italy by a final non-appealable judgement in respect of any infringement by the Skye Technology or the sale of Finished Product in accordance herewith of any Third Party Intellectual Property rights.
- 16.4 The termination or expiry of this Agreement shall not release either of the parties from any liability which at the time of termination or expiry has already accrued to the other party, nor affect in any way the survival of any other right, duty or obligation of the parties which is expressly stated elsewhere in this Agreement to survive such termination or expiry.

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**17 Consequences of Termination**

- 17.1 On termination of this Agreement for any reason (and, if applicable, in respect of that country in respect of which termination occurs):
- 17.1.1 the licences and rights granted and appointments made under Clauses 2.1 and 2.2 shall terminate and Mundipharma shall (and shall procure that its Affiliates and sub-licensees shall) cease all activities licensed or appointed hereunder, subject to Clause 17.2;
  - 17.1.2 the Supply Agreement shall be terminated;
  - 17.1.3 the following provisions of this Agreement shall continue in full force and effect: this Clause 17 and Clauses 10 and 11;
  - 17.1.4 Mundipharma shall return to Skye all Skye IP in its possession;
  - 17.1.5 Mundipharma shall assign to Skye free of charge any domain name registrations it has registered pursuant to Clause 8.5 and any trade marks for which it has applied under Clause 8.6;
  - 17.1.6 Mundipharma shall promptly transfer to Skye or its nominee insofar as it is able to do so, each and every Regulatory Approval (including but not limited to any pricing and reimbursement approval) relating to the Product, together with all communications with the relevant Regulatory Authorities, and all notes and record thereof.
- 17.2 In the event that this Agreement is terminated by Skye in accordance with Clause 16.1, Mundipharma and its Affiliates, sub-licensees and sub-distributors shall be entitled to continue to sell existing stocks of

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the Finished Product in the Territory for so long as necessary to sell all such stocks, provided that Mundipharma continues to make any payments due to Skye in respect of such sales in accordance with the provisions of this Agreement. Immediately upon notification from Skye, such post termination sales shall cease, subject to Skye assuming Mundipharma's obligations to meet unfulfilled orders and acquiring all stocks of Finished Product held by Mundipharma, its Affiliates, sub-licensees and sub-distributors at the price paid for such stocks by Mundipharma's Affiliate.

**18 Force Majeure**

- 18.1 Neither Party shall be entitled to terminate this Agreement or shall be liable to the other under this Agreement for loss or damages attributable to any Force Majeure, provided the party affected shall give prompt notice thereof to the other party. Subject to Clause 18.2, the party giving such notice shall be excused from all affected obligations hereunder for so long as it continues to be affected by Force Majeure.
- 18.2 If such Force Majeure continues unabated for a period of at least 90 days, the parties will meet to discuss in good faith what actions to take or what modifications should be made to this Agreement as a consequence of such Force Majeure in order to alleviate its consequences on the affected party.

**19 Notices**

- 19.1 Any notice or other document given under this Agreement shall be in writing in the English language and shall be given by hand or sent by prepaid airmail, by fax transmission or e-mail to the address of the receiving Party as set out in Clauses 19.3 below unless a different address or fax number has been notified to the other in writing for this purpose.

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- 19.2 Each such notice or document shall:
- 19.2.1 if sent by hand, be deemed to have been given when delivered at the relevant address;
  - 19.2.2 if sent by prepaid airmail, be deemed to have been given 7 days after posting; or
  - 19.2.3 if sent by fax transmission be deemed to have been given when transmitted provided that a confirmatory copy of such facsimile transmission shall have been sent by prepaid airmail within 24 hours of such transmission.

19.3 The address for services of notices and other documents on the parties shall be:

**To Mundipharma**

**Address:** Mundipharma House,  
14 Par-la-Ville Road,  
P.O. Box HM 2332,  
Hamilton, HM JX,  
Bermuda

**Fax:** 001 809 292 1472

**Attention:** General Manager

**Copy To:** [\*\*]

**Fax:** [\*\*]

**To Skye**

**Address:** 10450 Sciences Center  
Drive, San Diego,  
California 92121  
USA

**Fax:** 001 858 623 0376

**Attention:** President 2

**Copy To:** Skye Legal Department,  
105 Piccadilly, London  
W1V 9FN

**Fax:** +44 20 7491 3338

**20 Assignment and Change of Control**

- 20.1 Each party shall have the right to sub-license, assign, license, transfer or delegate its rights or obligations under this Agreement in whole or in part to an Affiliate (for so long as such Affiliate remains an Affiliate). Subject to Clause 2.9, neither party shall, nor shall it purport to, assign, license, transfer, delegate or charge any of its rights or obligations under this Agreement to a Third Party without the prior written consent of the other, such consent not to be unreasonably withheld or delayed.

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- 20.2 Should there be a material change in the ownership or a change in the control of the Mundipharma (and for the purpose of this Clause the term “control” means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of the Mundipharma, whether through the ownership of voting securities, by contract or otherwise, or the ownership either directly or indirectly of 50% or more of the voting securities (or, in relation to any country where ownership of more than 50% of the voting securities is prohibited by law, the maximum percentage permitted, provided such percentage is no less than 30%) of Mundipharma), Skye may terminate this Agreement by not less than three (3) months written notice to the Mundipharma.

**21 General Provisions**

- 21.1 Nothing in this Agreement is deemed to constitute a partnership between the parties nor constitute either party the agent of the other party for any purpose.
- 21.2 If there is a disagreement between the Skye and Mundipharma on the interpretation of this Agreement or any aspect of the performance by either party of its obligations under this Agreement, the parties shall resolve the dispute in accordance with the dispute resolution procedure set out in Schedule VIII.
- 21.3 Each of the parties shall do execute and perform and shall procure to be done executed and performed all such further acts, deeds, documents and things as the other party may reasonably require from time to time to give full effect to the terms of this Agreement.

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- 21.4 In performing any respective obligations under this agreement, each party shall comply with the Data Protection Act 1998, any notification requirements under the Data Protection Act 1998 and the Data Protection Principles specified in that Act and any equivalent legislation in the Territory.
- 21.5 Each party shall pay its own costs, charges and expenses incurred in connection with the negotiation, preparation and completion of this Agreement.
- 21.6 This Agreement and the Supply Agreement sets out the entire agreement and understanding between the parties in respect of the subject matter of this Agreement. This Agreement supersedes any heads of agreement which shall cease to have any further force or effect. It is agreed that:
- 21.6.1 no party has entered into this Agreement in reliance upon any representation, warranty or undertaking of the other party which is not expressly set out in this Agreement;
- 21.6.2 no party shall have any remedy in respect of misrepresentation or untrue statement made by the other party or for any breach of warranty which is not contained in this Agreement;
- 21.6.3 this Clause shall not exclude any liability for, or remedy in respect of, fraudulent misrepresentation.
- 21.7 No variation of this Agreement shall be valid unless it is in writing and signed by or on behalf of both parties.
- 21.8 Unless expressly agreed, no variation shall constitute a general waiver of any provisions of this Agreement, nor shall it affect any rights, obligations or liabilities under or pursuant to this Agreement which have already accrued up to the date of variation, and the rights and obligations of the parties under or pursuant to this Agreement shall remain in full force and effect, except and only to the extent that they are so varied.

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- 21.9 If and to the extent that any provision of this Agreement is held to be illegal, void or unenforceable, such provision shall be given no effect and shall be deemed not to be included in this Agreement but without invalidating any of the remaining provisions of this Agreement. In such event the parties shall negotiate with a view to finding the nearest permissible provision to that found to be illegal, void or unenforceable. If the parties have been unable to agree as to the provision or provisions to be substituted within two (2) months then the parties shall refer the question of the re-drafting of the Agreement to an expert under the dispute resolution procedure in Schedule VIII.
- 21.10 No failure or delay by either party in exercising any right or remedy provided by law under or pursuant to this Agreement shall impair such right or remedy or operate or be construed as a waiver or variation of it or preclude its exercise at any subsequent time and no single or partial exercise of any such right or remedy shall preclude any other or further exercise of it or the exercise of any other right or remedy.
- 21.11 The rights and remedies of each of the parties under or pursuant to this Agreement are cumulative, may be exercised as often as such party considers appropriate and are in addition to its rights and remedies under general law.
- 21.12 This Agreement may be executed in any number of counterparts and by the parties on separate counterparts, each of which is an original but all of which together constitute one and the same instrument.
- 21.13 A person who is not a party to this Agreement, other than an Affiliate, shall have no right under the Contracts (Rights of Third Parties) Act 1999 to enforce any of its terms.



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- 21.14 This Agreement and the relationship between the parties shall be governed by, and interpreted in accordance with, English law.
- 21.15 Each of the parties agree that the courts of England are to have exclusive jurisdiction to settle any dispute (including claims for set off and counterclaims) which may arise in connection with the creation, validity, effect, interpretation or performance of, or the legal relationships established by, this Agreement or otherwise arising in connection with this Agreement and for such purposes irrevocably submit to the jurisdiction of the English courts.

AS WITNESS the hands of the parties or their duly authorised representatives the day and the year first above written

SIGNED for and by behalf of )  
**SKYEPHARMA INC** )  
 )

/s/ Michael R.D. Ashton

Michael R.D. Ashton  
**Print Name**

SIGNED for and by behalf of )  
**MUNDIPHARMA INTERNATIONAL** )  
**HOLDINGS LIMITED** )

/s/ James M. Keyes

James M. Keyes  
**Print name**

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SCHEDULE I

PATENTS

Patent entitled "[\*\*]"

<u>Country</u>	<u>Filing date</u>	<u>Application no.</u>	<u>Grant date</u>	<u>Publication no.</u>	<u>Status</u>
Norway	[**]	[**]	[**]	[**]	[**]
Sweden	[**]	[**]	[**]	[**]	[**]
Italy	[**]	[**]	[**]	[**]	[**]
Luxembourg	[**]	[**]	[**]	[**]	[**]
Netherlands	[**]	[**]	[**]	[**]	[**]
Portugal	[**]	[**]	[**]	[**]	[**]
United Kingdom	[**]	[**]	[**]	[**]	[**]
Denmark	[**]	[**]	[**]	[**]	[**]
Belgium	[**]	[**]	[**]	[**]	[**]
Ireland	[**]	[**]	[**]	[**]	[**]
Germany	[**]	[**]	[**]	[**]	[**]
EPO	[**]	[**]	[**]	[**]	[**]
Spain	[**]	[**]	[**]	[**]	[**]
Finland	[**]	[**]	[**]	[**]	[**]
France	[**]	[**]	[**]	[**]	[**]
Austria	[**]	[**]	[**]	[**]	[**]
Greece	[**]	[**]	[**]	[**]	[**]
Switzerland	[**]	[**]	[**]	[**]	[**]
Liechtenstein	[**]	[**]	[**]	[**]	[**]

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**SCHEDULE II**  
**TRADE MARKS**

<u>No.</u>	<u>Owner</u>	<u>Trade Mark</u>	<u>Country</u>	<u>Class(s)</u>	<u>Reg/App No.</u>	<u>Status</u>
1.	[**]	[**]	[**]	[**]	[**]	[**]
2.	[**]	[**]	[**]	[**]	[**]	[**]
3.	[**]	[**]	[**]	[**]	[**]	[**]
4.	[**]	[**]	[**]	[**]	[**]	[**]

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**SCHEDULE III**

**MILESTONE PAYMENTS**

Mundipharma shall pay Skye the following one-off milestone payments.

<u>No.</u>	<u>Milestone Event</u>	<u>Milestone Payment</u>
1.	Commercial Delivery for use in the intrathecal treatment of lymphomatous meningitis in each of UK, Germany, France and Spain provided Mundipharma's ex-company price for the Finished Product in the relevant country is equal to or greater than €[**] per Vial.	€[**] per country
2.	Subject to the inclusion of Italy within the Territory pursuant to Clause 2.11, Commercial Delivery for use in the intrathecal treatment of lymphomatous meningitis in Italy provided Mundipharma's ex-company price for the Finished Product in Italy is equal to or greater than €[**] per Vial.	€[**]
3.	Grant to Skye of EMEA marketing approval for use of the Product in the Neoplastic Indication.	€[**]
4.	Subject to the inclusion of Italy within the Territory pursuant to Clause 2.11, grant to Skye of EMEA marketing approval for use of the Product in the Neoplastic Indication.	€[**]
5.	Commercial Delivery for use in the Neoplastic Indication in each of UK, Germany, France and Spain provided Mundipharma's ex-company price for the Finished Product in the relevant country is equal to or greater than €[**] per Vial.	€[**] per country
6.	Subject to the inclusion of Italy within the Territory pursuant to Clause 2.11, Commercial Delivery for use in the Neoplastic Indication in Italy provided Mundipharma's ex-company price for the Finished Product in Italy is equal to or greater than €[**] per Vial.	€[**]

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## SCHEDULE IV

### ADVERSE EVENTS REPORTING PROCEDURE

#### Objective

To enable Skye to regularly update the safety profile of its procedures, and to ensure fulfilment of the regulatory obligations of Mundipharma and Skye in their respective territories with regard to timely submissions of individual adverse event reports.

#### Definitions

“Adverse Event” (or experience) - (“AE”): Any undesirable experience occurring following administration of a medical product. An adverse event does not necessarily have a causal relationship with the treatment.

“Adverse Drug Reaction/Adverse Reaction” - (“ADR”): A reaction (it implies a causal relationship) to a drug which is harmful and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis, or treatment of disease, or the modification of physiological function.

A reaction is characterised by the fact that a causal relationship between the drug (medicinal product) and the occurrence is suspected, i.e. judged possible by the reporting or reviewing health-care professional. If a reaction is spontaneously reported, this usually implies a positive judgement from the reporter unless the reporter explicitly gives a negative judgement on the causal relationship.

“Health Professional”: Medically-qualified doctors, coroners, dentists, pharmacists and nurses.

“Serious adverse event” - (“Serious AE”): Any event occurring at any dose that is:

- fatal

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- life threatening
  - disabling
  - incapacitating
  - results in, or prolongs hospitalisation
  - necessitates medical or surgical intervention to prevent permanent impairment or damage
  - a congenital anomaly/birth defect
  - in the opinion of a physician, is of major clinical significance

“Unexpected adverse event” – (“Unexpected AE’) Any event which is not mentioned in the local data sheet/SPC

**Procedure**

Any employee of Mundipharma receiving information on AEs or other data regarding the safety of the Product will forward that information immediately to an appropriate person (the Nominated Contact) appointed by Mundipharma for review/handling of safety data.

The Nominated Contact will forward reports of:

- Serious AEs or potentially Serious AEs to Skye within 1 working day of receipt of the information by Mundipharma.
- Non-serious AEs to Skye within ten (10) working days of receipt of the information by Mundipharma

AE reports should be sent by fax to:

Pharmacovigilance Department,

SkyePharma Inc.

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Clinical Safety Manager

Phone: +1 858 625 2414 ext 3162

Fax: +1 858 625 0804

Prompt forwarding to Skye is necessary to allow sufficient time for processing of the report and notification to other markets and if appropriate regulatory authorities. Information to be forwarded is specified in Attachment A and should be provided in English. An internationally recognised adverse event report form (e.g. CIOMS I form) which supplies the information specified in Attachment A may be used.

NB: Forwarding of reports of AEs should not be delayed while awaiting further information. The report should identify, the nature of the AE and source of report. If additional information is expected, this should be stated on the initial report. A follow-up report should be made as soon as the additional information is available. If there is any question as to whether an AE meets the criteria of a Serious AE, the AE report will be forwarded to Skye as a Serious AE.

Skye will acknowledge the receipt of the AE report, and provide their internal reference number to quote on any future exchange of correspondence. If acknowledgement is not received within 2 working days, the original fax should be resent by Mundipharma.

#### **Follow-up Reports**

Forwarding of an AE report should not be delayed while further information is awaited. If all the necessary details are not available at the time that the initial report is forwarded, the Nominated Contact will make further contact by telephone, correspondence or personal visit to the reporter to obtain the missing information. When serious reports originate from pharmacists, nurses or consumers, efforts should be made to obtain further information about the case from the physician responsible for the patient.

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Any additional information, including final outcome, will be forwarded to Skye as an addendum or 'follow-up' to the original report. This follow-up information should be identified with Skye's reference number.

### **Submission of reports to Regulatory Authorities**

#### **Reports originating in the Territory**

Skye is responsible for submitting AE reports to the EMEA and in other countries where it holds the Regulatory Approval. Mundipharma shall be responsible for submitting AE reports in countries where it holds the Regulatory Approval. A copy of all correspondence with the Regulatory Authority will be submitted to the other party.

#### **Reports originating in territories other than the Territory**

Skye will notify Mundipharma of any serious unexpected foreign reports for information. Where Mundipharma is holder of the Regulatory Approval Mundipharma will submit the report to the local Regulatory Authority if appropriate. Where Skye is the holder of the Regulatory Approval, notification will be by copy of the report submitted to the Regulatory Authority.

### **The activities of both parties summarised below.**

#### **Mundipharma**

- Nominates an appropriate person for receipt of safety information (Nominated Contact, NC). All information received by Mundipharma to be directed by the NC. The NC is Skye's contact for Safety matters.
- NC is responsible for safety data collection and follow up for Mundipharma territories



- 
- NC completes an Adverse Event form for any Adverse Event/safety related issue associated with the Product and FAXES the form to the address set out above within the time limits set out above.
  - Submits report to the local Regulatory Authority according to local requirements where it holds the Regulatory Approval.
  - Follows-up report to obtain further details, medical confirmation, and forwards additional information (identified with Skye reference number) to Skye.

#### **Skye**

- Acknowledges receipt of report, advising reference number assigned.
- Maintains a database of Adverse Event reports.
- Copies Mundipharma on any correspondence with the Regulatory Authorities in the Territory.
- Notifies Mundipharma of serious unexpected reports received from outside the Territory either directly, or by copy of notification to the regulator in the Territory.
- Notifies other markets of serious unexpected reports and submits relevant reports to regulators in those markets, according to their requirements.
- Notifies details of all non-serious Adverse Events.
- On reasonable request from Mundipharma provides summaries of reports as line listings and obtains further details, medical confirmation and forwards to Mundipharma.

#### **Attachment A**

##### **Adverse Event Reports - Data Elements**

###### **General**

- Local identification number
- Date of receipt
- Reporter details, i.e. Health Professional (physician/pharmacist, nurse, consumer)

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**Patient details**

- Identification (initials)
- Age (date of birth if known)
- Sex
- Race
- Hospital number if applicable
- Relevant medical history
- Relevant diagnostic tests

**Adverse event**

- Description of event, diagnosis where possible
- Onset date (or time to onset if date not known)
- Time to onset if less than 24 hours
- Outcome
- Relationship to suspect product, in the opinion of the reporting Health Professional Treatment given, if any
- Information on dechallenging/rechallenge (if applicable)

**Suspect Product**

- Name of product
- date treatment started; date treatment stopped (or duration of treatment if dates not know)
- Dose and route of administration
- Reason for use
- Batch No

**Concomitant medication (or any medication given in previous month)**

- Name
- Date started; date treatment stopped (or duration of treatment and temporal relationship to AE if dates not know)

- 
- Dose and route of administration
  - Reason for use

**Product Recall**

In the event Skye is required or voluntarily decides to initiate a recall, withdrawal or field correction of the Product, Skye shall notify Mundipharma and provide a copy of its proposal, including the recall letter, for review prior to initiation of such action and the parties shall fully consult and cooperate with each other concerning the need for such a recall and in order to develop and execute a recall plan, as necessary. In conjunction with such recall, Mundipharma shall assist, at Skye's sole discretion and expense, in the investigation to determine the cause and extent of the problem.

In the event that Mundipharma independently believes that a recall, withdrawal or field correction of the Product may be necessary or appropriate, Mundipharma shall notify Skye of Mundipharma's belief, and the parties shall fully cooperate with each other concerning the necessity and nature of such action.

All coordination of any recall or field correction activities involving Product shall be handled by Skye, in cooperation with Mundipharma, whether or not such action was initially requested by Mundipharma.

In the event that any Product is recalled as a direct result of the negligent or intentionally wrongful acts or omissions of Mundipharma or its representatives, then Mundipharma shall bear all of the costs and expenses of such recall, including expenses related to communications and meetings with all required Regulatory Authorities, expenses of replacement stock, the cost of notifying customers and costs associated with shipment of recalled Product from customers and shipment of an equal amount of replacement Product to those same customers. In the event that any Product is recalled as a direct result of the negligent or intentionally wrongful acts or omissions of Skye or its representatives or as a result of Product misbranding or failure to meet Specification, then Skye shall bear all of the costs and expenses of such

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recall, including expenses related to communications and meetings with all required Regulatory Authorities, expenses of replacement stock, the cost of notifying customers and costs associated with shipment of recalled Product from customers and shipment of an equal amount of replacement Product to those same customers. To the extent that the reason for any recall of Product hereunder is in part the responsibility of Skye and in part the responsibility of Mundipharma or is not due to the fault of either Party, then the expenses shall be allocated in an equitable manner between the parties.

**SCHEDULE V**  
**MINIMUM NET SALES**

**A. Neoplastic Indication not granted by EMEA**

<u>Marketing Year</u>	<u>Minimum Aggregate Net Sales in Territory (millions)</u>
[**]	€[**]
[**]	€[**]
[**]	€[**]
[**]	€[**]

**B. Neoplastic Indication granted by EMEA by the end of Year 2**

<u>Marketing Year</u>	<u>Minimum Aggregate Net Sales in Territory (millions)</u>
[**]	€[**]
[**]	€[**]
[**]	€[**]
[**]	€[**]

**C. Neoplastic Indication granted by EMEA by the end of Year 3**

<u>Marketing Year</u>	<u>Minimum Aggregate Net Sales in Territory (millions)</u>
[**]	€[**]
[**]	€[**]
[**]	€[**]
[**]	€[**]

If the Neoplastic Indication is not granted by the end of Year [\*\*] the minimum Net Sales will be as set out in Section A above.

**European marketing rights for DepoCyt®**

**Licensed to Mundipharma International Holdings Limited**

LONDON, ENGLAND, June \*\*, 2003 – SkyePharma PLC (Nasdaq: SKYE; LSE: SKP) announced today that it had reacquired the European marketing and distribution rights for DepoCyt®, a treatment for lymphomatous meningitis, and relicensed exclusive marketing and distribution rights for the product to Mundipharma International Holdings limited (“Mundipharma”) for most European countries.

Under the terms of the agreement, Mundipharma will pay SkyePharma €[\*\*] on signature plus additional milestone payments that may amount in total to €[\*\*]. SkyePharma will manufacture the drug at its San Diego facility and supply to Mundipharma associates at an agreed transfer price. Mundipharma will also pay SkyePharma an additional royalty on sales above an agreed threshold.

SkyePharma’s chief executive officer, Michael Ashton, said “We are delighted to have found in Mundipharma a partner which can bring the focused marketing and sales support needed for a specialist product like DepoCyt®. Mundipharma shares our view that lymphomatous meningitis is both under-diagnosed and under-treated and that DepoCyt® offers great potential to bring relief of suffering from this devastating complication of cancer. We look forward to working together.”

DepoCyt® (known as DepoCyt® in the USA) is a sustained release injectable formulation of cytarabine and is approved in both the USA and Europe for the treatment of lymphomatous meningitis, a serious late-stage complication of lymphoma, a form of cancer affecting the lymphatic system. Lymphomatous meningitis is a subset of neoplastic meningitis (see explanation below). Cytarabine is known to be an effective treatment for neoplastic meningitis but is rapidly metabolised and so patients require spinal (intrathecal) injections every two days. SkyePharma’s proprietary DepoFoam™ delivery technology encapsulates cytarabine in water solution within minute particles of lipid. After injection, these particles gradually degrade, prolonging the release of the drug and extending the period between injections to two weeks. This brings quality of life benefits to the patient and also savings in hospital costs. Furthermore, maintenance of sustained higher levels of cytarabine in the cerebrospinal fluid may also prolong the time to neurological progression.

Lymphomatous meningitis is a comparatively uncommon condition with approximately 10,000 cases reported worldwide each year. Consequently DepoCyt® has been granted “Orphan Drug” status in the USA. SkyePharma is currently conducting a Phase IV study, the data from which will be submitted in applications to the PDA and EMEA to expand the treatment indication for DepoCyt®/DepoCyt® to neoplastic meningitis associated with solid tumours. This is a more common condition and would increase the number of patients eligible for treatment with DepoCyt®/DepoCyt® approximately threefold.

DepoCyt® was approved by the US Food & Drug Administration in April 1999 and is marketed in North America by Enzon Pharmaceuticals. Rights in Japan were licensed to

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Nippon-Sbinyaku in 2001 although the product is not yet on the market. DepoCyt<sup>®</sup> was approved by the European Medicines Evaluation Authority in August 2001. European marketing and distribution rights for DepoCyt<sup>®</sup> were licensed to Elan Pharmaceuticals (“Elan”) in June 2001 but following Elan’s decision not to proceed with the planned establishment of an oncology sales force, SkyePharma has reacquired these European rights for a nominal amount.

## **Notes to Editors**

### **About SkyePharma**

SkyePharma PLC uses its world-leading drug delivery technology to develop easier-to-use and more effective formulations of drugs. The majority of challenges faced in the formulation and delivery of drugs can be addressed by one of the Company’s proprietary technologies in the areas of oral, injectable, inhaled and topical delivery, supported by advanced solubilisation capabilities. For more information, visit <http://www.skyepharma.com>.

### **About neoplastic meningitis**

In many forms of cancer, secondary tumours (metastases) form in the meninges, the membrane that surrounds the brain and spinal cord. From autopsy data, neoplastic meningitis affects up to 20% of all cancer patients (Posner, Neurological Complications of Cancer 1995) but the condition is only diagnosed in 4-7% of cancer patients. The symptoms are pain and progressive neurological deterioration and few patients survive more than a few months, either from neurological dysfunction or from the primary tumour. The goal of therapy for neoplastic meningitis is palliation, not cure. The principal treatments are normally radiotherapy and chemotherapy to clear the cerebrospinal fluid of malignant cells and to prevent or slow recurrence. Most cytotoxic drugs do not cross the blood-brain barrier so the main chemotherapy treatments are methotrexate or cytarabine, injected intrathecally. These drugs reduce pain and slow neurological degradation but have the disadvantage of short half-lives that require frequent injections.

### **About DepoFoam™**

DepoFoam™ is SkyePharma’s proprietary sustained release injectable delivery technology. This is fully commercialised and approved by regulatory agencies in both the USA and Europe. DepoFoam™ consists of tiny lipid-based particles which contain discrete water-filled chambers dispersed through the lipid matrix. The particles are 10-30 microns in diameter and are suspended in saline. The suspension resembles skimmed milk and can be injected through a fine needle. The water-filled chambers containing active drug account for most of the weight of the particles. The lipids are naturally occurring substances (or close analogues) such as lecithin and triglycerides. The small amount of lipid is cleared rapidly in the body as the particles deliver their drug payload over a period that can be modified from 1 to 30 days. For example in DepoCyt<sup>®</sup>/DepoCyt<sup>®</sup> the circulating half-life of the drug cytarabine is increased from 3.4 hours to 141 hours.

### **About Mundipharma**

The Purdue/Mundipharma/Napp independent associated companies are privately owned companies and joint ventures covering the world’s pharmaceutical markets. The companies have particular expertise in bringing to patients the benefits of novel drug delivery systems such as those used to enhance medicines for the relief of severe pain.

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Except for the historical information herein, the matters discussed in this news release include forward-looking statements that may involve a number of risks and uncertainties. Actual results may vary significantly based upon a number of factors, which are described in SkyePharma's 20-F and other documents on file with the SEC. These include without limitation risks in obtaining and maintaining regulatory approval for existing, new or expanded indications for DEPOCYT® and other regulatory risks, risks relating to SkyePharma's ability to manufacture pharmaceutical products on a large scale, risks that customer inventory will be greater than previously thought, risks concerning SkyePharma's ability to manage growth, market a pharmaceutical product on a large scale and integrate and manage an internal sales and marketing organization and maintain or expand sales and market share for DEPOCYT®, risks relating to the ability to ensure regulatory compliance, risks related to the research, development and regulatory approval of new pharmaceutical products, risks related to research and development costs and capabilities, market acceptance of and continuing demand for SkyePharma's products and the impact of increased competition, risks associated with anticipated top and bottom line growth and the possibility that upside potential will not be achieved, competitive products and pricing, and risks associated with the ownership and use of intellectual property rights. SkyePharma undertakes no obligation to revise or update any such forward-looking statement to reflect events or circumstances after the date of this release.

**For further information please contact:**

SkyePharma PLC +44 207 491 1777

Michael Ashton, Chief Executive Officer  
Peter Laing, Director of Corporate Communications

Sandra Haughton, US Investor Relations +1 212 753 5780

Buchanan Communications +44 207 466 5000  
Tim Anderson / Nicola How



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**SCHEDULE VII**  
**THE TERRITORY**

**Territory for DepoCyte**

Part A

Belgium

Germany

France

Luxembourg

Sweden

Netherlands

Denmark

Ireland

United Kingdom

Greece

Spain

Portugal

Austria

Finland

---

Part B

Cyprus

Czech Republic

Estonia

Hungary

Latvia

Lithuania

Malta

Poland

Slovakia

Bulgaria

Romania

Former Soviet Union

Norway

Switzerland

Iceland

Liechtenstein

Slovenia

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## SCHEDULE VIII

### DISPUTE RESOLUTION

1. Representatives of the parties will, within 14 days of receipt of a written request from either party to the other, convene a meeting of the Committee to discuss in good faith and try to resolve the disagreement without recourse to legal proceedings.
2. If resolution does not occur within 7 days after meeting, the matter shall be escalated for determination by the respective Chief Executive Officer of the parties who may resolve the matter themselves or by agreement jointly appoint a mediator or independent expert to do so.
3. Nothing in this Agreement restricts either party's freedom to seek urgent relief to preserve a legal right or remedy, or to protect a proprietary trade secret or other right.

#### **Appointment of an Expert**

4. In the event that the Chief Executive Officers agree to resolve a dispute by referral to an expert ("Referral Notice") or in the event of one party wishing to refer a matter under Clause 3.3, 6.6 or 21.9 of the Agreement to an expert the following procedure shall be followed.
  - 4.1 The dispute or matter shall be determined by a single independent impartial expert who shall be agreed between the parties or, in the absence of agreement between the parties within 30 days of the service of a Referral Notice, be appointed by the Association of the British Pharmaceutical Industry or any successor thereto, or such other competent body agreed by the parties.
  - 4.2 30 days after the appointment of the expert pursuant to paragraph 4.1 both parties shall exchange simultaneously statements of case in no more than 10,000 words, in total, and each side shall simultaneously send a copy of its statement of case to the expert.

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- 4.3 Each party may, within 30 days of the date of exchange of statement of case pursuant to paragraph 4.2, serve a reply to the other side's statement of case in no more than 10,000 words. A copy of any such reply shall be simultaneously sent to the expert
- 4.4 Subject to paragraph 4.6 there shall be no oral hearing. The expert shall issue his decision in writing to both parties within 30 days of the date of service of the last reply pursuant to paragraph 4.3 above or, in the absence of receipt of any replies, within 60 days of the date of exchange pursuant to paragraph 4.2.
- 4.5 The seat of the dispute resolution shall be the normal place of residence of the expert.
- 4.6 The expert shall not have power to alter, amend or add to the provisions of this Agreement, except that the expert shall have the power to decide all procedural matters relating to the dispute, and may call for a one day hearing if desirable and appropriate.
- 4.7 The expert shall have the power to request copies of any documents in the possession and/or control of the parties which may be relevant to the dispute. The parties shall forthwith provide to the expert and the other party copies of any documents so requested by the expert
- 4.8 The decision of the expert shall be final and binding upon both parties except in the case of manifest error. The parties hereby exclude any rights of application or appeal to any court, to the extent that they may validly so agree, and in particular in connection with any question of law arising in the course of the reference out of the award.
- 4.9 The expert shall determine the proportions in which the parties shall pay the costs of the expert's procedure. The expert shall have the authority to order that all or a part of the legal or other costs of a party shall be paid by the other party.

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- 4.10 All documents and information disclosed in the course of the expert proceedings and the decision and award of the expert shall be kept strictly confidential by the recipient and shall not be used by the recipient for any purpose except for the purposes of the proceedings and/or the enforcement of the expert's decision and award.

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

**DATED July 27, 2005**

**SKYEPHARMA INC**

**and**

**MUNDIPHARMA INTERNATIONAL HOLDINGS LIMITED**

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**DISTRIBUTION AGREEMENT  
(Depocyte - Additional Territories)**

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**THIS AGREEMENT** is made on July 27, 2005

**BETWEEN**

- (1) **SKYEPHARMA INC** a company incorporated in California whose principal place of business is 10450 Sciences Center Drive, San Diego, California 92121 USA (“Skye”); and
- (2) **MUNDIPHARMA INTERNATIONAL HOLDINGS LIMITED** a company incorporated in Bermuda whose principal place of business is Mundipharma House, 14 Par-la-Ville Road, P.O. Box HM 2332, Hamilton HM JX, Bermuda (“Mundipharma”).

**Recitals**

- A. Skye is the owner of certain Skye Technology (as defined below) and possesses expertise relating to the Product (as defined below), which may be useful in the treatment of cancer and holds the Marketing Authorisation (as defined below) relating to certain countries outside the Territory (as defined below).
- B. Mundipharma has, among other things, specialist knowledge and expertise in relation to the marketing and sale of pharmaceutical products.
- C. The Parties are parties to the 2003 Agreement (as defined below). Following good faith discussions carried pursuant to clause 2.12 of the 2003 Agreement, the Parties wish to enter into a new agreement in respect of the Territory.
- D. Skye desires to grant and Mundipharma desires to acquire the exclusive right to market the Product (as defined below) in the Territory.
- E. The Parties recognise and acknowledge that Skye is the holder of the Marketing Authorisation (in respect of countries outside the Territory) which may not be sufficient to permit Mundipharma to market and sell the Finished Product in the Territory and that Mundipharma shall satisfy itself of its rights to do so prior to any marketing and sale of the Product;

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F. The Parties recognise and acknowledge that Skye will provide the Product which may not be sufficient to comply with the requirements of all or any part of the Territory and that Mundipharma shall satisfy itself of its rights to do so prior to any marketing and sale of the Product.

## **Operative Provisions**

### **1. Definitions**

1.1. In this Agreement the following words and expressions have the following meanings:

**“2003 Agreement”** means that distribution agreement entered into between the Parties on 30<sup>th</sup> June 2003 in respect of certain countries of Europe (being outside the Territory);

**“Affiliate”** means any company, corporation, firm, individual, trust or other entity which controls, is controlled by or is under common control with a party to this Agreement, and for the purpose of this definition the term “control” means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such firm, person, trust or company, whether through the ownership of voting securities, by contract or otherwise, or the ownership either directly or indirectly, including the ownership by trusts with substantially the same beneficial interests, of 50% or more of the voting securities (or, in relation to any country where ownership of more than 50% of the voting securities is prohibited by law, the



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	maximum percentage permitted, provided such percentage is no less than 30%) of such company, corporation, firm, individual, trust or other entity;
<b>“Applicable Laws”</b>	means all laws, rules, regulations and codes of practice regarding the representation, promotion and marketing of the Product in any jurisdiction in the Territory;
<b>“Commercial Delivery”</b>	means the date of the first commercial sale to a Third Party customer for commercial use or on sale of Finished Product in any country within the Territory following Regulatory Approval;
<b>“Competing Product”</b>	means a product (other than the Product) available in a country in the Territory in which the Product is sold by Mundipharma or its distributors which is indicated for use in the Field;
<b>“Confidential Information”</b>	means all confidential information, data and materials in whatever form disclosed by one party to the other or received in connection with this Agreement including, without limitation, the terms of this Agreement, Mundipharma’s marketing plans and Mundipharma’s sales forecasts, but excluding information: <ul style="list-style-type: none"><li>(a) which, at the time of disclosure by one party to the other, is in the public domain;</li><li>(b) which, after disclosure by one party to the other, becomes part of the public domain by publication, except by breach of any obligation of confidentiality;</li></ul>

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- (c) which the receiving party can establish by competent proof was already in its possession at the time of its receipt and was not acquired directly or indirectly from the other party;
  - (d) which, after disclosure by one party to the other, was developed independently of the information received;  
or
  - (e) received from Third Parties who were lawfully entitled to disclose such information;

**“EEA”**

means the European Economic Area as at the Effective Date, together with any other countries joining the European Economic Area thereafter as from the date of their joining;

**“Effective Date”**

means the date of this Agreement;

**“EMEA”**

means the European Medicines Evaluation Agency or any successors thereto;

**“Field”**

means the intrathecal treatment of malignant disease (including without limitation lymphomatous meningitis and, if an approved indication, the treatment of neoplastic meningitis);

**“Finished Product”**

means in (i) respect of manufacture and supply by Skye hereunder and under the Supply Agreement Product presented in Vials, packaged and labelled for the European Market as specified in the 2003 Agreement and (ii) in respect of the grant of rights to Mundipharma hereunder the same or as may otherwise be adjusted by or on behalf of Mundipharma in order to meet labelling and

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packaging requirements within the Territory (the parties acknowledge that any adjustments to the labelling and/or packaging beyond those for the European Market as specified in the 2003 Agreement shall be the responsibility of and at the cost of Mundipharma);

**“Force Majeure”**

means in relation to either party, any cause affecting the performance of this Agreement or the Supply Agreement arising from or attributable to any acts, events, non happenings, omissions or accidents beyond the reasonable control of the party to perform and in particular but without limiting the generality thereof shall include strikes, lock outs, industrial action, civil commotion, riot, invasion, war, threat of or preparation for war, terrorist activity, fire, explosion, storm, flood, earthquake, subsidence, epidemic or other natural physical disaster, impossibility of the use of railways, shipping, aircraft, motor transport, or other means of public or private transport, failure or suspension of utilities, and political interference with the normal operation of either party;

**“Improvements”**

means any discovery, development, improvement, Know-How or Patent relating to the Product and/or the Field generated, conceived, reduced to practice or otherwise created during the Term by Skye (or any Affiliate or licensee of Skye);

**“Intellectual Property”**

means Patents, Trade Marks, service marks, logos, trade names, rights in designs, copyright, utility models, rights in Know-How and other intellectual

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property rights, in each case whether registered or unregistered and including applications for registration, and all rights or forms of protection having equivalent or similar effect anywhere in the world;

**“Know-How”**

means all information, procedures, instructions, techniques, data, technical information, knowledge and experience (including, without limitation, toxicological, pharmaceutical, clinical, non-clinical and medical data, health registration data and marketing data), designs, dossiers (including, without limitation, manufacturing assay and quality control dossiers) manufacturing formulae, processing specifications, sales and marketing materials and technology relating to or concerned with the Product and/or the Finished Product whether in written, electronic or other form including without limitation the Product Data and the Manufacturing Technology;

**“Lymphomatous Meningitis Indication”**

means the use of the Product for the treatment of lymphomatous meningitis;

**“Manufacturing Technology”**

means all methods, processes, designs, data, procedures and other information relating to the manufacture of the Product, including without limitation final quality assurance procedures, manufacturing procedures, product and raw material specifications, formulation data and other technology related thereto;

**“Marketing Authorisation”**

means the approval by the EMEA numbered

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EU/1/01/187/001 permitting the commercial marketing of the Product in certain countries (outside the Territory) for the intrathecal treatment of lymphomatous meningitis;

**“Marketing Plan”**

means the plan for the marketing, distribution and sale of the Finished Product in the Territory submitted to the Committee in accordance with Clause 4;

**“Neoplastic Indication”**

means the use of the Product for the treatment of neoplastic meningitis;

**“Net Sales”**

means total gross sales of Finished Product invoiced by Mundipharma, its Affiliates, sub-distributors and sub-licensees to Third Parties, less:

- (a) transport, freight and insurance costs;
- (b) sales and excise taxes and duties;
- (c) normal and customary trade, quantity and cash discounts and rebates;
- (d) amounts repaid, discounted or credited by reason of (i) retroactive price reductions; (ii) discounts; or (iii) rebates which are, in any case, imposed upon Mundipharma, its Affiliates, sub-licensees or sub-distributors by any governmental or non-governmental body with the authority to impose such price reductions, discounts or rebates;
- (e) billing errors; and

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	(f) amounts repaid or credited (other than in respect of outdated goods) for rejected, returned or recalled goods;
<b>“Patents”</b>	means any patent and patent application (including provisional and non-provisional applications) that may be issued or issue in any country, including all additions, divisions, confirmations, continuations-in-part, substitutions, re-issues, re-examinations, extensions, registrations, patent terms extensions, supplementary protection certificates and renewals of any of the above;
<b>“Pricing Approval”</b>	means grant of all necessary pricing and reimbursement approvals by a regulatory, governmental or non-governmental authority in any country of the Territory;
<b>“Product”</b>	means the DepoFoam formulation of cytarabine (a sustained release formulation of cytarabine (ara-C) a pyrimidine analogue (L01BC01));
<b>“Product Data”</b>	means all data, information or results generated in the performance of any clinical studies, non-clinical studies (including pharmacological and toxicological studies) or chemistry and analytical studies in respect of the Product conducted by or on behalf of either party whether before or after the Effective Date;
<b>“Quarter”</b>	means a three month period ending on the last day of March, June, September or December in any Year;

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<b>“Regulatory Approval”</b>	means the grant of all necessary regulatory and governmental approvals by a Regulatory Authority or other governmental body required to sell the Finished Product in any country of the Territory, but excluding Pricing Approval;
<b>“Regulatory Authority”</b>	means any competent regulatory authority or other governmental body responsible for granting Regulatory Approval in the Territory;
<b>“Skye IP”</b>	means all Intellectual Property owned by or in the possession or control of Skye at the Effective Date or coming into its possession or control at any time during the Term relating to the Product or Finished Product (including any Improvements);
<b>“Skye Patents”</b>	means those Patents set out in Schedule I and such other Patents as come into existence during the Term and relate to the Product or Finished Product (including any Improvements);
<b>“Skye Technology”</b>	means the Skye Patents and Skye IP;
<b>“Supply Agreement”</b>	means the agreement between Skye and Mundipharma Medical Company dated 30 <sup>th</sup> June 2003 for the manufacture and supply of the Finished Product by Skye;
<b>“Term”</b>	means the term of this Agreement as set out in Clause 15;
<b>“Territory”</b>	means each of the countries and territories listed or referred to in Schedule IV;

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<b>“Third Party”</b>	means any company, corporation, firm, individual or other entity but excluding a party to this Agreement or an Affiliate;
<b>“Trade Marks”</b>	means those trade marks registered or applied for set out in Schedule II and such other trade marks as are agreed between the parties from time to time;
<b>“Vial”</b>	means a [**] vial containing the Product; and
<b>“Year”</b>	means a calendar year.

- 1.2. In this Agreement, unless the context requires otherwise:
  - 1.2.1. the headings are included for convenience only and shall not affect the construction of this Agreement;
  - 1.2.2. references to “persons” includes individuals, bodies corporate (wherever incorporated), unincorporated associations and partnerships;
  - 1.2.3. words denoting the singular shall include the plural and vice versa;
  - 1.2.4. words denoting one gender shall include each gender and all genders; and
  - 1.2.5. any reference to an enactment or statutory provision is a reference to it as it may have been, or may from time to time be amended, modified, consolidated or re enacted.
- 1.3. The Schedules comprise part of and shall be construed in accordance with the terms of this Agreement. In the event of any inconsistency between the Schedules and the terms of this Agreement, the terms of this Agreement shall prevail.



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## 2. Grant of Rights

- 2.1. Subject to the terms of this Agreement, Skye hereby exclusively appoints Mundipharma in the Territory to use, import, warehouse, market, distribute, sell and dispose of the Finished Product in the Field for the Term of this Agreement.
- 2.2. Skye hereby grants Mundipharma and its Affiliates an exclusive licence to use the Trade Marks in relation to the use, import, warehousing, marketing, distribution, sale and disposal of Finished Product in the Field in the Territory for the Term of this Agreement. Mundipharma shall satisfy itself, at its own cost, of its rights to use any Trade Marks prior to Commercial Delivery.
- 2.3. Skye hereby grants Mundipharma and its Affiliates an exclusive license to use all other Skye Technology in relation to the use, import, warehousing, marketing, distribution, sale and disposal of the Product or Finished Product in the Field in the Territory for the Term of this Agreement.
- 2.4. The term “exclusive” means to the exclusion of all others, including Skye and its Affiliates, except to the extent necessary to enable Skye to perform its specific obligations under this Agreement.
- 2.5. Skye shall not in the Territory during the Term:
  - 2.5.1. grant any Third Party the right to use, import, warehouse, market, distribute, sell or dispose of the Product and/or Finished Product; or
  - 2.5.2. either itself or through or with any Affiliate or Third Party actively conduct or participate in any use, importation, warehousing, marketing, distribution, sale or disposal of the Product and/or Finished Product, except as specifically permitted by this Agreement.

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- 2.6. During the Term, Mundipharma and its Affiliates have an exclusive right to use, import, warehouse, market, distribute, sell and dispose of Improvements in the Product and/or the Field in the Territory at no additional cost to Mundipharma. Skye shall promptly disclose all Improvements to Mundipharma.
  - 2.7. Mundipharma and its Affiliates may describe itself as an “Authorised Distributor” of Skye for the Finished Product in the Territory but shall not hold itself out as Skye’s agent for sales of the Finished Product or otherwise as being entitled to bind Skye in any way.
  - 2.8. Mundipharma and its Affiliates shall be entitled to conduct clinical research in respect of the Product. The results of any such research (and any and all rights therein) shall be Mundipharma’s property but shall be made available to Skye on a basis to be agreed between the Parties in good faith in writing. Mundipharma shall satisfy itself, at its own cost, of any requirement to carry out any clinical research in any part of the Territory prior to Commercial Delivery.
  - 2.9. Mundipharma and its Affiliates shall be entitled to use the Skye Technology and Skye’s Confidential Information in any submission to any Regulatory Authority regarding registration, pricing or reimbursement, in each case insofar as it may be relevant.
  - 2.10. Mundipharma may sell the Finished Products in the Territory through its Affiliates. Mundipharma may also sell the Finished Products through Third Party sales agents or sub-distributors upon obtaining the express prior written permission of Skye (such permission not to be unreasonably withheld or delayed). Notwithstanding any such permission that may be granted by Skye, Mundipharma shall be and remain responsible in all respects for the acts and omissions of any Affiliate, sales agent or sub-distributor and those acts and omissions shall for the purpose of this Agreement be deemed the acts and omissions of Mundipharma. Mundipharma or its Affiliate shall consolidate all orders from any Affiliates, sales agents or sub-distributors.

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### 3. Obligations

- 3.1. Skye shall be under no obligation to Mundipharma in relation to obtaining Regulatory Approval of the Product in any part of the Territory for the Lymphomatous Meningitis Indication, the Neoplastic Indication or any other indication. Mundipharma acknowledges that, to the extent that any Regulatory Approval shall be required, Mundipharma shall satisfy itself at its own cost that it shall be permitted to market and sell the Product in each country of the Territory before commencing such marketing and sale in such country.
- 3.2. Skye shall:
  - 3.2.1. manufacture and supply, or procure the manufacture and supply of, the Finished Product in accordance with the Supply Agreement both parties recognising that such Finished Product has been produced to satisfy the requirements of the EEA and may not satisfy the requirements for Products sold in the Territory;
  - 3.2.2. promptly provide Mundipharma with all information in its possession or otherwise coming to its attention relating to the occurrence of a serious adverse event or an adverse event (in any jurisdiction throughout the world) in connection with the Product or the Finished Product;
  - 3.2.3. promptly provide Mundipharma at Mundipharma's cost with all Product Data and other Know How in its possession or which is or becomes available to it during the Term which it is entitled to disclose which is relevant or useful to Mundipharma in performing its obligations under this Agreement; and

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- 3.2.4. promptly provide Mundipharma with proofs of packaging and package inserts for the Finished Product.
- 3.3. Mundipharma's obligations in respect of Clauses 3.4 and 3.5 in any country in the Territory in any Year shall be subject to timely supply of Finished Product by Skye pursuant to the Supply Agreement and to Skye complying with its other material obligations under this Agreement in a timely way. In respect of any Year in any country of the Territory in which the exercise of any Third Party Intellectual Property rights materially prevents Mundipharma, its Affiliates, sub-licensees or sub-distributors from using, importing, warehousing, distributing, marketing, selling or disposing of Product in that country of the Territory the parties shall agree in good faith, where relevant, an appropriate amendment to Mundipharma's obligations under Clauses 3.4 and 3.5. If the parties cannot agree, an expert shall be appointed to resolve the issue pursuant to the dispute resolution procedure in Schedule V.
- 3.4. Mundipharma shall:
- 3.4.1. prior to any marketing and sale of the Finished Product in any country of the Territory ensure compliance of the Finished Product with all Applicable Laws and shall obtain all relevant consents and Regulatory Approval (if required) in respect of the Territory and, without limitation, shall ensure compliance of the Finished Product with all packaging and labelling requirements relevant to the Territory;
- 3.4.2. shall use commercially reasonable efforts to achieve Commercial Delivery and market and sell the Finished Product in each country of the Territory as soon as it is reasonably practicable;

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- 3.4.3. during the Term of this Agreement insofar as is legally permissible, promote, market, sell and distribute the Finished Product to customers within the Territory and use its commercially reasonable efforts to satisfy the demand for the Finished Product throughout the Territory and to attempt to increase the demand for such Finished Product by, among other things, servicing customer accounts with reasonable frequency. Mundipharma shall be solely responsible for, and shall bear all costs associated with, all marketing activities related to the Finished Product in the Territory;
  - 3.4.4. maintain adequate warehouse facilities and employ or procure a sufficient number of experienced, trained and qualified sales and marketing personnel to promote the sale of the Finished Product in the Territory and perform, or procure the performance of the activities set forth in the Marketing Plan;
  - 3.4.5. maintain a reasonable inventory of Finished Product taking into account the shelf life of the Product to reasonably fulfil the requirements of its customers in the Territory;
  - 3.4.6. maintain adequate records concerning the sale of the Finished Product as required by any applicable Regulatory Authority in the Territory;
  - 3.4.7. submit advertising literature proposed to be used in connection with the sale of the Product in the Territory to Skye at least [\*\*] ([\*\*]) business days in advance of its intended use of same to enable Skye to provide Mundipharma with comments within said [\*\*] ([\*\*]) business day period. Mundipharma shall ensure that all such advertising literature complies with all relevant codes of practice and Applicable Laws and shall indemnify Skye in respect of any breach;

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- 3.4.8. promptly provide Skye with all information in its possession or otherwise coming to its attention relating to the occurrence of a serious adverse event or an adverse event (in any jurisdiction throughout the world) in connection with the Product or Finished Product, and promptly forward to Skye information concerning any and all charges, complaints or claims reportable to any Regulatory Authority relating to the Product or Finished Product that may come to Mundipharma's attention, and otherwise comply in all respects with the Pharmacovigilance Agreement to be agreed between the parties and the recall procedures set out in Schedule III; and
- 3.4.9. obtain and maintain all necessary licenses, permits, records and authorizations required by law in respect of the marketing, distribution and sale of the Finished Product in the Territory and observe and comply with all Applicable Laws.
- 3.5. In connection with the promotion and marketing of the Finished Product (if any) Mundipharma shall:
- 3.5.1. observe and comply with such storage, stock control and operational practices and procedures as may be legally required in the Territory and as reasonably specified in writing by Skye from time to time;
- 3.5.2. subject to the provisions of clause 2.2 market the Product throughout the Territory under the Trade Marks and all marketing materials for the Finished Product shall display the Trade Marks. In addition, all packaging shall state that "Depocyte<sup>®</sup> is distributed by Mundipharma under an exclusive licence from SkyePharma Inc."

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- 3.6. Except as provided under the 2003 Agreement, Mundipharma shall not actively market distribute and/or sell the Finished Product outside the Territory.
  - 3.7. For [\*\*] ([\*\*]) years from the first Commercial Delivery in the Territory or during the Term, whichever is shorter, Mundipharma shall not market, distribute or sell a Competing Product in the Territory. Mundipharma shall procure the purchase of its total requirement of Finished Product from Skye under the terms of the Supply Agreement.
  - 3.8. If Mundipharma receives a request from a customer located both outside the EEA and outside the Territory for supply of the Product and/or Finished Product, Mundipharma shall forward such request to Skye.
  - 3.9. Nothing in this Agreement shall entitle Mundipharma to any right or remedy against Skye if the Product is sold in the Territory by any person outside the Territory other than by Skye or with Skye's consent.
  - 3.10. To the extent permissible by applicable law, Skye shall use commercially reasonable efforts to ensure that in the event that Skye grants exclusive marketing and distribution rights for the Product or Finished Product to a Third Party outside the Territory, provisions having equivalent effect to those contained in Clauses 3.6 to 3.8 inclusive shall be included mutatis mutandis in any agreement for such grant of rights to such Third Party.

#### **4. Committee**

- 4.1. The Parties shall establish a committee ("Committee") consisting of 4 individuals ("Committee Members"); 2 of whom shall be nominated by Skye; and 2 of whom shall be nominated by Mundipharma. The Committee Members may be replaced by notice to the other Party and shall be appropriately qualified and experienced in order to make a meaningful contribution to Committee meetings.

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- 4.2. The purpose of the Committee is to provide a forum for the Parties to share information and knowledge on the on-going development and marketing of the Product including, but not limited to, monitoring progress on clinical studies, reviewing clinical trial programmes, considering proposed marketing and promotional plans, reviewing market conditions and discussing any regulatory, technical, quality assurance or safety issues in relation to the Product. The Committee shall conduct its discussions in good faith with a view to operating to the mutual benefit of the Parties and in furtherance of the successful development and marketing of the Product.
  - 4.3. The Committee shall meet as often as the Committee Members may determine, but in any event not less than 2 times per Year. The Committee may invite individuals with special skills to attend such meetings where considered to be relevant and appropriate. The quorum for Committee meetings shall be 2 Committee Members, comprising 1 Committee Member from each Party.
  - 4.4. Mundipharma shall on or before 15 October of each Year thereafter provide the Committee with its Marketing Plan for the coming Year. Each Marketing Plan shall include, without limitation, Net Sales targets and projections with respect to sales force staffing levels, marketing research, physician education, marketing expenditure and advertising.

## **5. Product Supply**

- 5.1. The Parties acknowledge that Skye's obligation under the Supply Agreement shall be for the supply of Finished Product and Mundipharma shall satisfy itself, at its own cost, of its rights to sell Finished Product in the Territory. In consideration of the manufacture,



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packaging and supply of the Finished Product, Mundipharma agrees that the supply price under the Supply Agreement shall be [\*\*] Euros (€[\*\*]) per Vial supplied to Mundipharma in any country of the Territory during the Term, subject to adjustment in accordance with the other terms of the Supply Agreement.

- 5.2. Within 30 days of the end of each Quarter during the Term of this Agreement, Mundipharma shall send to Skye a statement setting out in respect of each country in the Territory in which Finished Product is sold, details of Finished Product sold during the previous Quarter itemised by presentation form, quantity, total gross receipts, itemised deductions which are applied to achieve the Net Sales figure and Net Sales of Finished Product. The statement shall (where appropriate) show:
- 5.2.1. the total Net Sales for each such country expressed both in local currency and in Euros and the conversion rate used; and
- 5.2.2. the total number of Vials sold in each such country (less rejected, returned or recalled Vials other than those rejected, returned or recalled in connection with the expiry of the shelf life of the Vials).
- 5.3. For the avoidance of doubt, Skye shall be liable for any Third Party royalty obligations existing at the date hereof relating to the Skye Technology.
- 5.4. The supply price specified in Clause 5.1 is for Finished Product supplied ex-works (as defined in Incoterms 2000) Lyon.

## **6. Payments**

- 6.1. In addition to any amounts payable by Mundipharma or its Affiliates pursuant to Clause 5.1, Mundipharma shall pay a royalty of:
- 6.1.1. [\*\*] Euros (€[\*\*]) per Vial of Finished Product supplied to Mundipharma Medical Company pursuant to the Supply Agreement within [\*\*] days of the date of Skye's invoice to Mundipharma Medical Company for such Vials; and

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- 6.1.2. in the event that [\*\*] per cent ([\*\*]%) of Net Sales in a Quarter is greater than the number of Vials sold (less rejected, returned or recalled Vials other than those rejected, returned or recalled in connection with the expiry of the shelf life of the Vials) in that Quarter multiplied by [\*\*] Euros (€[\*\*]) Mundipharma shall pay the difference to Skye within [\*\*] ([\*\*]) days of the end of the Quarter.
- 6.2. The Net Sales of Mundipharma, its Affiliates, sub-licensees and sub- distributors in the Territory in any Marketing Year during the Term under this Agreement shall be aggregated with Net Sales under the 2003 Agreement for the purposes of clause 6.8 of the 2003 Agreement and this clause 6.2 shall be regarded as a variation of the 2003 Agreement for these purposes.
- 6.3. If at any time the continued performance of this Agreement ceases to be commercially profitable or would otherwise involve financial hardship for either party, the parties shall discuss in good faith ways of restructuring this Agreement with a view to restoring commercial profitability or removing the financial hardship.

## **7. Payment, Accounting, Audit Rights**

- 7.1. Unless otherwise agreed between the parties, all payments to be made hereunder shall be made in Euros. Net Sales shall be determined in the currency in which the Finished Product was sold and shall be converted into Euros using closing mid point published in the Financial Times for the last business day of the Quarter for which such payment is being determined.

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- 7.2. Any amount payable under this Agreement shall be deemed to be exclusive of Value Added Tax, which shall be payable in addition, if applicable.
  - 7.3. Mundipharma shall be entitled to deduct from its payments to Skye the amount of any withholding taxes required to be withheld and shall on Skye's request provide proof of payment of such taxes.
  - 7.4. Mundipharma shall maintain and shall procure the maintenance of accurate and up to date records and books of account showing the quantity, description and value of the Finished Products supplied in each country of the Territory during the previous 6 years.
  - 7.5. Mundipharma shall during business hours, on no less than 14 days' notice from Skye and not more than once in any Year, make available for inspection the records and books referred to in Clause 7.4. Such inspection shall be undertaken by an independent auditor appointed by Skye and reasonably acceptable to Mundipharma for the purpose of verifying the accuracy of any statement or report given by Mundipharma to Skye and/or the amount of royalties due.
  - 7.6. Skye shall procure that any independent auditor appointed under Clause 7.5 shall maintain all information and materials received, directly or indirectly, by it from Mundipharma in strict confidence and shall not use or disclose the same to any Third Party, nor to Skye save for the sole purpose of reporting the results of the audit pursuant to this Clause.
  - 7.7. In the event that an auditor appointed pursuant to this Clause concludes that there has been an underpayment or overpayment, Skye shall deliver to Mundipharma a copy of such auditor's report. Any deficit payable by Mundipharma or any excess refundable by Skye shall be payable within [\*\*] days of Mundipharma's receipt of such report. The fees charged by such auditor shall be payable by Skye, provided that if

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the audit reveals that payments due to Skye for any Year have been understated by more than [\*\*]%, the fees charged by such auditor shall be payable by Mundipharma.

- 7.8. Should any amount not be paid pursuant to Clause 7.7 by either party on or before the due date for payment the non-payer shall pay to the other party in addition interest on such amount unpaid at the rate of [\*\*]% above the base rate from time to time of the National Westminster Bank Plc and such interest shall be calculated and payable in respect of the period from the date such amount is due until the date payment in full is received in cleared funds by the payee.

## **8. Intellectual Property and Trade Marks**

- 8.1. Except as set out in this Agreement, all right, title and interest in the Skye Technology shall belong to Skye and Mundipharma shall not have any right, title or interest in the Skye Technology.
- 8.2. Mundipharma shall:
- 8.2.1. use the Trade Marks in a manner which conforms to the reasonable directions and standards notified to it by Skye from time to time; and
  - 8.2.2. not do anything which could, in Skye's reasonable opinion, bring the Trade Marks or Skye into disrepute or otherwise damage the goodwill attaching to the Trade Marks.
- 8.3. Skye shall, at its own cost, take all steps required to maintain those registrations for the Trade Marks subsisting at the Effective Date, and prosecute any applications subsisting at the Effective Date for registration of the Trade Marks through to grant (including oppositions thereto) in the Territory.

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- 8.4. Mundipharma may request that Skye use reasonable efforts to obtain trade mark registrations in respect of the Trade Marks, in classifications which cover the Product, or Finished Product in any countries in the Territory. Skye shall promptly notify Mundipharma if it does not intend to make or pursue a trade mark registration in respect of the Trade Marks in any of the countries in the Territory and Mundipharma shall thereafter be entitled to make applications for such trade mark registrations in Skye's name.
  - 8.5. Mundipharma shall have the right during the Term to register domain names specific to the countries comprised in the Territory that incorporate the Trade Mark which shall be assigned to Skye on termination.
  - 8.6. In the event that the trade mark Depocyte® is unavailable for the Product or the Finished Product in any country of the Territory, the parties shall, via the Committee consider an appropriate alternative trade mark for registration in that country or territory. Upon registration, such trade marks shall comprise part of the Trade Marks hereunder.

**9. Representations and Warranties**

- 9.1. Each of the parties warrants and represents that:
  - 9.1.1. it has full power and authority and legal right to enter into this Agreement and perform the obligations under it;
  - 9.1.2. the execution of this Agreement has been duly authorised by all necessary actions;
  - 9.1.3. this Agreement is a legal and valid obligation, binding on each of the parties and enforceable in accordance with its terms; and

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- 9.1.4. entry into and exercise of the respective rights and obligations under this Agreement do not, and will not, violate any provision of any agreement or other instrument or document to which it is party or affect or be in conflict with or result in the breach of or constitute a default under any such agreement, instrument or document.
- 9.2. Skye represents and warrants that as at the Effective Date:
- 9.2.1. to the best of its knowledge and belief the Skye Technology includes all Intellectual Property in the possession, custody or control of Skye and its Affiliates which is reasonably necessary for the exploitation of the Product by Mundipharma in accordance with the terms of this Agreement;
- 9.2.2. it is the owner of, or has exclusive rights (for at least as long as the Term of this Agreement) to, all of the Skye Technology in existence at the Effective Date, and is exclusively entitled to grant the rights granted under this Agreement;
- 9.2.3. to the best of its knowledge and belief there are no Third Party interests or rights in the Skye Technology that may prevent, encumber or restrict in any way the exercise by Mundipharma of the rights granted under this Agreement nor will Skye grant any such rights after the Effective Date;
- 9.2.4. to the best of its knowledge and belief no Third Party is infringing or has infringed the Intellectual Property rights in any of the Skye Technology;
- 9.2.5. at the date hereof, Skye has no notice, and is not aware, that the exercise of Mundipharma's rights granted under this Agreement infringes or conflicts with any Third Party Intellectual Property rights and to the best of its knowledge and

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belief the exercise of Mundipharma's rights granted under this Agreement will not infringe or conflict with any Third Party Intellectual Property rights and will not incur any obligation to any Third Party;

- 9.2.6. all renewal and maintenance fees and all steps necessary for the filing, prosecution and maintenance of the Skye Patents have been paid or taken;
- 9.2.7. at the Effective Date it is the holder of the Marketing Authorisation and to the best of its knowledge such Marketing Authorisation is not subject to any threatened or pending claim, challenge or review by any Third Party nor is there any pre-clinical or clinical data or correspondence with a Regulatory Authority which suggests that there may exist quality, toxicity, safety or efficacy concerns which may materially impair the utility or safety of the Product;
- 9.2.8. all information, data and Third Party notices in relation to adverse events, serious adverse events or recalls relating to or connected with the Product or the Finished Product (in any jurisdiction throughout the world) and of which Skye is aware have been disclosed by Skye to Mundipharma;
- 9.2.9. to the best of its knowledge and belief Skye has disclosed all information in its possession or control concerning the Products and the Finished Product and the subject matter of this Agreement which would be material to a prudent distributor's decision to enter into this Agreement.

- 9.3. Skye confirms and agrees that where its representations and warranties in Clause 9.2 are subject to its knowledge, belief or awareness, Skye shall be deemed to have carried out due and careful enquiries into the subject matter of those representations and warranties.

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**10. Liability, Insurance and Indemnities**

- 10.1. Skye shall remain solely responsible for discharging creditors and for all Claims (as defined in this Clause 10) relating to the Territory relating to the development, manufacture, sale and supply of the Product or Finished Product resulting from any act, default, transaction or circumstance occurring prior to the Effective Date (including claims or demands arising after the Effective Date to the extent they are based on events occurring prior to the Effective Date), and Skye shall indemnify and hold harmless Mundipharma and its Affiliates from and against any and all such Claims or part thereof arising in connection therewith.
- 10.2. Skye shall indemnify and hold harmless Mundipharma and its Affiliates from and against;
  - 10.2.1. Claims arising from or in connection with Intellectual Property infringement proceedings with Third Parties in connection with the Skye Technology (except to the extent that the claim has arisen from Mundipharma's use of the Skye Technology other than in accordance with this Agreement) but excluding any Claims which arise out of any lack of Regulatory Approval for the Finished Product or inappropriate packaging and labelling in the Territory; and
  - 10.2.2. Claims against Mundipharma arising from or in connection with death or personal injury except to the extent arising out of any breach of this Agreement or the Supply Agreement by Mundipharma or its Affiliates or out of any negligent act or omission of Mundipharma or its Affiliates or their employees in the course of their employment.



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- 10.3. Mundipharma shall indemnify and hold harmless Skye from and against Claims arising from or in connection with:
- 10.3.1. the use, storage, marketing, distribution or sale of the Finished Product by Mundipharma or its Affiliates to the extent that such Claims arise out of any breach of this Agreement by Mundipharma or its Affiliates or out of any negligent act or omission of Mundipharma or its Affiliates or their employees in the course of their employment or which arise out of Claims which arise out of any lack of Regulatory Approval for the Finished Product or inappropriate packaging and labelling in the Territory; and
  - 10.3.2. death or personal injury to the extent arising out of any breach of this Agreement by Mundipharma or its Affiliates or out of any negligent act or omission of Mundipharma or its Affiliates or their employees in the course of their employment.
- 10.4. Promptly after receipt by a party of any Claim or alleged claim or notice of the commencement of any action, administrative or legal proceeding, or investigation as to which an indemnity provided for in this Clause 10 may apply, the indemnified party shall give written notice to the indemnifying party of such fact. The indemnifying party shall have the option to assume the defence thereof by election in writing within [\*\*] ([\*\*]) days of receipt of such notice. If the indemnifying party fails to make such election, the indemnified party may assume such defence and the indemnifying party will be liable for reasonable legal and other expenses subsequently incurred in connection with such defence. The parties will co-operate in good faith in the conduct of any defence, provide such reasonable assistance as may be required to enable any Claim to be properly defended, and the party with conduct of the action shall provide promptly to the other party copies of all proceedings relating to such action.

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- 10.5. Should the indemnifying party assume conduct of the defence:
- 10.5.1. the indemnified party may retain separate legal advisors in the event that it reasonably concludes that it may have defences available to it which are additional to, different from or inconsistent with those available to the indemnifying party, in which case the indemnifying party shall be liable for the indemnified party's reasonable costs and expenses so incurred; and
- 10.5.2. the indemnifying party will not, except with the consent of the indemnified party (such consent not be unreasonably withheld or delayed), consent to the entry of any judgment or enter into any settlement (other than for the payment of damages by the indemnifying party, which includes as an unconditional term a release from the claimant to the indemnified party from all liability in respect of all claims).
- 10.6. The indemnified party shall not admit liability in respect of, or compromise or settle any such action without the prior written consent of the indemnifying party, such consent not to be unreasonably withheld or delayed.
- 10.7. Each party shall maintain, at its own cost, either
- 10.7.1. comprehensive product liability insurance and general commercial liability insurance. Such insurance shall be with a reputable insurance company and where reasonably possible (taking into account the availability of such insurance) shall be maintained for not less than 6 years following the expiry or termination of this Agreement; or
- 10.7.2. a reasonable level of self-insurance.
- 10.8. Any and all liability of Skye to Mundipharma arising in respect of Clauses 9, 10.1 and 10.2.2 of this Agreement, shall be limited (except for death or personal injury caused by negligence) to [\*\*] Euros (€[\*\*]).

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- 10.9. Any and all liability of Mundipharma to Skye arising in respect of Clause 10.3 of this Agreement shall be limited (except for death or personal injury caused by negligence) to [\*\*] Euros (€[\*\*]).
- 10.10. Notwithstanding anything contained in this Agreement or the Supply Agreement in no circumstance shall either party be liable to the other in contract, tort (including negligence or breach of statutory duty) or otherwise howsoever, and whatever the cause thereof, for any special, indirect or consequential loss or damage of any nature whatsoever.
- 10.11. Nothing in this Clause shall be construed as excluding or limiting the liability of either party or any of its officers, employees and agents to the other party for death or personal injury of any person resulting from the negligence of such persons or in respect of fraud.
- 10.12. In this Clause 10, "Claims" shall mean any and all claims, actions and demands made or brought by Third Parties, and all judgements, losses, damages, settlements, costs and expenses in connection therewith, including reasonable legal and expert fees incurred in defending such claims, actions and demands.

## **11. Confidentiality, Press Releases and Publications**

- 11.1. Skye and Mundipharma undertake to each other to keep confidential, and to procure that their respective Affiliates, employees, directors, officers, contractors, lawyers and accountants (including those of their Affiliates) keep confidential, Confidential Information disclosed to it by or belonging to the other party, until it ceases to be Confidential Information.

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- 11.2. Any Confidential Information received from the other party shall not be disclosed to any Third Party or used for any purpose other than as provided or specifically envisaged by this Agreement, unless it ceases to be Confidential Information through no fault of the receiving party.
  - 11.3. The confidentiality and non-use obligations contained in this Agreement shall continue for the duration of this Agreement and for a period of [\*\*] years after termination for any reason of this Agreement.
  - 11.4. The parties shall consult with each other, in advance, with regard to the terms of all proposed press releases, public announcements and other public statements with respect to the transactions contemplated under this Agreement.
  - 11.5. The Confidential Information may be disclosed by the other parties to the extent that such disclosure has been ordered by a court of law or directed by a governmental authority, provided that, wherever practicable, the party disclosing the Confidential Information has given sufficient written notice in advance to the other party to enable it to seek protection or confidential treatment of such Confidential Information, and may be disclosed only to the extent that such disclosure has been so ordered or directed.

## **12. Patents**

- 12.1. Skye shall file, prosecute and maintain the Skye Patents, and meet all related costs and expenses.

## **13. Infringement of Third Party Rights**

- 13.1. In the event of a party becoming aware that the exercise of either party's rights and obligations pursuant to this Agreement are infringing or may infringe the rights of a Third Party, it will promptly so notify the other party and provide it with such details of the Third Party rights and the extent of the infringement as are known to it. Skye shall be

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entitled at its discretion to contest any such Third Party claim or proceedings or otherwise to take such steps to terminate any infringement or remedy the position and where necessary enter any Third Party licence agreement provided in each case that Mundipharma will lawfully be able to practice fully the rights and licenses granted hereunder. No later than [\*\*] days from becoming aware of or receiving notification in relation to any infringement of the rights of a Third Party, Skye shall inform Mundipharma whether it intends to contest the claim or take such other steps necessary to terminate any infringement (including the negotiation of a Third Party licence agreement) and Mundipharma may thereafter contest any such Third Party claim or proceedings at its cost. If Skye does contest the claim or take steps to terminate any infringement it shall keep Mundipharma informed of its actions in this regard. If Skye enters into a Third Party licence agreement any Third Party royalties or licence fees incurred in this regard shall be borne by Skye.

- 13.2. Where Mundipharma has assumed responsibility for contesting any such Third Party claim or proceedings in accordance with Clause 13.1 (including the negotiation of a Third Party licence agreement), Mundipharma shall keep Skye reasonably informed of its actions in this regard and Skye will provide Mundipharma with all reasonable co-operation in connection with such actions. Without limitation this shall include Mundipharma furnishing Skye with drafts of any proposed Third Party licence agreement and Mundipharma seeking Skye's approval to the terms of any such agreement. Mundipharma shall not enter into any such Third Party licence agreement without the prior written approval of Skye to such agreement (which shall not be unreasonably withheld or delayed). Skye shall reimburse Mundipharma's reasonable costs in defending any such claim and any Third Party licence fees incurred in this regard and Mundipharma or its Affiliate shall be entitled to credit any Third Party royalties against payments due to Skye pursuant to Clauses 5 and 6 or under the Supply Agreement.

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**14. Infringement of Skye Technology**

- 14.1. In the event that Mundipharma becomes aware of any actual or suspected infringement or misuse of the Skye Technology or an attack on its validity in the Territory it shall promptly notify Skye and provide it with all details thereof in its possession.
- 14.2. No later than [\*\*] days from becoming aware of or receiving notification of any actual or suspected infringement or misuse of the Skye Technology or attack on its validity in the Territory, Skye shall inform Mundipharma whether it intends to institute or defend proceedings against the infringer or attacker.
- 14.3. Skye shall be entitled at its discretion to take such action to seek an abatement of such infringement, or to defend such attack on validity, as it sees fit, which may include the institution or defence of proceedings against the infringer or attacker. Mundipharma shall provide all such assistance at Skye's cost and expense as Skye may reasonably require in the prosecution or defence of any such proceedings.
- 14.4. Any damages, award or settlement monies actually received by Skye in respect to such infringement and paid in compensation for sales lost by Mundipharma shall belong to Mundipharma, subject to such payments being treated as Net Sales and Skye deducting therefrom any payment it would be due had Mundipharma achieved such Net Sales. Any damages, award or settlement monies actually received by Skye in respect to such infringement and not paid in compensation for sales lost by Mundipharma shall belong to Skye.
- 14.5. Should in accordance with Clause 14.2 Skye notify Mundipharma that it does not intend to pursue any such infringement. Mundipharma may

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thereafter pursue such infringement. Any damages, award or settlement monies actually received by Mundipharma in respect to such infringement and paid in compensation for sales lost by Mundipharma shall belong to Mundipharma, subject to such payments (net of reasonable costs of pursuing the infringement) being treated as Net Sales and Mundipharma paying to Skye therefrom any payment which would be due to Skye had Mundipharma achieved such Net Sales. Any damages, award or settlement monies actually received by Mundipharma in respect to such infringement and not paid in compensation for sales lost by Mundipharma shall belong to Skye, save that Mundipharma shall be entitled to set off its reasonable costs in pursuing such infringement against such damages, award or settlement actually received by Mundipharma.

**15. Term**

- 15.1. This Agreement commences on the Effective Date and, subject to earlier termination in accordance with the provisions of Clause 16, shall continue in force until the expiry or termination (for any reason) of the 2003 Agreement.

**16. Termination**

- 16.1. Either party shall be entitled forthwith to terminate this Agreement by notice to the other if:
- 16.1.1. the other party commits a material or persistent breach of any obligation under this Agreement or the Supply Agreement, and in the case of a breach which is capable of remedy fails to remedy it within [\*\*] days of receipt of notice from the first party of such breach and of its intention to exercise its rights under this Clause; or

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- 16.1.2. a petition is presented, or a meeting is convened for the purpose of considering a resolution, or other steps are taken, for making an administration order against or for the winding up of the other party or an administration order or a winding up order is made against or a provisional liquidator is appointed with respect to the other party; or
  - 16.1.3. an encumbrancer takes possession of, or a trustee or administrative receiver or similar officer is appointed in respect of, all or any material part of the business or assets of the other party, or distress or any form of execution is levied or enforced upon or sued out against any such assets and is not discharged within [\*\*] days of being levied, enforced or sued out; or
  - 16.1.4. the other party is unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986 or becomes unable to pay its debts as they fall due or suspends or threatens to suspend making payments with respect to all or any class of its debts; or
  - 16.1.5. any voluntary arrangement is proposed under section 1 of the Insolvency Act 1986 in respect of the other party; or
  - 16.1.6. the other party proposes or makes any composition or arrangement or composition with, or any assignment for the benefit of, its creditors; or
  - 16.1.7. anything analogous to any of the events described in Clauses 16.1.2 - 16.1.6, inclusive, occurs under the laws of any applicable jurisdiction; or
  - 16.1.8. the other party ceases or threatens to cease to carry on the whole or any material part of its business.



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- 16.2. Skye shall be permitted to terminate this Agreement on a country by country basis (and such termination shall represent Skye's sole remedy in such event) if Mundipharma fails to achieve Commercial Delivery in that country as envisaged by clause 3.4.2 above within [\*\*] ([\*\*]) months of the Effective Date. In relation to any termination of this Agreement in respect of breach under clauses 2.2, 2.7, 3.4, 3.5 and 5.1 above, any such termination shall similarly only be permitted and take effect in respect of the particular country in the Territory in respect of which the breach has occurred.
- 16.3. Mundipharma or Skye shall be entitled forthwith to terminate this Agreement in the event of the Marketing Authorisation or a relevant Regulatory Approval being cancelled or withdrawn for a period likely to exceed [\*\*] ([\*\*]) months or in the event of Mundipharma, its Affiliates, sub-licensees or sub-distributors being prevented from selling the Product in the Territory by a final non-appealable judgement in respect of any infringement by the Skye Technology or the sale of Finished Product in accordance herewith of any Third Party Intellectual Property rights.
- 16.4. The termination or expiry of this Agreement shall not release either of the parties from any liability which at the time of termination or expiry has already accrued to the other party, nor affect in any way the survival of any other right, duty or obligation of the parties which is expressly stated elsewhere in this Agreement to survive such termination or expiry.

## **17. Consequences of Termination**

- 17.1. On termination of this Agreement for any reason (and, if applicable, in respect of that country in respect of which termination occurs):
- 17.1.1. the licences and rights granted and appointments made under Clauses 2.1 and 2.2 shall terminate and Mundipharma shall (and shall procure that its Affiliates and sub-licensees shall) cease all activities licensed or appointed hereunder, subject to Clause 17.2;

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- 17.1.2. the Supply Agreement shall be terminated as far as it relates to the Territory;
  - 17.1.3. the following provisions of this Agreement shall continue in full force and effect: this Clause 17 and Clauses 10 and 11;
  - 17.1.4. Mundipharma shall return to Skye all Skye IP in its possession;
  - 17.1.5. Mundipharma shall assign to Skye free of charge any domain name registrations it has registered pursuant to Clause 8.5 and any trade marks for which it has applied under Clause 8.6;
  - 17.1.6. Mundipharma shall promptly transfer to Skye or its nominee insofar as it is able to do so, each and every Regulatory Approval (including but not limited to any pricing and reimbursement approval) relating to the Product, together with all communications with the relevant Regulatory Authorities, and all notes and record thereof.
- 17.2. In the event that this Agreement is terminated by Skye in accordance with Clause 16.1, Mundipharma and its Affiliates, sub-licensees and sub-distributors shall be entitled to continue to sell existing stocks of the Finished Product in the Territory for so long as necessary to sell all such stocks, provided that Mundipharma continues to make any payments due to Skye in respect of such sales in accordance with the provisions of this Agreement. Immediately upon notification from Skye, such post termination sales shall cease, subject to Skye assuming Mundipharma's obligations to meet unfulfilled orders and acquiring all stocks of Finished Product held by Mundipharma, its Affiliates, sub-licensees and sub-distributors at the price paid for such stocks by Mundipharma's Affiliate.

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**18. Force Majeure**

- 18.1. Neither Party shall be entitled to terminate this Agreement or shall be liable to the other under this Agreement for loss or damages attributable to any Force Majeure, provided the party affected shall give prompt notice thereof to the other party. Subject to Clause 18.2, the party giving such notice shall be excused from all affected obligations hereunder for so long as it continues to be affected by Force Majeure.
- 18.2. If such Force Majeure continues unabated for a period of at least 90 days, the parties will meet to discuss in good faith what actions to take or what modifications should be made to this Agreement as a consequence of such Force Majeure in order to alleviate its consequences on the affected party.

**19. Notices**

- 19.1. Any notice or other document given under this Agreement shall be in writing in the English language and shall be given by hand or sent by prepaid airmail, by fax transmission or e-mail to the address of the receiving Party as set out in Clauses 19.3 below unless a different address or fax number has been notified to the other in writing for this purpose. Notice by email is not permitted.
- 19.2. Each such notice or document shall:
- 19.2.1. if sent by hand, be deemed to have been given when delivered at the relevant address;

19.2.2. if sent by prepaid airmail, be deemed to have been given 7 days after posting; or

19.2.3. if sent by fax transmission be deemed to have been given when transmitted provided that a confirmatory copy of such facsimile transmission shall have been sent by prepaid airmail within 24 hours of such transmission.

19.3. The address for services of notices and other documents on the parties shall be:

To Mundipharma

**Address:** Mundipharma House,  
14 Par-la-Ville Road,  
P.O. Box HM 2332,  
Hamilton, HM JX,  
Bermuda

**Fax:** 001 809 292 1472

**Attention:** General Manager

**Copy To:** [\*\*]

**Fax:** [\*\*]

To Skye

**Address:** 10450 Sciences  
Center Drive,  
San Diego,  
California 92121  
USA

**Fax:** 001 858 623 0376

**Attention:** President

**Copy To:** Skye Legal Department,  
105 Piccadilly,  
London  
W1J7NJ

**Fax:** +44 20 7491 3338

**20. Assignment and Change of Control**

20.1. Each party shall have the right to sub-license, assign, license, transfer or delegate its rights or obligations under this Agreement in whole or in part to an Affiliate (for so long as such Affiliate remains an Affiliate). Subject to Clause 2.9, neither party shall, nor shall it purport to, assign, license, transfer, delegate or charge any of its rights or obligations under this Agreement to a Third Party without the prior written consent of the other, such consent not to be unreasonably withheld or delayed.

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- 20.2. Should there be a material change in the ownership or a change in the control of the Mundipharma (and for the purpose of this Clause the term “control” means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of Mundipharma, whether through the ownership of voting securities, by contract or otherwise, or the ownership either directly or indirectly of 50% or more of the voting securities (or, in relation to any country where ownership of more than 50% of the voting securities is prohibited by law, the maximum percentage permitted, provided such percentage is no less than 30%) of Mundipharma), Skye may terminate this Agreement by not less than three (3) months written notice to the Mundipharma.

**21. General Provisions.**

- 21.1. Nothing in this Agreement is deemed to constitute a partnership between the parties nor constitute either party the agent of the other party for any purpose.
- 21.2. If there is a disagreement between the Skye and Mundipharma on the interpretation of this Agreement or any aspect of the performance by either party of its obligations under this Agreement, the parties shall resolve the dispute in accordance with the dispute resolution procedure set out in Schedule V.
- 21.3. Each of the parties shall do execute and perform and shall procure to be done executed and performed all such further acts, deeds, documents and things as the other party may reasonably require from time to time to give full effect to the terms of this Agreement.
- 21.4. In performing any respective obligations under this agreement, each party shall comply with the Data Protection Act 1998, any notification requirements under the Data Protection Act 1998 and the Data Protection Principles specified in that Act and any equivalent legislation in the Territory.

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- 21.5. Each party shall pay its own costs, charges and expenses incurred in connection with the negotiation, preparation and completion of this Agreement.
- 21.6. This Agreement, the 2003 Agreement and the Supply Agreement sets out the entire agreement and understanding between the parties in respect of the subject matter of this Agreement. This Agreement supersedes any heads of agreement which shall cease to have any further force or effect. It is agreed that:
- 21.6.1. no party has entered into this Agreement in reliance upon any representation, warranty or undertaking of the other party which is not expressly set out in this Agreement;
- 21.6.2. no party shall have any remedy in respect of misrepresentation or untrue statement made by the other party or for any breach of warranty which is not contained in this Agreement;
- 21.6.3. this Clause shall not exclude any liability for, or remedy in respect of, fraudulent misrepresentation.
- 21.7. No variation of this Agreement shall be valid unless it is in writing and signed by or on behalf of both parties.
- 21.8. Unless expressly agreed, no variation shall constitute a general waiver of any provisions of this Agreement, nor shall it affect any rights, obligations or liabilities under or pursuant to this Agreement which have already accrued up to the date of variation, and the rights and obligations of the parties under or pursuant to this Agreement shall remain in full force and effect, except and only to the extent that they are so varied.

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- 21.9. If and to the extent that any provision of this Agreement is held to be illegal, void or unenforceable, such provision shall be given no effect and shall be deemed not to be included in this Agreement but without invalidating any of the remaining provisions of this Agreement. In such event the parties shall negotiate with a view to finding the nearest permissible provision to that found to be illegal, void or unenforceable. If the parties have been unable to agree as to the provision or provisions to be substituted within two (2) months then the parties shall refer the question of the re-drafting of the Agreement to an expert under the dispute resolution procedure in Schedule V.
- 21.10. No failure or delay by either party in exercising any right or remedy provided by law under or pursuant to this Agreement shall impair such right or remedy or operate or be construed as a waiver or variation of it or preclude its exercise at any subsequent time and no single or partial exercise of any such right or remedy shall preclude any other or further exercise of it or the exercise of any other right or remedy.
- 21.11. The rights and remedies of each of the parties under or pursuant to this Agreement are cumulative, may be exercised as often as such party considers appropriate and are in addition to its rights and remedies under general law.
- 21.12. This Agreement may be executed in any number of counterparts and by the parties on separate counterparts, each of which is an original but all of which together constitute one and the same instrument.
- 21.13. A person who is not a party to this Agreement, other than an Affiliate, shall have no right under the Contracts (Rights of Third Parties) Act 1999 to enforce any of its terms.
- 21.14. This Agreement and the relationship between the parties shall be governed by, and interpreted in accordance with, English law.

21.15. Each of the parties agree that the courts of England are to have exclusive jurisdiction to settle any dispute (including claims for set off and counterclaims) which may arise in connection with the creation, validity, effect, interpretation or performance of, or the legal relationships established by, this Agreement or otherwise arising in connection with this Agreement and for such purposes irrevocably submit to the jurisdiction of the English courts.

AS WITNESS the hands of the parties or their duly authorised representatives the day and the year first above written

SIGNED for and by behalf of ) /s/ Steven Thornton  
**SKYEPHARMA INC** )  
 )  
 )  
 Steven Thornton  
 **Print Name**

SIGNED for and by behalf of ) /s/ Douglas Docherty  
**MUNDIPHARMA INTERNATIONAL** )  
**HOLDINGS LIMITED** )  
 )  
 )  
 Douglas Docherty  
 **Print name**



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**SCHEDULE I**

**PATENTS**

<u>SkyePharma reference</u>	<u>Country</u>	<u>Status</u>	<u>Filing Date</u>	<u>Application number</u>	<u>Grant Date</u>	<u>Grant number</u>
[**]	[**]	[**]	[**]	[**]	[**]	[**]

**SCHEDULE II**

**TRADE MARKS**

<u>Country</u>	<u>Status</u>	<u>Filing Date</u>	<u>Application No.</u>	<u>Registration Date</u>	<u>Registration No.</u>
[**]	[**]		[**]	[**]	[**]
[**]	[**]		[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]		[**]	[**]	[**]
	[**]		[**]	[**]	[**]
	[**]		[**]	[**]	[**]

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### SCHEDULE III

#### **Receipt of adverse events**

In each of the countries where the Product is marketed or distributed there will be a process for receiving adverse events from health care professionals and the public and appropriate distribution to the allocated local operating company. All adverse events received by the local operating company will then be forwarded to Skyepharma in accordance with agreed process and schedule.

#### **Regulatory Authorities**

In the countries where the Product is marketed or distributed it is the responsibility of the local company to make arrangements for appropriate transmission of adverse events to a local regulatory authority in accordance with local procedures, guidelines and directives.

#### **Other Territories**

In countries of territories where the Product is not marketed, licensed or distributed, there will be no reporting obligation for adverse events.

#### **Product Recall**

In the event Skye is required or voluntarily decides to initiate a recall, withdrawal or field correction of the Product, Skye shall notify Mundipharma and provide a copy of its proposal, including the recall letter, for review prior to initiation of such action and the parties shall fully consult and cooperate with each other concerning the need for such a recall and in order to develop and execute a recall plan, as necessary. In conjunction with such recall, Mundipharma shall assist, at Skye's sole discretion and expense, in the investigation to determine the cause and extent of the problem.

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In the event that Mundipharma independently believes that a recall, withdrawal or field correction of the Product may be necessary or appropriate, Mundipharma shall notify Skye of Mundipharma's belief, and the parties shall fully cooperate with each other concerning the necessity and nature of such action.

All coordination of any recall or field correction activities involving Product and/or Finished Product shall be handled by Mundipharma, in cooperation with Skye.

In the event that any Product is recalled as a direct result of the negligent or intentionally wrongful acts or omissions of Mundipharma or its representatives, then Mundipharma shall bear all of the costs and expenses of such recall, including expenses related to communications and meetings with all required Regulatory Authorities, expenses of replacement stock, the cost of notifying customers and costs associated with shipment of recalled Product from customers and shipment of an equal amount of replacement Product to those same customers. In the event that any Product is recalled as a direct result of the negligent or intentionally wrongful acts or omissions of Skye or its representatives or as a result of Product misbranding or failure to meet Specification, then Skye shall bear all of the costs and expenses of such recall, including expenses related to communications and meetings with all required Regulatory Authorities, expenses of replacement stock, the cost of notifying customers and costs associated with shipment of recalled Product from customers and shipment of an equal amount of replacement Product to those same customers. To the extent that the reason for any recall of Product hereunder is in part the responsibility of Skye and in part the responsibility of Mundipharma or is not due to the fault of either Party, then the expenses shall be allocated in an equitable manner between the parties.

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**SCHEDULE IV**  
**THE TERRITORY**

1. Egypt
2. Tunisia
3. Algeria
4. Morocco
5. Turkey
6. Singapore
7. Malaysia
8. China
9. Korea
10. Hong Kong
11. Philippines
12. Indonesia
13. Thailand
14. Bahrain
15. Jordan
16. Kuwait
17. Lebanon
18. Oman
19. Qatar
20. Saudi Arabia
21. Sudan
22. Syria
23. United Arab Emirates
24. Libya
25. Iraq
26. India

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## SCHEDULE V

### DISPUTE RESOLUTION

1. Representatives of the parties will, within 14 days of receipt of a written request from either party to the other, convene a meeting of the Committee to discuss in good faith and try to resolve the disagreement without recourse to legal proceedings.
2. If resolution does not occur within 7 days after meeting, the matter shall be escalated for determination by the respective Chief Executive Officer of the parties who may resolve the matter themselves or by agreement jointly appoint a mediator or independent expert to do so.
3. Nothing in this Agreement restricts either party's freedom to seek urgent relief to preserve a legal right or remedy, or to protect a proprietary trade secret or other right.

#### **Appointment of an Expert**

4. In the event that the Chief Executive Officers agree to resolve a dispute by referral to an expert ("Referral Notice") or in the event of one party wishing to refer a matter under Clause 3.3 or 21.9 of the Agreement to an expert the following procedure shall be followed.
  - 4.1 The dispute or matter shall be determined by a single independent impartial expert who shall be agreed between the parties or, in the absence of agreement between the parties within 30 days of the service of a Referral Notice, be appointed by the Association of the British Pharmaceutical Industry or any successor thereto, or such other competent body agreed by the parties.
  - 4.2 30 days after the appointment of the expert pursuant to paragraph 4.1 both parties shall exchange simultaneously statements of case in no more than 10,000 words, in total, and each side shall simultaneously send a copy of its statement of case to the expert.

- 
- 4.3 Each party may, within 30 days of the date of exchange of statement of case pursuant to paragraph 4.2, serve a reply to the other side's statement of case in no more than 10,000 words. A copy of any such reply shall be simultaneously sent to the expert.
- 4.4 Subject to paragraph 4.6 there shall be no oral hearing. The expert shall issue his decision in writing to both parties within 30 days of the date of service of the last reply pursuant to paragraph 4.3 above or, in the absence of receipt of any replies, within 60 days of the date of exchange pursuant to paragraph 4.2.
- 4.5 The seat of the dispute resolution shall be the normal place of residence of the expert.
- 4.6 The expert shall not have power to alter, amend or add to the provisions of this Agreement, except that the expert shall have the power to decide all procedural matters relating to the dispute, and may call for a one day hearing if desirable and appropriate.
- 4.7 The expert shall have the power to request copies of any documents in the possession and/or control of the parties which may be relevant to the dispute. The parties shall forthwith provide to the expert and the other party copies of any documents so requested by the expert.
- 4.8 The decision of the expert shall be final and binding upon both parties except in the case of manifest error. The parties hereby exclude any rights of application or appeal to any court, to the extent that they may validly so agree, and in particular in connection with any question of law arising in the course of the reference out of the award.
- 4.9 The expert shall determine the proportions in which the parties shall pay the costs of the expert's procedure. The expert shall have the authority to order that all or a part of the legal or other costs of a party shall be paid by the other party.

- 
- 4.10 All documents and information disclosed in the course of the expert proceedings and the decision and award of the expert shall be kept strictly confidential by the recipient and shall not be used by the recipient for any purpose except for the purposes of the proceedings and/or the enforcement of the expert's decision and award.

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

EXECUTION COPY

**CO-DEVELOPMENT, COLLABORATION AND LICENSE AGREEMENT**

**BY AND BETWEEN**

**ENZON PHARMACEUTICALS, INC.**

**AND**

**JAGOTEC, AG,**

**SKYEPHARMA, INC.,**

**AND**

**SKYEPHARMA PLC**

**DATED AS OF**

**JANUARY 2, 2003**



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## CO-DEVELOPMENT, COLLABORATION AND LICENSE AGREEMENT

This Co-DEVELOPMENT, COLLABORATION AND LICENSE AGREEMENT, dated as of January 2, 2003 (the “*Effective Date*”), is entered into by and among Enzon Pharmaceuticals, Inc., a corporation organized and existing under the laws of Delaware, having offices located at 685 Route 202/206 Bridgewater, New Jersey 08807 (“*Enzon*”), and SkyePharma, Inc., a corporation organized and existing under the laws of the State of California and wholly-owned subsidiary of Parent, having offices located at 1450 Science Center Drive, San Diego, California 92121 (“*Skye*”), Jagotec, AG, a corporation organized and existing under the laws of Switzerland and wholly-owned subsidiary of Parent, having offices located at Eptingerstrasse 51, CH-4132 Muttenz, Switzerland (“*Jagotec*,” and together with Skye, “*SkyePharma*”), and solely with respect to Section 13.3, SkyePharma PLC, a corporation organized and existing under the laws of England and Wales, having offices located at 105 Piccadilly, London W1J 7NJ, England (“*Parent*”).

### PRELIMINARY STATEMENTS

A. Skye and Jagotec, together with their Affiliates (as defined below), own and have all right, title and interest in, or have acquired the exclusive rights to, the SkyePharma Technology and the SkyePharma Compound IP (each as defined below).

B. Enzon, together with its Affiliates, owns and has all right, title and interest in, or has acquired the exclusive rights to, the Enzon Technology and the Enzon Compound IP (each as defined below).

C. SkyePharma and Enzon wish to conduct collaborative co-development activities for the purpose of engaging in a research and development program to discover and develop up to an aggregate total of six (6) compounds from which the Parties (as defined below) shall choose up to three (3) Products (as defined below) for further development and commercialization, all under the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the foregoing preliminary statements and the mutual agreements and covenants set forth herein, the Parties hereby agree as follows:

#### 1. DEFINITIONS.

As used in this Agreement, the following terms shall have the meanings set forth in this Section 1 unless context clearly and unambiguously dictates otherwise:

1.1 “*Affiliate*,” with respect to any Party, shall mean any entity controlling, controlled by, or under common control with, such Party, for only so long as such control exists. For these purposes, “*control*” shall refer to: (i) the possession, directly or indirectly, of the power to direct the management or policies of an entity, whether through the ownership of voting securities, by contract or otherwise, or (ii) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of an entity.

1.2 “*Agreement*” shall mean this co-development collaboration and license agreement together with the preliminary statements and all exhibits, schedules and attachments hereto.

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1.3 “*Annual Operating Plan and Budget*” shall mean, as applicable, each plan and budget defined in Section 2.2 and, when used in the plural, shall mean all such plans and budgets.

1.4 “*Audited Party*” shall have the meaning assigned to such term in Section 5.4.1 and the Financial Appendix, as used in those Sections respectively.

1.5 “*Auditing Party*” shall have the meaning assigned to such term in Section 5.4.1 and the Financial Appendix, as used in those Sections respectively.

1.6 “*Bankruptcy Code*” shall have the meaning assigned to such term in Section 11.3.2.

1.7 “*Breaching Party*” shall have the meaning assigned to such term in Section 11.2.

1.8 “*cGMP*” shall mean current Good Manufacturing Practice as defined in Parts 210 and 211 of Title 21 of the Code of Federal Regulations, as may be amended from time to time, or any successor thereto.

1.9 “*Commercially Reasonable Efforts*” shall mean, with respect to a Party, those commercially reasonable efforts by that Party similar to the efforts that Party in good faith believes it would make in similar circumstances for its own operations at that time, it being understood that a Party’s Commercially Reasonable Efforts will not in any event require that Party to take any action that would be reasonably likely to result in a breach of any other provision of this Agreement, or any other agreement between the Parties, or any other agreement between a Party Affiliate of such Party and/or Third Parties existing as of the Effective Date, or that the Party in good faith believes may violate any applicable law, regulation, rule, order, permit, direction or license of any court or governmental authority having appropriate jurisdiction over the Party and subject matter or would be reasonably likely to be disruptive of any material service conducted or product made at or from any of its facilities or impair its ability to provide services or products hereunder.

1.10 “*Compound*” shall mean a chemical compound with application in the Field selected by the Joint Development Committee for development and which is then subject to ongoing development activities under this Agreement.

1.11 “*Confidential Information*” shall have the meaning assigned to such term in Section 9.2.

1.12 “*Development Costs*” shall have the meaning assigned to such term in the Financial Appendix.

1.13 “*Development Program*” shall mean the program of research, discovery, characterization, optimization, pre-clinical and clinical development of the Compounds and Products to be conducted by the Parties, as set forth in Section 2.

1.14 “*Early Stage Development Activities*” shall have the meaning assigned to such term in Section 2.3.1.



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- 1.15 “*Effective Date*” shall have the meaning assigned to such term in the introductory paragraph of this Agreement.
- 1.16 “*Enzon*” shall have the meaning assigned to such term in the introductory paragraph of this Agreement.
- 1.17 “*Enzon Compound IP*” shall mean all Know-how and Patents owned or controlled by Enzon or its Affiliates (and to which Enzon has rights to grant licenses or sub-licenses) as of the Effective Date or during the term of this Agreement, to the extent directly relating to any Compound or Product.
- 1.18 “*Enzon Technology*” shall mean the PEGylation technology, including, without limitation, all Know-how and Patents that directly relate to any of the foregoing; in all cases which are owned or controlled by Enzon or its Affiliates (and to which Enzon has rights to grant licenses or sub-licenses) as of the Effective Date or during the term, of this Agreement.
- 1.19 “*Executive Officers*” shall have the meaning assigned to such term in Section 2.2.2.
- 1.20 “*Expert*” shall have the meaning set forth in Section 13.14.2(a).
- 1.21 “*FDA*” shall mean the United States Food and Drug Administration, and any successor entity thereto.
- 1.22 “*Field*” shall mean all human therapeutic or prophylactic uses for the treatment (but not the diagnosis) of diseases and conditions in humans.
- 1.23 “*Financial Appendix*” shall mean *Exhibit 1.23* hereto.
- 1.24 “*GAAP*” shall mean generally accepted accounting principles in the United States, consistently applied by the Party at issue.
- 1.25 “*IND*” shall mean, with respect to the U.S., an effective Notice of a Claimed Investigational New Drug Exemption as defined in Title 21 of the Code of Federal Regulations, and, with respect every other country in the Territory, the equivalent of such notice for such country, in each case required to be on file with the applicable Regulatory Authority in such country prior to the commencement of clinical trials of a Compound or Product in humans in such country.
- 1.26 “*Indemnitee*” shall have the meaning assigned to such term in Section 10.4.
- 1.27 “*Infringement*” shall have the meaning assigned to such term in Section 6.7.1.
- 1.28 “*Initial Development Term*” shall have the meaning assigned to such term in Section 2.1.
- 1.29 “*Invention*” shall mean any new or useful process, compound or composition of matter, Know-how, Patent, and any improvement, enhancement, modification or derivative work

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to any SkyePharma Technology, SkyePharma Compound IP, Enzon Technology or Enzon Compound IP, that is conceived or first reduced to practice or first demonstrated to have utility during the term of this Agreement in connection with the development or commercialization activities for Compounds and Products contemplated herein.

1.30 “*Jagotec*” shall have the meaning assigned to such term in the introductory paragraph of this Agreement.

1.31 “*Joint Development Committee*” or “*JDC*” shall have the meaning assigned to such term in Section 3.1.

1.32 “*Know-how*” shall mean any and all unpatented formulae, processes, trade secrets, technologies and know-how, whether or not patentable, including, without limitation, synthesis, preparation, recovery and purification processes and techniques, control methods and assays, chemical data, toxicological and pharmacological data and techniques, clinical data, medical uses, product forms and product formulations and specifications.

1.33 “*Net Sales*” shall have the meaning assigned to such term in the Financial Appendix.

1.34 “*Non-breaching Party*” shall have the meaning assigned to such term in Section 11.2.

1.35 “*Operating Profit or Loss*” shall have the meaning assigned to such term in the Financial Appendix.

1.36 “*Party*” shall mean, as applicable, SkyePharma or Enzon and, when used in the plural, shall mean SkyePharma and Enzon.

1.37 “*Patents*” shall mean the patents and patent applications in any country in the Territory, together with any patents that may issue therefor in any country in the Territory, including any and all extensions, renewals, continuations, continuations-in-part, divisions, patents-of-additions, reissues, supplementary protection certificates or foreign counterparts of any of the foregoing and any patents based on applications that claim priority from any of the foregoing.

1.38 “*Phase I Clinical Trial(s)*” shall mean studies in humans of a Compound, the purpose of which is preliminary determination of safety in healthy individuals or patients and for which there are no primary endpoints relating to efficacy in the protocol.

1.39 “*Phase II Clinical Trial(s)*” shall mean studies in humans of Product including dose exploration, dose response, duration of effect, kinetic/dynamic relationship and initial Phase II efficacy and safety studies.

1.40 “*Phase III Clinical Trial(s)*” shall mean a human clinical trial conducted to demonstrate evidence of the efficacy and safety of a Product for inclusion in a Registration Application to support Registration as more fully defined in Section 312.21(c) of Title 21 of the U.S. Code of Federal Regulations.

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1.41 “*Product*” shall mean any pharmaceutical formulation that contains as the sole active ingredient or as one of its active ingredients a Compound for use in the Field and for which the IDC has determined to undertake the Proof of Concept Activities and, if applicable, the Registration Activities and commercialization.

1.42 “*Proof of Concept Activities*” shall have the meaning assigned to such term in Section 2.3.2.

1.43 “*Registration*” shall mean, with respect to each country in the Territory, approval of the Registration Application for a Product filed in such country, including pricing or reimbursement approvals, where applicable, by the Regulatory Authority in such country.

1.44 “*Registration Activities*” shall have the meaning assigned to such term in Section 2.3.3.

1.45 “*Registration Application*” shall mean any filing(s) made with the Regulatory Authority in any country in the Territories for regulatory approval of the marketing, manufacture and sale, and pricing when applicable, of a Product in such country.

1.46 “*Regulatory Authority*” shall mean, the FDA in the U.S., and any health regulatory authority(ies) in any country in the Territory that is a counterpart to the FDA and has responsibility for granting regulatory approval for the marketing, manufacture, and sale of a Product in such country, including but not limited to pricing and reimbursement approvals.

1.47 “*Serious Adverse Drug Experience*” shall have the meaning assigned to such term in Section 7.1.2.

1.48 “*Skye*” shall have the meaning assigned to such term in the introductory paragraph of this Agreement.

1.49 “*SkyePharma*” shall have the meaning assigned to such term in the introductory paragraph of this Agreement.

1.50 “*SkyePharma Compound IP*” shall mean all Know-how and patents owned or controlled by SkyePharma or its Affiliates (and to which SkyePharma has rights to grant licenses or sublicenses) as of the Effective Date or during the term of this Agreement, to the extent directly relating to any Compound or Product.

1.51 “*SkyePharma Technology*” shall mean the Geomatrix® drug release technologies, the IDD® insoluble drug delivery technology, the DepoFoam® injectable technology, the Biosphere® injectable technology, and the HIT-Oralease technology, including, without limitation, all Know-how and Patents that directly relate to any of the foregoing; in all cases which are owned or controlled by SkyePharma or its Affiliates (and to which SkyePharma has rights to grant licenses or sublicenses) as of the Effective Date or during the term of this Agreement.

1.52 “*Sole Developing Party*” shall have the meaning assigned to such term in Section 4.4.

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1.53 “*Special Arbitration Provisions*” shall have the meaning assigned to such term in Section 13.14.2.

1.54 “*Subcommittee*” shall have the meaning assigned to such term in Section 3.7.

1.55 “*Sublicensee*” shall mean a Third Party to which a Party has granted a sublicense under a license granted under this Agreement.

1.56 “*Sublicensing Income*” shall have the meaning assigned to such term in the Financial Appendix.

1.57 “*Territory*” shall mean all countries world-wide.

1.58 “*Third Party*” shall mean any person who or which is neither a Party nor an Affiliate of a Party.

1.59 “*Transfer Agreement*” shall have the meaning assigned to such term in Section 4.4.

1.60 “*United States*” or “*U.S.*” shall mean The United States of America, including its possessions and territories.

## 2. THE DEVELOPMENT PROGRAM.

2.1 *Overview of the Development Program*. The Development Program shall commence as soon as practicable after the Joint Development Committee has selected the first of the six (6) Compounds on which the Parties shall focus their collaborative development efforts and shall include the research and development activities of either or both of the Parties under this Agreement to: (i) identify for initial development an aggregate of six (6) Compounds for initial preclinical studies up to selection as a lead compound for formal preclinical development, (ii) further develop up to three (3) Products from the six (6) selected Compound(s) for formal preclinical development and clinical development as determined appropriate by the JDC, including through Phase III Clinical Trials, if appropriate, and (iii) such other activities as necessary to implement the activities approved by the JDC in the Annual Operating Plan and Budget. Subject to Section 11.4, the initial term of the Development Program (the “*Initial Development Term*”) shall expire on the fourth (4th) anniversary of the Effective Date, and thereafter the Development Program shall be automatically extended for successive two (2) year extension periods; *provided, however*, that at any time following expiration of the initial Development Term, either Party shall have the right to terminate the Development Program upon ninety (90) days prior written notice. Notwithstanding such termination of the Development Program, the Parties shall fulfill their respective development obligations under any then current Annual Operating Plan and Budget and this Agreement shall continue to remain in full force and effect with respect to any Products under commercialization at the time of such termination.

2.2 *Annual Operating Plan(s)*. Promptly after the Effective Date and in any event no later than February 15, 2003, and annually on or before September 15<sup>th</sup> thereafter, the JDC shall prepare a report of the research, development, marketing, sales, and regulatory activities to be taken during the upcoming year with respect each Compound and Product, if any, then under

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development. Such report shall include a description of the timelines, milestones and deliverables for such actions, as well as goals and scope of such actions, the allocation of responsibilities to the respective Parties, and an agreed plan and budget for the activities to be undertaken as part of the Development Program or to commercialize Product(s) in the next succeeding calendar year (each such report, an “*Annual Operating Plan and Budget*”).

2.2.1 Provided that the JDC is able to establish and approve an Annual Operating Plan and Budget for the upcoming year (excluding 2003) on or before September 15<sup>th</sup> of any particular year, development priorities shall be in accordance with such Annual Operating Plan and Budget.

2.2.2 In the event that the Joint Development Committee is unable to establish and approve an Annual Operating Plan and Budget for the upcoming year (excluding 2003) on or before September 15<sup>th</sup> of any particular year, then the Parties agree to submit the issue to the Chief Executive Officer of SkyePharma, or such other person holding a similar position designated by SkyePharma from time to time, and the Chief Executive Officer of Enzon, or such other person holding a similar position designated by Enzon from time to time (collectively, the “*Executive Officers*”), for resolution. The Executive Officers shall meet promptly to discuss each Party’s proposals regarding the Annual Operating Plan and Budget and objections to same in order to reach a mutually acceptable resolution.

### *2.3 Scope of Development Activities.*

2.3.1 After the Joint Development Committee selects a Compound for development in the Development Program, the Parties shall, as directed by the JDC and each Annual Operating Plan and Budget, focus their collaborative development efforts in order to measure the feasibility of developing each such Compound into Products. Such feasibility development efforts shall, with respect to each Compound, be directed to initial preclinical studies up to selection as a lead compound for formal preclinical development for each Compound pursuant to the applicable Annual Operating Plan and Budget (the “*Early Stage Development Activities*”). At the conclusion of the Early Stage Development Activities for each Compound, the JDC shall review available information and decide whether, when, and how to proceed with further development of such Compound as a Product. The JDC shall select not more than a total of three (3) Compounds for further development as Products.

2.3.2 In the event that the JDC selects a Compound for further development as a Product, the Parties shall, as directed by the JDC and each Annual Operating Plan and Budget, focus their collaborative development efforts with respect to such Product to demonstrate “proof-of-concept” for such Product in the target patient populations, including, without limitation, designing and conducting clinical trials for such Product, conducting process development and formulation activities necessary or useful for the manufacture of bulk drug substance and/or drug product material for such clinical trials, and preparing for further clinical trials (the “*Proof of Concept Activities*”). At the conclusion of the Proof of Concept Activities for each Product, the JDC shall review available information and decide whether, when, and how to proceed with further development of such Product.

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2.3.3 In the event that the JDC selects a Product for further development following the conclusion of the Proof of Concept Activities, the Parties shall, as directed by the JDC and each Annual Operating Plan and Budget, focus their collaborative development efforts with respect to such Product in order to design and conduct appropriate clinical trial(s) and undertake all research, development and regulatory activities necessary up through Registration of Products (the “*Registration Activities*”).

2.4 *Responsibilities of Each Party under the Development Program*. As part of the Development Program for a Compound and/or Product, and in accordance with the applicable Annual Operating Plan and Budget, the Parties shall undertake such activities as may be assigned to it by the JDC and assist the other Party with its assigned activities in order to:

2.4.1 conduct such research and development activities deemed necessary or desirable by the JDC, including without limitation, formulation development, pre-clinical studies, pre-Registration clinical trials and toxicology studies;

2.4.2 manufacture and supply the Compounds in bulk form for use in the pre-clinical and clinical trials;

2.4.3 during the Development Program, keep the JDC informed, through regular, periodic written reports, which may be brief summaries, at least once in each calendar quarter, of all development progress being made by such Party with respect to all activities related to the Compounds and Products;

2.4.4 prepare and file with the applicable Regulatory Authorities those regulatory filings deemed necessary or desirable by JDC to undertake development activities and obtain all Registrations that the JDC deems necessary or desirable to market and sell the Products in the Territory and the applicable Field;

2.4.5 perform pre-commercialization analysis, planning, market preparation, and relating marketing activities for the relevant countries in the Territory as deemed necessary or desirable by the JDC;

2.4.6 conduct post-Registration clinical trials and marketing studies as the JDC deems necessary or useful to maintain Registration for each Product for the target indications selected by the JDC in the relevant countries in the Territory; and

2.4.7 perform such other responsibilities with respect to the Development Program as may be assigned by the Joint Development Committee pursuant to this Agreement or as may be mutually agreed upon by the Parties from time to time.

2.5 *Conduct of Development Program and Commercialization Activities*. The Parties, acting in accordance with this Section 2, and the relevant Annual Operating Plan and Budget, shall use Commercially Reasonable Efforts to develop and commercialize the Compounds and Products in the Field, in the Territory. The Parties shall use Commercially Reasonable Efforts to market and sell all Products in the Field, in the Territory, for the target indications selected by the Joint Development Committee. Without limiting the generality of the foregoing, each Party shall:

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2.5.1 cooperate with the other Party to implement the Annual Operating Plans and Budget, and such other activities that, from time to time, the JDC decides are necessary or useful for the success of the Development Program or commercialization of the Products, if any;

2.5.2 use Commercially Reasonable Efforts to perform the work set out for such Party to perform in the Annual Operating Plans and Budget;

2.5.3 conduct their activities under the Development Program in good scientific manner, and in compliance in all material respects with all requirements of applicable laws, rules and regulations, and all other requirements of any applicable cGMP, good laboratory practice and current good clinical practice to attempt to achieve the objectives of the Development Program efficiently and expeditiously;

2.5.4 maintain records, in sufficient detail and in good scientific manner, which shall be complete and accurate and shall fully and properly reflect all work done and results achieved in connection with the Development Program in the form required under all applicable laws and regulations. The other Party shall have the right, during normal business hours and upon reasonable prior written notice, to inspect and copy all such records at its own expense, so long as doing so is not unreasonably disruptive. The other Party shall maintain such records and information contained therein in confidence in accordance with Section 9 and shall not use such records or information except to the extent otherwise permitted by this Agreement;

2.5.5 allow representatives of the other Party, upon reasonable prior written notice and during normal business hours, to visit such Party's facilities where any activities under the Development Program are being conducted, and consult, during such visits and by telephone, with such Party's personnel performing work on the Development Program, so long as such visits and consultations are not unreasonably disruptive. The other Party shall maintain any information received (whether by observation or otherwise) during such visit in confidence in accordance with Section 9 and shall not use such information except to the extent otherwise permitted by this Agreement; and

2.5.6 agree and hereby do agree that the Parties shall at all times have at least one (1) Compound or Product in development or being commercialized that incorporates the Enzon Technology unless the JDC determines that it is in the best interests of the collaboration not to do so.

2.6 *Recall*. In the event that a Party shall become aware that the Regulatory Authority in any country in the Territory alleges or has proved that a Product does not comply with applicable rules and regulations in such country, that Party shall notify the other Party immediately and both Parties shall cooperate fully regarding the investigation and disposition of any such matter. The details regarding each Party's rights and obligations in the event of a recall of any such Product shall be stipulated in a separate agreement to be entered into by the Parties prior to the commercialization of any Product(s) hereunder, or in a separate agreement among the Parties and their respective Affiliates and/or Sublicensees, as the Parties mutually deem to be appropriate.

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### 3. JOINT DEVELOPMENT COMMITTEE.

3.1 *Members; Officers.* Promptly after the Effective Date, the Parties shall establish a joint development committee (the “*Joint Development Committee*” or “*JDC*”) as more fully described in this Section 3. The JDC shall be comprised of an equal number of representatives from each of SkyePharma and Enzon. The exact number of such representatives shall be four (4) members, two (2) members from each Party, or such other number as the Parties may agree. The initial members of the JDC are set forth on *Exhibit 3.1*. Each Party may replace any or all of its representatives on the JDC at any time upon written notice to the other Party in accordance with Section 13.6 of this Agreement, Such representatives shall include individuals within the senior management of each Party, and those representatives of each Party shall, individually or collectively, have expertise in business, biopharmaceutical drug development and commercialization of drug products. Any member of the JDC may designate a substitute to attend and perform the functions of that member at any meeting of the JDC. Each Party may, in its discretion, invite non-member representatives of such Party to attend meetings of the JDC. A chairperson and secretary of the JDC shall serve co-terminous one (1) year terms, commencing on the Effective Date or an anniversary thereof, as the case may be. The right to name the chairperson and the secretary of the JDC shall alternate annually between the Parties, and each chairperson shall be named no later than ten (10) days after the commencement of his or her term. The initial chairperson shall be selected by SkyePharma, the initial secretary shall be selected by Enzon and each is designated on *Exhibit 3.1*.

3.2 *Responsibilities of the Joint Development Committee.* The Joint Development Committee shall be responsible for overseeing the entire collaboration between SkyePharma and Enzon under this Agreement, including both the Development Program and all commercialization activities. Without limiting the foregoing, the JDC shall perform the following functions:

3.2.1 determine and revise the overall strategy for the Development Program;

3.2.2 annually determine the Annual Operating Plan and Budget for each Compound and Product, and revise same from time to time as needed;

3.2.3 determine target indications for each Compound and Product, and revise same from time to time as needed;

3.2.4 determine and revise multi-year expense forecasts and projected financial results of the Parties activities under this Agreement;

3.2.5 evaluate progress and provide direction to the conduct of the Development Program and any commercialization activities undertaken by the Parties;

3.2.6 determine, the selection of (i) Compounds on which to focus collaborative development efforts, (ii) criteria to be met to demonstrate “proof-of-concept” for such Compounds in the target patient populations, (iii) indications for which each Compound is to be developed (which determination may include adjustments to the respective responsibilities of the Parties, and corresponding financial arrangements between the Parties, with respect to such indication(s)), and (iv) other development criteria to be met for continued development;



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3.2.7 determine which pre-clinical studies, clinical trials, and toxicology studies are necessary or desirable to meet the requirements of the applicable Regulatory Authorities for the Registration of the Products in the countries of interest in the Territory;

3.2.8 review, approve and determine ownership of all INDs, Registration Applications, Registrations and other regulatory filings and approvals for the Compounds and Products on a Compound/Product by Compound/Product basis;

3.2.9 evaluate data on all Compounds and Products under development;

3.2.10 review and approve activities related to manufacturing and the identification of manufacturer(s) in connection with the development and commercialization of Compounds and Products;

3.2.11 select and determine ownership of the trademarks, trade names and logos under which each Product shall be marketed and sold in each country in the Territory;

3.2.12 decide whether and how to institute Infringement actions against Third Parties based on any Compound or Product being developed or commercialized by the Parties under this Agreement;

3.2.13 review and approve "go/no-go" decisions and recommendations; and

3.2.14 perform such other responsibilities as may be assigned to the Joint Development Committee pursuant to this Agreement or as may be mutually agreed upon by the Parties from time to time.

3.3 *Meetings*. The first meeting of the JDC shall be held promptly, and in no case later than thirty (30) days, after the Effective Date, to establish procedures and review proposed compound candidates for joint development under this Agreement. The Parties acknowledge that the JDC shall identify within six (6) months of the Effective Date the first two (2) of the six (6) Compounds the Parties intend to jointly develop under the Development Program with the intention of having two new (2) Compounds identified for development in each of the three (3) years of the Term. It is the current expectation of the Parties that several of the six (6) Compounds selected shall utilize the Enzon Technology, and several shall utilize the SkyePharma Technology. However, final identification and selection of each Compound shall be made by unanimous consent of the JDC, or mutual consent of the Executive Officers of the Parties as provided in Section 3.5, but shall not be made by further dispute resolution pursuant to Section 3.5 (as both Parties must agree to the selection of any Compound), and in any event shall be subject to conflicts found in any patent clearance investigations. While development activities under the Development Program are ongoing, the JDC shall meet in person at least once each calendar quarter, and more frequently as the Parties may deem appropriate, on such dates, and at such places and times, as the Parties shall agree. Thereafter, the JDC shall meet, in person or otherwise, only on an ad hoc basis as needed to perform the responsibilities assigned to it under this Agreement. The members of the JDC may also convene or be polled or consulted from time to time by means of telecommunications, video conferences, electronic mail or correspondence, as deemed necessary or appropriate.

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3.4 *Cooperation of Parties for Selection of Compounds*. Both Parties shall cooperate to provide all available data and information to the JDC regarding potential compounds each Party has the right to offer for consideration for development under this Agreement. Each Party recognizes that the other Party has, as of the Effective Date, and may have, during the term of the Development Program, arrangements with Third Parties relating to compounds and products that will prohibit such Party from offering such compounds and/or products for consideration for development under this Agreement. For instance, and without limiting the generality of the foregoing, SkyePharma acknowledges that Enzon is prohibited from offering PEGylated interferon alpha (licensed to Schering-Plough Corp., Sobering Corp. and their respective affiliates, successors, assigns, distributors, customers or licensees) and certain PEGylated compounds for which Inhale Therapeutics has a license. The Parties acknowledge and agree that neither Party shall provide any data or information relating to any such prohibited compounds and/or products to the other Party pursuant to this Agreement, and no rights are granted to the other Party under this Agreement with respect to any such prohibited compounds and/or products.

3.5 *Decision-making*. Except as otherwise provided herein, decisions of the JDC shall be made by consensus, with each Party having collectively one (1) vote in all decisions. In the event that the JDC is unable to reach a consensus decision within fifteen (15) days after it has met and attempted to reach such decision, then either Party may, by written notice to the other, have such issue referred to Executive Officers for resolution. The Executive Officers shall meet promptly to discuss the matter submitted and to determine a resolution. If the Executive Officers are unable to determine a resolution in a timely manner, which shall in no case be more than thirty (30) days after the matter was referred to them, the issue shall be conclusively settled in accordance with the Special Arbitration Provisions set forth in Section 13.14.2; *provided that*, with respect to decisions regarding the selection of Compounds pursuant to Section 3.3 and any determination of the JDC to be made pursuant to Section 2.5.6, disputes shall not be referred to the Special Arbitration Provisions. If the JDC or the Executive Officers cannot agree on such decisions, any such compound shall not be selected as a Compound, or no such determination shall be deemed to have been made, as the case may be. For all purposes under this Agreement, any decision made pursuant to this Section 3.5, whether by the JDC, the Executive Officers, or an Expert, shall be deemed to be the decision of the Joint Development Committee.

3.6 *Minutes*. With the sole exception of specific items of the JDC meeting minutes to which the chairperson and the secretary cannot agree and which are escalated as provided in Section 3.5, definitive minutes of all meetings of the IDC shall be finalized no later than thirty (30) days after the meeting to which the minutes pertain, as follows:

3.6.1 Within ten (10) days after each meeting, the secretary of the JDC shall prepare and distribute to all members of the JDC draft minutes of the meeting. Such minutes shall provide a description, in reasonable detail, of the discussions at the meeting and a list of any actions, decisions or determinations approved by the JDC and a list of any issues to be resolved under the Special Arbitration Provisions.

3.6.2 The chairperson of the JDC shall then have ten (10) days after receiving such draft minutes to collect comments thereon from the members of the JDC and provide them to the secretary.

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3.6.3 Upon the expiration of such second ten (10)-day period, the chairperson and the secretary shall have an additional ten (10) days to discuss each other's comments and finalize the minutes. The secretary and chairperson shall each sign and date the final minutes. The signature of the chairperson and the secretary of the JDC upon the final minutes shall indicate each Party's assent to the minutes.

3.6.4 If at any time during the preparation and finalization of JDC meeting minutes, the secretary and the chairperson do not agree on any issue with respect to the minutes, such issue shall be resolved by the Executive Officers. The decision resulting from the escalation process shall be recorded by such secretary in amended finalized minutes for said meeting.

3.7 *Subcommittee(s)*. From time to time, the JDC may establish subcommittees to oversee particular projects or activities, as it deems necessary or advisable (each, a "*Subcommittee*"). Each Subcommittee shall consist of such number of members of each Party as the JDC determines is appropriate from time to time. Such members shall be individuals with expertise and responsibilities in the areas of preclinical development, clinical development, intellectual property, process sciences, manufacturing, regulatory affairs, product development and/or product commercialization, as applicable to the stage of development of the applicable Compound(s) or Product(s). Each Subcommittee shall meet with such frequency as the JDC shall determine. Each Subcommittee shall operate by consensus, and each Party shall have collectively one (1) vote in all decisions. If, with respect to a matter that is subject to a Subcommittee's decision-making authority, the Subcommittee cannot reach consensus within fifteen (15) days after it has met and attempted to reach such consensus, the matter shall be referred to the JDC, which shall resolve such matter in accordance with Section 3.5.

3.8 *Term*. The JDC shall exist throughout the term of this Agreement.

3.9 *Expenses*. Each Party shall be responsible for all travel and related costs and expenses for its members and approved invitees to attend meetings of, and otherwise participate on, the JDC or any Subcommittee.

#### 4. FEES, MILESTONES, AND FUNDING.

4.1 *Up-front Payments*. In consideration for access to and use of the Enzon Technology pursuant to this Agreement, SkyePharma shall pay a non-refundable, non-creditable up-front payment of [\*\*] U.S. Dollars (US\$[\*\*]) to Enzon upon the execution of this Agreement by both Parties.

4.2 *Milestone Payments*. As consideration to SkyePharma for the license and other rights granted to Enzon under this Agreement, Enzon shall, upon the commencement under this Agreement of Phase II Clinical Trials for any Products incorporating SkyePharma Technology, pay a non-refundable, non-creditable milestone payment of [\*\*] U.S. Dollars (\$[\*\*]) to SkyePharma.

4.3 *Funding of Development Program*. Pursuant to the Financial Appendix, each of the Parties shall pay the Development Costs as follows:

4.3.1 Each Party shall fund [\*\*] percent ([\*\*]%) of the Development Costs actually incurred by either Party in undertaking the Early Stage Development Activities for each Compound.

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4.3.2 Within thirty (30) days after the completion of the Early Stage Development Activities for each Compound (including the receipt of all results therefrom), the Parties shall meet to discuss: (i) estimated costs and overall development plans if such Compound were to be further developed under the Development Program as a Product through completion of the Proof of Concept Activities; and (ii) their respective desires to continue to fund [\*\*] percent ([\*\*]%) of the Development Costs for the Proof of Concept Activities. Within twenty (20) days after such meeting, the JDC shall meet to determine if the Parties shall continue the development of the Compound as a Product under the Development Program and fund, on [\*\*], [\*\*]/[\*\*] ([\*\*]), basis the Development Costs of same. If either Party elects not to proceed, this Agreement shall be deemed to be terminated by mutual consent as to such Compound and the termination effects set forth in Section 4.5 shall become effective upon such termination. If both Parties elect to proceed, each Party shall fund [\*\*] percent ([\*\*]%) of the Development Costs actually incurred by either Party in undertaking the Proof of Concept Activities for such Compound. If only one Party wishes to proceed with the development of such Compound, the Parties shall, pursuant to Section 4.4, negotiate in good faith in order to reach a mutually acceptable agreement pursuant to which such Party would become the Sole Developing Party for such Compound.

4.3.3 Within thirty (30) days after the completion of the Proof of Concept Activities for each Product (including the receipt of all results therefrom), the Parties shall meet to discuss: (i) estimated costs and overall development plans if such Product were to be further developed under the Development Program through completion of the Registration Activities and into commercialization, if appropriate; and (ii) their respective desires to continue to fund [\*\*]% of the Development Costs for such Registration Activities. Within twenty (20) days after such meeting, the JDC shall meet to determine if the Parties shall continue the Development of the Product under the Development Program and fund, on [\*\*], [\*\*]/[\*\*] ([\*\*]/[\*\*]), basis the Development Costs of same. If either Party elects not to proceed, this Agreement shall be deemed to be terminated by mutual consent as to such Product and the termination effects set forth in Section 4.5 shall become effective upon such termination. If both Parties elect to proceed, each Party shall fund [\*\*] percent ([\*\*]%) of the Development Costs actually incurred by either Party in undertaking such Registration Activities and the Parties shall share, in accordance with the Financial Appendix, the Operating Profit or Loss associated with the commercialization of such Product(s). If only one Party wishes to proceed with the development of such Product, that Parties shall, pursuant to Section 4.4, negotiate in good faith in order to reach a mutually acceptable agreement pursuant to which such Party would become the Sole Developing Party for such Product.

4.3.4 In the event the Registration Activities fail to result in a Registration for a Product, the Parties shall consider, in good faith, undertaking additional Phase III Clinical Trials for such Product and the provisions of Section 4.3.3 shall apply to the Parties' decisions regarding whether and how to proceed with such additional Phase III Clinical Trials.

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4.3.5 Development Costs actually incurred by either Party under Sections 4.3.1, 4.3.2 or 4.3.3 that are more than [\*\*] percent ([\*\*]%) in excess of the Annual Operating Plan and Budget applicable to such Party's expenditures shall not be shared by the Parties unless and to the extent such excess Development Costs are expressly approved in writing by the other Party.

4.4 *Sole Developing Party; Royalties*. In the event one Party (a "Sole Developing Party"), but not the other Party, desires to continue the development and commercialization of a Compound and/or Product in the Field following the termination of the Development Program with respect to same as set forth in Sections 4.3.2 or 4.3.3, the Parties shall negotiate in good faith in order to reach a mutually acceptable agreement regarding licensing the intellectual property rights to such Compound and/or Product to the Sole Developing Party (including possible retention of certain rights by the other Party), and the transfer to the Sole Developing Party of Know-how and other relevant data, as well as any INDs and other regulatory filings, pertaining to such Compounds and Products, as the case may be, to enable the Sole Developing Party to continue such development and commercialization efforts (each such agreement, a "Transfer Agreement"). Each such Transfer Agreement shall provide that the Sole Developing Party shall: (i) be solely responsible for, in its sole discretion, and shall have the exclusive right to engage in, all activities relating to the further development and commercialization of such Compound or Product, in the Field, throughout the Territory; and (ii) pay to the other Party royalties on Net Sales of the Compound(s) and/or Product(s) for which it is a Sole Developing Party and appropriate development milestone payments payable and sharing of Sublicensing Income with respect to such Compound(s) and/or Product(s) based upon the application of the following factors: (1) the then current market practices for pharmaceutical products of similar commercial promise; (2) the relative financial contributions of the Parties to the development and commercialization of such Compound or Product; (3) the market potential of such Compound or Product; and (4) the apparent risks of going forward with development and commercialization.

4.5 *Termination of Development*. In the event neither Party desires to proceed with the continued development of a Compound or Product pursuant to Sections 4.4: (i) each Party shall at its own expense promptly return to the other Party all relevant records and materials in its possession or control containing Confidential Information of the other Party (provided that such Party may keep one copy of such Confidential Information of the other Party for archival purposes only); and (ii) the licenses granted under Sections 6.1 and 6.2, including any sublicenses thereunder, shall terminate with respect to such Compound and all Products which contain such Compound.

## 5. PAYMENTS AND REPORTS.

5.1 *Payments*. Payments to be made in connection with sharing of Development Costs and sharing of Operating Profit and Loss shall be made in accordance with the Financial Appendix. All other payments to be made under this Agreement shall be made in accordance with the terms set forth in the applicable Section(s) regarding such payments.

5.2 *Mode of Payment*. Each Party shall make all payments required under this Agreement in U.S. Dollars, via wire transfer of immediately available funds as directed by the other Party from time to time, net of any out-of-pocket transfer costs or fees, in accordance with the provisions of this Section 5 and the Financial Appendix.

5.3 *Records Retention.* The Parties shall keep complete and accurate records pertaining to the development and the sale of Products including, but not limited to, all Development Costs and, if relevant, to the calculation of Operating Profit or Loss, for a period of seven (7) calendar years after the year in which such sales or costs are actually incurred, and in sufficient detail to permit the other Party to confirm the accuracy of the Development Cost calculations and aggregate royalty and/or Operating Profit or Loss calculations hereunder.

5.4 *Audits.*

5 . 4 . 1 A t t h e r e q u e s t a n d e x p e n s e o f accountant appointed by the Auditing Party and reasonably acceptable to the Audited Party, at reasonable times and upon reasonable written notice, to examine such records as may be necessary to: (i) determine the correctness of any report or payment made under this Agreement; or (ii) obtain information as to the Development Cost calculations, all other calculations governed by the Financial Appendix and aggregate Operating Profit or Loss and/or royalties payable for any calendar quarter in the case of either Party's failure to report or pay pursuant to this Agreement; *provided, however*, that such accountant shall sign a confidentiality agreement in a form reasonably satisfactory to the Audited Party, and, *provided further*, that such examination shall not be permitted more than once in any twelve (12)-month period. Said accountant shall not disclose to the Auditing Party or any other person any information, except that such accountant may disclose to the Auditing Party the fact of a deficiency, the lack of a deficiency or any overpayment, and the degree thereof, including the dollar amount. All results of any such examination shall be made available to the Audited Party.

5.4.2 In the event that any audit reveals an over- or under- payment in the amount that should have been paid by one Party to the other, then the over- or under- payment amount shall be paid within forty-five (45) days after a Party makes a demand therefor, plus interest thereon if such amount is in excess of [\*\*] percent ([\*\*]%) of the amount that actually should have been paid. Such interest shall be calculated from the date such amount was due until the date such amount is actually paid, at the rate of [\*\*] percent ([\*\*]%) over the prime rate of interest reported in the East Coast edition of *The Wall Street Journal* for the date such amount was due. In addition, in the event of underpayment, if the underpaid amount is in excess of [\*\*] percent ([\*\*]%) of the amount that actually should have been paid, then the paying Party shall reimburse the party due payment for the reasonable cost of such audit.

5.5 *Taxes.* In the event that a Party is mandated under the laws of a country to withhold any tax to the tax or revenue authorities in such country in connection with any payment to the other Party, such amount shall be deducted from the payment to be made by such withholding Party, *provided* that the withholding Party shall take reasonable and lawful actions to avoid and minimize such withholding and promptly notify the other Party so that the other Party may take lawful actions to avoid and minimize such withholding. The withholding Party shall promptly furnish the other Party with copies of any tax certificate or other documentation evidencing such withholding as necessary to satisfy the requirements of the United States

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Internal Revenue Service related to any application by such other Party for foreign tax credit for such payment. Each Party agrees to cooperate with the other Party in claiming exemptions from such deductions or withholdings under any agreement or treaty from time to time in effect.

## 6. GRANT OF RIGHTS; RESTRICTIONS; OWNERSHIP; PATENTS.

### 6.1 *License Grant to Enzon*. Subject to the terms and conditions of this Agreement:

6.1.1 SkyePharma hereby grants to Enzon during the term of this Agreement: (i) a non-exclusive license under the SkyePharma Technology, (ii) a non-exclusive license under SkyePharma's rights in any Inventions to the extent relating to the SkyePharma Technology, (iii) a co-exclusive license under the SkyePharma Compound IP, and (iv) a co-exclusive license under SkyePharma's rights in any Inventions to the extent relating to the SkyePharma Compound IP or any Compound or any Product; in each case, the preceding licenses extend solely to the Compounds and Products identified and selected as provided in Sections 2.1 and 2.2, to enable Enzon to perform its obligations under the Development Program for such Compounds and Products and to commercialize any Products hereunder; and

6.1.2 Except as expressly set forth in this Agreement, no license is granted by SkyePharma under its rights in any Patents or Know-how whatsoever for any activities by Enzon that are outside the scope of the license grant in Section 6.1.1.

### 6.2 *License Grant to SkyePharma*. Subject to the terms and conditions of this Agreement:

6.2.1 Enzon hereby grants to SkyePharma during the term of this Agreement: (i) a non-exclusive license under the Enzon Technology, (ii) a non-exclusive license under Enzon's rights in any Inventions to the extent relating to the Enzon Technology, (iii) a co-exclusive license under the Enzon Compound IP, and (iv) a co-exclusive license under Enzon's rights in any Inventions to the extent relating to the Enzon Compound IP or any Compound or any Product; in each case, the preceding licenses extend solely to the Compounds and Products identified and selected as provided in Sections 2.1 and 2.2, solely to enable SkyePharma to perform its obligations under the Development Program for such Compounds and Products and to commercialize any Products hereunder; and

6.2.2 Except as expressly set forth in this Agreement, no license is granted by Enzon under its rights in any Patents or Know-how whatsoever for any activities by SkyePharma that are outside the scope of the license grant in Section 6.2.1.

6.3 *Sublicensing*. Neither Party shall have the right to grant any sublicensee under the rights and licenses granted to it under this Section 6 without first obtaining the written consent of the granting Party, which consent shall not be unreasonably withheld or delayed; *provided that* any sublicense granted under this Agreement shall provide that: (i) the Party granting the sublicense shall guarantee and be responsible for the making of all payments due, and the making of any reports under this Agreement, with respect to sales of Products by its Affiliates or Sublicensees and their compliance with all applicable terms of this Agreement; (ii) each Affiliate or Sublicensee agrees in writing to maintain financial and scientific books and records and permit the Parties to review such books and records and to visit such Affiliate's or Sublicensee's

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facilities pursuant to the relevant provisions of pursuant to the relevant provisions, and to observe all other applicable terms, of this Agreement; and (iii) in the event of a breach by such an Affiliate or Sublicensee in the observance of applicable terms of this Agreement, each Party shall be entitled to proceed against either such Affiliate or Sublicensee or directly against the other Party, as such Party may determine in its sole discretion, to enforce this Agreement.

6.4 *Restriction on Activities*. Each of the Parties acknowledge and agree that except as expressly permitted under this Agreement, neither Party nor their respective Affiliates or Sublicensees shall work with any Third Party on the Compounds and Products that are then subject to development or commercialization activities under this Agreement.

6.5 *Ownership*.

6.5.1 The Parties shall own all INDs, Registration Applications, Registrations and other regulatory filings and approvals for the Compounds and Products as determined by the JDC in accordance with Section 3.2.8; *provided, however*, in the event one Party desires to become a Sole Developing Party for a Compound and/or Product, the Parties shall, as set forth in Section 4.4, and as may be necessary, enter into good faith negotiations regarding the transfer of ownership of the INDs, Registration Applications, Registrations and other regulatory filings and approvals which pertain to such Compound and/or Product, taking into consideration what other Compounds, Products, development, and commercialization plans would be impacted by a change in ownership.

6.5.2 Subject to the licenses granted to Enzon pursuant to Section 6.1, SkyePharma shall retain all right, title and interest in and to the SkyePharma Technology and SkyePharma Compound IP.

6.5.3 Subject to the licenses granted to SkyePharma pursuant to Section 6.2, Enzon shall retain all right, title and interest in and to the Enzon Technology and the Enzon Compound IP.

6.5.4 SkyePharma shall solely own all Inventions to the extent any such Invention is dominated by any Patent included in the SkyePharma Technology or SkyePharma Compound IP, regardless of which Party made such Inventions. Enzon shall solely own all Inventions, to the extent any such Invention is dominated by any Patent included in the Enzon Technology or the Enzon Compound IP, regardless of which Party made such Inventions. All other Inventions relating to both the SkyePharma Technology and/or the SkyePharma Compound IP, on the one hand, and the Enzon Technology and/or the Enzon Compound IP, on the other hand, shall be owned jointly by the Parties, regardless of which Party made such other Inventions. To the extent ownership of Inventions is not assigned by any of the foregoing sentences: (i) Inventions made solely by employees or contractors of SkyePharma shall be owned solely by SkyePharma, (ii) Inventions made solely by employees or contractors of Enzon shall be owned solely by Enzon, and (iii) Inventions made jointly by employees or contractors of both Parties shall be owned jointly by the Parties. Each Party shall have the right to exploit any jointly owned Inventions, to the extent it can do so without infringing on the other Party's other intellectual property, without compensation, liability or other obligation (including without limitation accounting obligations) to the other Party.



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6.5.5 ownership of the trademarks, trade names and logos each Product shall be marketed and sold under in each country in the Territory shall be determined by the JDC pursuant to Section 3.2.11.

*6.6 Patent Prosecution and Maintenance.*

6.6.1 Each Party shall have full responsibility for, and shall control the preparation and prosecution of all patent applications and the maintenance of all patents relating to the Inventions owned solely by it (including the Patents) throughout the Territory. Each Party shall pay all costs and expenses of filing, prosecuting and maintaining such patent applications and patents relating to Inventions owned by it.

6.6.2 Each Party agrees promptly to provide to the other Party with a complete written disclosure of any Invention made by such Party. SkyePharma shall determine whether any Invention owned solely by it is patentable, and if so, shall, in its sole discretion, determine whether or not to proceed with the preparation and prosecution of a patent application covering any such Invention. Enzon shall determine whether any Invention owned solely by it is patentable, and if so, shall, in its sole discretion, determine whether or not to proceed with the preparation and prosecution of a patent application covering any such Invention. If either Party determines not to file an application on an Invention so disclosed or to abandon an application that has been filed, it shall promptly and timely so notify the other Party. The other Party may at its option pursue such Invention by an application it files or by continued pursuit of an existing application at its own expense. The non-filing or abandoning Party shall assign all its rights to the Invention and any related application to the filing or continuing Party but shall retain for itself and its Affiliates a covenant-not-to-sue immunity under any Patent that issues from an Invention and/or application so assigned.

6.6.3 Each Party shall select qualified patent counsel reasonably acceptable to the other Party to prepare and file and prosecute all patent applications such Party may, in its sole discretion, determine to be appropriate pursuant to Section 6.6. Each Party shall promptly provide copies to the other Party of any filings made to, and any written communications received from, any patent office relating, in whole or in part, to such patent applications or patents granted thereon reasonably in advance of the relevant proposed filing or response date. Each Party and the selected patent counsel shall give reasonable consideration to any comments that may be made by the other Party reasonably in advance of the relevant proposed filing or response date relating to the filing and prosecution of such patent applications or the maintenance of patents granted thereon.

6.6.4 SkyePharma and Enzon shall together determine whether any Invention jointly owned by SkyePharma and Enzon is patentable. SkyePharma and Enzon shall share equally all costs and expenses of preparing, filing, prosecuting and maintaining patent applications and patents relating to Inventions that are owned jointly by SkyePharma and Enzon. If either Party elects not to pay for: (i) the filing of a patent application in any country in the Territory on any jointly owned Invention that the other Party reasonably believes is patentable, or (ii) the further prosecution or maintenance of any patent application or patent on any jointly owned Invention in any country in the Territory, or (iii) the filing of any divisional or continuing patent application (based on a prior patent application or patent) on a jointly owned Invention in

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any country in the Territory, such Party shall notify the other Party in writing in a timely manner and the other Party may do so at its own expense. In the event that the other Party elects to proceed with any such filing or further prosecution or maintenance, the Party electing not to pay shall assign its rights in and to such patent or patent application in such country to the other Party, and all of such assigning Party's rights in such patent or patent application in such country shall cease. In the case where Enzon is the assigning Party, the license granted to Enzon under Section 6.1 with respect to such assigned patent or patent application (and any associated sublicense(s)) shall terminate in such country. In the case where SkyePharma is the assigning Party, the license granted to SkyePharma under Section 6.2 with respect to such assigned patent or patent application (and any associated sublicense(s)) shall terminate in such country.

6.6.5 Each Party agrees to cooperate with the other Party to execute all lawful papers and instruments, to make all rightful oaths and declarations, and to provide consultation and assistance as may be necessary in the preparation, prosecution, maintenance and enforcement of all such patents.

*6.7 Patent Enforcement.*

6.7.1 If either Party learns of an infringement, unauthorized use, misappropriation or ownership claim or threatened infringement or other such claim (an "*Infringement*") by a Third Party with respect to any Compound or Product within the Territory, such Party shall promptly notify the other Party in writing and shall promptly provide such other Party with available evidence of such Infringement.

6.7.2 The JDC shall decide whether and how to institute Infringement actions against Third Parties based on such Compound or Product within the Territory. The costs and expenses of any such action (including fees of attorneys and other professionals) and any award paid by Third Parties as a result of such an Infringement action (whether by way of settlement or otherwise) shall be included in Operating Profit or Loss and shared between the Parties in accordance with the Financial Appendix. Each Party shall execute all necessary and proper documents and take such actions as shall be appropriate to allow the other Party to institute and prosecute such Infringement actions.

*6.8 Infringement Action by Third Parties.*

6.8.1 In the event of the institution or threatened institution of any suit by a Third Party against either Party for patent infringement involving the sale, distribution or marketing of any Products in the Territory, the JDC shall meet to decide how the Parties shall respond to such suit. Each Party shall execute all necessary and proper documents and take such actions as shall be appropriate to allow the other Party to defend such actions. The costs and expenses of any such action (including fees of attorneys and other professionals) and any award paid to Third Parties as a result of such an infringement action (whether by way of settlement or otherwise) shall be included in Operating Profit or Loss and shared between the Parties in accordance with the Financial Appendix.

6.8.2 In the event of the institution or threatened institution of any suit by a Third Party against either Party for patent infringement involving the sale, distribution or

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marketing of a Product in the Territory where such infringement claim is a result of the use of the SkyePharma Technology or the Enzon Technology, SkyePharma or Enzon, respectively as applicable shall have the responsibility to defend such suit at its own expense and shall be responsible for all damages incurred as a result thereof. Each Party hereby agrees to assist and cooperate with the other, at the defending Party's reasonable request and expense, in the defense of any such suit.

## 7. ADVERSE REACTION REPORTING.

### 7.1 *Adverse Reaction Reporting.*

7.1.1 Each Party responsible for clinical trials shall, with respect to such trials, record, evaluate, summarize and review all adverse drug experiences associated with the Compounds and the Products. In addition, supplemental information must be provided regarding Compounds at periodic intervals and adverse drug experiences must be reported at more frequent intervals depending upon the severity of the experience. Consequently, each Party agrees to:

(a) in a timely manner, provide to the other Party for initial and/or periodic submission to government agencies significant information on the Compound from preclinical laboratory, animal toxicology and pharmacology studies, as well as adverse drug experience reports from clinical trials and commercial experiences with each Compound and/or Product;

(b) in connection with investigational Compounds and/or Products, promptly report to the other Party the receipt of a report of any unexpected serious adverse drug experience with the Compound and/or Product, if required for either Party to comply with regulatory requirements; and

(c) in connection with marketed Products, promptly report to the other Party any serious adverse drug experience with the Product that is unexpected.

7.1.2 For purposes of this Agreement, "*Serious Adverse Drug Experience*" means any adverse drug experience occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. An unexpected adverse drug experience is one that is not listed in the current labeling for the drug product. This includes events that may be symptomatically and pathophysiologically related to an event listed in the labeling, but differ from the event because of greater severity or specificity.

7.1.3 Each Party shall promptly report to the other Party the information set forth above affecting any of the Compounds or any of the Products in any country.

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7.1.4 Each Party agrees that if it contracts with a Third Party for research to be performed by such Third Party on the drug, that Party agrees to require such Third Party to report to the contracting Party the information set forth above.

7.1.5 The details of adverse drug experience reporting shall be stipulated in separate agreements to be entered into by the Parties in due course.

7.1.6 Any information required pursuant to this Section 7.1 shall be deemed to have been sufficiently given if in writing and personally delivered or sent by certified mail (return receipt requested), facsimile transmission (receipt verified), or overnight express courier service (signature required), prepaid, to the Party for which such notice is intended, at the address set forth for such Party below:

(a) in the case of SkyePharma, to:

SkyePharma, Inc.  
10450 Science Center Drive  
San Diego, CA 92121  
Attention: Dr. Gordon Schooley  
Facsimile No.: (858) 623-0376  
Telephone No.: (858) 625-2414

(b) in the case of Enzon, to:

Enzon Pharmaceuticals, Inc.  
685 Route 202/206  
Bridgewater, New Jersey 08807  
Attention: Anthony Killian  
Facsimile No.: (732) 980-4638  
Telephone No.: (732) 980-4523

or to such other address for such Party as it shall have specified by like notice to the other Party, *provided* that notices of a change of address shall be effective only upon receipt thereof. If delivered personally or by facsimile transmission, the date of delivery shall be deemed to be the date on which such notice or request was given. If sent by overnight express courier service, the date of delivery shall be deemed to be the next business day after such notice or request was deposited with such service. If sent by certified mail, the date of delivery shall, be deemed to be the third business day after such notice or request was deposited with the U.S. Postal Service.

## 8. REPRESENTATIONS AND WARRANTIES.

8.1 *Representations and Warranties of Both Parties.* Each Party represents and warrants to the other Party, as of the Effective Date, that:

8.1.1 such Party is duly organized and validly existing under the laws of the jurisdiction of its incorporation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

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8.1.2 such Party is free to enter into this Agreement;

8.1.3 in so doing, such Party will not violate any other agreement to which it is a party;

8.1.4 such Party has taken all corporate action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement; and

8.1.5 such Party has the right to grant the exclusive and non-exclusive licenses under its respective Patents and Know-how granted in this Agreement.

8.2 *Representations and Warranties of SkyePharma.* SkyePharma represents and warrants to Enzon, as of the Effective Date, that:

8.2.1 without having conducted any patent search or other investigation, SkyePharma is not aware of any valid claim or demand which leads it to believe that the Parties' exercise of any rights to the SkyePharma Technology or SkyePharma Compound IP as contemplated by this Agreement will infringe any patent or other intellectual property right of any Third Party; and

8.2.2 other than as set forth in Section 8.2.1, SkyePharma hereby expressly disclaims any representation or warranty as to the validity or enforceability of any Patents relating to the SkyePharma Technology or SkyePharma Compound IP, the non-infringement of any Third Party patent or other intellectual property right or the prospects or likelihood of development or commercial success of any Compound or any Product.

8.3 *Representations and Warranties of Enzon.* Enzon represents and warrants to SkyePharma, as of the Effective Date, that:

8.3.1 without having conducted any patent search or other investigation, Enzon is not aware of any valid claim or demand which leads it to believe that the Parties' exercise of any rights to the Enzon Technology or Enzon Compound IP as contemplated by this Agreement will infringe any patent or other intellectual property right of any Third Party: and

8.3.2 other than as set forth in Section 8.3.1, Enzon hereby expressly disclaims any representation or warranty as to the validity or enforceability of any Patents relating to the Enzon Technology or the Enzon Compound IP, the non-infringement of any Third Party patent or other intellectual property right or the prospects or likelihood of development or commercial success of any Compound or any Product.

8.4 *Disclaimer.* EXCEPT AS EXPRESSLY SET FORTH IN THIS SECTION 8, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, AND EACH PARTY EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY AND OF FITNESS FOR A PARTICULAR PURPOSE OR USE.

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## 9. PUBLICATION; CONFIDENTIALITY.

### 9.1 *Notification and Review with Respect to SkyePharma and Enzon* .

9.1.1 Both Parties recognize that each may wish to publish the results of their work relating to the subject matter of this Agreement. However, both Parties also recognize the importance of acquiring patent protection. Consequently, any proposed publication, by either Party (including its Affiliates and/or Sublicensees), that includes information related to the Compounds or Products, or which otherwise includes proprietary information of the other Party or Confidential Information, shall comply with this Section 9. At least forty-five (45) days before a manuscript is to be submitted to a publisher, the publishing Party shall provide the JDC with a copy of the manuscript. If the publishing Party wishes to make an oral presentation, it shall provide the JDC with a summary of such presentation at least fifteen (15) business days before such oral presentation and, if an abstract is to be published, three business days before such abstract is to be submitted. Any oral presentation, including any question period, shall not include any Confidential Information unless both Parties otherwise mutually agree in writing in advance of such oral presentation.

9.1.2 The JDC shall review the manuscript, abstract, text or any other material provided under Section 9.1.1 to determine whether patentable subject matter is or may be disclosed. The JDC shall notify the publishing Party in writing within thirty (30) days (or two (2) business days in the case of abstracts) of receipt of the proposed publication if it, in good faith, determines that patentable subject matter is or may be disclosed, or if the JDC, in good faith, believes Confidential Information (as defined in Section 9.2) is or may be disclosed. To the extent solely determined by the JDC, that patent applications should be filed, the publishing Party shall delay its publication or presentation for a period not to exceed one hundred twenty (120) days from the JDC's receipt of the proposed publication or presentation to allow time for the filing of patent applications covering patentable subject matter. In the event that the delay needed to complete the filing of any necessary patent application will exceed the one hundred twenty (120)-day period, the JDC will discuss the need for obtaining an extension of the publication delay beyond the one hundred twenty (120)-day period. If the JDC determines in good faith that Confidential Information or proprietary information is or may be disclosed, the JDC will determine mutually acceptable modifications to the proposed publication or presentation to avoid such disclosure.

9.1.3 Except as expressly provided in this Section 9, each Party agrees not to make any public announcement or disclosure (including, without limitation, any press release, summary or Q&A) of the terms of this Agreement or the documents ancillary thereto, or the identity or potential applications of any Compound or Product, without first obtaining the written approval of the other Party and agreement upon the nature and text of such public announcement or disclosure. On and after the Effective Date, either Party may issue a press release, the content of which will be agreed upon in advance by the Parties, with respect to the execution of this Agreement and the documents ancillary thereto. The Party desiring to make any such public announcement shall provide the other Party with a copy of the proposed announcement for review and comment in reasonably sufficient time prior to public release.

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9.1.4 Each Party agrees that it shall cooperate fully with the other with respect to all disclosures regarding this Agreement and the documents ancillary thereto required under applicable laws and regulations to the United States Securities and Exchange Commission and any other comparable governmental or regulatory agencies.

9.1.5 In addition, each Party agrees not to disclose, under any circumstances except as set forth in this Section 9 or as otherwise required by law, the terms of this Agreement or the documents ancillary thereto, or the identity or potential applications of any Compound or Products, to any Third Party other than to professional advisors and financing sources, and in that case, only under confidentiality terms at least as stringent in material respects as this Section 9.

9.2 *Confidentiality; Exceptions*. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, during the term of this Agreement and thereafter, the receiving Party shall keep, and shall ensure that its employees, officers and directors keep, completely confidential and shall not publish or otherwise disclose and shall not use for any purpose: (i) any information furnished to it by the other Party or (ii) developed under or in connection with this Agreement by either Party; except in each of subclause (i) and (ii) to the extent that it can be established by the receiving Party by competent proof that such information: (1) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the other Party; (2) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party; (3) became generally available to the public or was otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement; or (4) was disclosed to the receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the disclosing Party not to disclose such information to others (all such information to which none of the foregoing exceptions applies, “*Confidential Information*”).

9.3 *Exceptions to Obligation*. The restrictions contained in Section 9.2 shall not apply to Confidential Information that: (i) is submitted by the recipient to governmental authorities to facilitate the issuance of Registrations for the Products, provided that reasonable measures shall be taken to assure confidential treatment of such information; (ii) is provided by the recipient to Third Parties under confidentiality agreements having provisions at least as stringent as those in this Agreement, for consulting, manufacturing development, manufacturing, external testing, marketing trials and to Third Parties who are Sublicensees or other development/marketing partners hereunder with respect to any of the subject matter of this Agreement; (iii) is otherwise required to be disclosed in compliance with applicable laws or regulations or order by a court or other regulatory body having competent jurisdiction; *provided* that if a Party is required to make any such disclosure of the other Party’s Confidential Information such Party will give reasonable advance written notice to the other Party of such disclosure requirement and, except to the extent inappropriate in the case of patent applications, will use its best efforts to secure confidential treatment of such Confidential Information required to be disclosed; or (iv) was developed by the receiving Party independent of any disclosure received under this Agreement. In addition, the restrictions contained in Section 9.2 shall not apply to SkyePharma or Enzon to the extent the Confidential Information relates to any application of the SkyePharma Technology or Inventions solely owned by SkyePharma or the

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Enzon Technology or Inventions solely owned by Enzon, as the case may be (i) outside the field or (ii) to any compounds or products other than those Compounds and Products then under development or commercialization under this Agreement.

9.4 *Limitations on Use.* Each Party shall use any Confidential Information obtained by such Party from the other Party, its Affiliates, or its Sublicensees, pursuant to this Agreement or otherwise, solely in connection with the activities or transactions contemplated hereby or expressly permitted hereunder.

9.5 *Remedies.* Each Party shall be entitled, in addition to any other right or remedy it may have, at law or in equity, to an injunction, without the posting of any bond or other security, enjoining or restraining the other Party from any violation or threatened violation of this Section 9.

## 10. INDEMNIFICATION.

10.1 *By SkyePharma.* SkyePharma shall indemnify, defend and hold harmless Enzon and its Affiliates, and their respective directors, officers, employees and agents, from and against any and all liabilities, damages, losses, costs and expenses (including the reasonable fees of attorneys and other professionals) for claims of any Third Party arising out of or resulting from:

10.1.1 negligence or wrongful intentional acts or omissions of SkyePharma or its Affiliates or Sublicensees, and their respective directors, officers, employees and agents, in connection with the activities contemplated under this Agreement; or

10.1.2 any warranty claims, Product recalls or any tort claims of personal injury (including death) or property damage relating to or arising out of any sale, offer for sale or importation of any Product by SkyePharma to the extent due to any a Product manufactured by, or on behalf of, SkyePharma not meeting the specifications for such Product or which was not manufactured in accordance with cGMP, but only to the extent not due to the negligence or wrongful intentional acts or omissions of Enzon or its Affiliates or Sublicensees, and their respective directors, officers, employees and agents; or

10.1.3 any claims relating to or arising out of the marketing or sales activities of SkyePharma or its Affiliates or its Sublicensees, but only to the extent not due to the negligence or wrongful intentional acts or omissions of Enzon or its Affiliates or Sublicensees, and their respective directors, officers, employees and agents; or

10.1.4 any breach of any representation or warranty made by SkyePharma pursuant to Section 8.

10.2 *By Enzon.* Enzon shall indemnify, defend and hold harmless SkyePharma, its Affiliates and its Sublicensees, and their respective directors, officers, employees and agents, from and against any and all liabilities, damages, losses, costs and expenses (including the reasonable fees of attorneys and other professionals) for claims of any Third Party arising out of or resulting from:

10.2.1 negligence or wrongful intentional acts or omissions of Enzon or its Affiliates or Sublicensees, and their respective directors, officers, employees and agents, in connection with the activities contemplated under this Agreement; or



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10.2.2 any warranty claims, Product recalls or any tort claims of personal injury (including death) or property damage relating to or arising out of any sale, offer for sale or importation of any Product by Enzon to the extent due to any a Product manufactured by, or on behalf of, Enzon not meeting the specifications for such Product or which was not manufactured in accordance with cGMP, but only to the extent not due to the negligence or wrongful intentional acts or omissions of SkyePharma or its Affiliates or Sublicensees, and their respective directors, officers, employees and agents; or

10.2.3 any claims relating to or arising out of the marketing or sales activities of Enzon or its Affiliates or its Sublicensees, but only to the extent not due to the negligence or wrongful intentional acts or omissions of SkyePharma or its Affiliates or Sublicensees, and their respective directors, officers, employees and agents; or

10.2.4 any breach of any representation or warranty made by Enzon pursuant to Section 8.

10.3 *Jointly*. In the event of a Third Party claim against either Party relating to or arising out of either Party's activities under this Agreement which is not covered under Section 10.1 or 10.2, the Parties agree to share all liabilities, damages, losses, costs and expenses (including the reasonable fees of attorneys and other professionals) arising out of or resulting from such Third Party claim on [\*\*], [\*\*]/[\*\*] ([\*\*]/[\*\*]), basis as set forth in the Financial Appendix.

10.4 *Notice*. In the event that any person (an "Indemnitee") entitled to indemnification under Section 10.1 or 10.2 is seeking such indemnification, such Indemnitee shall inform the indemnifying Party of the claim as soon as reasonably practicable after such Indemnitee receives notice of such claim, shall permit the indemnifying Party to assume direction and control of the defense of the claim (including the sole right to settle it at the sole discretion of the indemnifying Party, provided that such settlement does not impose any obligation on the Indemnitee or the other Party) and shall cooperate as requested (at the expense of the indemnifying Party) in the defense of the claim.

10.5 *Complete Indemnification*. As the Parties intend complete indemnification, all costs and expenses, including without limitation, legal fees and expenses, actually incurred by an Indemnitee in connection with enforcement of Sections 10.1 and 10.2 shall also be reimbursed by the indemnifying Party.

## 11. TERM; TERMINATION.

11.1 *Term*. This Agreement shall become effective as of the Effective Date and, unless earlier terminated pursuant to the other provisions of this Section 11.1 shall expire as follows:

11.1.1 with respect to each Product, on a Product-by-Product, country-by-country basis, upon the expiration of the last to expire of all patents covering such Product in each country within the Territory; and

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11.1.2 in its entirety upon the expiration of this Agreement with respect to all Products in all countries in the Territory.

11.2 *Termination for Cause.* Either Party (the “*Non-breaching Party*”) may, without prejudice to any other remedies available to it at law or in equity with respect to any Compound or Product, in the event the other Party (the “*Breaching Party*”) shall have materially breached or defaulted in the performance of any of its material obligations hereunder with respect to such Compound or Product and such breach or default shall have continued for sixty (60) days after written notice thereof was provided to the Breaching Party by the Non-breaching Party (or, if such breach or default cannot be cured within such sixty (60)-day period, if the Breaching Party does not commence and diligently continue actions to cure such breach or default during such sixty (60) day period). In addition, if a breach or default or group of related breaches or defaults by a Breaching Party within the preceding sentence also materially affects the entirety of this Agreement, and such breach or default or group of related breaches or defaults shall have continued for sixty (60) days after written notice thereof was provided to the Breaching Party by the Non-breaching Party (or, if such breach(es) or default(s) cannot be cured within such sixty (60)-day period, if the Breaching Party does not commence and diligently continue actions to cure such noticed breach(es) or default(s) during such sixty (60)-day period), the Non-breaching Party may, without prejudice to any other remedies available to it at law or in equity with respect to any Compound or Product, terminate this Agreement in its entirety. Any such termination under this Section shall become effective at the end of such sixty (60)-day period unless the Breaching Party has cured any such noticed breach(es) or default(s) prior to the expiration of such sixty (60)-day period (or, if such breach(es) or default(s) cannot be cured within such sixty (60)-day period, if the Breaching Party has commenced and diligently continued actions to cure such breach(es) or default(s)). The right of either party to terminate this Agreement as provided in this Section 11.2 shall not be affected in any way by its waiver or failure to take action with respect to any previous breach or default.

11.3 *Termination for Insolvency.*

11.3.1 Either Party may terminate this Agreement, if, at any time, the other Party shall file in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Party or of substantially all of its assets, or if the other Party proposes a written agreement of composition or extension of substantially all of its debts, or if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, or if the other Party shall propose or be a party to any dissolution or liquidation, or if the other Party shall make an assignment of substantially all of its assets for the benefit of creditors.

11.3.2 All rights and licenses granted under or pursuant to any section of this Agreement are and shall otherwise be deemed to be for purposes of Section 365(n) of Title 11, United States Code (the “*Bankruptcy Code*”) licenses of rights to “intellectual property” as

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defined in Section 101(56) of the Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code. Upon the bankruptcy of any Party, the non-bankrupt Party shall further be entitled to a complete duplicate of, or complete access to, any such intellectual property, and such, if not already in its possession, shall be promptly delivered to the non-bankrupt Party, unless the bankrupt Party elects to continue, and continues, to perform all of its obligations under this Agreement.

#### 11.4 *Termination for Inactivity.*

11.4.1 Either Party may terminate this Agreement as to a particular Compound or Product, effective upon thirty (30) days prior written notice, if, for a period of [\*\*] ([\*\*]) consecutive months there is no Development Program activity for such Compound and/or Product or, for a Product at the commercialization stage, such Product is not being commercialized and/or marketed due to lack of Party activity; *provided that* in the event prior to the expiration of such thirty (30)-day period the Parties agree to resume development or commercialization activities hereunder or the Parties negotiate a mutually acceptable agreement for one Party to become a Sole Developing Party under Section 4.4, any such termination notice shall be without force or effect.

11.4.2 Either Party may terminate this Agreement, in its entirety, effective upon thirty (30) days prior written notice, if, for a period of [\*\*] ([\*\*]) consecutive months no Compounds and/or Products are being developed under the Development Program and no Products are being commercialized and/or marketed by a Party hereunder; *provided that* in the event the Parties agree to resume development or commercialization activities hereunder prior to the expiration of such thirty (30)-day period, any such termination notice shall be without force or effect.

#### 11.5 *Effect of Expiration or Termination.*

11.5.1 Following the expiration of the term of this Agreement with respect to a Product in any country in the Territory pursuant to Section 11.1, each Party shall have a non-exclusive, royalty-free, paid-up, perpetual, irrevocable and sublicensable right and license, to develop, make, have made, use, market, sell, have sold, offer to sell, import, distribute and otherwise exploit such Product in the such country in the Territory. To that end, each Party may hold and use all data, reports, records, information and materials that relate to or are prepared in the course of the Development Program with respect to such Product and may in its sole discretion continue any sublicense granted by it under this Agreement.

11.5.2 If this Agreement is terminated by a Non-breaching Party with respect to particular Compound(s) and/or Product(s) pursuant to Sections 11.2, in addition to any other remedies available to such Non-breaching Party at law or in equity: (i) at the Breaching Party's expense, the Breaching Party shall promptly (1) transfer to the Non-breaching Party all relevant data, reports, records and materials in the Breaching Party's possession or control that relate to such Compound and/or Product; (2) provide the Non-breaching Party with all information necessary or desirable to cross-reference and/or assume responsibility for any INDs, Registrations Applications, Registrations and other regulatory filings in the Breaching Party's name with respect to such Compounds and/or Products; and (3) return to the Non-breaching

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Party all relevant records and materials in such Breaching Party's possession or control containing Confidential Information of the Non-breaching Party relating to such Compound(s) and/or Product(s) (*provided* that the Breaching Party may keep one copy of such Confidential Information for archival purposes only); (ii) to the extent the Breaching Party owns or holds any right, title and interest in any trademarks, trade names, and logos under which such Compound(s) and/or Product(s) have been or are being marketed or sold in the Territory, the Breaching Party shall assign the same to the Non-breaching Party; (iii) the licenses granted under Section 6.1 or 6.2, as applicable, shall continue in full force, *except that* such licenses shall bear a royalty payable to the Breaching Party in accordance with Section 11.5.4; and (iv) all sub-licenses granted by the Breaching Party under this Agreement shall continue in full force and effect in accordance with the terms and conditions of the respective sublicense agreements, and the Breaching Party will assign to the Non-breaching Party those sublicense agreements to the extent relating to such Compound(s) and/or Product(s); *provided, however,* that this Section 11.4.2 shall not apply to any Confidential Information, licenses and sublicenses to the extent relating to any Compound(s) and/or Product(s) for which there has not been a termination.

11.5.3 If this Agreement is terminated in its entirety or as to each Compound and Product by (i) a Non-breaching Party pursuant to Section 11.2; or (ii) a Party for the other's insolvency pursuant to Section 11.3 (either of subclause (i) or (ii), the "*Terminating Party*"), in addition to any other remedies available to the Terminating Party at law or in equity: (1) at the non-Terminating Party's expense, the non-Terminating Party shall promptly transfer to the Terminating Party (A) all relevant data, reports, records and materials in the non-Terminating Party's possession or control that relate to the Development Program; (B) provide the Terminating Party with all information necessary or desirable to cross-reference and/or assume responsibility for all INDs, Registrations Applications, Registrations and other regulatory filings in the non-Terminating Party's name with respect to all Compounds and/or Products; and (C) return to the Terminating Party all relevant records and materials in the non-Terminating Party's possession or control containing Confidential Information of the Terminating Party (*provided* that the non-Terminating Party may keep one copy of such Confidential Information for archival purposes only); (2) to the extent the non-Terminating Party owns or holds any right, title and interest in any trademarks, trade names, and logos under which any Compounds or Products have been or are being marketed or sold in the Territory, the non-Terminating Party shall assign the same to the Terminating Party; (3) the licenses granted under Section 6.1 or 6.2, as applicable, shall continue in full force, *except that* such license shall bear a royalty payable to the non-Terminating Party in accordance with Section 11.5.4; and (4) all sublicenses granted by the non-Terminating Party under this Agreement shall continue in full force and effect in accordance with the terms and conditions of the respective sublicense agreements, and the non-Terminating Party will assign all such sublicense agreements to the Terminating Party.

11.5.4 Each license grant continued pursuant to Sections 11.5.2 and 11.5.3 shall, on a Product-by-Product basis, bear royalties on Net Sales of the Compound(s) and/or Product(s) that are subject to such termination and appropriate development milestone payments payable and sharing of Sublicensing Income with respect to such Compound(s) and/or Product(s). Upon such a termination occurring, the Parties shall enter into good faith negotiations regarding: (i) the applicable royalty rate(s); (ii) the development milestone payments; and (iii) the sharing of Sublicensing Income; in each case: (1) payable with respect to such Compound or Product; and (2) based upon the application of the following factors: (A) the then current market practices for

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pharmaceutical products of similar commercial promise; (B) the relative financial contributions of the Parties to the development and commercialization of such Compound or Product; (C) the market potential of such Compound or Product; and (D) the apparent risks of going forward with development and commercialization; *provided that* the royalties, milestone payments, and sharing of Sublicensing Income shall each be reduced by **[\*\*]** (**[\*\*]**) what each otherwise would have been after application of the foregoing factors. Such matters on which the Parties cannot reach consensus within thirty (30) days after such termination shall be conclusively settled in accordance with the Special Arbitration Provisions in a manner consistent with the foregoing guidelines.

11.6 *Accrued Rights; Surviving Obligations*.

11.6.1 Termination, relinquishment or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of either Party prior to such termination, relinquishment or expiration. Such termination, relinquishment or expiration shall not relieve either Party from obligations that are expressly indicated to survive termination or expiration of this Agreement.

11.6.2 All of the Parties' rights and obligations under Sections 5.3, 5.4, 6.5, 6.7 6.8 (as to then pending actions) 7, 8, 9, 10, 11.5, 13.4 through and including 13.18 shall survive termination, relinquishment or expiration of this Agreement.

12. FORCE MAJEURE.

Any delay in the performance of any of the duties or obligations of either Party hereto (except the payment of money due hereunder) shall not be considered a breach of this Agreement, and the time required for performance shall be extended for a period equal to the period of such delay, if such delay has been caused by or is the result of acts of God; acts of public enemy; insurrections; riots; injunctions; embargoes; labor disputes, including strikes, lockouts, job actions, or boycotts; fires; explosions; earthquakes; floods; shortages of energy; governmental prohibition or restriction; or other unforeseeable causes beyond the reasonable control and without the fault or negligence of the Party so affected. The Party so affected shall give prompt notice to the other Party of such cause, and shall take whatever reasonable steps are necessary to relieve the effect of such cause as rapidly as reasonably possible.

13. MISCELLANEOUS.

13.1 *Relationship of Parties*. Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency, employer-employee or joint venture relationship between the Parties. No Party shall incur any debts or make any commitments for the other, except to the extent, if at all, specifically provided herein.

13.2 *Assignment*. Except pursuant to a sub-license permitted under this Agreement, neither Party shall be entitled to assign its rights or delegate its obligations hereunder without the express written consent of the other Party hereto, except that each Party may assign its rights and transfer its duties hereunder to any assignee of all or substantially all of its business (or that portion thereof to which this Agreement relates) or in the event of such Party's merger, consolidation or involvement in a similar transaction. No assignment and transfer shall be valid

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or effective unless done in accordance with this Section 13.2 and unless and until the assignee/transferee shall agree in writing to be bound by the provisions of this Agreement.

13.3 *Affiliates of SkyePharma*. Parent shall cause the applicable Affiliates of SkyePharma to grant such rights to SkyePharma and to take such actions as are necessary for SkyePharma to fulfill its obligations under this Agreement,

13.4 *Books and Records*. Any books and records to be maintained under this Agreement by a Party shall be maintained in accordance with GAAP.

13.5 *Further Actions*. Each Party shall execute, acknowledge and deliver such further instruments, and do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

13.6 *Notice*.

13.6.1 Any notice or request required or permitted to be given under or in connection with this Agreement shall be deemed to have been sufficiently given if in writing and personally delivered or sent by certified mail (return receipt requested), facsimile transmission (receipt verified), or overnight express courier service (signature required), prepaid, to the Party for which such notice is intended, at the address set forth for such Party below:

(a) in the case of SkyePharma, to:

SkyePharma, Inc.  
10450 Science Center Drive  
San Diego, CA 92121  
Attention: Steve Thornton  
Facsimile No.: (858) 623-0376

(b) in the case of Enzon, to:

Enzon Pharmaceuticals, Inc.  
685 Route 202/206  
Bridgewater, New Jersey 08807  
Attention: Peter Cicala  
Facsimile No.: (908) 541-8838

or to such other address for such Party as it shall have specified by like notice to the other Party, provided that notices of a change of address shall be effective only upon receipt thereof. With respect to notices given pursuant to this Section 13.6.1: (i) if delivered personally or by facsimile transmission, the date of delivery shall be deemed to be the date on which such notice or request was given; (ii) if sent by overnight express courier service, the date of delivery shall be deemed to be the next business day after such notice or request was deposited with such service; and (iii) if sent by certified mail, the date of delivery shall be deemed to be the third business day after such notice or request was deposited with the U.S. Postal Service.

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13.6.2 All correspondence, notices and other communications received by a Party from a Regulatory Authority in the Territory relating to the parties activities under this Agreement shall be promptly provided to the other Party.

13.7 *Use of Name*. Except as otherwise provided herein, neither Party shall have any right, express or implied, to use in any manner the name or other designation of the other Party or any other trade name, trademark or logo of the other Party for any purpose in connection with the performance of this Agreement.

13.8 *Public Announcements*. Except as required by law (including, without limitation, disclosure requirements of the U.S. Securities and Exchange Commission, Nasdaq or any other stock exchange on which securities issued by a Party are traded) and as permitted by Section 9.1.3 or 9.1.4, neither Party shall make any public announcement concerning this Agreement or the subject matter hereof without the prior written consent of the other, which shall not be unreasonably withheld, provided that it shall not be unreasonable for a Party to withhold consent with respect to any public announcement containing any financial terms or any of such Party's Confidential Information. In the event of a required public announcement, to the extent practicable under the circumstances, the Party making such announcement shall provide the other Party with a copy of the proposed text prior to such announcement and with financial terms sufficiently in advance of the scheduled release of such announcement to afford such other Party a reasonable opportunity to review and comment upon the proposed text.

13.9 *Waiver*. A waiver by either Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any subsequent breach hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be in limitation of any other remedy, right, undertaking, obligation or agreement of either Party.

13.10 *Compliance with Law*. Nothing in this Agreement shall be deemed to permit a Party to export, re-export or otherwise transfer any Products sold under this Agreement without compliance with applicable laws.

13.11 *Severability*. When possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be prohibited by or invalid under applicable law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement

13.12 *Amendment*. No amendment, modification or supplement of any provisions of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

13.13 *Governing Law*. This Agreement shall be governed by and interpreted in accordance with the laws of New York without regard to conflict of law principles.

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13.14 *Arbitration.*

13.14.1 Except as expressly otherwise provided in this Agreement, any dispute arising out of or relating to the interpretation of any provisions of this Agreement or the failure of any Party to perform or comply with any obligations or conditions applicable to such Party pursuant to this Agreement shall be finally settled by arbitration under the then current commercial arbitration rules of the American Arbitration Association in accordance with the terms set forth in this Section 13.14.1:

(a) The place of arbitration of any dispute shall be New York, New York. Such arbitration shall be conducted by three (3) arbitrators, one (1) appointed by each of SkyePharma and Enzon and the third (3<sup>rd</sup>) selected by the first two (2) appointed arbitrators. Each arbitrator shall be a person with relevant experience in the pharmaceutical industry. SkyePharma and Enzon shall instruct such arbitrators to render a determination of any such dispute within four months after the appointment of the third arbitrator.

(b) Any award rendered by the arbitrators shall be final and binding upon the Parties. Judgment upon any award rendered may be entered in any court having jurisdiction, or application may be made to such court for a judicial acceptance of the award and an order of enforcement, as the case may be. Each Party shall pay its own expenses of arbitration, and the expenses of the arbitrators shall be equally shared between the Parties unless the arbitrators assess as part of their award all or any part of the arbitration expenses of a Party or Parties (including reasonable attorneys' fees) against the other Party or Parties, as the case may be.

(c) This Section 13.14.1 shall not prohibit a Party from seeking injunctive relief from a court of competent jurisdiction in the event of a breach or prospective breach of this Agreement by any other Party which would cause irreparable harm to the first Party.

13.14.2 Whenever a dispute arising out of or relating to the interpretation of any provisions of this Agreement or the failure of any Party to perform or comply with any obligations or conditions applicable to such Party pursuant to this Agreement arises or any other matter arising under or relating to this Agreement and such dispute is expressly designated as one to be resolved through the Special Arbitration Provisions, then such dispute shall be finally settled by arbitration under the then current expedited procedures applicable to the then current commercial arbitration rules of the American Arbitration Association in accordance with the terms set forth in this Section 13.14.2 (the "*Special Arbitration Provisions*"). The dispute in question shall be referred to the Executive Officers for resolution. The Executive Officers shall use reasonable efforts to resolve the matter referred to them. If the Executive Officers cannot reach a mutually acceptable decision within thirty (30) days after the matter was referred to them, or such longer period as the Executive Officers may collectively agree, then either Party shall have the right to refer such dispute to an Expert for expedited arbitration as set forth in Sections 13.14.2(a) through (c).

(a) Upon written request by either Party to the other Party, the Parties shall promptly negotiate in good faith to appoint a mutually acceptable independent person, with



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scientific, technical and regulatory experience with respect to the development of pharmaceutical products in the same Field as the Compounds and/or Products in question necessary to resolve such dispute (an “*Expert*”). If the Parties are not able to agree within five (5) business days after the receipt by a Party of the written request in the immediately preceding sentence, the American Arbitration Association shall be responsible for selecting an Expert within ten (10) business days of being approached by a Party. The fees and costs of the Expert and the American Arbitration Association, if applicable, shall be shared equally by the Parties. The place of arbitration of any dispute shall be New York, New York, unless the Parties agree otherwise or the selection of the Expert requires otherwise.

(b) Within five (5) business days after the designation of the Expert, the Parties shall each simultaneously submit to the Expert and one another a written statement of their respective positions on such disagreement. Each Party shall have fifteen (15) business days from receipt of the other Party’s submission to submit to the Expert and the other Party a written response thereto, which shall include any scientific and technical information in support thereof. The Expert shall have the right to meet with the Parties, either alone or together, as necessary to make a determination.

(c) No later than thirty (30) business days after the designation of the Expert, the Expert shall make a determination by selecting the resolution proposed by one (1) of the Parties that the Expert deems as a whole to be the most fair and reasonable to the Parties in light of the totality of the circumstances. The Expert, shall provide the Parties with a written statement setting forth the basis of the determination in connection therewith. The decision of the Expert shall be final and conclusive.

13.15 *Entire Agreement*. This Agreement, together with the Exhibits hereto and every Annual Operating Plan and Budget, sets forth the entire agreement and understanding between the Parties as to the subject matter hereof and merges all prior discussions and negotiations between them, and neither of the Parties shall be bound by any conditions, definitions, warranties, understandings or representations with respect to such subject matter other than as expressly provided herein or as duly set forth on or subsequent to the date hereof in writing and signed by a proper and duly authorized officer or representative of the Party to be bound thereby.

13.16 *Parties in Interest*. All of the terms and provisions of this Agreement shall be binding upon, inure to the benefit of and be enforceable by the Parties hereto and their respective permitted successors and assigns.

13.17 *Descriptive Headings*. The descriptive headings of this Agreement are for convenience only, and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement.

13.18 *Counterparts*. This Agreement may be executed simultaneously in any number of identical counterparts, any one of which need not contain the signature of more than one Party, but all such counterparts taken together shall constitute one and the same agreement.

\* \* \*

IN WITNESS WHEREOF, each of the Parties has caused this Co-development, Collaboration and License Agreement to be executed by its duly authorized representative as of the date first above written.

**ENZON PHARMACEUTICALS, INC.**

By: /s/ Arthur J. Higgins  
Arthur J. Higgins, Chairman and Chief Executive Officer

**SKYEPHARMA, INC.**

<sup>BY:</sup> /s/ Michael R.D. Ashton  
Michael R.D. Ashton, Chief Executive Officer of  
SkyePharma PLC

**JAGOTEC, AG**

<sup>BY:</sup> /s/ Michael R.D. Ashton  
Michael R.D. Ashton, Chief Executive Officer of  
SkyePharma PLC

Solely with respect to Section 13.3:

**SKYEPHARMA PLC**

<sup>BY:</sup> /s/ Michael R.D. Ashton  
Michael R.D. Ashton, Chief Executive Officer of  
SkyePharma PLC

## FINANCIAL APPENDIX

This provides the definitions of certain financial terms applicable to the parties for purposes of the Agreement. All capitalized terms used herein without definition shall have the meanings ascribed thereto in the Agreement, unless otherwise expressly provided herein.

**A.1 Principles of Reporting**

The presentation of results of operations of the Parties shall be based on each Party's respective financial information for each Compound and Product being developed and commercialized by the Parties presented separately, by Party and by Compound and by Product, and on a consolidated basis, by Party (across all Compounds and Products), by Compound and by Product (across the Parties) and across all Compounds and Products and the Parties, in the reporting format depicted as follows:

<u>[Product/Compound/all Products and Compounds]</u>	<u>SkvePharma</u>	<u>Enzon</u>	<u>Total</u>
<b>Development Costs</b>			
<b>Net Sales*</b>			
<b>Sublicensing Income</b>			
less Cost of Goods Sold			
less Marketing Costs			
less Sales Costs			
less Post-Registration Development Costs			
less Distribution Costs			
less Other Operating Income/Expense			
<b>= Operating Profit or Loss</b>			

\* The components of each Net Sales amount reported by a Party shall also be reported in supporting documentation.

It is the intention of the Parties that the interpretation of these definitions shall be consistent with GAAP.

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If necessary, a Party shall make the appropriate adjustments to the financial information it supplies under the Agreement to conform to the above format of reporting results of operation.

### **A.2 Frequency of Reporting**

The fiscal year shall be a calendar year.

Reports of results compared to the applicable Annual Operating Plan and Budget shall be made to the Joint Development Committee on a quarterly basis and on a year-to-date basis, for the Territory, by Party and by Compound/Product, and on a consolidated basis, by Party (across all Compounds/Products), by Compound/Product (across the Parties) and across all Compounds/Products and the Parties.

SkyePharma shall be responsible for the preparation of consolidated reporting, calculation of the profit/loss sharing, and determination of the cash settlement. SkyePharma shall provide the same within thirty (30) business days of receipt of each Party's financial information, a statement showing the consolidated results, and calculations of the sharing of Operating Profit or Loss and cash settlement required in a format agreed to by the parties.

### **A.3 Definitions**

*"Allocable Overhead"* means costs directly related to the Products or Compounds, as the case may be, and incremental costs actually incurred by a Party or for its account including, but not limited to, those which are attributable to such Party's supervisory services, occupancy costs, and its payroll, information systems, or purchasing functions and which are allocated to company departments based on space occupied or headcount or other activity-based method consistently applied by a Party, or a standard rate if agreed to by the Parties, relating to activities of such Party under the Development Program or as part of its commercialization activities. Allocable Overhead shall be approved by the JDC and included in the Annual Operating Plan and Budget. Allocable Overhead shall not include any costs attributable to general corporate activities including, by way of example, executive management, investor relations, business development, legal affairs, human relations, and finance, related to activities of a Party under the Development Program or as part of its commercialization activities.

*"Cost of Goods Sold"* means Fully Burdened Manufacturing Costs (as defined below) of each Party relating to sales of Products.

*"Development Costs"*

(a) *"Development Costs"* means the development costs actually incurred by each Party with respect any Compound or Product in the Field, in all jurisdictions within the Territory from the Effective Date of the Agreement through the later of (i) the date of Registration (not including costs actually incurred thereafter to maintain or expand such Registration) of such Products in the Field, in such jurisdiction, (ii) the date of termination of all development efforts with respect to Compound or Product in the Field for which Registration is sought in all jurisdictions throughout, the Territory, or (iii) the date on which the Parties cease to continue joint development of such Compound or Product pursuant to Sections 4.3.2 or 4.3.3. Such costs shall comprise those costs required to maintain and/or expand such first Registration and to obtain, maintain and/or expand any subsequent Registrations for Product in the Field and to obtain, maintain and/or expand the ability to manufacture, formulate, fill, use, ship, sell and/or distribute such Product in commercial quantities to Third Parties.

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(b) “*Development Costs*” shall include, without limitation, costs of research or development including costs of studies on the lexicological, pharmacokinetic, metabolic or clinical aspects of a Product conducted internally or by individual investigators or consultants (using an assumed scientific FTE rate of \$[\*\*] per year for preclinical development, and using an FTE rate to be determined by the JDC for clinical development), necessary for the purpose of obtaining, maintaining and/or expanding marketing approval of a Product, costs for preparing, submitting, reviewing or developing data or information for the purpose of submission to a Regulatory Authority to obtain, maintain and/or expand marketing approval of a Product, and applicable Allocable Overhead.

(c) “*Development Costs*” shall also include, without limitation, expenses for data management, statistical designs and studies, document preparation, and other administration expenses associated with the clinical testing program or post-marketing studies required to maintain product approvals.

(d) In determining Development Costs chargeable under the Agreement, each Party shall use its respective project accounting systems and shall review and approve its respective project accounting systems and methodologies with the other Party.

(e) In determining Development Costs chargeable under the Agreement, the FTE rate set forth in (b) shall apply for Contract Year One. Thereafter, the FTE rate shall be adjusted annually, to be effective at the beginning of each Contract Year, to reflect the increase in the Consumer Price Index for All Urban Consumers for All Items over the prior year, as reported in the CPI Detailed Report published by the U.S. Department of Labor Bureau of Labor Statistics.

“*Distribution Costs*” means the costs, including applicable Allocable Overhead, specifically identifiable to the distribution of a Product by a Party including customer services, collection of data about sales to hospitals and other end users, order entry, billing, shipping, bad debt, credit and collection and other such activities.

“*First Commercial Sale*” shall mean, with respect to any Product, the first sale for which payment has been received for use or consumption by the general public of such Product in the Field in a country in the Territory after all required Registrations, including pricing approvals (if applicable), have been granted by the Regulatory Authority in such country.

“*Fully Burdened Manufacturing Costs*” of a Product means 100% of the fully burdened manufacturing cost (as defined through the supplying Party’s consistent application of GAAP to such manufacturing activities) of producing finished, packaged, and labeled Product which shall be comprised of “the cost of goods produced, including but not limited to, direct labor and material costs and product quality assurance/control costs, as well as applicable Allocable Overhead.

“*Marketing Costs*”

(a) “*Marketing Costs*” means the costs actually incurred for marketing, promotion, advertising, Product promotional materials, professional education, Product related public relations, relationships with opinion leaders and professional societies, market research (after the first Registration), healthcare economics studies, post-marketing studies not required to maintain Registrations, and other similar activities, relating to commercialization activities of a Party for a Product. Such costs of a Party shall include (i) both direct internal costs actually incurred by a Party or for its account which are attributable to commercialization activities of such Party under the applicable Annual Operation Plan and Budget ( e.g., without limitation, salaries, benefits, supplies

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and materials, *etc.*), and (ii) applicable Allocable Overhead, outside services and expenses ( *e.g.*, without limitation, consultants, agency fees, meeting costs, *etc.*), relating to such commercialization activities of such Party.

(b) “*Marketing Costs*” shall also include, without limitation, the cost of activities related to obtaining reimbursement from payers and costs of sales and marketing data.

(c) “*Marketing Costs*” shall specifically exclude the costs of activities which promote any Party’s business as a whole without being product specific (such as corporate image advertising).

“*Net Sales*” means, with respect to each Product, the gross amount invoiced for sales of a Product in arm’s length sales by the Parties or individual Party and its Affiliates and Sublicensees to Third Parties which are not Sublicensees, commencing with the First Commercial Sale of such Product, less the following deductions from such gross amounts which are actually incurred, allowed, accrued or specifically allocated:

(a) credits, price adjustments or allowances for damaged products, returns or rejections of Products;

(b) normal and customary trade, cash and quantity discounts, allowances and credits (other than price discounts granted at the time of invoicing which have been already been included in the gross amount invoiced);

(c) chargeback payments and rebates (or the equivalent thereof) granted to group purchasing organizations, managed health care organizations or to federal, state/provincial, local and other governments, including their agencies, or to trade customers;

(d) any invoiced freight, postage, shipping, insurance and other transportation charges (excluding such charges that are included in Distribution Costs); and

(e) sales, value-added (to the extent not refundable in accordance with applicable- law), and excise taxes, tariffs and duties, and other taxes directly related to the sale (but not including taxes assessed against the income derived from such sale).

“*Net Sales*” shall also include the average selling price for a Product times the number of units transferred to Third Parties which are not Sublicensees for non-cash consideration or where no invoice is generated. The Parties or Party marketing each Product shall use Commercially Reasonable Efforts to reconcile such amounts invoiced and deducted annually. For the avoidance of doubt, Net Sales shall not include sales of Products among the Parties or their respective Affiliates or Sublicensees. Net Sales, as set forth in this definition, shall be calculated applying, in accordance with GAAP, the standard accounting practices each Party customarily applies to other products sold by it.

“*Operating Profit or Loss*” means Net Sales of all Products and Sublicensing Income with respect to all Compounds and Products, less the following items with respect to each Product sold or transferred to a Third Party (including, without limitation, Sublicensees) or relating to commercialization activities of a Party regarding a Product, all for a given period: Cost of Goods Sold, Marketing Costs, Sales Costs, Post-Registration Development Costs, General and Administrative Costs, Distribution Costs, and Other Operating Income/Expense.

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“*Other Operating Income/Expense*” means other operating income or expense from or to Third Parties, relating to the manufacturing or selling of Products by a Party, which is not part of the primary business activity being conducted by the Parties under this Agreement, but is considered and approved by the JDC as income or expense for purposes of this activity and is limited to the following, each of which is to be related to manufacturing or selling of Products by a Party:

- actual inventory write-offs of any Product
- patent and trademark costs
- product liability insurance to the extent the Parties obtain a joint policy
- indemnification costs (as described in Section 10.3 of the Agreement, but excluding costs under Sections 10.1 and 10.2)
- other (to be approved by JDC)
- cost of capital
- foreign exchange hedging (gains/losses)

The methodology used to determine the amount of each item set forth above shall be approved by the JDC.

“*Post-Registration Development Costs*” means the Development Costs actually incurred by each Party with respect to a Product in the Field, in a jurisdiction within the Territory after the Registration of such Product in such jurisdiction.

“*Sales Costs*” means costs, including Allocable Overhead, approved by the JDC within the applicable Annual Operating Plan and Budget, actually incurred by the Parties or for their account and specifically identifiable to the commercialization activities of a Party for a Product in the Territory in all markets, including without limitation, the managed care market.

(a) “*Sales Costs*” shall include, without limitation, costs associated with sales representatives for Products, including compensation, benefits and travel, supervision and training of such sales representatives, sales meetings, and other sales related expenses.

(b) “*Sales Costs*” shall not include the start-up costs associated with any Party’s sales force relating to that Party’s sales efforts, including recruiting, relocation and other similar costs.

“*Sublicensing Income*” shall mean all monetary consideration (for example and not by way of limitation, up-front payments, royalties, milestones and the like) received by a Party or its Affiliates from Sublicensees pursuant to a sublicense granted pursuant to this Agreement, excluding (i) any amounts received from Sublicensees to reimburse such Party for reasonably documented research and development services which would not otherwise be required to be performed by such Party pursuant to this Agreement, and (ii) any consideration received for the issuance of securities at the fair market value for such securities.

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#### **A.4 Foreign Exchange**

Accounting for Operating Profit or Loss shall be U.S. dollars. For billing and reporting, the statement of operations and sales shall be translated into U.S. dollars at the average rate of exchange listed in *The Wall Street Journal* on each business day of the applicable calendar quarter.

#### **A.5 Audits and Interim Reviews**

Either Party shall have the right to request that the other Party's independent, certified accounting firm perform an audit or interim review of the other Party's books in order to express an opinion regarding such Party's compliance with GAAP. Such audits or review shall be conducted at the expense of the requesting Party.

At the request and expense of either Party ("*Auditing Party*"), the other Party ("*Audited Party*") shall permit an independent, certified public accountant appointed by the Auditing Party and reasonably acceptable to the Audited Party, at reasonable times and upon reasonable written notice, to examine such records as may be necessary to: (i) determine the correctness of any report or payment made under this Agreement; or (ii) obtain information as to Development Costs or the aggregate Operating Profit or Loss payable for any calendar quarter in the case of the other Party's failure to report or pay pursuant to this Agreement; *provided, however*, that such accountant shall sign a confidentiality agreement in a form reasonably satisfactory to the Audited Party, and, *provided further*, that such examination shall not be permitted more than once in any twelve (12) month period. Said accountant shall not disclose to the Auditing Party or any other person any information, except that such accountant may disclose to the Auditing Party the fact of a deficiency, the lack of a deficiency or any overpayment, and the degree thereof, including the dollar amount. All results of any such examination shall be made available to the Audited Party.

In the event that any audit reveals a deficiency in the amount that should have been paid by one Party to the other Party, then the underpaid amount shall be paid within forty-five (45) days after the Party who is owed payment makes a demand therefor, plus interest thereon if such deficiency is in excess of [\*\*] percent ([\*\*]%) of the amount that actually should have been paid. Such interest shall be calculated from the date such underpaid amount was due until the date such underpaid amount is actually paid, at the rate of [\*\*] percent ([\*\*]%) over the prime rate of interest reported in *The Wall Street Journal* for the date such amount was due. In addition, if such underpaid amount is in excess of [\*\*] percent ([\*\*]%) of the amount that actually should have been paid, then the Party who is owed payment shall be reimbursed for the reasonable cost of such audit. In the event of an overpayment, such amounts shall be deducted from future amounts due. If such overpaid amounts have not been settled by such future deductions three years from the date originally overpaid, the Party who is owed payment such overpayment shall invoice the other Party for such amounts.

#### **A.6 Payments between the Parties**

Payments to each Party of the agreed upon percentages of Development Costs or Operating Profit or Loss shall be made quarterly, based on actual results within forty-five (45) days after the end of each quarter, adjusted for reimbursement of the net expenses or income actually incurred or received by each Party. A report specifying how each payment was calculated shall also be submitted with each payment to the non-paying Party. Balancing payments by one Party to reimburse the other Party's Development Costs for purposes of the sharing of such costs under the Agreement shall be approved by the Development Committee. Within forty-five (45) days of the end of each calendar quarter, there shall be reconciliation of the Development Costs that are to be shared and that are actually incurred during that year by the Parties, with a payment by one Party to



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the other to the extent necessary so that each Party bears its appropriate percentage of such shared Development Costs. In the event any payment is made after the date specified herein, the paying Party shall increase the amount otherwise due and payable by adding interest thereon, computed at the rate of [\*\*] percent ([\*\*]%) over the prime rate of interest reported in *The Wall Street Journal* on the date so specified.

#### **A.7 Operating Profit and Loss Sharing**

The Parties agree to share the Operating Profit or Loss from the sale of Products in the Field in the following manner:

- (a) Enzon shall be allocated [\*\*] percent ([\*\*]%) of the Operating Profit or Loss from the sale of Products in the Field, in the Territory; and
- (b) SkyePharma shall be allocated [\*\*] percent ([\*\*]%) of the Operating Profit or Loss from the sale of Products in the Field, in the Territory.

#### **A.8 Limits on Sharing of Costs in Excess of Budget**

Notwithstanding the sharing of Operating Profit or Loss set forth in Section A.7, Marketing Costs, Sales Costs, Post-Registration Development Costs, expenses within Other Operating Income/Expense, Distribution Costs, and/or General and Administrative Costs actually incurred by either Party more than [\*\*] percent ([\*\*]%) in excess of the Annual Operating Plan and Budget applicable to such Party's expenditures shall not be shared by the Parties unless and to the extent such excess costs are expressly approved in writing by the other Party.

**JOINT DEVELOPMENT COMMITTEE MEMBERS**

**For Enzon:**

Mr. Charles Conover and Mr. Jack Lipman;

**For SkyePharma:**

Mr. Carsten Niederlander and Mr. Richard Jones.

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

EXECUTION COPY

**DEPOCYT®  
SUPPLY AND DISTRIBUTION AGREEMENT**

**BY AND BETWEEN**

**SKYEPHARMA, INC.**

**AND**

**ENZON PHARMACEUTICALS, INC.**

**DATED AS OF**

**DECEMBER 31, 2002**

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**DEPOCYT® SUPPLY AND DISTRIBUTION AGREEMENT**

**THIS DEPOCYT® SUPPLY AND DISTRIBUTION AGREEMENT** dated as of the 31<sup>st</sup> day of December, 2002, is entered into by and between **ENZON PHARMACEUTICALS, INC.**, a corporation organized and existing under the laws of Delaware, having offices located at 685 Route 202/206, Bridgewater, New Jersey 08807 (“*Enzon*”) and *SKYEPHARMA, INC.*, a corporation organized and existing under the laws of the State of California, having offices located at 1450 Science Center Drive, San Diego, California 92121 (“*Skye*”).

**PRELIMINARY STATEMENTS**

**WHEREAS**, Skye is in possession of proprietary know-how and technology and has the expertise and skill needed to manufacture and further develop the Product (as defined below); and

**WHEREAS**, Skye is party to certain agreements with Chiron Corporation (“*Chiron*”), pursuant to which Skye has granted Chiron the exclusive marketing, sale and distribution rights for the Product in the United States; and

**WHEREAS**, effective as of December 31, 2002, and subject to the terms of that certain Acquisition Agreement dated November 22, 2002, by and between Skye and Chiron (the “*Chiron Acquisition Agreement*”), Chiron shall transfer, convey, assign and deliver to Skye all its rights to the Product in the United States; and

**WHEREAS**, Enzon is interested in marketing the Product and purchasing its supply of Product from Skye, and Skye is willing to grant Enzon an exclusive license to market and sell the Product in the Territory (as defined below) and supply Enzon with its requirements of Product, all upon the terms and conditions recited hereinafter.

**NOW, THEREFORE**, in consideration of the foregoing preliminary statements and the mutual agreements and covenants set forth herein, the Parties (as defined below) hereby agree as follows:

**1. DEFINITIONS.**

As used in this Agreement the following terms shall have the meanings set forth in this Section 1 unless context dictates otherwise:

1.1 “*AAA*” shall have the meaning assigned to such term in Section 17.2.

1.2 “*Additional Indication*” shall have the meaning assigned to such term in Section 3.4.3.

1.3 “*Affiliate*” shall mean, with respect to a Party, any entity controlling, controlled by, or under common control with, such Party. For these purposes, “control” shall refer to (i) the possession, directly or indirectly, of the power to direct the management or policies of an entity, whether through the ownership of voting securities, by contract or otherwise, or (ii) the ownership, directly or indirectly, of at least fifty percent (50%) of the voting securities or other ownership interest of an entity.

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1.4 “*Agreement*” shall mean this supply and distribution agreement together with the preliminary statements and all exhibits, schedules and attachments hereto.

1.5 “*Breaching Party*” shall have the meaning assigned to such term in Section 11.2.

1.6 “*Calendar Quarter*” shall mean a period of three (3) consecutive months ending at midnight, eastern time on the last day of March, June, September, or December, respectively.

1.7 “*CFR*” shall mean the United States Code of Federal Regulations.

1.8 “*cGMP*” shall mean current Good Manufacturing Practice as defined in Parts 210 and 211 of Title 21 of the CFR, as may be amended from time to time, or any successor thereto.

1.9 “*Chiron*” shall have the meaning assigned to such term in the second preliminary statement.

1.10 “*Chiron Acquisition Agreement*” shall have the meaning assigned to such term in the third preliminary statement.

1.11 “*Commercially Reasonable Efforts*” shall mean, with respect to a Party, those commercially reasonable efforts by that Party similar to the efforts that Party in good faith believes it would make in similar circumstances for its own operations at that time, it being understood that a Party’s Commercially Reasonable Efforts will not in any event require that Party to take any action that would be reasonably likely to result in a breach of any other provision of this Agreement, or any other agreement between the Parties, or any other agreement between a Party, Affiliate of such Party and/or Third Parties existing as of the Effective Date, or that the Party in good faith believes may violate any applicable law, regulation, rule, order, permit, direction or license of any court or governmental authority having appropriate jurisdiction over the Party and subject matter or would be reasonably likely to be disruptive of any material service conducted or product made at or from any of its facilities or impair its ability to provide services or Product hereunder.

1.12 “*Confidential Information*” shall mean, with respect to either Party, all confidential or proprietary information and materials, patentable or otherwise, in any form (written, oral, photographic, electronic, magnetic, or otherwise) which is disclosed by or on behalf of such Party to the other Party pursuant to and in contemplation of this Agreement, including, without limitation, information relating to the Product or any other product of either Party and the pricing thereof; *provided* that such Confidential Information is identified as confidential either: (i) at the time of disclosure; or (ii) in writing, within thirty (30) days of disclosure.

1.13 “*Contract Year*” shall mean each calendar year period during the Term; *provided, however, that* the first such Contract Year shall commence on the Effective Date and end on December 31, 2003 and the last such Contract Year shall end on the final day of the Term. “*Contract Year One*” shall mean the first such year; “*Contract Year Two*” shall mean the second such year, and so on, year-by-year.

1.14 “*Disclosing Party*” shall have the meaning assigned to such term in Section 10.1.

1.15 “*Effective Date*” shall mean the date of this Agreement as set forth in the Preamble.

1.16 “*Enzon*” shall have the meaning assigned to such term in the preamble.

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- 1.17 “*Executive Officers*” shall have the meaning assigned to such term in Section 17.1.
- 1.18 “*Failure to Supply*” shall have the meaning assigned to such term in Section 5.8.
- 1.19 “*FDA*” shall mean the United States Food and Drug Administration, or any successor agency having regulatory jurisdiction over the manufacture, distribution and sale of drugs in the United States, and its territories and possessions.
- 1.20 “*FDC Act*” shall mean the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §321 et seq., as amended, and the regulations promulgated thereunder from time to time.
- 1.21 “*Generic Event*” shall mean when a generic pharmaceutical product that is therapeutically equivalent to the Product is sold in the Territory and Unit sales of the Product in the Territory in any subsequent [\*\*] ([\*\*]) sequential calendar quarters decrease by [\*\*] percent ([\*\*]%) or more as compared to the prior [\*\*] ([\*\*]) sequential calendar quarters of sales. As used in this definition, “therapeutically equivalent” means that, for purposes of the United States, an AB rating is assigned to the product’s entry in the list of drug products with effective approvals published in the then-current edition of FDA’s publication “Approved Drug Products with Therapeutic Equivalence Evaluations” and any current supplement to the publication (also known as the “Orange Book”) referred to in 21 CFR 314.3 and such product is covered by an Abbreviated New Drug Application (as defined in the FDC Act). For purposes of other countries in the Territory, as used in this definition, “therapeutically equivalent” means that a rating equivalent to the FDA’s AB rating is assigned to the product by that country’s Regulatory Authority.
- 1.22 “*Gross Margin*” shall mean, with respect to a Unit of Product, the Net Unit Selling Price of such Product less the minimum Supply Price with respect to such Product of [\*\*] U.S. Dollars (US\$[\*\*]) per Unit.
- 1.23 “*IND*” shall mean any filing made with an appropriate Regulatory Authority in the respective jurisdiction within the Territory for initiating clinical trials in such jurisdiction with respect to the use of the Product in an Additional Indication.
- 1.24 “*HPB*” shall mean the Health Protection Branch of Health Canada, or any successor agency having regulatory jurisdiction over the manufacture, distribution and sale of drugs in Canada.
- 1.25 “*Indemnitee*” shall have the meaning assigned to such term in Section 13.3.
- 1.26 “*Indemnitor*” shall have the meaning assigned to such term in Section 13.3.
- 1.27 “*Infringement*” shall have the meaning assigned to such term in Section 15.1.
- 1.28 “*Initial Term*” shall have the meaning assigned to such term in Section 11.1.
- 1.29 “*Laboratory*” shall have the meaning assigned to such term in Section 5.6.2.
- 1.30 “*Marketing Plan*” and “*Marketing Plans*” shall have the meaning assigned to such terms in Section 3.3.
- 1.31 “*Minimum Annual Net Sales*” shall have the meaning assigned to such term in Section 8.1.2.

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1.32 “*Neo-plastic Indication*” shall mean the use of the Product in the treatment of solid tumor neo-plastic meningitis.

1.33 “*Net Sales*” shall mean the aggregate of all Net Unit Selling Prices for Units sold in the Territory by Enzon, its Affiliates and sub-distributors, if any.

1.34 “*Net Unit Selling Price*” shall mean, with respect to each Unit of the Product, the gross invoiced sales price with respect thereto, less the total value of the following deductions to the extent included in the gross invoiced sales price for the Unit of Product or otherwise directly paid or incurred by Enzon, its Affiliates or sub-distributors, if any, with respect to the sale of such Unit of Product: (i) reasonable and customary discounts, credits, rebates, allowances, and adjustments; (ii) price reductions or rebates retroactively or otherwise imposed by government authorities; (iii) sales, excise, turnover, value-added, and similar taxes assessed on the sale of Product (but excluding income taxes); (iv) transportation and importation directly chargeable to the sale of Product; (v) credits or refunds actually allowed for returned Product; and (vi) reasonable and customary charge backs granted to drug wholesalers based upon sales to their customers, if any; *provided however*, that total aggregate deductions per Unit shall be not more than what is reasonable and customary in the industry and consistent with Enzon’s normal business practices.

1.35 “*Non-breaching Party*” shall have the meaning assigned to such term in Section 11.2.

1.36 “*Party*” shall mean Skye or Enzon and, when used in the plural, shall mean Skye and Enzon.

1.37 “*Phase IV Trial*” shall have the meaning assigned to such term in Section 3.4.2.

1.38 “*Product*” shall mean the formulation of cytarabine known as DTC 101 which is currently sold under the tradename DepoCyt as further described on *Exhibit 1.38*.

1.39 “*Product Specifications*” shall mean the specifications for the Product set forth on Exhibit 1.39 and such other packaging and labeling specifications as are approved by the applicable Regulatory Authorities.

1.40 “*QI*” shall have the meaning assigned to such term in Section 5.2.

1.41 “*Receiving Party*” shall have the meaning assigned to such term in Section 10.1.

1.42 “*Registration*” shall mean, with respect to each country in the Territory, written approval of a Registration Application for the Product filed in such country, including pricing or reimbursement, where applicable, by the Regulatory Authority in such country.

1.43 “*Registration Application*” shall mean a New Drug Application under the FDC Act and the regulations promulgated thereunder, or a comparable filing for Registration in a country, in each case with respect to the Product in the Territory.

1.44 “*Regulatory Authority*” shall mean the FDA in the U.S., the HPB in Canada, and any successor(s) thereto as well as any other state or local health regulatory authorities having jurisdiction for any activities contemplated by the Parties.

1.45 “*Renewal Term*” shall have the meaning assigned to such term in Section 11.1.

1.46 “*Skye*” shall have the meaning assigned to such term in the second preliminary statement.

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1.47 “*Skye Know-How*” shall mean all information and data, which is not generally known, including formulae, procedures, protocols, techniques and results of experimentation and testing, which are necessary or useful to make, use, develop, sell or seek regulatory approval in the Territory to market the Product, which Skye owns or controls and which is in the possession of Skye on the Effective Date or thereafter during the Term.

1.48 “*Skye Patents*” shall mean all patents (including, without limitation, all reissues, extensions, substitutions, re-registrations, re-examinations, re-validations, supplementary protection certificates and patents of addition) and patent applications (including, without limitation, all provisional applications, continuations, continuations-in-part and divisions) which are useful or necessary for the development, manufacture, use, marketing or sale of Product and which Skye owns, possesses or controls during the Term. A list of the Patents as of the Effective Date is attached as *Exhibit 1.48*.

1.49 “*Skye Technology*” shall mean the Skye Know-How and the Skye Patents.

1.50 “*Supply Price*” shall have the meaning assigned to such term in Section 8.1.1.

1.51 “*Term*” shall have the meaning assigned to such term in Section 11.1.

1.52 “*Territory*” shall mean the United States and Canada.

1.53 “*Testing Methods*” shall have the meaning assigned thereto in Section 5.6.

1.54 “*Third Party*” shall mean any person who or which is neither a Party nor an Affiliate of a Party.

1.55 “*Trademark(s)*” shall mean the DepoCyt trademark that Skye has registered in the United States and applied for registration in Canada in connection with the Product, or such other trademark that Skye registers for use with the Product.

1.56 “*Unit*” shall mean a vial of the Product as described in *Exhibit 1.38*.

1.57 “*United States*” or “*U.S.*” shall mean The United States of America, including its possessions and territories.

## 2. REPRESENTATIONS, WARRANTIES AND COVENANTS.

2.1 *Representations by Each Party*. Each Party hereby represents and warrants to the other Party, as of the Effective Date, that:

2.1.1 such Party (i) is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is incorporated; (ii) has the corporate power and authority and the legal right to own and operate its property and assets, to lease the property and assets it operates under lease, and to carry on its business as it is now being conducted; and (iii) is in compliance with all requirements of applicable law, except to the extent that any noncompliance would not have a material adverse effect on the properties, business, financial or other condition of such Party and would not materially adversely affect such Party’s ability to perform its obligations under this Agreement;

2.1.2 such Party (i) has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder; and (ii) has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. The Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms;

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2.1.3 such Party has obtained all necessary consents, approvals and authorizations of all governmental authorities and Third Parties required to be obtained by such Party in connection with this Agreement; and

2.1.4 the execution and delivery of this Agreement and the performance of such Party's obligations hereunder (i) do not, to the best of such Party's knowledge, conflict with or violate any requirement of applicable laws or regulations; and (ii) do not conflict with, or constitute a default under, any contractual obligation of such Party.

2.2 *Representations by Skye.* Skye hereby represents, warrants and covenants to Enzon that:

2.2.1 Skye is the owner of, or has exclusive rights to, all of the Skye Patents in existence on the Effective Date, and has the exclusive right to grant the rights granted under this Agreement. Without limiting the foregoing, Skye has made all payments necessary to effect the closing of the Chiron Acquisition Agreement on or before the Effective Date. No Skye Patent is, or during the Term of this Agreement will be, the subject of any lien or other encumbrance that interferes or could in the future interfere with Enzon's enjoyment of the rights granted to Enzon in this Agreement. To the knowledge of Skye, all of the issued Skye Patents as of the Effective Date are valid, in full force and effect and have been maintained to date, and are not the subject of any interference or opposition proceedings;

2.2.2 there is no pending or, to the knowledge of Skye, threatened claim, interference, opposition or demand of any Third Party challenging the ownership, validity or scope of any of the Skye Patents in existence as of the Effective Date;

2.2.3 Skye is the owner of a Registration for the Product in the lymphomatous meningitis indication in the U.S. and in Canada and, to the knowledge of Skye, each of such Registrations is in full force and effect and has been maintained to date;

2.2.4 Skye shall perform its obligations as set forth in this Agreement, in compliance with good laboratory and clinical practices and cGMP, in each case as applicable under the laws and regulations of the Territory;

2.2.5 Skye has not entered into any agreement with any Third Party that is in conflict with the rights granted to Enzon pursuant to this Agreement; and

2.2.6 as of the Effective Date, the amount of the Product in the distribution channel does not exceed a six (6) week inventory of such Product based on historical, customary sales levels for the Product in the normal course of business.

2.3 *Representations by Enzon.* Enzon hereby represents, warrants and covenants to Skye that:

2.3.1 Enzon shall use Commercially Reasonable Efforts to market and sell the Product throughout the Territory;

2.3.2 Enzon shall comply with all applicable laws, rules and regulations (including, without limitation, those applicable to the importation and exportation of Product) in connection with the performance of its obligations under this Agreement;

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2.3.3 Enzon is legally qualified to conduct the business contemplated herein in all jurisdictions where such qualification is necessary to perform its obligations under this Agreement, except to the extent that failure to so qualify would not have a material adverse effect on its business or on its performance of such obligations; and

2.3.4 Enzon shall make no warranty, guaranty or other assurance with regard to the Product other than as set forth in Section 9.

### 3. APPOINTMENT; RIGHTS AND OBLIGATIONS.

3.1 *Appointment.* Subject to the terms and conditions of this Agreement and Chiron's rights under the Chiron Acquisition Agreement to supply transitional services and use the Trademark in connection therewith, Skye hereby appoints Enzon as of the Effective Date to be its exclusive distributor for the sale of the Product in the Territory. Enzon hereby accepts such appointment and agrees to fulfill its obligations and responsibilities as set forth in this Agreement. In connection with the appointment of Enzon set forth herein, and subject to Chiron's rights under the Chiron Acquisition Agreement to supply transitional services and use the Trademark in connection therewith, Skye hereby grants to Enzon as of the Effective Date:

3.1.1 the exclusive right and license (including as to Skye) under the Skye Technology to use, market, sell, have sold and distribute the Product in the Territory during the Term; and

3.1.2 the exclusive right and license to use the Trademark(s) and Skye's trade name in each country of the Territory during the Term in connection with the marketing and sale of Product as contemplated in this Agreement.

3.2 *Right to Appoint Sub-distributors.* Enzon shall have the right to appoint sub-distributors of the Product in the Territory; *provided that* no such appointment shall be valid unless: (i) Enzon shall guarantee and be responsible for the making of all payments due, and the making of any reports under this Agreement, with respect to sales of Product by its sub-distributors and their compliance with all applicable terms of this Agreement; and (ii) each sub-distributor agrees in writing to maintain books and records and permit Skye to review such books and records pursuant to the relevant provisions, and to observe all other applicable terms, of this Agreement.

3.3 *Marketing Plan.* Within forty-five (45) days of the Effective Date, and on or before November 15<sup>th</sup> of each Contract Year during the Term, Enzon shall provide to Skye, for its review and approval (which approval shall not be unreasonably withheld), Enzon's marketing plan for the Product for the following Contract Year (each such plan a "*Marketing Plan*", and collectively, the "*Marketing Plans*"). Each Marketing Plan which shall include, without limitation, good faith purchase and distribution objectives, Net Sales targets and projections with respect to sales force staffing levels, marketing research, physician education, advertising and detailing.

#### 3.4 *Maintenance of Registration(s); Additional Development Efforts.*

3.4.1 Skye shall use Commercially Reasonable Efforts to maintain in full force and effect the Registrations for the Product, and to comply with all conditions attached to such Registrations.

3.4.2 The Parties acknowledge that Skye is currently conducting a phase IV clinical trial entitled Skye 0101-010 as set forth in *Exhibit 3.4* (the "*Phase IV Trial*"). Skye shall at its sole expense, use Commercially Reasonable Efforts to conduct the Phase IV Trial, as may be

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amended by Skye from time to time in consultation with the FDA and Enzon, as may be applicable, and prepare and file any and all Registration Applications and other regulatory filings in the Territory through and including Registration, and, thereafter shall use Commercially Reasonable Efforts to maintain any such Registrations.

3.4.2.1 For the avoidance of doubt, Skye shall not be required to (i) undertake any clinical trials not set forth in the clinical plan annexed hereto as Exhibit 3.4 unless required to do so by the FDA to maintain the Registration of the Product in the lymphomatous meningitis indication or any other indication(s) that may be approved; and/or (ii) prepare or file any Registration Applications or other regulatory filings with respect to the Neo-plastic Indication unless the clinical trials conducted by Skye pursuant to Section 3.4.2 produce statistically significant results sufficient to support such a filing.

3.4.2.2 To better allow Enzon to prepare to market the Product in the Neo-plastic Indication following receipt of Registration, Skye agrees to provide to Enzon copies of all protocols and other documentation related to the conduct of the clinical trials for Enzon's review and comment and, to the extent reasonable, permit Enzon, at its sole cost and expense, to participate in meetings with investigators and clinicians regarding such clinical trials.

3.4.3 The Parties also recognize that from time to time Skye may conduct research resulting in the discovery that the Product demonstrates utility outside the currently approved indication of lymphomatous meningitis and the Neo-plastic Indication (each such use, an " *Additional Indication*"). In each such case, Skye shall, as may be appropriate, in its sole discretion, conduct all clinical trials and prepare and file any and all INDs, Registration Applications and other regulatory filings for the use of the Product in any Additional Indication in the Territory through and including Registration, and, thereafter shall be responsible for maintaining such Registrations, as it may deem appropriate, in its sole discretion; *provided however*, that in the event the Parties determine that there is an Additional Indication that they wish to develop together, they shall negotiate in good faith the funding responsibilities of the respective Parties as well as appropriate changes to the financials regarding the supply and distribution of the Product for such Additional Indication(s), including but not limited to adjustments to the Supply Price, which shall be set forth in an amendment or addendum to this Agreement, as may be appropriate.

3.4.4 Skye shall appoint, and hereby does appoint, Enzon as its exclusive distributor under the Skye Technology to use, market, sell, have sold and distribute the Product in the Neo-plastic Indication and, subject to the provisions of Section 3.4.3, any Additional Indication(s) that may be developed by Skye during the Term for which Registration may be obtained.

#### 4. SALES AND MARKETING.

4.1 *Obligations of Enzon*. During the term of this Agreement, Enzon shall use Commercially Reasonable Efforts to promote, sell and distribute the Product to customers within the Territory as if Enzon were undertaking such efforts for a product of its own. Enzon shall be solely responsible for, and shall bear all costs associated with, all marketing activities related to the Product in the Territory including, but not limited to, the development of advertising campaigns, sales material, trade show support and educational campaigns; *provided, however*, that to the extent that it is permitted to do so, Skye shall provide to Enzon, free of charge, access to the marketing materials (including detail aids, promotional tools, graphics, slides and journal advertisements) used by Skye's distributors of the Product outside the Territory. Any and all costs associated with such access including, without limitation, copying and/or printing expenses or other costs of transferring such marketing materials to the Territory shall be the sole responsibility of Enzon. Furthermore, Enzon agrees that it shall:

4.1.1 use Commercially Reasonable Efforts to satisfy the demand for the Product throughout the Territory and attempt to increase the demand for such Product by, among other things, servicing substantially all customer accounts with reasonable frequency;



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4.1.2 maintain adequate sales and warehouse facilities and employ a sufficient number of experienced and qualified personnel to promote the sale of the Product and perform the activities approved and set forth in the Marketing Plan;

4.1.3 maintain a sufficient inventory of Product and support material to reasonably fulfill the requirements of its customers in the Territory;

4.1.4 maintain adequate records concerning the sale of the Product as required by any applicable Regulatory Authority in the Territory;

4.1.5 use only advertising literature approved by Skye; *provided that* Enzon shall submit such advertising literature to Skye at least fifteen (15) business days in advance of its intended use of same and such advertising literature shall be deemed to have received Skye's approval unless Skye provides Enzon with written notice of rejection within fifteen (15) business days following submission by Enzon;

4.1.6 immediately forward to Skye information concerning any and all charges, complaints or claims reportable to any Regulatory Authority relating to the Product that may come to Enzon's attention; and

4.1.7 obtain and maintain in full force and effect all necessary licenses, permits, records and authorizations required by law (excluding the Registrations for the Product) and fully observe and comply with all applicable laws, ordinances, rules and regulations including, but not limited to, those of the applicable Regulatory Authorities.

4.2 *Trademark; Logos.* Enzon shall market the Product throughout the Territory under the Trademark(s) and all marketing materials for the Product shall display the Trademark(s). In addition: (i) all marketing materials shall display the trade names and logos of Skye and Enzon, subject in all cases to the requirements of the applicable Regulatory Authorities; and (ii) all labeling and packaging shall state that the Product is manufactured by Skye and distributed by Enzon.

4.3 *Extra-territorial Sales.* The Parties acknowledge that some of Enzon's customers in the Territory may have facilities/operations located outside the Territory where Product may be shipped for use. The Parties also acknowledge that Skye already has appointed, and/or intends to appoint, Third Parties to distribute Product outside the Territory. Therefore, during the Term, Enzon agrees to undertake in good faith and use Commercially Reasonable Efforts not to market or sell Product to or for:

4.3.1 customers located entirely outside the Territory; or

4.3.2 customers who Enzon reasonably believes intend to use Product purchased from Enzon primarily outside the Territory.

## 5. SUPPLY.

5.1 *Generally.* Subject to the terms and conditions of this Agreement, Skye shall supply Enzon, and Enzon shall purchase from Skye, all of Enzon's requirements of Product for sale in the Territory. Skye shall maintain sufficient inventory of the Product to fulfill its supply obligations under this Section 5.

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5.2 *Forecasts.* Enzon's initial forecast of Units of Product estimated to be required on; a quarterly basis during the first twelve (12) months after the Effective Date shall be provided by Enzon to Skye within ten (10) days after the Effective Date, and shall serve as the first firm commitment for quantities of Product (for the current Calendar Quarter) and rolling written forecast required by this Section 5.2. Thereafter not later than ninety (90) days prior to the first day of each Calendar Quarter ("Q1"), Enzon shall place a firm commitment for quantities of the Product, in writing, for Q1 and simultaneously indicate its estimated requirements for each of the following three (3) Calendar Quarters,

5.3 *Orders.* All orders of Product shall be made on Enzon's form of purchase order; *however*, each purchase order or any acknowledgement thereof, whether printed, stamped, typed or written shall be governed by the terms of this Agreement and none of the provisions of such purchase orders or acknowledgements shall be applicable, except those specifying the quantity of Product ordered or general delivery date and shipping instructions and other general non-contractual invoice information.

5.3.1 Enzon shall submit orders for Product at least ninety (90) days in advance of its requested delivery date.

5.3.2 Said orders shall be consistent with Skye's current minimum batch sizes for the Product, or multiples thereof, currently estimated to be between [\*\*] ([\*\*]) and [\*\*] ([\*\*]) Units.

5.3.3 Notwithstanding the foregoing, Skye will be required to accept firm orders for Product placed in Q1 only for quantities equal to the lesser of: (i) the quantities of such Product reflected in the most recent forecast for Q1, (ii) +/-[\*\*]% of the quantities of such Product reflected for Q2 in the forecast provided immediately preceding the most recent forecast, and (iii) +/-[\*\*]% of the quantities of such Product reflected for Q3 in the forecast provided immediately preceding the forecast referred to in subclause (ii). Skye will use Commercially Reasonable Efforts to supply quantities of Product exceeding the amounts set forth in this Section 5.3.3; *provided however* the Parties agree that Skye does not have an obligation to do so pursuant to this Agreement.

5.4 *Packaging.* Enzon and Skye shall agree upon the secondary packaging of the Product for the Territory. Skye shall be responsible for the content of the prescribing information and Enzon shall be responsible for correctly labeling and packaging the Product supplied by Skye hereunder, which labeling and packaging shall in all cases be in compliance with all requirements of the applicable Regulatory Authorities.

5.5 *Shipment.* All Product shall be shipped FOB Skye's facility in San Diego, United States, via the carrier specified in Enzon's purchase order or, if not specified, by any commercially reasonable carrier, to the location specified by Enzon in its purchase order. Freight and insurance shall be for the account of Enzon, and all risk of loss, delay or damage in transit shall be with Enzon from and after delivery to the carrier. Each shipment of Product hereunder shall be accompanied by a certified quality control protocol and certificate of analysis for each lot of Product therein as set forth in Section 7.2.4, as well as such customs and other documentation as is necessary or appropriate. Enzon shall notify Skye of any partial loss, damage, defect or non-delivery of any shipment, or part thereof within five (5) business days after delivery of such shipment to Enzon or, if such loss, damage or non-delivery is not evident at the time of delivery, not later than thirty (30) days after delivery, or such longer period as may be agreed upon by the Parties.

5.6 *Acceptance/Rejection.* Within thirty (30) days from the date of receipt of each shipment of the Product, and prior to releasing such Product for sale to customers, Enzon shall

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conduct (i) a visual inspection of the Product for defects or damages; (ii) an inspection of all associated quality assurance documents, including, without limitation, the certificate of analysis; and (iii) random testing of Units of Product which shall be done in accordance with the test procedures established by Skye from time to time (the “*Testing Methods*”). Enzon shall have the right to return any Product to the extent Enzon determines that the Product fails to conform with the Product Specifications following such inspection. All or any part of any shipment may be held for Skye’s disposition and at Skye’s expense if found to be not in conformance with the Product Specifications.

5.6.1 All Product delivered to Enzon hereunder shall be deemed to materially conform with the Product Specifications unless Skye receives from Enzon written notice, not later than thirty (30) days after Enzon’s receipt of a given shipment, specifying the shipment, purchase order number and the exact nature of the failure of such shipment to conform, along with reasonable evidence of such non-conformity (including a sample of the Product from the shipment analyzed); *provided, however*, that Enzon’s failure to advise Skye in a timely manner that a shipment of the Product does not conform to the Product Specifications shall not prejudice Enzon’s right to reject or revoke acceptance of the Product if the defect or other non-conforming condition which justifies rejection or revocation could not have been detected by Enzon’s inspection undertaken pursuant to Section 5.6.

5.6.2 If at any time Enzon does not accept, or revokes its acceptance of, all or any part of a shipment of the Product, then the Parties shall have sixty (60) days from the date of Skye’s receipt of Enzon’s notification to resolve any dispute regarding whether all or any part of such shipment of the Product conforms with the Product Specifications. Disputes between the Parties as to whether all or any part of a shipment rejected by Enzon conforms with the Product Specifications not resolved in the sixty (60) day period shall be resolved by an independent cGMP testing laboratory or consultant acceptable to both Enzon and Skye (the “*Laboratory*”). The determination of the Laboratory with respect to all or part of any shipment of Product shall be final and binding upon the Parties. The fees and expenses of the Laboratory making such determination shall be paid by the Party against which the determination is made.

5.7 *Replacement Product*. If any Product is determined not to conform to the Product Specifications, upon Enzon’s request, Skye shall promptly deliver, or cause to be delivered, to Enzon conforming Product in the same quantity as the rejected Product.

5.8 *Failure to Supply*. In the event that for a period of not less than [\*\*] ([\*\*]) consecutive months Skye has shipped none of the quantities of Product ordered by Enzon during such [\*\*] ([\*\*]) month period (a “Failure to Supply”):

5.8.1 the Minimum Annual Net Sales requirements set forth in Section 8.1.2 shall be waived for the Contract Year(s) in which such Failure to Supply occurs and continues to occur; and

5.8.2 in the event that such a Failure to Supply occurs during Contract Year One or Contract Year Two, Skye shall pay to Enzon a one-time only payment of [\*\*] U.S. Dollars (US\$[\*\*]) within thirty (30) days of the expiration of the [\*\*] ([\*\*]) month period as liquidated damages for such Failure to Supply and in lieu of any and all other payments (including, but not limited to, damages or other relief in the event of a termination by Enzon for breach by Skye under Section 11.2) to Enzon. In the event that such a Failure to Supply occurs during Contract Year Three or thereafter, no payment shall be due Enzon under this Section 5.8.2, *provided however*, that at such time and in the event of termination of this Agreement by Enzon pursuant to Section 11.2, Enzon shall be entitled to seek damages for such Failure to Supply.

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## 6. REGULATORY MATTERS.

6.1 *Adverse Experience Reporting.* Skye and Enzon shall report to the other any information of which they have knowledge concerning any adverse drug experience in connection with the use of the Product, including the incidence or severity thereof, associated with non-clinical toxicity studies, clinical uses, studies, investigations or tests, whether or not determined to be attributable to the Product Reports of routine adverse drug experiences of the type defined in Section 214.80 of Title 21 of the CFR shall be exchanged by each Party on a Calendar Quarter basis. Reports of serious adverse drug experiences of the type defined in Sections 312.32 and 314.80 of Title 21 of the CFR shall be made available to the other Party within twenty-four (24) hours after a Party becomes aware of such serious adverse drug experience. Upon receipt of any such information concerning any serious adverse drug experience by either Skye or Enzon, the Parties shall promptly consult each other and use Commercially Reasonable Efforts to arrive at a mutually acceptable procedure for taking such possible actions as appropriate or required under the circumstances; *provided, however*, that nothing contained herein shall be construed as restricting the right or duty of either Party to make a required report or submission to the FDA, or take any other action that it deems to be appropriate or required by applicable law or regulation. Notwithstanding anything to the contrary contained in this Agreement, Skye shall be responsible for making all reports of adverse drug experience to the FDA and/or any other applicable Regulatory Authority.

### 6.2 *Recall Action.*

6.2.1 In the event Skye is required or voluntarily decides to initiate a recall, withdrawal, or field correction of the Product, Skye shall notify Enzon and provide a copy of its proposal, including the recall letter, for review prior to initiation of such action and the Parties shall fully consult and cooperate with each other concerning the need for such a recall and in order to develop and execute a recall plan, as necessary. In conjunction with such recall, Enzon shall assist, at Skye's sole discretion and expense, in the investigation to determine the cause and extent of the problem.

6.2.2 In the event that Enzon independently believes that a recall, withdrawal, or field correction of the Product may be necessary or appropriate, Enzon shall notify Skye of Enzon's belief, and the Parties shall fully cooperate with each other concerning the necessity and nature of such action.

6.2.3 All coordination of any recall or field correction activities involving Product shall be handled by Skye, in cooperation with Enzon, whether or not such action was initially requested by Enzon.

6.3 *Recall Expenses.* In the event that any Product is recalled as a direct result of the negligent or intentionally wrongful acts or omissions of Enzon or its representatives, then Enzon shall bear all of the costs and expenses of such recall, including expenses related to communications and meetings with all required regulatory agencies, expenses of replacement stock, the cost of notifying customers and costs associated with shipment of recalled Product from customers and shipment of an equal amount of replacement Product to those same customers. In the event that any Product is recalled as a direct result of the negligent or intentionally wrongful acts or omissions of Skye or its representatives or as result of Product misbranding or failure to meet Product Specifications, then Skye shall bear all of the costs and expenses of such recall, including expenses related to communications and meetings with all required regulatory agencies, expenses of replacement stock, the cost of notifying customers and costs associated with shipment of recalled Product from customers and shipment of an equal amount of replacement Product to those same customers. To the extent that the reason for any recall of Product hereunder is in part the responsibility of Skye and in part the responsibility of Enzon or is not due to the fault of either Party, then the expenses shall be allocated in an equitable manner between the Parties.

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6.4 *Debarment*. Each of Enzon and Skye represent that it is not debarred under the Generic Drug Enforcement Act of 1992 and that it does not employ or use the services of any person or entity who is debarred or has engaged in activity that could lead to debarment.

7. MANUFACTURE.

7.1 *Manufacturing Rights*. Except as otherwise provided herein, Skye shall have the exclusive right to manufacture or have manufactured the Product in the Territory.

7.2 *Manufacturing Obligations*.

7.2.1 The Product shall be manufactured in accordance with cGMPs promulgated by the FDA, the Product Specifications and in accordance with the regulatory specifications and methods described and approved in the Registration.

7.2.2 For quality control, Skye shall conduct in-process and final controls in accordance with the Testing Methods. Skye shall be responsible for the validation of all manufacturing processes and processing systems and shall maintain its programs for change control for the validated process, systems, and computer systems.

7.2.3 Skye shall store for each shipment of manufactured Product the respective documentation as well as retain a sample for one (1) year beyond expiration of the Product. Skye shall provide quality control examination of the retained sample representing the beginning, middle and end of the packaging operation prior to release to assure the Product's packaging is in accordance with the Product Specifications.

7.2.4 Skye shall provide a certificate of analysis to Enzon for each batch of the Product delivered hereunder.

7.2.5 Skye will provide final reports, including recommendation for the Product disposition for all investigations involving:

7.2.5.1 foreign matter/particulate contamination;

7.2.5.2 initial sterility test failure (if applicable); and

7.2.5.3 initial endotoxin test failure (if applicable).

7.2.6 Skye shall be responsible for the investigation of any Product complaints arising from the manufacturing process, packaging or labeling following notification from Enzon.

7.2.7 Skye will provide Enzon with annual product reviews which will include complaint and stability analysis. Such reviews shall be available at time of audits or upon reasonable request.

7.2.8 Skye will provide Enzon with Material Safety Data Sheets as required for the Product, and updates as necessary.

7.2.9 Skye shall be responsible for maintaining compliance with official compendia.

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7.3 *Inspections*. In performing its obligations hereunder, Skye shall:

7.3.1 At any time during the Term, but not more than once per Contract Year, permit Enzon's representatives to inspect, upon reasonable prior notice, which shall in no case be less than fifteen (15) days, and during normal business hours, Skye's facilities where the Product is manufactured or stored to review Skye's compliance with the Product Specifications, applicable environmental, health and safety regulations, cGMP and good laboratory practices, and to evaluate Skye's capability for responding effectively to any spills or releases of hazardous materials utilized or produced by Skye in the manufacture of the Product. In the event such representatives conclude that any non-conformity exists with respect to such Product Specifications or regulations: (i) the Parties, in addition to any other rights or remedies available to such Parties, shall use their respective diligent efforts to resolve the issue as promptly as possible, and (ii) Skye shall permit Enzon's representatives to re-inspect such facilities thereafter to determine whether such non-conformity has been rectified.

7.3.2 Report to Enzon as soon as possible any of the following incidents related to the manufacture of the Product:

7.3.2.1 fire;

7.3.2.2 explosion;

7.3.2.3 environmental event;

7.3.2.4 serious injury; and/or

7.3.2.5 physical damage.

7.3.3 Permit Enzon to review Skye's licenses and permits relating to the manufacture of the Product.

7.3.4 Notify Enzon of any inspection by the FDA, or similar government regulatory entity, of any facility where the Product is manufactured where such inspection could result in an adverse effect on the Product, and provide a copy of the results of that inspection and corrective actions taken or to be taken in response to their observations.

## 8. CONSIDERATION; PAYMENTS; REPORTS.

### 8.1 *Supply Price; Minimums*.

8.1.1 In consideration of the Product supplied, licenses granted and the services provided by Skye under this Agreement, Enzon shall pay to Skye the price (the "*Supply Price*") for Product ordered and shipped hereunder equal to the greater of: (i) (A) [\*\*] percent ([\*\*]%) of the Net Unit Selling Price on annual Net Sales up to and including [\*\*] U.S. Dollars (US\$[\*\*]); and (B) [\*\*] ([\*\*]%) of the Net Unit Selling Price on incremental annual Net Sales in excess of [\*\*] U.S. Dollars (US\$[\*\*]); or (ii) [\*\*] U.S. Dollars (US\$[\*\*]) per Unit. The Supply Price shall be paid as follows:

8.1.1.1 Skye shall submit invoices to Enzon for payment of [\*\*] U.S. Dollars (US\$[\*\*]) per Unit for quantities of Product ordered promptly after each shipment thereof. Payments shall be made by Enzon within forty-five (45) days of the invoice date; and

8.1.1.2 within sixty (60) days after the end of each Calendar Quarter during the Term, Enzon shall provide Skye with a quarterly reconciliation report, in the form attached hereto as *Exhibit 8.1.1*, that reflects (i) the calculation of the actual Net Unit Selling Price, (ii) aggregate Net Sales that accrued during such Calendar Quarter, (iii) the amount previously invoiced by, and paid to, Skye, and (iv) the reconciliation amount to be paid to Skye. Each such statement shall also set forth any amounts to be reimbursed to Enzon under Section 8.3 with respect to any discounts, chargebacks, returns or rebates relating to sales of Product that occurred prior to the Effective Date, and be accompanied by payment of the amount set forth in the reconciliation, calculated as set forth on *Exhibit 8.1.1* together with reasonable evidence of the discount, chargeback, return and/or rebate amounts being reimbursed. For purposes of this Agreement, the Net Unit Selling Price and Net Sales shall accrue when the Product is shipped by Enzon, its Affiliates or sub-distributors, if any.

8.1.2 Notwithstanding anything contained herein to the contrary, and subject to Section 5.8 and this Section 8.1.2, Enzon agrees that Enzon, together with its Affiliates and sub-distributors, if any, shall achieve minimum annual Net Sales of Product in the Territory (the "*Minimum Annual Net Sales*") which, in the aggregate, shall not be less than as follows:

8.1.2.1 by the end of Contract Year One, [\*\*] percent ([\*\*]%) of aggregate Net Sales for the Product during calendar year 2002. Skye shall provide a report to Enzon of Net Sales for the Product during calendar year 2002 by February 28, 2002;

8.1.2.2 unless otherwise provided in Section 8.1.2.3, for each Contract Year thereafter and throughout the Term, [\*\*] U.S. Dollars (US\$[\*\*]);

8.1.2.3 in the event that: (i) Enzon is acquired (whether through merger, sale of stock representing sixty percent (60%) or more of the outstanding voting stock of Enzon, or sale of all or substantially all of Enzon's assets or otherwise), or (ii) a sale of the division or portion of the business of Enzon which markets and distributes the Product is consummated; then for each Contract Year thereafter and throughout the Term, the Net Sales of Product in the Territory for the four (4) sequential calendar quarters immediately prior to the consummation of such event: and

8.1.2.4 notwithstanding the preceding, all such Minimum Annual Net Sales requirements shall cease commencing with the calendar quarter following the calendar quarter in which a Generic Event occurs, and the Minimum Annual Net Sales shall be pro rated for the Contract Year in which such Generic Event occurs.

In the event Enzon fails to achieve the Minimum Annual Net Sales requirements set forth in this Section 8.1.2 during any Contract Year, Enzon shall pay to Skye, within sixty (60) days of the end of such Contract Year, the difference between: (i) the aggregate Supply Price actually owed and/or paid by Enzon to Skye during such Contract Year; and (ii) the aggregate Supply Price that would have been paid to Skye for such Contract Year upon the achievement of the Minimum Annual Net Sales requirements set forth herein. In addition to the foregoing, commencing in Contract Year Two, in the event Enzon fails to achieve the Minimum Annual Net Sales requirements set forth in this Section 8.1.2 in any two consecutive Contract Years, Skye shall, in addition to any other rights or remedies available hereunder, be entitled to terminate this Agreement pursuant to Section 11.3.

8.1.3 In the event that a Generic Event occurs, the Parties shall discuss in good faith, for a period of thirty (30) days thereafter, whether, and to what extent, if any, changes should be made to the Supply Price to fairly allocate the economic burdens of such Generic Event between the Parties.

8.1.4 In the event that, as a result of changes in market conditions beyond the reasonable control of Enzon, the average Gross Margin for the Product during any two (2) consecutive Calendar Quarters falls below [\*\*] percent ([\*\*]%), the Parties shall meet and discuss appropriate changes, if any, to the minimum Supply Price; *provided however*, that in no case shall the Supply Price fall below Skye's fully burdened manufacturing cost plus [\*\*] percent ([\*\*]%). If after ninety (90) days of negotiations, the Parties are unable to agree on appropriate changes, if any, to the minimum Supply Price, the matter shall be resolved through arbitration in accordance with the provisions set forth in Section 17.2.

8.2 *Milestones.*

8.2.1 In further consideration of the Product supplied, licenses granted and the services provided by Skye under this Agreement, Enzon shall pay to Skye a non-refundable, non-creditable up-front payment of [\*\*] U.S. Dollars (US\$[\*\*]) upon the execution of this Agreement.

8.2.2 In further consideration of the Product supplied, licenses granted and the services provided by Skye under this Agreement, Enzon shall, within thirty (30) days of the first occurrence of each event set forth in the table below, pay to Skye the corresponding non-refundable milestone payment:

MILESTONE EVENT	MILESTONE PAYMENT
[**] of [**] in the [**] in any [**] ([**]) consecutive [**] equals [**] U.S. Dollars (US\$[**])	[**] U.S. Dollars (US\$[**])
[**] of [**] in the [**] in any [**] ([**]) consecutive [**] equals [**] U.S. Dollars (US\$[**])	[**] U.S. Dollars (US\$[**])
[**] in the [**] of the [**] for the [**] on or [**]	[**] U.S. Dollars (US\$[**])
[**] in the [**] of the [**] for the [**] after [**] but on or before [**]	[**] U.S. Dollars (US\$[**])
[**] in the [**] of the [**] for the [**] after [**]	[**] U.S. Dollars (US\$[**])

8.3 *Transitional Services.* In further consideration of the Product supplied, licenses granted and the services provided by Skye under this Agreement, Enzon shall reimburse Skye for payments to Chiron for those transitional services provided by Chiron pursuant to the Chiron Acquisition Agreement in connection with the wind-down by Chiron and transition of responsibility for such services to Enzon, solely to the extent that Enzon has requested and approved such transitional services as set forth on *Exhibit 8.3A*. The transition services to be provided by Chiron which Enzon may request and fees therefor are set forth on *Exhibit 8.3B*



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which is attached hereto and made a part hereof. Skye shall submit invoices to Enzon for the payment of such requested and approved transitional services promptly after receipt of same from Chiron. Payments shall be made by Enzon to Skye within thirty (30) days of the invoice date. In addition, if during the period commencing as of the Effective Date and ending on May 15, 2003, Enzon is charged any discounts, chargebacks, rebates or returns with respect to sales of the Product, Skye shall reimburse Enzon for such amounts as set forth in Section 8.1.1.2.

8.4 *Mode of Payment.* Enzon shall make all payments required under this Agreement as directed by Skye from time to time in U.S. Dollars. For the purposes of computing Net Sales of Product sold in a currency other than U.S. Dollars, such currency shall be converted into U.S. Dollars at an exchange rate equal to the buy rate of U.S. dollars published in the East Coast Edition of *The Wall Street Journal* for the last business day of the applicable Calendar Quarter. Such payments shall be without deduction of exchange, collection or other charges.

8.5 *Late Charges.* Amounts not paid when due as set forth in this Section 8 shall be subject to a late charge at a rate of interest equal to the base lending rate on corporate loans posted by at least [\*\*] percent ([\*\*]%) of the U.S.'s largest banks, as reported on the date such payment is due by the East Coast Edition of *The Wall Street Journal* as the prime rate, plus [\*\*] percent ([\*\*]%), with daily compounding of interest. Payment by Enzon of such late charges shall not foreclose any other rights or remedies which Skye may have hereunder with respect to such late payments.

8.6 *Records Retention.* Enzon shall keep true, accurate and complete records with respect to the calculation of the Net Unit Selling Price, Net Sales and Supply Price paid under this Agreement for a period of three (3) years after the year in which the sale of the Product generating the same occurred, and in sufficient detail to allow Skye to confirm the accuracy of all payments made hereunder.

8.7 *Audit Rights.* At the request of Skye, Enzon, its Affiliates and sub-distributors, if any, shall permit an independent certified public accountant appointed by Skye, at reasonable times and upon reasonable notice (but in no event more than once per calendar year), to examine those records and all other material documents relating to or relevant to the Net Unit Selling Price, Net Sales and Supply Price in the possession or control of Enzon, its Affiliates, and/or sub-distributors, if any, for a period of two (2) years after same have accrued, as may be necessary: (i) to determine the correctness of any report or payment made under this Agreement; or (ii) to obtain information as to same with respect to any Calendar Quarter in the event of Enzon's failure to report or pay pursuant to this Agreement. Said accountant shall not disclose to Skye any information other than information relating to said reports and payments. The results of any such examination shall be made available to both Parties. Skye shall bear the full cost of the performance of any such audit except as hereinafter set forth. If, as a result of any inspection of the books and records of Enzon, its Affiliates and/or sub-distributors, if any, it is shown that Enzon's payments under this Agreement were less than the amount which should have been paid, then Enzon shall make all payments required to be made to eliminate any discrepancy revealed by said inspection within forty-five (45) days after Skye's demand therefor. Furthermore, if the payments made by Enzon were less than [\*\*] percent ([\*\*]%) of the amount of payments that should have been paid with respect to the period in question, Enzon shall also reimburse Skye for the cost of such examination.

8.8 *Taxes.* In the event that Enzon is required to withhold any tax to the tax or revenue authorities in the Territory regarding any payment to Skye, such amount shall be deducted from the payment to be made by Enzon, and Enzon shall promptly notify Skye of such withholding and, within a reasonable amount of time after making such deduction, furnish Skye with copies of any tax certificate or other documentation evidencing such withholding. Each

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Party agrees to cooperate with the other Party in claiming exemptions from such deductions or withholding under any agreement or treaty from time to time in effect.

#### 9. PRODUCT WARRANTY.

9.1 *Guaranty and Warranty.* Skye guarantees and warrants to Enzon that the Product shipped to Enzon pursuant to this Agreement shall:

9.1.1 at the time of shipment, not be adulterated or misbranded within the meaning of the FDC Act, as such FDC Act is constituted and effective at the time of shipment, and shall not be an article which may not under the provisions of Section 404 and 505 of such FDC Act be introduced into interstate commerce; and

9.1.2 conform with the Product Specifications throughout its shelf life and shall be in compliance with applicable laws and regulations and all regulatory requirements of the applicable Regulatory Authorities in effect at the time of shipment.

9.2 *Disclaimer.* SKYE MAKES NO WARRANTIES, EXPRESS OR IMPLIED, OTHER THAN THOSE EXPRESSLY MADE HEREIN WITH RESPECT TO THE PRODUCT. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE HEREBY DISCLAIMED BY SKYE.

#### 10. CONFIDENTIALITY.

10.1 *Confidential Treatment.* Any Party receiving any Confidential Information (a “*Receiving Party*”) from the other Party (a “*Disclosing Party*”) in connection with the execution, delivery and performance of this Agreement agrees that all such Confidential Information: (i) shall not be used by the Receiving Party except in connection with the activities contemplated by this Agreement or in order to further the purposes of this Agreement; (ii) shall be maintained in confidence by the Receiving Party; and (iii) shall not be disclosed by the Receiving Party to any Third Party who is not a consultant of, or an advisor to, the Receiving Party or an Affiliate or sublicensee/sub-distributor, as applicable, of the Receiving Party, without the prior written consent of the Disclosing Party.

10.2 *Exceptions.* The obligations of confidentiality and non-use set forth in Section 10.1 shall not apply to any such Confidential Information which:

10.2.1 either before or after the date of the disclosure to the Receiving Party becomes published or otherwise part of the public domain through no fault or omission on the part of the Receiving Party or its Affiliates;

10.2.2 either before or after the date of the disclosure to the Receiving Party is lawfully disclosed to the Receiving Party or its Affiliates by sources other than the Disclosing Party rightfully in possession of the Confidential Information and without restriction as to confidentiality or use;

10.2.3 was known or used by the Receiving Party or its Affiliates prior to its date of disclosure to the Receiving Party as demonstrated by legally admissible evidence available to the Receiving Party or its Affiliates;

10.2.4 is independently developed by or for the Receiving Party or its Affiliates without reference to or in reliance upon the Disclosing Party’s Confidential Information as demonstrated by competent written records; or

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10.2.5 is required to disclose under applicable laws or regulations or an order by a court or other regulatory body having competent jurisdiction; *provided, however*, that except where impracticable, the Receiving Party shall give the Disclosing Party reasonable advance notice of such disclosure requirement (which shall include a copy of any applicable subpoena or order) and shall cooperate with the Disclosing Party to oppose, limit or secure confidential treatment for such required disclosure. In the event of any such required disclosure, the Receiving Party shall disclose only that portion of the Confidential Information of the Disclosing Party that the Receiving Party is legally required to disclose.

10.3 *Term of Obligation*. The obligations of the Parties under this Section 10 shall continue for a period of [\*\*] ([\*\*]) years after the date of disclosure with respect to any particular item of Confidential Information.

10.4 *Return of Materials*. Upon expiration or termination of this Agreement and the written request of the Disclosing Party, the Receiving Party shall return to the Disclosing Party all Confidential Information of the Disclosing Party that the Receiving Party possesses in tangible form and shall return to the Disclosing Party, or destroy, at the Disclosing Party's request, all Confidential Information of the Disclosing Party that the Receiving Party possesses in electronic form. Notwithstanding the foregoing, each Party may retain one copy of all Confidential Information provided by the other Party solely for archival and legal purposes.

## 11. TERM AND TERMINATION.

11.1 *Term*. This Agreement shall take effect on the Effective Date and shall remain in force for ten (10) years unless earlier terminated pursuant to one of the other provisions of this Section 11 (the "*Initial Term*"). Following expiration of the Initial Term, this Agreement shall be automatically renewed for successive two (2) year renewal periods (each, a "*Renewal Term*"); *provided, however*, that at any time following expiration of the Initial Term, Enzon shall have the right to terminate this Agreement upon ninety (90) days prior written notice (the Initial Term and all Renewal Terms, or parts thereof, collectively, the "*Term*").

11.2 *Termination for Cause*. Either Party (the "*Non-breaching Party*") may, without prejudice to any other remedies available to it at law or in equity (except for a termination by Enzon hereunder during Contract Year One or Contract Year Two in the Event of a Failure to Supply as more fully set forth in Section 5.8), terminate this Agreement, in whole or in part, in the event the other Party (the "*Breaching Party*") shall have materially breached or defaulted in the performance of any of its material obligations hereunder, and such default shall have continued for sixty (60) days after written notice thereof was provided to the Breaching Party by the Non-breaching Party (or, if such default cannot be cured within such sixty (60)-day period, if the Breaching Party does not commence and diligently continue actions to cure such default during such sixty (60)-day period). Any such termination shall become effective at the end of such sixty (60)-day period unless the Breaching Party has cured any such breach or default prior to the expiration of such sixty (60)-day period (or, if such default cannot be cured within such sixty (60)-day period, if the Breaching Party has commenced and diligently continued actions to cure such default).

11.3 *Termination by Skye*. Skye may terminate this Agreement without penalty upon thirty (30) days prior written notice in the event that Skye exercises its right to terminate this Agreement for Enzon's failure to achieve the Minimum Annual Net Sales in accordance with and as set forth in Section 8.1.2.

11.4 *Termination by Enzon*. In the event that a final decision is issued (including a decision to grant a permanent injunction) by a court or other governmental agency of competent jurisdiction which is unappealable or unappealed within the time allowed for such appeal, or a

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settlement is entered into by Skye pursuant to Section 13.2(ii), that prohibits the manufacture, use or sale of the Product in the U.S., Enzon shall have the right to terminate this Agreement upon written notice of such event.

11.5 *Termination in the Generic Event.* In the event that a Generic Event occurs and the thirty (30) day period set forth in Section 8.1.3 has expired without agreement between the Parties as to an equitable adjustment, if any, to the Supply Price, either Party shall have the right to terminate this Agreement without penalty upon one hundred eighty (180) days prior written notice to the other Party.

11.6 *Effect of Termination.* Upon termination, relinquishment or expiration of this Agreement the Parties hereto shall have no further obligations towards each other, except the fulfillment of obligations that have accrued before the date of termination or expiration. Such termination, relinquishment or expiration shall not relieve either Party from obligations which are expressly indicated to survive termination or expiration of this Agreement.

11.6.1 All of the Parties' rights and obligations under, and/or the provisions contained in, Sections 2, 3.2, 4.1.4, 4.1.6, 6.1, 6.3, 7.2.3, 8.1 (solely for payments due for sales before the expiration, termination or relinquishment of the Agreement or pursuant to Section 11.6.2), 8.4, 8.5, 8.6, 8.7, 8.8, 9, 10, 11.6, 13, 16, 17, 19, 20, 21 and 22 shall survive termination, relinquishment or expiration of this Agreement.

11.6.2 Following the termination of this Agreement, Enzon shall retain the right to distribute the quantity of the Product that was purchased by Enzon prior to such termination for a period not to exceed [\*\*] ([\*\*]) months, subject to the terms and conditions of this Agreement, including without limitation, Enzon's payment obligations under Section 8.

## 12. ASSIGNMENT.

This Agreement shall not be assignable by either Party without the prior written consent of the other Party, which consent shall not be unreasonable withheld, except that either Party may assign its rights and transfer its duties under this Agreement in whole or in part to any of its Affiliates or in the event of such Party's merger, consolidation or sale of all or substantially all of its assets or a sale of the division or portion of the business of such Party to which the Product relates, in which case such Affiliate or assignee shall thereafter be substituted directly for such Party hereunder. In connection with any such assignment, the assigning Party hereby unconditionally guarantees the performance of any of its Affiliates or assignees hereunder. In the event of a breach by an Affiliate or assignee in the observance of applicable terms of this Agreement, the non-assigning Party may proceed against the assigning Party and/or such Affiliate or assignee in order to enforce this Agreement. No assignment and transfer shall be valid or effective unless done in accordance with this Section 12 and unless and until the assignee, transferee or successor-in-interest shall agree in writing to be bound by the provisions of this Agreement, and upon such agreement, all references herein to the assignor, transferor or predecessor shall be deemed to refer and apply to the assignee, transferee or successor in interest.

## 13. INDEMNIFICATION.

13.1 *Indemnification by Enzon.* Enzon shall indemnify and hold Skye and its directors, officers, employees, representatives and agents harmless from and against any and all liabilities, claims, demands, actions, suits, losses, damages, costs and expenses (including reasonable attorney's fees and disbursements, but excluding any anticipated or actual lost profits or revenues or other special, indirect, incidental or consequential damages), based upon any Third Party claims of death, actual bodily injury or physical property damage: (i) to the extent resulting from Enzon's handling, storage, promotion, testing, use, marketing, distribution or sale of the Product;

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or (ii) otherwise resulting from Enzon's negligence, willful misconduct or material breach of this Agreement (including, without limitation, of the representations, and warranties hereunder); except to the extent covered by subclause (i) of Section 13.2.

13.2 *Indemnification by Skye*. Skye shall indemnify and hold Enzon and its directors, officers, employees, representatives and agents harmless from and against any and all liabilities, claims, demands, actions, suits, losses, damages, costs and expenses (including reasonable attorney's fees and disbursements, but excluding any anticipated or actual lost profits or revenues or other special, indirect, incidental or consequential damages): (i) based upon Third Party claims of death, actual bodily injury or physical property damage (A) to the extent resulting from Skye's manufacture, handling, storage, packaging and labeling of the Product, or (B) to the extent otherwise resulting from Skye's negligence, willful misconduct or material breach of this Agreement (including, without limitation, of the representations and warranties hereunder); or (ii) which Enzon may incur, suffer or be required to pay by reason of any patent infringement suit or claim of violation of any patents, trademarks, trade secrets or other intellectual property rights of any Third Party (including but not limited to Paul Capital Partners or any of its affiliates, successors or assigns) brought against Enzon and arising from the manufacture, use or sale of the Product or the use of the Trademark.

13.3 *Procedure*. In the event that any person entitled to indemnification under this Section 13 (an "*Indemnitee*") is seeking such indemnification, such Indemnitee shall inform the other Party (the "*Indemnitor*") of the claim as soon as reasonably practicable after such Indemnitee receives notice of such claim, shall permit the Indemnitor to assume direction and control of the defense of the claim (including the sole right to settle it at the sole discretion of the Indemnitor, provided that such settlement provides for the unconditional release of the Indemnitee and does not impose any obligation on the Indemnitee or the other Party) and shall cooperate as requested (at the expense of the Indemnitor) in the defense of the claim.

13.4 *Complete Indemnification*. As the Parties intend complete indemnification, all costs and expenses incurred by an Indemnitee in connection with enforcement of this Section 13 shall also be reimbursed by the Indemnitor.

#### 14. INSURANCE.

Each Party shall use Commercially Reasonable Efforts to maintain insurance (including general and product liability coverage) and upon such terms (including coverages, deductible limits and self-insured retentions) as is customary for the activities to be conducted by it under this Agreement and is appropriate to cover its indemnification obligations hereunder (provided that product liability coverage shall be with limits of not less than \$[\*\*]). Each Party shall furnish to the other Party evidence of such insurance, upon request.

#### 15. ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS.

15.1 *Notice to Skye*. If Enzon learns of an infringement, unauthorized use, misappropriation or ownership claim or threatened infringement or other such claim (any of the foregoing, an "*Infringement*") by a Third Party with respect to any Skye Technology or Trademark(s) within the Territory, Enzon shall promptly notify Skye and shall provide Skye with available evidence of such Infringement.

15.2 *Enforcement*. Skye shall have the first right, but not the duty, to institute Infringement actions against Third Parties based on any Skye Technology or Trademark(s) in the Territory. If Skye does not secure actual cessation of such Infringement or institute an Infringement proceeding against an offending Third Party within one-hundred twenty (120) days of learning of such Infringement, Enzon shall have the right, but not the duty, to institute such an action with respect to any Infringement by such Third Party. The costs and expenses of any such

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action (including fees of attorneys and other professionals) shall be borne by the Party instituting the action, or, if the Parties elect to cooperate in instituting and maintaining such action, such costs and expenses shall be borne by the Parties in such proportions as they may agree in writing. Each Party shall execute all necessary and proper documents, take such actions as shall be appropriate to allow the other Party to institute and prosecute such Infringement actions- and shall otherwise cooperate in the institution and prosecution of such actions (including, without limitation, consenting to being named as a nominal party thereto). Any award paid by Third Parties as a result of such an Infringement action (whether by way of settlement or otherwise) shall be applied first to reimburse both Parties for all costs and expenses incurred by the Parties with respect to such action on a pro rata basis and, if after such reimbursement any funds shall remain from such award they shall be allocated to Enzon to be included in Net Sales (and subject to payment to Skye of the Supply Price); *provided however* that to the extent that any damage award includes specific damage awards to the individual Parties, the remaining funds shall be allocated between the Parties in the same proportion as the total damage award was allocated to each Party.

15.3 *Infringement Action by Third Parties*. In the event of the institution or threatened institution of any suit by a Third Party against Enzon for infringement of any patent, trademark or other intellectual property right involving the marketing or sale of the Product in the Territory where such infringement claim is a result of the manufacture, use or sale of the Product, Enzon shall promptly notify Skye in writing of such suit. Skye agrees to indemnify and defend Enzon as more fully set forth in Section 13 hereof.

#### 16. LIMITATION ON LIABILITY.

NOTWITHSTANDING ANY OTHER PROVISION OF THE AGREEMENT, NO PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT OR CONSEQUENTIAL DAMAGES HEREUNDER, SUCH AS LOSS OF REVENUE OR ANTICIPATED PROFITS OR LOST BUSINESS, REGARDLESS OF WHETHER SUCH PARTY HAS NOTICE OR KNOWLEDGE THEREOF, AND NO PARTY SHALL BE LIABLE FOR ANY SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES HEREUNDER: EXCEPT WITH RESPECT TO ITS INDEMNIFICATION OBLIGATIONS UNDER SECTION 13.

#### 17. DISPUTE RESOLUTION.

17.1 *Referral to Executive Officers*. The Parties recognize that disputes, as to certain matters may from time to time arise during the Term which relate to a Party's rights and/or obligations hereunder. If the Parties cannot resolve any such dispute within thirty (30) calendar days after notice of a dispute from one Party to the other, either Party may, by notice to another, have such dispute referred to the Chief Executive Officer of SkyePharma, plc (having offices located at 105 Piccadilly, London W1J 7NJ, England), or such other person holding a similar position as designated by Skye from time to time, and the Chief Executive Officer of Enzon, or such other person holding a similar position as designated by Enzon from time to time (such officers collectively, the "*Executive Officers*"). The Executive Officers shall meet promptly to negotiate in good faith the matter referred and to determine a resolution. During such period of negotiations, any applicable time periods under this Agreement shall be tolled, if the Executive Officers are unable to determine a resolution in a timely manner, which shall in no case be more than thirty (30) days after the matter was referred to them, the matter shall be resolved through arbitration in accordance with the provisions set forth in Section 17.2, upon notice by either Party to the other specifically requesting such arbitration.

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17.2 *Arbitration*. Any dispute arising out of or relating to any provisions of this Agreement shall be finally settled by arbitration to be held in New York, New York, under the auspices and then current Commercial Arbitration Rules of the American Arbitration Association (the “AAA”). The arbitration shall be conducted by one arbitrator who is knowledgeable in the subject matter which is at issue in the dispute and who is selected by mutual agreement of the Parties or, failing such agreement, shall be selected according to the AAA rules. The Parties shall have such discovery rights as the arbitrator may allow, but in no event broader than that discovery permitted under the Federal Rules of Civil Procedure, in conducting the arbitration, the arbitrator(s) shall apply the New York Rules of Evidence and shall be able to decree any and all relief of an equitable nature, including but not limited to such relief as a temporary restraining order, a preliminary injunction, a permanent injunction, or replevin of property, as well as specific performance. The arbitrator(s) shall also be able to award direct damages but shall not award any other form of damages (e.g., consequential, punitive or exemplary damages). The reasonable fees and expenses of the arbitrator(s), along with the reasonable legal fees and expenses of the Parties (including all expert witness fees and expenses), the fees and expenses of a court reporter, and any expenses for a hearing room, shall be paid as follows: (i) if the arbitrator(s) rule in favor of one Party on all disputed issues in the arbitration, the losing Party shall pay one hundred percent (100%) of such fees and expenses; if the arbitrator(s) rule in favor of one Party on some issues and the other Party on other issues, the arbitrators shall issue with the rulings a written determination as to how such fees and expenses shall be allocated between the Parties. The decision of the arbitrators shall be final and may be entered, sued on or enforced by the Party in whose favor it runs in any court of competent jurisdiction at the option of such Party. Whether a claim, dispute or other matter in question would be barred by the applicable statute of limitations, which statute of limitations also shall apply to any claim or disputes subject to arbitration under this Section 17, shall be determined by binding arbitration pursuant to this Section 17.2.

17.3 *Injunctive Relief*. Notwithstanding the foregoing, nothing contained herein shall prohibit a Party from seeking injunctive relief from a court of competent jurisdiction in the event of a breach or prospective breach of this Agreement by the other Party which would cause irreparable harm to the Non-breaching Party.

#### 18. FORCE MAJEURE.

Any delay in the performance of any of the duties or obligations of either Party hereto (except the payment of money due hereunder) shall not be considered a breach of this Agreement, and the time required for performance shall be extended for a period equal to the period of such delay, if such delay has been caused by or is the result of acts of God; acts of public enemy; insurrections; riots; injunctions; embargoes; labor disputes, including strikes, lockouts, job actions, or boycotts; fires; explosions; earthquakes; floods; shortages of energy; governmental prohibition or restriction; or other unforeseeable causes beyond the reasonable control and without the fault or negligence of the Party so affected. The Party so affected shall give prompt notice to the other Party of such cause, and shall take whatever reasonable steps are necessary to relieve the effect of such cause as rapidly as reasonably possible.

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19. NOTICE.

Any notice or communication required or permitted to be given under or in connection with this Agreement shall be deemed to have been sufficiently given if in writing and personally delivered or sent by certified mail (return receipt requested), facsimile transmission (receipt verified), or overnight express courier service (signature required), prepaid, to the Party for which such notice is intended as follows:

- (i) If to Enzon, to: Enzon Pharmaceuticals, Inc.  
685 Route 202/206  
Bridgewater, New Jersey 08807  
Attention: Peter Cicala  
Facsimile: 908.541.8838  
Telephone: 908.541.8767  
  
With a copy to: Dorsey & Whitney LLP  
250 Park Avenue  
New York, New York 10177  
Attention: Kevin T. Collins, Esq.  
Facsimile: 212.953.7201  
Telephone; 212.415.9200
  
- (ii) If to Skye, to: SkyePharma, Inc.  
1450 Science Center Drive  
San Diego, California 92121  
Attention: Mr. Steve Thornton  
Facsimile: 858.623.0376  
Telephone: 858.625.2424  
  
With a copy to: Skye-Pharma PLC  
105 Piccadilly  
London W1J 7NJ  
England  
Attention: Chief Executive Officer  
Facsimile: 011.44.20.7491.0452  
Telephone: 011.44.20.7491.1777

or to such other address as the addressee shall have last furnished in writing to the addressor; such notice shall be effective upon receipt by the addressee. If delivered personally or by facsimile transmission, the date of delivery shall be deemed to be the date on which such notice or request was given. If sent by overnight express courier service, the date of delivery shall be deemed to be the next business day after such notice or request was deposited with such service. If sent by certified mail, the date of delivery shall be deemed to be the third (3<sup>rd</sup>) business day after such notice or request was deposited with the U.S. Postal Service.

20. BOOKS AND RECORDS.

Any books and records to be maintained under this Agreement by a Party or its Affiliates shall be maintained in accordance with U.S. generally accepted accounting principles, consistently applied.

21. GOVERNING LAW.

This Agreement shall be governed by the laws of the State of New York, in all respects of validity, construction and performance thereof, without regard to principles of conflicts of law.



---

22. MISCELLANEOUS.

22.1 *Relationship of Parties*. Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency, employer-employee or joint venture relationship between the Parties. No Party shall incur any debts or make any commitments for the other, except to the extent, if at all, specifically provided herein.

22.2 *Further Actions*. Each Party shall execute, acknowledge and deliver such further instruments, and do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

22.3 *Use of Name; Publicity*. Except as otherwise provided herein, (i) neither Party shall have any right, express or implied, to use in any manner the name or other designation of the other Party or any other trade name, trademark or logos (including the Trademark) of the other Party for any purpose in connection with the performance of this Agreement; and (ii) neither Party shall make any public announcement concerning this Agreement or the subject matter hereof without the prior written consent of the other Party; provided however, that nothing in this Section 22.3 shall prevent either Party from issuing statements that such Party determines to be necessary to comply with applicable law (including the disclosure requirements of the U.S. Securities and Exchange Commission, Nasdaq or any other stock exchange on which securities issued by such Party are traded).

22.4 *Waiver*. A waiver by either Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any subsequent breach hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be in limitation of any other remedy, right, undertaking, obligation or agreement of either Party.

22.5 *Severability*. When possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be prohibited by or invalid under applicable law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement.

22.6 *Amendment*. No amendment, modification or supplement of any provisions of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

22.7 *Entire Agreement*. This Agreement together with the schedules and exhibits hereto, sets forth the entire agreement and understanding between the Parties as to the subject matter hereof and merges all prior discussions and negotiations between them, and neither of the Parties shall be bound by any conditions, definitions, warranties, understandings or representations with respect to such subject matter other than as expressly provided herein or as duly set forth on or subsequent to the date hereof in writing and signed by a proper and duly authorized officer or representative of the Party to be bound thereby.

22.8 *Parties in Interest*. All of the terms and provisions of this Agreement shall be binding upon, inure to the benefit of and be enforceable by the Parties hereto and their respective permitted successors and assigns.

22.9 *Descriptive Headings*. The descriptive headings of this Agreement are for convenience only, and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement.

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22.10 *Counterparts*. This Agreement may be signed in counterparts, each and every one of which shall be deemed an original, notwithstanding variations in format or file designation which may result from the electronic transmission, storage and printing of copies of this Agreement from separate computers or printers. Facsimile signatures shall be treated as original signatures.

\* \* \*

---

**IN WITNESS WHEREOF**, the Parties hereto have caused this DepoCyt® Supply and Distribution Agreement to be executed by their duly authorized representative as of the Effective Date.

**ENZON PHARMACEUTICALS, INC.**

**SKYEPHARMA, INC.**

By: \_\_\_\_\_  
Name: Arthur J. Higgins  
Title: Chairman and Chief Executive Officer

By: \_\_\_\_\_  
Name: Michael R.D. Ashton  
Title: Chief Executive Officer of SkyePharma PLC

---

IN WITNESS WHEREOF, the Parties hereto have caused this DepoCyt® Supply and Distribution Agreement to be executed by their duly authorized representative as of the Effective Date.

**ENZON PHARMACEUTICALS, INC.**

By: /s/ Arthur J. Higgins  
Name: Arthur J. Higgins  
Title: Chairman and Chief Executive Officer

**SKYEPHARMA, INC.**

By: \_\_\_\_\_  
Name: Michael R.D. Ashton  
Title: Chief Executive Officer of SkyePharma PLC

---

IN WITNESS WHEREOF, the Parties hereto have caused this DepoCyt® Supply and Distribution Agreement to be executed by their duly authorized representative as of the Effective Date.

**ENZON PHARMACEUTICALS, INC.**

By: \_\_\_\_\_  
Name: Arthur J. Higgins  
Title: Chairman and Chief Executive Officer

**SKYEPHARMA, INC.**

By: /s/ Michael R.D. Ashton  
Name : Michael R.D. Ashton  
Title: Chief Executive Officer of SkyePharma PLC

---

**EXHIBIT 1.38**

THE PRODUCT

DepoCyt® in all dosage strengths and including all improvements and line extensions.

DepoCyt® is a sterile, white to off-white [\*\*]mL suspension of [\*\*]mg [\*\*] encapsulated into multivesicular lipid-based particles in a single-use glass vial.

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**EXHIBIT 1.39****PRODUCT SPECIFICATIONS**

<b>Test Parameter (and Method Type/Source)</b>	<b>Acceptance Limits</b>	
	<b>I. Shelf Life</b>	<b>II. Release</b>
Appearance (Visual)	[**]	[**]
Identity (HPLC)	[**]	[**]
Total Cytarabine (HPLC)	[**]	[**]
% Free Cytarabine (HPLC)	[**]	[**]
Content Uniformity, USP (HPLC)	[**]	[**]
pH	[**]	[**]
Particle Size (Light Scattering, USP)	[**]	[**]
Uracil Arabinoside (HPLC)	[**]	[**]
Cytosine (HPLC)	[**]	[**]
Cytidine (HPLC)	[**]	[**]
Uridine (HPLC)	[**]	[**]
Uracil (HPLC)	[**]	[**]
Total Cytarabine related impurities not including Uracil Arabinoside	[**]	[**]
Cholesterol (HPLC)	[**]	[**]

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Triolein (HPLC)	[**]	[**]
DPPG (HPLC)	[**]	[**]
DOPC (HPLC)	[**]	[**]
Lyso DOPC (HPLC)	[**]	[**]
Dextrose (HPLC)	[**]	[**]
L-Lysine (Capillary Electrophoresis)	[**]	[**]
Chloroform (GC)	[**]	[**]
Osmolality (Vapor Pressure)	[**]	[**]
Fill Volume	[**]	[**]
Particulates (Light Obscuration, USP)	[**]	[**]
In-Vitro Release Assay (HPLC)		
Day 1	[**]	[**]
	[**]	[**]
Day 2	[**]	[**]
	[**]	[**]
Day 3	[**]	[**]
	[**]	[**]
Day 4	[**]	[**]
	[**]	[**]
Bacterial Endotoxins (USP)	[**]	[**]
Sterility (USP)	[**]	[**]

**NOTE:** The above table presents product specifications as approved in the product registrations for the two territories



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**EXHIBIT 1.48**

PATENTS

US Patent number [\*\*]

US Patent number [\*\*]

US Patent number [\*\*]

CA Patent number [\*\*]

CA Patent number [\*\*] (pending)

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**EXHIBIT 3.4**

CLINICAL PLAN

(See attached)

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**DepoCyt Study SKY0101-010***23+ Study Sites in US & Canada*

<u>Investigator First Name</u>	<u>Investigator Last Name</u>	<u>Investigator's Institution</u>	<u>Location</u>
William	Shapiro	Barrow Neurological Institute	Phoenix
Pamela	New	University of Texas Health Science Center	San Antonio
Pamela	Khosla	Rush Cancer Institute	Chicago
Surasak	Phuphanich	H. Lee Moffitt Cancer Center and Research Inst.	Tampa
Glenn	Lesser	Comprehensive Cancer Center of Wake Forest Univ.	Winston-Salem
Erie	Wong	Beth Israel Deaconess Medical Center	Boston
Said	Baidas	Georgetown University Medical Center	Washington
Denise	Damek	University of Colorado	Aurora
Paul	Moots	Vanderbilt University Medical Center	Nashville
Rena	Buckstein	Toronto Sunnybrook Regional Cancer Centre	Toronto
Kurt	Jaeckle	Mayo Clinic	Jacksonville
Stephen	Sagar	Case Western Reserve University	Cleveland
Deborah	Blumenthal	Huntsman Cancer Institute	Salt Lake City
Marc	Chamberlain	USC	Los Angeles
Subramanian	Hariharan	JFK Neuroscience Institute	Edison
Lynne	Taylor	Virginia Mason Medical Center	Seattle
Martin	Lee	Park Nicollet Health Services	Minneapolis
David	Eisenstat	CancerCare Manitoba	Winnipeg
Lynn	Ashby	Straub Clinic and Hospital	Honolulu
Jeffrey	Olson	Windship Cancer Institute	Atlanta
David	Irwin	Alta Bates Comprehensive Cancer Center	Berkeley
Thomas	Coyle	SUNY Upstate Medical University	Syracuse

*24 Study Sites – EUSwitzerland – 1 site*

German – 6 sites total  
Ireland – 3 sites  
United Kingdom – 5 sites  
Belgium – 1 site  
France – 5 sites  
The Netherlands – 2 sites

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*FDA Agreements*

*Post-Marketing Study (Sky0101-010)*

- Objectives of Post-Marketing Study
  - Fulfill FDA post-marketing requirement (all patients)
    - NDA expedited review of surrogate endpoint pivotal LM study based on CSF clearance of malignant cells
    - Patient population: lymphomatous meningitis and solid tumor
    - Primary endpoint neurological progression free survival
  - Expand label (STNM Subgroup of patients)
    - Current NDA indication lymphomatous meningitis
    - Add solid tumor neoplastic meningitis
  - Expand study to include European study sites
    - Improve enrollment
    - Pooling of US and European data acceptable
    - Differences in patient management acknowledged by FDA
  - One significant pivotal study sufficient for STNM approval
  - $P < .0366$  for each of two independent primary efficacy analysis
  - Enroll patients until 72 events occur in STNM subgroup
    - Event driven analysis
    - Interim sample size adjustment not necessary
    - 67% of patient enrolled are STNM
    - >90% of patients will have an event prior to 2-yr. follow-up
    - Approximately 110 additional patients will be enrolled
    - Enrollment complete 2H'04

- 
- *As of 18 December 2002*
    - 42 Patients Randomized
      - 12 lymphoma patients
      - 30 solid tumor patients
  - *Regulatory Filings*
    - *US*
      - Pre-supplemental NDA meeting 1Q2005
      - NDA 2Q2005
    - *Europe*
      - Pre-MAA Meeting 1Q2005
      - Scientific Advice 1Q2005
      - MAA (EU) 2Q2005

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**EXHIBIT 8.1.1****QUARTERLY PAYMENT RECONCILIATION****Supply Price Calculation**

Gross invoiced sales price per Unit	\$
Less Trade Discounts/Rebates, Etc.	(\$ )
Net Unit Selling Price	\$
* where X equals the total number of Units sold by Enzon, its Affiliates and sun-distributors, if any.	<u>    </u> x X*
Net Sales	\$
* where Y equals either 35 or 30 depending on cumulative annual Net Sales to date.	<u>    </u> x Y*%
Supply Price A	
Minimum per Unit Supply Price	\$ [**]
* where X equals the total number of Units sold by Enzon, its Affiliates and sun-distributors, if any.	<u>    </u> x X*
Supply Price B	
<b>Total Supply Price (the greater of A or B)</b>	<b>[**]</b>

**Payment Reconciliation**

Supply Price	\$
Less Amounts Previously Paid to Skye	(\$ )
Net Supply Price	(\$ )
Less Reimbursement due Enzon under Section 8.3	(\$ )
<b>Amount Payable to Skye:</b>	<b>[**]</b>

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**EXHIBIT 8.3A**

TRANSITIONAL SERVICES  
REQUESTED AND APPROVED BY ENZON

The following transitional services as described on Exhibit 8.3B are hereby requested and approved by Enzon for the period commencing as of the Effective Date and terminating on the date set forth next to such services:

Marketing – March 31, 2003;

Manufacturing – June 30, 2003;

Distribution – March 31, 2003;

Professional Services – February 28, 2003;

Reimbursement Services – February 28, 2003; and

Medical Affairs – February 28, 2003.

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**EXHIBIT 8.3B**

## TRANSITIONAL SERVICES

<u>Transition Service</u>	<u>Description</u>	<u>Monthly Cost +[**]%</u>	<u>Termination Date</u>
Marketing	Consulting services as mutually agreed by the parties	\$[**] per day plus out-of-pocket expenses	03/31/03
Manufacturing	Labeling of finished Product	\$[**] per lot	06/30/03
Sales	Product details by field sales force ([**]% of available time); Field Operations ([**]% of available time); Field Management [**]% of available time	\$[**]	03/31/03
Distribution	Product warehousing; order taking; order fulfillment; invoicing; collections; returns processing	\$[**] plus out-of- pocket costs of shipping	06/30/03
Professional Services	Maintain toll-free number for receiving and responding to inquiries from health care professionals regarding the Product	\$[**]	03/31/03
Reimbursement Services	Reimbursement services provided by Quintiles	\$[**] (at cost)	03/31/03
Medical Affairs		\$[**]	03/31/03



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INTERCOMPANY QUALITY AGREEMENT

DepoCyt®

Revision: Original

Enzon Pharmaceuticals Inc.  
685 Route 202/206  
Bridgewater, NJ 08807

(hereinafter called "Enzon")

Approved by: /s/ Ralph delCampo

Date: 11/3/03

Ralph delCampo  
Senior Vice President Operations

AND

SkyePharma, Inc.  
10450 Science Center Drive  
San Diego, California 92121

(hereinafter called "SkyePharma")

Approved by:

Approved by: /s/ Steve Thornton

Date: 11/6/03

Steve Thornton  
President, SkyePharma Inc.

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## I. QUALITY AGREEMENT

### A. Purpose

This INTERCOMPANY QUALITY AGREEMENT (this “Quality Agreement”) defines the roles and responsibilities of SkyePharma and Enzon with respect to the quality assurance of the PRODUCTS referenced in the DepoCyt® Supply and Distribution Agreement entered into by and between SkyePharma and Enzon dated as of December 31, 2002 (the “SUPPLY AGREEMENT”).

This Quality Agreement also defines how SkyePharma’s Quality Operations and Enzon’s Quality Department will interact with each other.

### B. Relationship to the SUPPLY AGREEMENT

This Quality Agreement shall be attached to and made a part of the SUPPLY AGREEMENT.

In the event of a conflict between any of the provisions of this Quality Agreement and the SUPPLY AGREEMENT, the provisions of this Quality Agreement shall govern.

All capitalized terms, unless otherwise set forth below, shall have the meaning set forth in the SUPPLY AGREEMENT.

## II. PRODUCTS

The PRODUCTS prepared for Enzon by SkyePharma are defined in the SUPPLY AGREEMENT including

DepoCyt®, (cytarabine liposome injection, SKY0101) Formulation 1.5 (US)

## III. ADMINISTRATIVE INFORMATION

Enzon contact names: See Appendix II

SkyePharma contact names: See Appendix II

Emergency contact names and numbers

	<u>Enzon Pharmaceuticals, Inc.</u>	<u>SkyePharma</u>
Name	K. Alice Preville	Patrick McCormick, Ph.D.
Title	Associate Director Quality Assurance	Senior Director Global Quality Assurance
Work	908 412-2331	858 625-2424, Extn. 3224
FAX	908 668-5997	858 625-2439
e-mail	alice.preville@enzon.com	patrick_mccormick@skyepharma.com

## IV. DURATION OF QUALITY AGREEMENT

The Quality Agreement will expire one (1) year after the expiration date of PRODUCTS associated with the SUPPLY AGREEMENT. The Quality Agreement will be reviewed annually to ensure that the roles and responsibilities reflect current practice. This Quality Agreement can be modified as needed with the written approval of both parties.

---

## V. MANUFACTURING cGMP COMPLIANCE

### A. General

The manufacturing operations for the PRODUCTS to be performed by SkyePharma are defined in the SUPPLY AGREEMENT, and responsibilities are illustrated in Appendix I of this document.

### B. Premises

The premises and equipment used to manufacture the PRODUCTS will be maintained according to current local state and federal regulatory requirements.

The manufacture of the PRODUCTS will be conducted by SkyePharma in a suitably controlled environment, and such facilities will be regularly monitored for parameters critical to the process to demonstrate compliance with applicable cGMP guidelines and any conditions registered, in the manufacturing authorization (NDA or ANDA or investigational application).

SkyePharma will maintain controlled access to the premises. All visitors must sign in and be escorted during any visit to the area of the premises used to manufacture, test or store the PRODUCTS.

### C. Personnel

Each PARTY shall be responsible for providing documented training to each employee engaged in the manufacture and testing of PRODUCTS sufficient to ensure that the assigned function is performed correctly. Additionally each PARTY shall maintain documented evidence demonstrating that all employees associated with PRODUCTS have received annual training on the principles of cGMP. This documentation will be available during facility audits.

Both Parties hereby certify that neither they, or any employees, agents, officers, directors or consultants is debarred, or is under threat of debarment under the US Generic Drug Enforcement Act of 1992, or any other applicable statute, code or regulation.

Use of subcontractors directly engaged in the manufacturing and testing of PRODUCTS not specified in this, or the SUPPLY AGREEMENT must be disclosed prior to use.

### D. cGMP Guidelines

cGMP guidelines shall include the principles detailed in the US Current Good Manufacturing Practices (21 CFR 210 and 211) that cover the standards of manufacture for any product intended for human use, as well as the Product Specifications and any applicable product license, the NDA application, pharmacopoeia or formulary requirements.

### E. Materials

#### 1. Materials Procured by SkyePharma

SkyePharma will use only raw materials and components that have been tested in accordance with the NDA and applicable cGMP.

---

Prior to commercial use, all materials used in the PRODUCTS must meet SkyePharma's requirements for production use.

SkyePharma is responsible for auditing and qualifying vendors of actives and raw materials used in PRODUCTS and will provide Enzon with a Certificate of Conformance statement for such vendors when requested. SkyePharma will audit raw material vendors / suppliers at regular intervals according to a defined program. The identity of the vendors / suppliers audited and date of audit will be available for review by Enzon upon request.

SkyePharma is responsible for ensuring that all materials procured by SkyePharma for use in the PRODUCTS are in compliance with the specifications listed in the product registration. Raw Materials are given a reassay date upon the satisfactory completion of all initial, testing. Reassay testing will be performed at defined time intervals to ensure the chemical and physical stability of the raw materials. Reassay dates assigned by SkyePharma are not to exceed vendor assigned expiration or retest dates.

SkyePharma is responsible for ensuring that all materials are stored properly, used correctly, appropriately tested upon receipt and traceable to the relevant Certificate of Analysis for the materials.

2. Materials Procured by Enzon

Enzon is responsible for auditing and qualifying vendors / suppliers of labels and labeling used with PRODUCTS and will provide SkyePharma with a Certificate of Conformance statement for such vendors when requested. Enzon will audit vendors / suppliers at regular intervals according to a defined program. The identity of the vendors / suppliers audited and date of audit will be available for review by SkyePharma upon request.

Enzon is responsible for assuring that labels and packaging are received, identified, stored, handled, sampled examined and/or tested prior to use, to assure that labels and packaging are issued and controlled during use to prevent mix-up and to examine representative samples of labeled and packaged PRODUCTS to assure label correctness.

F. Standard Operating Procedures

SkyePharma is responsible for maintaining any SOPs required to manufacture, test and store the PRODUCTS at SkyePharma and to support applicable cGMPs.

G. Methods Validation Certification

SkyePharma is responsible for providing to Enzon a Certification of Methods Validation Compliance for all critical methods practiced by SkyePharma (raw materials testing, in-process product testing, product batch release, drug and product stability and cleaning validation). The certifications should state, "The methods are appropriate for the intended purpose, are validated per relevant regulatory guidelines and are readily available in case of a regulatory inspection."

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H. Batch Numbers

Enzon is responsible to code labels and packaging with an Enzon lot number and an expiration date provided, by SkyePharma. The batch number applied to the crimp cap will be in the SkyePharma format.

SkyePharma Batch Number – A six digit number of the form WW-XYZZ. “WW” represents the last two digits of the current year. “X” represents a one-digit code which is specific for the product by active ingredient, “Y” represents a one-digit code to differentiate the type of lot, e.g., commercial, process development clinical, etc. “ZZ” represents a sequential number from 1 to 99. The batch number will be applied to the crimp cap of the vial product immediately after filling.

Enzon Lot Number – A six digit alpha numeric code in the form A B CC DD where “A” represents the product, “B” represents the scheduled month of manufacture. “CC” represents the last two digits of the year of manufacture and “DD” represents a sequential number from 1 to 99. The Enzon lot number will be applied to the product labeling.

I. Dates of Manufacture and Expiration

The date of manufacture of a PRODUCT will be defined by SkyePharma as the date that active drug and excipients are first placed together into a mixing vessel. Expiration dates are computed from the date of manufacture, and are listed in month/year format.

SkyePharma will calculate the expiry date from the date of manufacture using the currently approved expiry period. The expiration date will be the last day of the month computed above. Changes to the expiration period will be handled by Change Management (see Section X) and SkyePharma will provide any necessary notification to FDA.

J. Manufacturing and Equipment Data

SkyePharma is responsible for keeping records of equipment usage (previous PRODUCT produced in non-dedicated equipment), cleaning and any maintenance and/or calibration performed.

K. Storage and Shipment

When the PRODUCTS are in the possession, custody or control of a Party, such Party will (i) store the PRODUCTS under cGMP conditions with appropriate temperature control, and (ii) ensure that appropriate controls are in place to prevent interference, theft, product contamination and mixture with any other products or materials.

SkyePharma will suitably pack the unlabeled PRODUCTS in validated shippers for transit. At least one (1) temperature monitor will be included in each shipping container. Shipments will be arranged for next day delivery. Shipments will not be made on Thursday or Friday unless prior written approval from Enzon is received.

Only interim approved, unlabeled PRODUCTS will be shipped by SkyePharma to Enzon in accordance with Appendix III attached hereto, except as otherwise provided.

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SkyePharma will not skip any PRODUCT that is unapproved or under quarantine, unless mutually agreed by the parties.

When the PRODUCTS are in the possession, custody or control of a Party, such Party will maintain proper segregation of the PRODUCTS. Each Party shall be permitted to review the other Party's segregation systems. Different lots of a single PRODUCT or different types of products will not be mixed on a pallet.

## **VI. PRODUCT TESTING**

### **A. General**

The testing activities for the PRODUCTS are to be performed by SkyePharma as set forth in the NDA and defined in the SUPPLY AGREEMENT. Following SkyePharma's release of the PRODUCTS to Enzon, the Enzon Quality Unit will be responsible for authorization for distribution based upon the full release documentation package provided by SkyePharma.

The DepoCyt final PRODUCT specification is attached as Appendix IV.

### **B. In-Process and Finished Product Testing**

All testing must be done in accordance with the NDA and under cGMP guidelines.

At the completion of each packaging operation (including partial subplot packaging) Enzon will provide SkyePharma with one packaged unit of PRODUCTS for the purposes of identity testing of the contents to assure correct labeling. SkyePharma will provide the results of the identity test for inclusion in the Enzon labeling and packing records.

### **C. Retain Samples**

For each lot of PRODUCT manufactured by SkyePharma. SkyePharma will retain samples of the active ingredients and excipients used in the manufacture of the PRODUCTS for a period of no less than three years following the labeled expiration or last retest date determined, by SkyePharma for that component. The amount of sample retained will be at least twice the amount necessary to carry out all of the tests required to determine if the material meets its specifications, with the exception of sterility and endotoxin testing.

For each lot of PRODUCTS manufactured by SkyePharma, Enzon will provide SkyePharma with packaged material. SkyePharma will retain these samples for at least one year beyond the expiry period. The amount of sample retained will be twice the quantity required to carry out all of the tests required to determine if the material meets its specifications, with the exception of sterility and endotoxin testing. SkyePharma will use these samples for annual visual inspection.

For each lot of PRODUCTS manufactured by SkyePharma. Enzon will retain a sample of the commercial package under the proper storage conditions. SkyePharma will notify Enzon prior to the destruction of any PRODUCTS designated as Clinical Trial Material involved in clinical trials in which Enzon was engaged.



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D. Routine Stability Program

SkyePharma is responsible for maintaining a routine stability testing program for the PRODUCTS and will provide a formal stability report to Enzon annually and a data summary semi-annually. The stability program will be in compliance with the NDA commitments. At a minimum, one lot of each product, of each strength and in each package type (largest and smallest) will be placed on stability each year. The stability program will follow ICH guidelines with the exception of humidity control and monitoring for products packaged in glass. SkyePharma will inform Enzon at the time of occurrence, of any material changes to the stability protocol for any PRODUCT.

Any confirmed problems that arise as a result of the stability program will be promptly communicated by SkyePharma to Enzon.

E. Out-of-Specification (OOS) Investigations

SkyePharma is responsible for investigating any testing performed by SkyePharma that fails to meet specifications. Each investigation will be reviewed by SkyePharma's designated Quality person and will follow internal procedures that are in accordance with regulatory guidelines.

**VII. QUALITY ASSURANCE**

A. Investigations

Any deviation from the process or OOS result will be carefully documented and approved by SkyePharma Quality Assurance and appropriate area management, in accordance with controlling SkyePharma SOPs. In addition to the tracking number, a brief description of each investigation, deviation from the process or OOS associated with, the batch will be provided to Enzon with the batch release documentation.

SkyePharma will notify Enzon if any problems are discovered that may impact PRODUCT batch(es) previously shipped to Enzon.

SkyePharma will perform any additional testing, stability and validation that is necessary as a result of any such investigation. SkyePharma will keep Enzon informed of the conduct and progress of such work if shipping schedules will be impacted.

B. Batch Disposition

1. Interim Release by SkyePharma

To facilitate labeling and packaging by Enzon, SkyePharma will provide an interim release of unlabeled vials for shipment to Enzon after the tests specified for Interim Release in Appendix III have been completed and results meet the criteria stated in the NDA and the SUPPLY AGREEMENT.

2. Batch Disposition by SkyePharma

For each batch, SkyePharma will provide release documentation as defined in Appendix III, including a standard Certificate of Analysis indicating the test results and specification of each test performed, as well as a signed Certificate of Compliance confirming that the PRODUCTS have been manufactured, tested and stored according to the requirements of the Master Production Record and cGMPs.

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C. Authorization for Distribution by Enzon

Authorization for distribution of PRODUCTS, released by SkyePharma, is the responsibility of Enzon's Quality Assurance department. Enzon's authorization will be based on Enzon's internal procedures, and the full release documentation package provided by SkyePharma.

Upon review of SkyePharma documents and the Enzon labeling and packaging records, the Enzon Quality Assurance department will issue authorization for distribution.

Any problem discovered by Enzon likely to cause rejection of the PRODUCTS will be communicated to SkyePharma within 30 days from receipt of the full release documentation package (see Appendix III).

D. Product Complaints and Recalls

Enzon is responsible for receiving and initially evaluating any PRODUCT complaints. Enzon will promptly notify SkyePharma of all complaints received. Recalls of the PRODUCTS will be conducted in accordance with the appropriate SUPPLY AGREEMENT entered into by SkyePharma and Enzon. SkyePharma is responsible for reporting complaints to the appropriate regulatory authority, including adverse drug-events reports. Any complaint relating to any PRODUCT received by SkyePharma will be promptly forwarded to Enzon.

SkyePharma, with data and assistance provided by Enzon, is responsible for filing Field Alerts.

E. Records Retention

SkyePharma will retain, at a minimum, batch production records for the PRODUCTS and materials for seven (7) years from manufacture of lots. Validation records may need to be held for longer than seven (7) years.

SkyePharma will retain batch records for the expiry date of the Clinical Trial Material involved in clinical trials in which Enzon was engaged for a maximum of three (3) years, unless notified of a shorter retention period by Enzon, but at a maximum one (1) year past the stop use date.

F. QA Presence in the Manufacturing Facility

SkyePharma will maintain adequate QA presence in the manufacturing facility during the manufacture of the PRODUCTS to ensure compliance with cGMPs.

## **VIII. REGULATORY**

A. Regulatory Inspections

SkyePharma will promptly inform Enzon of any regulatory inspections that may involve the PRODUCTS and permit a representative from Enzon Quality to be present; provided such inspection may proceed without the presence of a representative from Enzon Quality.

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SkyePharma will promptly inform Enzon of all material manufacturing related commitments to Regulatory Authorities regarding the PRODUCTS.  
Enzon will promptly inform SkyePharma in writing of any regulatory issue that may impact SkyePharma's ability to manufacture the PRODUCTS.

B. Regulatory Actions

Enzon will notify SkyePharma of any regulatory actions on the PRODUCTS that may impact SkyePharma. Enzon will promptly forward any regulatory correspondence on the PRODUCTS to SkyePharma.

SkyePharma is responsible for supporting all batch record investigations associated with regulatory actions.

C. Regulatory Affairs

SkyePharma is responsible for ensuring all appropriate regulatory filings and import/export documentation are filed with Regulatory Agencies prior to shipment/human administration.

D. Right to Audit

SkyePharma will allow representatives from Enzon Quality to perform one standard no-cause cGMP compliance audit per year, and will provide access to their manufacturing, warehousing, and laboratory premises and associated records pertinent to PRODUCTS for audit purposes. In the event any non-conformity is identified, Enzon shall be permitted to re-inspect SkyePharma's facilities to determine whether such non-conformity has been rectified. Reasonable copying of records will be allowed. Enzon representatives will be escorted at all times by SkyePharma personnel. All such audits will be conducted at reasonable times and will not unduly disrupt SkyePharma's operations.

Enzon will allow representatives from SkyePharma Quality to perform one standard no-cause cGMP compliance audit per year, and will provide access to their labeling and packaging area and associated records pertinent to PRODUCTS for audit purposes. In the event any non-conformity is identified, SkyePharma shall be permitted to re-inspect Enzon's facilities to determine whether such non-conformity has been rectified. Reasonable copying of records will be allowed. SkyePharma representatives will be escorted at all times by Enzon personnel. All such audits will be conducted at reasonable times and will not unduly disrupt Enzon's operations.

E. Audit Closeout

An exit meeting will be held with representatives from SkyePharma and Enzon to discuss significant audit observations.

The auditing party will provide a written report of all observations within thirty (30) days to the audited party. Within 30 days of the audit report receipt, the audited party will provide a written response to all findings that details corrective action to be implemented with follow up to ensure that all corrective actions are implemented.

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## **IX. DISPUTE RESOLUTION**

### **A. Non-Conformity Dispute**

In the event that a dispute arises between SkyePharma and Enzon in the nonconformity of a batch of the PRODUCTS, the heads of the Quality departments from both companies will in good faith promptly attempt to reach an agreement. Financial liability will be determined according to the Supply Agreement.

### **B. Test Result Dispute**

In the event that a dispute arises between SkyePharma and Enzon in the testing performed by SkyePharma for the PRODUCTS, the resolution will proceed in stages. The first stage requires direct communication between analysts from both parties to determine that the methods of analysis are the same and are being executed in the same manner at both sites. Second, carefully controlled and split samples should be sent from one site to another in an attempt to reach agreement. Should there be a failure to achieve resolution, analysts from both parties will be required to meet to work through the analysis of a mutually agreeable sample. If these actions fail to achieve resolution, and only after these avenues have been exhausted, a qualified referee laboratory will be used to achieve resolution. This laboratory must be agreeable to both parties prior to use. The results from this referee laboratory will be used as final authority to determine responsibilities, but whatever the outcome, SkyePharma retains the right to determine product release status. Financial liability will be determined according to the SUPPLY AGREEMENT.

In the event that an independent third party laboratory must be retained to settle dispute between the Parties with respect to the conformity or nonconformity of a Product, SkyePharma will be responsible for the technology transfer to such laboratory, and will confirm that the technology transfer had been successful, the laboratory was capable of reproducing SkyePharma laboratory results and that the laboratory was in compliance with cGMP.

## **X. CHANGE MANAGEMENT**

A. Changes for Commercial PRODUCTS – All material changes to the PRODUCTS will undergo a technical and cGMP impact assessment by SkyePharma's expert groups coordinated by SkyePharma's Quality Operations' Change Management personnel. Such changes will be communicated to Enzon Quality.

B. Control of Master Labels and Labeling – Change control for each printed component accompanying PRODUCTS will be administered by both Enzon and SkyePharma (an exception is made for SkyePharma supplied shipper and WTP labels) depending upon the change requested. This includes, but is not limited to, the vial label, the unit carton and the package insert.

Both parties will be responsible for approval of master printed material including the respective Quality organizations. SkyePharma will be solely responsible for technical, content, language and validity as it applies to PRODUCTS and PRODUCT characteristics or specifications.

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Enzon is responsible for supplying approved artwork for the purchase of printed packaging components.

C. Changes to the Quality Agreement

This Quality Agreement and any appendices attached hereto may be amended at anytime upon mutual written agreement between the Parties.

Contact names may be changed by issuing a memo provided to both companies and attaching the memo to the original agreement. The updated information will be incorporated into the next revision of the agreement.

**XI. PRODUCT AND PROCESS VERIFICATION/VALIDATION**

- A. Process Verification – SkyePharma is responsible for the verification of the manufacturing process for the PRODUCTS, as might be required. The verification should ensure that the process is capable of consistently achieving the PRODUCTS acceptance specification.

Process Validation – SkyePharma is responsible for the validation of the manufacturing process for PRODUCTS, as might be required. The validation, should ensure that the process is capable of consistently achieving the PRODUCTS acceptance specification.

- B. Cleaning Validation – SkyePharma is responsible for ensuring that adequate cleaning is carried out between batches of different products to prevent contamination. Data should be available to support the campaign of batches of the same product, and the type of cleaning that will be performed in between manufacturing of the same product.

- C. Equipment, Computer, Facility and Utilities Qualification – SkyePharma is responsible for all equipment, computer, facility and utility qualification and calibration activities associated with the manufacture of PRODUCTS. Such qualification/calibration should be in accordance with cGMP regulations.

- D. Laboratory Qualification – SkyePharma is responsible for ensuring that all laboratories are in compliance with applicable cGMP guidelines.

If analytical work is subcontracted by SkyePharma, SkyePharma will be responsible for the technology transfer to such laboratory and will confirm that the technology transfer had been successful, that the laboratory is capable of reproducing SkyePharma laboratory results and that the laboratory is in compliance with cGMP. SkyePharma will perform an audit on such vendors to be used for analytical testing. SkyePharma will be responsible for ensuring that the vendor is practicing within cGMP compliance.

In the event that an ENZON quality control laboratory will perform analytical testing of a Product, SkyePharma will be responsible for the technology transfer to such laboratory and will confirm that the technology transfer has been successful and that the laboratory is capable of reproducing SkyePharma laboratory results.

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## **XII. ANNUAL PRODUCT REVIEW, ANNUAL PRODUCT REPORT AND DRUG LISTING**

### **A. Annual Product Review**

SkyePharma will perform an Annual Product Review which includes an executive summary for the PRODUCTS. This report will cover all manufacturing and testing performed by SkyePharma. It will be a review of any changes at SkyePharma in the manufacturing, testing or validation of the PRODUCTS in the previous calendar year and a summary of lots made, released and rejected. Also, control charting or trend analysis of key product parameters will be performed. Any abnormalities will be explained in the annual, product review.

The executive summary and documented evidence that responsible officials of SkyePharma have reviewed and endorsed the Annual Product Review will be provided to Enzon during cGMP compliance audits.

### **B. Annual Product Report**

SkyePharma is responsible for preparing and submitting an Annual Product Report to FDA as required by applicable regulations, including 21 CFR 314.70, 314.81, and/or 601.12.

### **C. Drug Listing**

SkyePharma is responsible for drug listing domestic products as the manufacturer of the PRODUCTS, while Enzon is responsible for drug listing as the distributor of the PRODUCTS. Enzon and SkyePharma will provide each other with all required information needed to register the PRODUCTS.

### **D. Adverse Drug Experience Reports**

SkyePharma is responsible for submitting Adverse Drug Experience reports.

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APPENDIX I

OUTLINE OF RESPONSIBILITIES

<u>FUNCTION</u>	<u>SkvePharma</u>	<u>Enzon</u>
EXPIRATION DATE ASSIGNMENT	X	
BATCH/LOT NUMBER ASSIGNMENT	X	X
MANUFACTURING	X	
IN-PROCESS TESTING (Physical, Chemical Microbial)	X	
FINAL PRODUCT TESTING (Physical Chemical, Microbial)	X	
ID TESTING POST LABELING	X	
INVESTIGATIONS INTO DEVIATIONS AND NON-CONFORMANCES	X	
BATCH RECORD REVIEW/SIGNOFF	X	
FINAL PRODUCT RELEASE to ENZON	X	
CERTIFICATE OF ANALYSIS	X	
FINAL PRODUCT RETAINS	X	
ANNUAL PRODUCT INSPECTION	X	
FINAL PRODUCT STABILITY	X	
FINAL PRODUCT RELEASE to MARKET		X
DISTRIBUTION		X
ADVERSE EVENT REPORTS	X	X
COMPLAINT RECEIPTS	X	X
COMPLAINT INVESTIGATIONS	X	
RECALLS	X	X
VALIDATION	X	
FIELD ALERT REPORTS	X	
CUSTOMER RETURNS		X

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APPENDIX I continued

OUTLINE OF RESPONSIBILITIES

<u>FUNCTION</u>	<u>SkvePharma</u>	<u>Enzon</u>
RAW MATERIAL (Active/ Inactives) PURCHASE	X	
RAW MATERIAL (Active/ Inactives) TESTING and RELEASE	X	
COMPONENTS (Printed Packaging Materials) PURCHASE		X
COMPONENTS (Printed Packaging Materials) TESTS		X
COMPONENTS (Printed Packaging Materials) RELEASE		X
RAW MATERIAL/COMPONENT RETAINS	X	X
MAINTENANCE OF VENDOR LISTS	X	X
SUPPLIER AUDITS (Active / Inactives)	X	
SUPPLIER AUDITS (Printed Packaging Materials)		X
RECORD RETENTION	X	X
DOCUMENT CHANGE CONTROL	X	X
NOTICE OF PROPOSED CHANGES (either party may initiate)	X	X
FINAL PRODUCT SPECIFICATION MAINTENANCE	X	
ANNUAL PRODUCT REVIEW	X	
DRUG LISTING	X	X
ANNUAL PRODUCT REPORT TO FDA	X	



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APPENDIX II

LIST OF QUALITY CONTACTS  
(name, phone, fax, e-mail)

ISSUE		
Product Release	Enzon Kathy Buchanan Ph: (908) 412-2458 Fax (908) 668-5997 <a href="mailto:kathy.buchanan@enzon.com">kathy.buchanan@enzon.com</a>	SkyePharma Russell Owen Ph: (858) 625-2424 X3260 Fax (858) 625-0213 <a href="mailto:RussellO@skvepharma.com">RussellO@skvepharma.com</a>
Laboratory Testing	Beverly Wilson Ph: (908) 412-2338 Fax (908) 668-5997 <a href="mailto:beverly.wilson@enzon.com">beverly.wilson@enzon.com</a>	Lorie Opelanio Ph: (858) 625-2424 X3268 Fax (858) 625-2439 <a href="mailto:LorieO@skvepharma.com">LorieO@skvepharma.com</a>  Rick Summers Ph: (858) 625-2424 X3103 Fax (858) 625-2439 <a href="mailto:RickS@skvepharma.com">RickS@skvepharma.com</a>
Investigations	Kathy Buchanan Ph: (908) 412-2458 Fax (908) 668-5997 <a href="mailto:kathy.buchanan@enzon.com">kathy.buchanan@enzon.com</a>	Rick Summers Ph: (858) 625-2424 X3103 Fax (858) 625-2439 <a href="mailto:RickS@skvepharma.com">RickS@skvepharma.com</a>  Russell Owen Ph: (858) 625-2424 X3260 Fax (858) 625-0213 <a href="mailto:RussellO@skvepharma.com">RussellO@skvepharma.com</a>
Regulatory Affairs	Kathryn Bishburg, PharmaD Ph: (732) 980-4755 Fax: (732) 980-5991 <a href="mailto:kathryn.bushburg@enzon.com">kathryn.bushburg@enzon.com</a>	Steve Jensen Ph: (858) 625-2424 X3227 Fax (858) 625-0804 <a href="mailto:SteveJ@skvepharma.com">SteveJ@skvepharma.com</a>
Pharmacovigilance	Anthony Killian, Ph.D., M.D. Ph: (732) 980-4523 Fax: (732) 980-5991 <a href="mailto:anthony.killian@enzon.com">anthony.killian@enzon.com</a>	John Gait, M.D. Ph: (858) 625-2424 X3253 Fax (858) 625-0804 <a href="mailto:JohnG@skvepharma.com">JohnG@skvepharma.com</a>
Stability	Not Applicable	Rick Summers Ph: (858) 625-2424 X3103 Fax (858) 625-2439 <a href="mailto:RickS@skvepharma.com">RickS@skvepharma.com</a>

APPENDIX II continued

LIST OF QUALITY CONTACTS  
(name, phone, fax, e-mail)

ISSUE	Enzon	SkyePharma
Validation	Not Applicable	Nicole Plumb Ph: (858) 625-2424 X2259 Fax (858) 625-0213 <a href="mailto:NicoleP@skyepharma.com">NicoleP@skyepharma.com</a>
Compliance Audits	Alice Preville Ph: (908) 412-2331 Fax: (908) 668-5997 <a href="mailto:alice.preville@enzon.com">alice.preville@enzon.com</a> Joel Schwartzman Ph: (908) 412-2321 Fax (908) 668-5997 <a href="mailto:joel.schwartzman@enzon.com">joel.schwartzman@enzon.com</a>	Russell Owen Ph: (858) 625-2424 X3260 Fax (858) 625-0213 <a href="mailto:RussellO@skyepharma.com">RussellO@skyepharma.com</a>
Product Complaints	Kathy Buchanan Ph: (908) 412-2458 Fax (908) 668-5997 <a href="mailto:kathy.buchanan@enzon.com">kathy.buchanan@enzon.com</a>	Russell Owen Ph: (858) 625-2424 X3260 Fax (858) 625-0213 <a href="mailto:RussellO@skyepharma.com">RussellO@skyepharma.com</a>
Change Management	Dottie Sluzas Ph: (908) 412-2417 Fax (908) 668-5997 <a href="mailto:dorothy.sluzas@enzon.com">dorothy.sluzas@enzon.com</a> Kathy Welsch Ph: (908) 412-2342 Fax (908) 668-5997 <a href="mailto:kathy.welsch@enzon.com">kathy.welsch@enzon.com</a>	Russell Owen Ph: (858) 625-2424 X3260 Fax (858) 625-0213 <a href="mailto:RussellO@skyepharma.com">RussellO@skyepharma.com</a> Nicole Plumb Ph: (858) 625-2424 X2259 Fax (858) 625-0213 <a href="mailto:NicoleP@skyepharma.com">NicoleP@skyepharma.com</a>

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APPENDIX III

RELEASE DOCUMENTATION

The Batch/Lot Release Document Package will include a batch, specific Certificate of Analysis, identity test results of PRODUCTS post-labeling/packaging and a Certificate of Compliance.

Interim Certificate of Analysis (Interim COA)

An Interim COA, to support packaging and labeling, will be provided in SkyePharma standard format and will include the manufacturing address, the PRODUCTS name, SkyePharma batch number, Enzon assigned lot number, date of manufacture, date of expiration, analytical specifications for the tests performed by SkyePharma laboratories, actual test results and a statement releasing the PRODUCTS for labeling and packaging.

Testing to support interim release will include appearance, identity by HPLC, in-vitro release assay, total cytarabine, % free cytarabine and content uniformity.

The batch specific SkyePharma Interim Release Checklist will be attached. The Interim COA and Interim Release Checklist will be signed and dated by a responsible member of the SkyePharma Quality organization.

Certificate of Analysis (COA)

A COA will be provided in SkyePharma standard format and will include the manufacturing address, PRODUCTS name, SkyePharma batch number, Enzon assigned lot number, date of manufacture, date of expiration and analytical specifications as provided in the NDA, the Supply Agreement, and in SkyePharma product specification 006-40001 (refer to APPENDIX IV). The COA will list the Release tests performed by SkyePharma laboratories and actual test results. The COA will make reference to the product specification which identifies the analytical methods used for product testing.

The batch specific SkyePharma QA Release Checklist will be attached. The COA and the QA Release Checklist will be signed and dated by a responsible member of the SkyePharma Quality organization.

Certificate of Analysis for Identity Test – Post Labeling and Packaging

Test results with a statement that the conditions of the test were met. A COA will be provided in SkyePharma standard format and will include the manufacturing address, the PRODUCTS name, SkyePharma batch number, Enzon assigned lot number, date of manufacture, and date of expiration. The test report and test results will be signed and dated by a responsible member of the SkyePharma Quality Control organization. The COA will be signed and dated by a member of the SkyePharma Quality organization.

Certificate of Compliance (COC)

This document will be provided in SkyePharma standard format and will certify that the batch of PRODUCTS was made in accordance with all applicable regulations, licenses, and company policies and meets specifications as provided in the NDA, the Supply Agreement, and in SkyePharma product specification 006-40001 (refer to APPENDIX IV). This document will include the PRODUCT's SkyePharma batch number and Enzon lot number, batch yield (in vials), the quantity approved (in vials), and the expiration date. It will also include a listing of all deviations, OOSs and investigations associated with the batch including a brief description of each.

The COC will be signed and dated by a responsible member of the SkyePharma Quality organization.

APPENDIX IV

SkyePharma Regulatory Specification for SKY01001 – Formulation 1.5 (US)

**SkyePharma Inc.  
Specifications**

OFFICIAL COPY

**Document Number: 006-40001.008  
PCDOC#:0085877.01 Page 1 of 3**

**Regulatory Specifications for SKY0101- Formulation 1.5 (US)**

*Effective Date: May 22, 2003*

1. Definitions:

1.1. Regulatory Specifications - specifications approved by the regulatory agency to be applied to the product throughout its shelf life.

2. Associated Documents:

2.1. 002-10005, "SKY0101. Formulation 1.5 (US)"

2.2. 002-10008, "SKY0101, Formulation 1.5. Interim Release (US)"

3. References:

3.1. 005-00019. "Dextrose in SKY0101"

3.2. 005-00046. "Lyso-DOPC in SKY0101"

3.3. 005-01002. "Appearance Test for DepoFoam™ Suspension Final Product"

3.4. 005-01003, "Cholesterol in SKY0101"

3.5. 005-01010, "Total and Percent Free Cytarabine in SKY0101"

3.6. 005-01011. "Measurement of pH"

3.7. 005-01012. "Chloroform in SKY0101"

3.8. 005-01014. "Measurement of Osmolality"

3.9. 005-01016. "Particle Size Analysis of DSKY0101"

3.10. 005-01025. "DOPC in SKY0101"

3.11. 005-01029. "Fill Volume of Final Product"

3.12. 005-01054. "Triolein in SKY0101"

3.13. 005-01059. "Cytarabine Related Substances in SKY0101"

3.14. 005-01075. "DPPG in SKY0101"

3.15. 005-01076. "Content Uniformity of SKY0101"

3.16. 005-10003. "L-Lysine Level in SKY0101 Final Product by FSCE"

3.17. 005-10012. "HIAC/ROYCO Particulate Matter Test for DSKY0101 Final Product"

3.18. 005-90021. "In Vitro Release Assay for SKY0101"

## Regulatory Specifications for SKY0101- Formulation 1.5 (US)

4. Regulatory Specifications for SKY0101 – Formulation 1.5 (US)- :

<u>Test</u>	<u>Method**</u>	<u>Specification</u>
Appearance	005-01002	[**]
Identity by HPLC	005-01010	[**]
Total Cytarabine	005-01010	[**]
% Free Cytarabine	005-01010	[**]
Content Uniformity	005-01076	[**]
pH	005-01011	[**]
Particle Size	005-01016	[**]
		[**]
Oracil Arabinoside	005-01059	[**]
Cytosine	005-01059	[**]
Cytidine	005-01059	[**]
Uridine	005-01059	[**]
Uracil	005-01059	[**]
Total Cytarabine related imparities not including Uracil Arabinoside	005-01059	[**]
Cholesterol	005-01003	[**]
Triolein	005-01054	[**]
DPPG	005-01075	[**]
DOPC	005-01025	[**]
Lyso-DOPC	005-00046	[**]
Dextrose	005-00019	[**]
L-Lysine	005-10003	[**]
Chloroform	005-01012	[**]
Osmolality	005-01014	[**]
Fill Volume	005-01029	[**]

SkyePharma Inc.  
Specifications

Document Number: 006-40001.008  
PCDOC#:0085877.01 Page 3 of 3

Regulatory Specifications for SKY0101- Formulation 1.5 (US)

4. Regulatory Specifications for SKY0101 – Formulation 1.5 (US)\* (Continuation):

<u>Test</u>	<u>Method**</u>	<u>Specification</u>
Particulates	005-10012 or USP <788>	[**] [**]
In-Vitro Release Assay (ACSF)	005-90021	
Day-0		
Day-1		
Day-2		
Day-3		
Day-4		[**]
Bacterial Endotoxins	LAL Chromogenic	[**]
Sterility	USP	[**]

\* Revision of these tests and specifications will affect Referenced Documents.

\*\* Latest revision level applies.

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

**DATED: OCTOBER 15, 2009**

**PACIRA PHARMACEUTICALS, INC.**

**and**

**EKR THERAPEUTICS, INC.**

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**AMENDED AND RESTATED  
STRATEGIC LICENSING, DISTRIBUTION AND MARKETING AGREEMENT**

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**THIS AMENDED AND RESTATED STRATEGIC LICENSING, DISTRIBUTION AND MARKETING AGREEMENT** (the “**Agreement**”) is made on October 15, 2009 (the “**Agreement Date**”) and is effective as of the Effective Date (as defined below), between:

**PACIRA PHARMACEUTICALS, INC. (F/K/A SKYEPHARMA, INC.)** a company incorporated in the state of California whose principal place of business is 10450 Sciences Center Drive, San Diego, California 92121 USA (“**PPI**”); and

**EKR THERAPEUTICS, INC.**, a company incorporated in the state of Delaware whose principal place of business is 1545 Route 206 South, Third Floor, Bedminster, New Jersey 07921 (“**EKR**”).

#### **Recitals**

PPI owns and has all right title and interest in or has acquired exclusive rights to the PPI IP (as defined below), the Trademark (as defined below) and the Product (as defined below).

EKR has, among other things, specialized knowledge and expertise in relation to the marketing and sale of pharmaceutical products.

Pursuant to that certain Strategic Licensing, Distribution and Marketing Agreement between EKR and PPI dated as of August 10, 2007 (the “**Original Agreement**”), PPI granted and EKR acquired the exclusive right and license to sell, offer to sell, distribute and market the Product in the Territory (as defined below) in the Field (as defined below).

EKR and PPI desire to amend and restate the Original Agreement in its entirety as set forth herein in order to provide for: (i) certain changes to the financial terms set forth in the Original Agreement, (ii) the transfer of Marketing Authorizations (as defined below) from PPI to



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EKR, and EKR's assumption of obligations thereunder, (iii) the transfer of title to certain manufacturing equipment from PPI to EKR and the lease of such equipment back from EKR to PPI and (iv) certain other changes as are set forth herein; all of the foregoing subject to and in accordance with the terms and conditions of this Agreement.

**NOW THEREFORE**, in consideration of the following mutual agreements and covenants set forth herein and intending to be legally bound hereby, PPI and EKR (each, a "**Party**" and collectively, the "**Parties**") acknowledge and agree that this Agreement shall amend and supersede in its entirety the Original Agreement and hereby agree as follows:

**Operative Provisions**

1. **Definitions**

1.1 As used in this Agreement, the following words and expressions have the following meanings:

"Affiliate"

With respect to any Party to this Agreement shall mean any company, corporation, firm, individual or other entity which Controls, is Controlled by or is under common Control with such Party to this Agreement for only so long as such Control exists;

“Applicable Laws”	Shall mean all laws, rules and regulations regarding the manufacture, packaging, labeling, import, export, storage, distribution, representation, promotion, marketing and sale of the Products including but not limited to the Federal Food, Drug and the Controlled Substances Act, as amended (21 U.S.C. §801 et seq.), or as defined in attendant regulations promulgated under authorities granted by the FD&C Act, together with any equivalent laws, rules, regulations, codes or guidelines having effect in any jurisdiction in the Territory;	A
“Calendar Year”	Shall mean the period of twelve months commencing on 1st January in any year, and each consecutive period of twelve months thereafter during the Term;	
“cGMP”	Means Current Good Manufacturing Practices pursuant to 21 CFR Parts 210 and 211, as may be amended from time to time;	
“Commercial Launch”	Shall mean the date of the first arm’s length sale by EKR to an unaffiliated Third Party customer for commercial use of Product in a country within the Territory following the grant of Marketing Authorization and any necessary pricing approval in that country;	
“Commercialization Committee”	Shall mean the committee to be set up under the terms of <u>Article 5</u> ;	

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“Competing Product”	Means any [**] ([**] hours) [**] preparation (other than the Product) available in a country in the Territory which competes or would compete directly with the Product. For the avoidance of doubt, the definition of “Competing Product” does not include Depobupivacaine or any improvement thereto;
“Confidential Information”	Means all confidential information, data and materials in whatever form disclosed by or on behalf of one Party or its Affiliates to the other Party or its Affiliates including, without limitation, the terms of this Agreement, data, formulae, unpublished patent disclosures, processes, protocols, marketing studies, sales information, specifications and know-how, (and, in the case of EKR’s Confidential Information, EKR’s marketing plans and EKR’s sales forecasts), but excluding information which either Party can establish by written documentation: <ul style="list-style-type: none"><li data-bbox="406 346 1463 378">(i) at the time of disclosure, is in the public domain or is public knowledge;</li><li data-bbox="406 388 1463 441">(ii) after disclosure, becomes part of the public domain by publication, except by breach of any obligation of confidentiality by a Party hereto or an Affiliate of such Party;</li><li data-bbox="406 451 1463 504">(iii) was already in its possession at the time of its receipt and was not acquired directly or indirectly from the other Party or its Affiliates; or</li><li data-bbox="406 514 1463 537">(iv) received from Third Parties who were lawfully entitled to disclose such information;</li></ul>

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“Control”	Means in relation to any Party or an Affiliate the possession directly or indirectly, of the power to direct or cause the direction of the management and policies of such firm, person or entity, by contract or otherwise, or the ownership either directly or indirectly of 50% or more of the voting securities of such Party;
“Copyrights”	Means (i) the copyright registrations and applications for registration identified on <u>Schedule III</u> , (ii) works of authorship whether or not copyrightable and (iii) any other copyrights and works, together with all common law rights, used or held for use by PPI or any of its Affiliates in connection with the Products in the Territory (including, but not limited to, any license or other rights of PPI or any of its Affiliates, whether as a licensor, licensee or otherwise relation to any of the foregoing);
“Current Base Price”	Means the Product’s current (as of the Effective Date) net average selling price of \$[**] ([**] mg) and \$[**] ([**] mg);
“DEA”	Shall mean the United States Drug Enforcement Administration and any successor thereto performing similar functions;
“Distribution Rights”	Shall have the meaning set forth in <u>Section 2.1</u> hereof;
“Domain Name”	Shall mean Depodur.com and any other domain names owned or licensed by PPI related to the Product set forth on <u>Schedule IV</u> hereto;

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“EKR Improvement”	Means any Improvement generated, conceived, reduced to practice or other created during the Term by EKR or any of its Affiliates.
Endo/PPI Unit Sales	Shall have the meaning set forth in <u>Section 3.19</u> hereof;
Endo Product	Means: (i) DepoDur Injectable Liposomal Epidural 10 mg/ml NDC # [**]; and (ii) DepoDur Injectable Liposomal Epidural 15 mg/1.5 ml NDC # [**];
“Effective Date”	Means August 10, 2007;
“FDA”	Means the United States Food and Drug Administration or any successor thereto performing similar functions;
“Field”	Means the management of post-operative pain following major orthopedic, abdominal or pelvic surgery;

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“Force Majeure”	Means in relation to either Party, any cause affecting the performance of this Agreement or the Supply Agreement arising from or attributable to any acts, events, non-happenings, omissions or accidents beyond the reasonable control of the Party to perform and in particular but without limiting the generality thereof shall include strikes and labor disturbances, lock-outs, industrial action, civil commotion, riot, invasion, war, threat of or preparation for war, terrorist activity, fire, explosion, storm, flood, earthquake, subsidence, epidemic or other natural physical disaster, impossibility of the use of railways, shipping, aircraft, motor transport, or other means of public or private transport, failure or suspension of utilities, unavailability, shortage or interruption in the supply of raw material, and political interference with the normal operation of either Party;
“Improvements”	Means any discovery, development, improvement, know-how or patent relating to the Product generated, conceived, reduced to practice or otherwise created during the Term by PPI or EKR (or any Affiliate of PPI or EKR);
“Joint Improvements”	Means any Improvements generated, conceived, reduced to practice or other created jointly by EKR and PPI or their Affiliates.
“Known In-Channel Product Units”	Shall have the meaning set forth in <u>Section 3.19</u> hereof;

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“Marketing Authorization”	Means the new drug application (“ <b>NDA</b> ”) and all other necessary regulatory and governmental approvals by a Regulatory Authority or other governmental body required to market and sell the Product in any country of the Territory, including, but not limited to, those set forth on <u>Schedule V</u> hereto;
“Marketing Plan”	Means the plan for the marketing, distribution and sale of the Product in the Territory submitted to the Commercialization Committee in accordance with <u>Section 5.4</u> ;

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“Net Sales”

Means total gross sales of Product invoiced by EKR, its Affiliates and sub-distributors in arms length sales to Third Parties, less the following amounts actually incurred, deducted, accrued or allowed:

- (i) transport, freight and insurance costs which are separately stated;
- (ii) sales and excise taxes and duties;
- (iii) normal and customary trade, quantity and cash discounts, rebates and chargebacks;
- (iv) amounts repaid or credited for properly rejected, returned or recalled goods or resulting from retroactive price adjustments related to the Product;
- (v) amounts incurred or resulting from government (or an agency thereof) mandated or managed care or other rebate programs now existing or implemented hereafter;
- (vi) any other identifiable amounts included in gross sales of the Product that were or ultimately will be credited and that are substantially similar to those listed hereinabove; and
- (vii) any other deductions allowed by GAAP which effectively reduce the net selling price of Product;

“PPI Improvement”

Means any Improvement generated, conceived, reduced to practice or otherwise created during the Term by PPI or any of its Affiliates;



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“PPI IP”	Means the Copyrights, PPI Know-How, PPI Patents and PPI Improvements; and PPI’s interest in Joint Improvements;
“PPI Know-How”	Means all information, procedures, instructions, techniques, data, technical information, knowledge and experience (including, without limitation, toxicological, pharmaceutical, clinical, non-clinical and medical data, health registration data and marketing data), designs, dossiers (including, without limitation, manufacturing assay and quality control dossiers) manufacturing formulae, processing specifications, sales and marketing materials and technology relating to the Product;
“PPI Patents”	Means those patents set out in <u>Schedule I</u> which cover the Products and such other patents as PPI may include from time to time, including additions, divisions, confirmations, continuations-in-part, substitutions, re-issues, re-examinations, extensions, registrations, patent terms extensions, supplementary protection certificates and renewals of any of the above or any other patents owned or licensed by PPI subsequent to the Effective Date which cover the Products or any Improvements;

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“Product(s)”	Means: (i) DepoDur Injectable Liposomal Epidural [**] mg/ml [**]; (ii) DepoDur Injectable Liposomal Epidural [**] mg/[**] ml [**]; (iii) such other presentations and dosages which hereafter receive Marketing Authorization in any country of the Territory; in each case for epidural administration presented in Vials or other approved vessels, appropriately packaged and labeled for sale to end users and (iv) any and all Improvements of the items listed in clauses (i) through (iii).
“Promotional Materials”	Means promotional, sales, marketing, educational and training materials which are necessary to support the marketing of the Products;
“Quarter”	Means a three month period ending on the last day of March, June, September or December in any Calendar Year;
“Regulatory Authority”	Means any competent regulatory authority or other governmental body (for example, but not by way of limitation the FDA and DEA) responsible for granting a Marketing Authorization in the Territory;
“Royalty Cap”	Shall have the meaning set forth in <u>Section 6.4</u> ;
“Supply Agreement”	Means: (i) with respect to periods between the Effective Date and the Agreement Date, that certain Supply Agreement entered into by the Parties on the Effective Date and (ii) with respect to periods on or after the Agreement Date, that certain Amended and Restated Supply Agreement entered into by the Parties on the Agreement Date (as may be amended from time to time);

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“Term”	Means the term of this Agreement as set out in Section 15;
“Territory”	Means each of the countries and territories listed in <u>Schedule VII</u> ;
“Third Party”	Means any company, corporation, firm, individual or other entity but excluding a Party to this Agreement or an Affiliate;
“Trademarks”	Means those Trademarks registered or applied for set out in <u>Schedule II</u> ;
“Transition Services and Inventory Agreement”	Means that certain Transition Services and Inventory Agreement entered into between the Parties on the Effective Date;
“Vial”	Means a vial containing the Product supplied to EKR in presentations and dosages and other relevant terms set out in the Supply Agreement;
“Year”	Means the period of twelve months commencing on the first Commercial Launch of the Product in the Territory, and each consecutive period of twelve months thereafter during the Term.

1.2 In this Agreement, unless the context requires otherwise:

- (a) the headings are included for convenience only and shall not affect the construction of this Agreement;
- (b) references to “persons” includes individuals, bodies corporate (wherever incorporated), unincorporated associations and partnerships;
- (c) words denoting the singular shall include the plural and vice versa;
- (d) words denoting one gender shall include each gender and all genders; and

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- (e) any reference to an enactment or statutory provision is a reference to it as it may have been, or may from time to time be amended, modified, consolidated or re-enacted.
- 1.3 The Schedules comprise part of and shall be construed in accordance with the terms of this Agreement. In the event of any inconsistency between the Schedules and the terms of this Agreement, the terms of this Agreement shall prevail.
2. **Grant of Rights**
- 2.1 **Retention of EKR.** Subject to the terms of this Agreement, PPI hereby appoints EKR and EKR agrees to be retained as the exclusive distributor, and Authorized Distributor of Record, of the Products in the Field in the Territory during the Term to market, distribute, warehouse and sell the Products. EKR shall have the right to appoint sub-distributors hereunder in each country of the Territory.
- 2.2 **Grant of License and Distribution Rights.** PPI hereby grants EKR the exclusive right and license (with the right to sublicense) to use, market, promote, sell, distribute and warehouse the Products (the “**Distribution Rights**”) in the Field in the Territory during the Term, as well as to make or have made the Products anywhere in the world for import or sale in the Field in the Territory in each case, under the PPI IP provided that PPI retains all rights necessary to manufacture and supply the Products to EKR in accordance with this Agreement and the Supply Agreement. Such grant by PPI shall include the right of EKR to market the Product in the Territory during the Term as an EKR product using in addition to the Trademarks, EKR’s own trademarks, trade dress, trade names and other proprietary designations in combination with the Trademarks.
- 2.3 **Grant of Trademark Rights.** PPI hereby grants to EKR a royalty free and exclusive license (with the right to sublicense) to use the Trademarks in the Territory solely in connection with the exercise of the Distribution Rights in the Territory during the Term (and thereafter as set forth in Section 17.4) and EKR shall market and sell the Products under the Trademarks. For the avoidance of doubt, the term “exclusive” for the

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purposes of Sections 2.1, 2.2 and 2.3 means to the exclusion of all others, including PPI and its Affiliates, except to the extent necessary to enable PPI to perform its specific obligations under this Agreement and the Supply Agreement. Notwithstanding the foregoing, nothing contained herein shall prohibit PPI from utilizing the Trademarks in the Territory in connection with its business for the sole purpose of signifying that PPI is the manufacturer of the Products for EKR.

- 2.4 Transfer of Domain Names. On the Effective Date, PPI has transferred the Domain Names to EKR for use in connection with the exercise of the Distribution Rights. PPI has provided EKR with reasonable assistance as was necessary to effectuate the transfer of the Domain Names. Upon any termination or expiration of this Agreement, EKR shall promptly transfer the Domain Names back to PPI.
- 2.5 Condition of Appointment. The acceptance of forecasts and orders for the Products (as provided in the Supply Agreement), and PPI's obligation to supply the Product to EKR shall at all times be conditioned by the Marketing Authorization for the Product being in force in the country of Territory to which such acceptance and order relates.
3. Undertakings of PPI
- 3.1 Manufacturing Activities. Subject to Section 17.5, PPI shall manufacture and supply, or procure the manufacture and supply of, the Product in accordance with the terms and conditions of the Supply Agreement.
- 3.2 Transfer of Transferred NDA. Effective as of the Agreement Date, PPI hereby sells, transfers, conveys and assigns to EKR all right, title and interest in and to [\*\*] (the "**Transferred NDA**"). Each Party shall, within five (5) business days after the Agreement Date, file with the FDA a notice letter, substantially in the form attached as Schedule XI(A) or Schedule XI(B) (as applicable), regarding the transfer to EKR of the Transferred NDA. PPI represents, warrants and covenants that: (i) prior to the Agreement Date, it has provided EKR with complete, up-to-date copies of the Transferred NDA and all material correspondence with Regulatory Authorities in the

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Territory in connection with the Transferred NDA (including, but not limited to, any periodic and annual report submissions, and all adverse event reports and data) and (ii) on the Agreement Date, EKR shall receive sole ownership of, and good and valid title to, the Transferred NDA, free and clear of any liens and encumbrances. For the avoidance of doubt, nothing in this Agreement regarding the appointment of EKR as PPI's distributor of the Products shall be construed to diminish any rights of EKR as holder of the Transferred NDA. Upon termination of this Agreement for any reason except by EKR pursuant to Section 16.1(a), EKR shall promptly transfer the Transferred NDA and related regulatory documentation to PPI in accordance with Section 17.1(e).

- 3.3 Maintenance of Transferred NDA. The Parties acknowledge that prior to the Agreement Date, PPI was responsible at its own cost and expense for maintaining and updating the Transferred NDA, and agree that PPI shall retain all liabilities with respect to the foregoing obligations to the extent relating to periods prior to the Agreement Date. Commencing as of the Agreement Date, EKR shall, at its own cost and expense, maintain and update the Transferred NDA and be responsible for all liabilities with respect to the foregoing obligations to the extent relating to periods after the Agreement Date.
- 3.4 Assistance. PPI shall, at EKR's cost and expense, provide EKR with all assistance, information and guidance, including where appropriate direct access to employees of and consultants to PPI and its Affiliates and shall use reasonable efforts to obtain such assistance and access from any sub-contractors of PPI and its Affiliates (including for the avoidance of doubt any manufacturers of the Product) which is reasonably necessary in relation to the conduct of any post-marketing or Phase IV studies to be conducted by EKR in the Territory or otherwise in connection with the discharge of EKR's obligations under the terms of this Agreement (including, but not limited to, the maintenance of the Transferred NDA); provided, however, that any such post-marketing or Phase IV studies to be conducted by EKR shall be at EKR's sole cost and expense. Any labor

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costs of PPI employees related to this assistance shall be reimbursed by EKR at a rate of [\*\*] dollars (\$[\*\*]) per hour. PPI represents and warrants that as of the Agreement Date, except for the studies set forth on Schedule X attached hereto (the “**Required Studies**”), no post-marketing or Phase IV studies are required by any applicable Regulatory Authority to be conducted with respect to the Product. EKR shall be responsible for the conduct of the Required Studies after the Agreement Date, at its own expense, in accordance with the requirements of the applicable Regulatory Authorities. PPI shall be responsible for all costs and liabilities incurred prior to the Agreement Date with respect to the Required Studies, and shall indemnify and hold harmless EKR from such costs and liabilities. Promptly after the Agreement Date, PPI shall provide EKR with copies of all agreements relating to the Required Studies and shall assign such agreements to EKR if and to the extent (i) such agreements are assignable in accordance with their terms and (ii) requested by EKR.

- 3.5 Adverse Events. PPI shall at its own cost and expense promptly provide EKR with all information in its possession or otherwise coming to its attention relating to the occurrence of a serious adverse event or an adverse event (in any jurisdiction throughout the world) in connection with the Product. PPI shall be responsible, to the extent required by Applicable Laws, to report all charges, complaints or claims reportable to the FDA relating to the Product, to the extent such charges, complaints or claims are made prior to the Agreement Date. EKR shall be responsible, to the extent required by Applicable Laws, to report all charges, complaints or claims reportable to the FDA relating to the Product, to the extent such charges, complaints or claims are made after the Agreement Date.
- 3.6 Reserved.
- 3.7 Delivery of Materials. The Parties acknowledge that prior to the Agreement Date, PPI has delivered to EKR (i) all existing PPI produced Promotional Materials (if any) and (ii) any existing market research in its possession related to the Product.

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- 3.8 Customer Orders. PPI shall at its own cost and expense during the Term, promptly forward to EKR any customer orders or inquiries for the Product within the Territory received after the Effective Date and shall inform any customers ordering the Product that EKR is now distributing the Product and provide such customers with EKR's address and telephone number.
- 3.9 Payment of Third Party Royalties. During the Term, PPI shall be solely responsible for and pay any royalties or other amounts due to Third Parties related to the Product and shall indemnify and hold EKR harmless from any claims arising from or related thereto.
- 3.10 Customer Returns. PPI shall at its own cost and expense be responsible for all customer returns of Product sold prior to the Effective Date.
- 3.11 Governmental Rebates. PPI shall at its own cost and expense be responsible for all discounts, rebates, or promotional allowances/incentive programs deemed to be "discount[s] or other reduction[s] in price" for purposes of 42 U.S.C. Section 1320a-7b(b)(3)(A) and may be subject to the reporting requirements under state and federal Medicaid and Medicare laws for sales of Product prior to the Effective Date. PPI represents that it is aware of its obligations to report discounts resulting from this Agreement to the appropriate reimbursing agencies and authorities (including Medicaid and Medicare). PPI is responsible for complying with and agrees to comply with all applicable requirements, if any, in respect of providing information on such discounts to reimbursing agencies (including Medicaid and Medicare) and other entities in accordance with Applicable Laws and regulations for sales of Product prior to the Effective Date and for sales of any PPI labeled product subsequent the Effective Date.
- 3.12 Chargebacks. PPI shall at its own cost and expense be responsible for all chargebacks for sales of Product prior to the Effective Date.
- 3.13 Exclusivity. During the Term, PPI and its Affiliates shall not: (i) file for Marketing Authorization with respect to any Competing Product in any country in the Territory, (ii) manufacture or have manufactured any Competing Product in any country in the Territory, (iii) market or have marketed any Competing Product in any country in the Territory or (iv) license any Third Party to do any of the foregoing.



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3.14 Product Development. PPI shall at its own cost and expense cooperate fully and assist EKR with the preparation of any necessary submissions to any of the Regulatory Authorities in the Territory for the development and approval or supplemental approval(s) of the Products, including, but not limited to, by providing access to all PPI Know-How, the drug master file and any other information necessary for approval or supplemental approval of the Product in any country of the Territory. In addition, PPI shall cooperate fully in participating in interactions with the appropriate Regulatory Authorities including FDA related to such product development so as to enable EKR to fully exploit the Distribution Rights granted hereunder. For purpose of this Section, the contact person for each of the parties is set forth below.

EKR – [\*\*], MD - CMO

PPI – [\*\*], MD - CMO

3.15 Reserved.

3.16 Recalls and PostMarket Notifications. All costs of safety alerts and all other forms of notifications regarding safety risks associated with the Products in the United States shall be borne by PPI to the extent arising prior to the Agreement Date and by EKR to the extent arising after the Agreement Date.

3.17 Compliance. During the Term PPI shall at its own cost and expense take all actions necessary to comply with all Applicable Laws and obtain and maintain all necessary license, permits, records and authorizations PPI is required to obtain and maintain hereunder so as to enable PPI to perform its obligations hereunder and under the Supply Agreement so as to enable EKR to fully exercise the Distribution Rights.

3.18 Assignment of ICS Agreement. The Parties acknowledge that effective upon the termination or expiration of the Transition Services and Inventory Agreement, PPI has

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assigned to EKR all of PPI's right, title and interest under that certain Commercial Outsourcing Services Agreement between PPI (f/k/a SkyePharma, Inc.) and Integrated Commercialization Solutions, Inc. ("ICS") dated April 3, 2007 (the "ICS Agreement"), and EKR has assumed all obligations and liabilities under the ICS Agreement arising after the Effective Date. The Parties further acknowledge that as of the Effective Date, the Parties have entered into an Assignment and Assumption Agreement to further evidence the foregoing assignment and assumption of the ICS Agreement.

- 3.19 Product in Channel. All sales of Product conducted by PPI and its distributors and wholesalers (and, to the knowledge of PPI, by Endo Pharmaceuticals and its distributors and wholesalers) during the six month period prior to the Effective Date have been conducted in the ordinary course upon standard payment terms. PPI has provided EKR: (i) all information regarding sales by Endo Pharmaceuticals during the six month period prior to the Effective Date and (ii) all information regarding the number of units of Product and Endo Product that were in the possession or control of PPI or Endo Pharmaceuticals (and their respective distributors or wholesalers) as of the Effective Date (the "**Known In-Channel Product Units**"). Within 10 days of the end of each month following the Effective Date, PPI shall provide EKR with copies of: (i) any reports provided by Endo Pharmaceuticals of the number of units of Endo Product sold to hospitals or other customers during the preceding month by Endo, and (ii) information possessed by PPI of such sales by PPI or any of their respective distributors or wholesalers (the "**Endo/PPI Unit Sales**").
- 3.20 Sale and Leaseback of Transferred Equipment.
- (a) In consideration of and subject to EKR's payment of the Equipment Purchase Price (as defined below), effective as of the Agreement Date, PPI hereby sells, transfers, conveys and assigns to EKR all right, title and interest in and to the equipment described on Schedule XII (the "**Transferred Equipment**"). The

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Parties shall share equally the responsibility for any and all sales, transfer and conveyance taxes occasioned by the sale of the Transferred Equipment by PPI to EKR. PPI represents and warrants that: (i) on the Agreement Date, EKR shall receive sole ownership of, and good and valid title to, the Transferred Equipment, free and clear of any liens and encumbrances, (ii) the Transferred Equipment as of the Agreement Date is in good operating condition, normal wear and tear excepted and (iii) the Transferred Equipment constitutes all specialized equipment that is used in the manufacture of Product by PPI as of the Agreement Date. For purposes of clarity, the Transferred Equipment does not include any standard, non-specialized equipment generally found in manufacturing facilities or available to manufacturers of products similar to the Product (e.g., refrigerators, freezers, safes, incubators, stability chambers, clean utilities, supportive utilities, temperature control units and other supportive equipment). On the Agreement Date, PPI shall execute and deliver to EKR a Bill of Sale with respect to the Transferred Equipment substantially in the form attached hereto as Exhibit 3.20(a).

- (b) EKR will pay PPI [\*\*] Dollars (\$[\*\*]) for the Transferred Equipment (the “**Equipment Purchase Price**”) as follows:
  - (i) within five (5) days after the Agreement Date, EKR will pay PPI [\*\*] Dollars (\$[\*\*]) of the Equipment Purchase Price in cash; and
  - (ii) concurrently with the execution of this Agreement, EKR will issue to PPI a promissory note in principal amount of [\*\*] Dollars (\$[\*\*]), such note to be substantially in the form attached hereto as **Exhibit 3.20(b)** (the “**Promissory Note**”).
- (c) Commencing as of the Agreement Date, EKR agrees to lease the Transferred Equipment to PPI through the end of the then-current calendar quarter and, subject to renewal as provided below, on a calendar quarter-to-calendar quarter

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basis thereafter (the “**Lease Term**”), for use solely in connection with the (i) performance of PPI’s obligations under the Supply Agreement, (ii) the supply of Products to PPI’s other licensees and collaborators and (iii) the supply of placebo for PPI’s Exparel product to PPI’s other licensees and collaborators. The Lease Term shall automatically renew at the end of each calendar quarter of the Lease Term. The Lease Term will automatically terminate immediately upon (i) any termination or expiration of this Agreement and/or the Supply Agreement or (ii) any exercise by EKR of the Step-in Right described in Section 17.5 below.

- (d) At any time between the Agreement Date and July 1, 2015, EKR shall have the right, exercisable upon sixty (60) days prior written notice to PPI, to terminate the Lease Term and sell the Transferred Equipment back to PPI, subject to payment by PPI to EKR within five (5) days of such notice of \$[\*\*] in cash, which if exercised shall result in (i) an offset against the unpaid balance of principal and interest under the Promissory Note pursuant to Section 3.20(f) below; and (ii) the termination of the Step-in Right described in Section 17.5.
- (e) At any time after July 1, 2015, PPI shall have the right, exercisable upon sixty (60) days prior written notice to EKR, to terminate the Lease Term and repurchase the Transferred Equipment from EKR, subject to payment by PPI to EKR within five (5) days of such notice of any principal paid by EKR under the Promissory Note, which if exercised shall result in the termination of the Step-in Right set forth in Section 17.5.
- (f) If, upon the expiration or earlier termination of the Lease Term (except as provided in Section 3.20(e) above), the aggregate amount of repayments and Royalty Offsets (as defined below) earned by EKR pursuant to Section 6.3 below have not equaled or exceeded the Advanced Royalty Payment (as defined below), then EKR shall have the right, at its option, to offset against the unpaid balance of principal and interest under the Promissory Note, by an amount equal to the

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then-current balance of the Advanced Royalty Payment that has not yet been recouped by EKR through repayments and Royalty Offsets pursuant to Section 6.3 below (the “**Remaining Balance**”), in which event PPI’s obligations under Section 6.3 below with respect to repayment of the Advanced Royalty Payment shall be deemed to have been paid in full.

- (g) In consideration of the foregoing lease, PPI shall pay EKR [\*\*] lease payments in the amount of \$[\*\*] per calendar quarter, with the first lease payment due on the Agreement Date and each subsequent lease payment due during the Lease Term on the first day of each calendar quarter thereafter.
- (h) PPI shall not, without the prior, written consent of EKR, remove any of the Transferred Equipment from the locations within the Approved Facilities (as defined in the Supply Agreement) where such Transferred Equipment is installed as of the Agreement Date.
- (i) During the Lease Term, PPI shall: (i) assume the risk of loss or damage to the Transferred Equipment; (ii) maintain the Transferred Equipment in good operating condition and appearance, ordinary wear and tear excepted; (iii) comply with all requirements necessary to enforce any warranty rights and to maintain eligibility for any manufacturer maintenance program; (iv) promptly repair any repairable damage to the Transferred Equipment and (v) maintain property damage and liability insurance and insurance against loss or damage to the Transferred Equipment as part of PPI’s general liability insurance.
- (j) If any of the Transferred Equipment is lost, stolen, destroyed, damaged beyond repair or in the event of any condemnation, confiscation, seizure or expropriation of any Transferred Equipment (“**Casualty Transferred Equipment**”), PPI shall promptly (i) notify EKR of the same, and (ii) pay to EKR an amount equal to the estimated in-place, fair market value of the Casualty Transferred Equipment as of the date of the loss, as determined by a mutually agreed nationally recognized

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appraiser; provided that (i) in the event there are any amounts owed to PPI under the Promissory Note as of the date of such loss, PPI shall have the right, at its option, to offset against the unpaid balance of principal and interest under the Promissory Note, the amounts owed to EKR pursuant to this Section 3.20(k), and (ii) in no event shall PPI be required to pay EKR an amount that exceeds [\*\*] Dollars (\$[\*\*]) plus the amounts paid by EKR pursuant to the Promissory Note.

- (k) Subject to Sections 3.20(d) and (e) and Section 6.3(d) and PPI's right to repurchase the Transferred Equipment thereunder, upon the expiration or earlier termination of the Lease Term, EKR shall remove the Transferred Equipment from PPI's premises (unless EKR at its option elects to retain the Transferred Equipment at PPI's premises in connection with EKR's exercise of step-in rights under Section 17.5). PPI agrees to cooperate with EKR in the removal of the Transferred Equipment, including providing the necessary access to the Transferred Equipment and the facilities where it is located at times mutually agreed by the Parties, such agreement not to be unreasonably withheld or delayed by either Party.
- (l) Upon termination of the Lease Term, unless PPI has repurchased the Transferred Equipment, EKR will, at PPI's request, use commercially reasonable efforts to (i) supply the Product and (ii) supply placebo for [\*\*], to PPI's other licensees and collaborators outside the Territory, excluding PPI and any of its Affiliates (the "**Other PPI Customers**"), in each case in accordance with the commercially reasonable requirements of any existing agreements between PPI and such Other PPI Customers, subject to EKR's receipt of payment required under such agreements for supplying such Products and/or other products. PPI will use commercially reasonable efforts to cooperate with EKR so as to enable EKR to supply Product and, if applicable, other products, to such Other PPI Customers.

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4. **Undertakings of EKR.**

- 4.1 **Marketing Authorizations.** EKR shall, as determined in its sole discretion to be commercially reasonable, prepare studies of the markets and sales potential of the Products for countries in the Territory other than the United States and present such studies to the Committee. EKR shall at its own cost and expense use commercially reasonable efforts to take those steps reasonably necessary in order to obtain and thereafter maintain Marketing Authorizations (including pricing and reimbursement approvals) for the Product in those countries of the Territory other than the United States which the Committee determines to present commercially viable opportunities for the Product. EKR shall provide PPI with a copy of any original certificates of approval/registration in each country in the Territory other than the United States. EKR shall provide PPI with a copy of any other registration matters received from the appropriate Regulatory Authorities concerning maintenance, renewal or variations to the original certificates of approval/registration in each country in the Territory. Except as provided in Section 3.17, EKR shall be solely responsible for, and shall bear all costs associated with, all regulatory activities related to the development and approval of the Product in the countries of the Territory (including, after the Agreement Date, the United States) and shall own the Marketing Authorizations for the Product in each other country of the Territory. EKR will comply with all conditions and requirements attaching to such Marketing Authorizations.
- 4.2 **Liaison with Regulatory Authorities.** Pursuant to Section 4.1 above, EKR shall at its own cost and expense liaise with the relevant Regulatory Authorities in respect of each Marketing Authorization and notify PPI of all material communications relating thereto. The cost of submitting any data generated by any Phase IV studies conducted by EKR which is required to be filed with the FDA shall be borne by EKR and the cost of submitting any other data (including data submitted to support the use of the Product for additional indications) shall also be borne by EKR;

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- 4.3 Submission of Promotional Materials. Pursuant to Section 4.1 above, EKR shall at its own cost and expense submit and obtain the approvals of Regulatory Authorities in the Territory of Promotional Materials as required by Applicable Laws;
- 4.4 Pre-Launch and Post Launch Activities. Pursuant to Section 4.1 above, EKR shall at its own cost and expense carry out reasonable pre-launch market development and conduct such post-marketing clinical trials (as determined solely by EKR in its reasonable business judgment) in accordance with the Marketing Plan. Any data resulting from such trials shall be owned by EKR but shall be provided on a royalty-free license to PPI for use outside of the Territory. PPI shall cooperate with EKR in connection with such pre-launch and post launch activities as provided in sections 3.3 and 3.14 hereof;
- 4.5 Launch of Products. Pursuant to Section 4.1 above, EKR shall at its own cost and expense launch and achieve Commercial Launch of the Products in accordance with the Marketing Plan but no later than 18 months following receipt of Marketing Authorization in each country in the Territory provided however that EKR shall not be obligated to launch such Product in such country of the Territory where the approved pricing in such country provides EKR a gross margin of less than [\*\*]% (after payment of Royalties, Additional Royalties and Cost of Goods) or where the launch of the Product in such country of the Territory as determined by EKR is not commercially reasonable.
- 4.6 Marketing Activities. EKR shall at its own cost and expense, during the term of this Agreement, promote, market, sell and distribute the Products to customers within the Territory and provided that PPI has supplied EKR with necessary quantities of Product, satisfy the demand for the Product throughout the Territory. EKR shall be solely responsible for, and shall bear all costs associated with, all marketing and selling activities related to the Products in the Territory;
- 4.7 SubDistributors. EKR shall at its own cost and expense maintain, or use reasonable commercial efforts to ensure that sub-distributors maintain, adequate sales and, where



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appropriate, warehouse facilities and employ, or use reasonable commercial efforts to procure that sub-distributors employ, a sufficient number of experienced, trained and qualified personnel to promote the sale of the Product in the Territory and perform, or procure the performance of the activities set forth in the Marketing Plan;

- 4.8 Inventory and Promotional Materials. EKR shall maintain a sufficient inventory of Product and support material to reasonably fulfill the requirements of its customers in the Territory provided that, subject to Section 17.5, PPI shall comply with the Supply Agreement;
- 4.9 Records. EKR shall maintain adequate records concerning the sale of the Product as required by any applicable Regulatory Authority in the Territory;
- 4.10 Promotional Materials. EKR shall provide PPI with copies of the Promotional Materials proposed to be used in connection with the sale of the Products in the United States for approval, solely with respect to Trademark usage, (such approval not to be unreasonably withheld, conditioned or delayed) to the extent such Promotional Materials include any Trademark. EKR shall submit such Promotional Materials to PPI at least five (5) business days in advance of its intended use of the same and such Promotional Material shall be deemed to have received PPI's approval unless PPI Provides EKR with written notice of rejection within said five (5) business day period and EKR shall be authorized to finalize and use same. For the avoidance of doubt, any Trademark usage set forth on any Promotional Materials in use as of or prior to the Agreement Date are hereby deemed to be approved by PPI.
- 4.11 Adverse Events. Each Party shall promptly provide the other Party with all information in its possession or otherwise coming to its attention relating to the occurrence of a serious adverse event or an adverse event (in any jurisdiction throughout the world) in connection with the Product, and promptly forward to such other Party information concerning any and all charges, complaints or claims reportable to any Regulatory Authority relating to the Product that may come to the first Party's attention, and

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otherwise comply in all respects with the adverse drug event reporting and recall procedures set out or referred to in the Supply Agreement from time to time. EKR shall be responsible, to the extent required by Applicable Law, to report all charges, complaints or claims reportable to any Regulatory Authority outside of the United States relating to the Product, as well as any such charges, complaints or claims reportable to any Regulatory Authority inside the United States to the extent such charges, complaints or claims are made after the Agreement Date.

- 4.12 Permits. EKR shall obtain and maintain all necessary licenses, permits, records and authorizations required by Applicable Laws as holder of the Transferred NDA after the Agreement Date and in order to exercise the Distribution Rights and observe and comply with all Applicable Laws, ordinances, rules and regulations including, but not limited to those of the applicable Regulatory Authorities in the exercise of the Distribution Rights save insofar as PPI is required to obtain the same as holder of the Marketing Authorizations prior to the Agreement Date, or under the terms of this Agreement;
- 4.13 Compliance. EKR shall conduct the promotion and marketing and sale of the Products in accordance with Applicable Laws and with all due care and diligence.
- 4.14 Sales and Promotional Activities. In connection with the promotion, marketing and sale of the Product, EKR shall, without limitation:
- (a) observe and comply with such storage, stock control and operational practices and procedures as may be legally required in the Territory and as reasonably specified in writing by PPI from time to time;
  - (b) from time to time consult with PPI's representatives for the purpose of assessing the state of the market in each country of the Territory and permit representatives of PPI, on reasonable prior notice, to inspect any premises or documents used in connection with the marketing, distribution and sale of the Products;

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- (c) provide PPI on reasonable prior notice but not more than once in any Calendar Year, copies of its up-to-date price list for the Product together with full details of standard discounts and any special pricing arrangements entered into or proposed to be entered into;
  - (d) market the Product throughout the Territory under the Trademarks and any EKR trademarks and ensure that all marketing materials for the Product shall display the Trademarks; and
  - (e) comply with all applicable regulatory and statutory requirements imposed in relation to the Product, including, without limitation, those imposed by the US Drug Enforcement Agency (“**DEA**”) and other equivalent agencies in the Territory.
- 4.15 Prohibition on Sales Outside the Territory. EKR shall not directly or indirectly market distribute and/or sell the Product outside the Territory, or sell the product to any Third Party that EKR knows intends to sell or distribute the Product outside the Territory. In addition, the Parties acknowledge that since the Product is a controlled substance, the DEA and other law enforcement agencies will not permit any sale outside the Territory without relevant clearances and approvals.
- 4.16 Non-Compete. EKR shall not, during [\*\*], market, distribute or sell a Competing Product in the Territory unless during such time an A/B rated generic product of the Product(s) is launched in such country of the Territory or in the event this Agreement is terminated or EKR exercises its rights under Section 17.4 hereof.
- 4.17 PPI as Exclusive Provider. During the Term, except if PPI is unable to supply Products (including, but not limited to, in connection with EKR’s exercise of its rights under Section 17.5 below) or as provided in the Supply Agreement, EKR shall purchase all of its requirements for the Product from PPI.
- 4.18 Packaging. During the Term, EKR shall not use in relation to the Product any packaging, labeling and Product inserts, nor any advertising literature that has not been

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approved by PPI in writing with respect to Trademark usage (such approval not to be unreasonably withheld, conditioned or delayed) or deemed approved pursuant to Section 4.10, to the extent such materials include any Trademark. EKR shall be responsible for insuring that any packaging, labeling and Product inserts, and advertising literature complies with Applicable Laws.

- 4.19 Customer Orders. If EKR receives a request from a customer located outside the Territory for supply of the Product outside of the Territory, EKR shall promptly forward such request to PPI.
- 4.20 Governmental Rebates. Any discounts, rebates, or promotional allowances/incentive programs provided are “discount[s] or other reduction[s] in price” for purposes of 42 U.S.C. Section 1320a-7b(b)(3)(A) and may be subject to the reporting requirements under state and federal Medicaid and Medicare laws. EKR represents that it is aware of its obligations to report discounts resulting from this Agreement to the appropriate reimbursing agencies and authorities (including Medicaid and Medicare). EKR is responsible for complying with and agrees to comply with all applicable requirements, if any, in respect of providing information on such discounts to reimbursing agencies (including Medicaid and Medicare) and other entities in accordance with Applicable Laws and regulations.
- 4.21 Resale Pricing. In exercising the Distribution Rights, EKR shall determine resale pricing of the Products in its sole discretion.
5. **Commercialization Committee**.
- 5.1 Establishment of Committee. The Parties have established a Commercialization Committee (“**Committee**”) consisting of 4 individuals (“**Committee Members**”); 2 of whom were nominated by PPI; and 2 of whom were nominated by EKR. The Committee Members may be replaced by notice to the other Party and shall be appropriately qualified and experienced in order to make a meaningful contribution to Committee meetings.

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- 5.2 Purpose. The purpose of the Committee is to provide a forum for the Parties to share information and knowledge on the on-going Commercialization of the Product including, but not limited to, monitoring progress on clinical studies, reviewing clinical trial programs, discussing the appropriate regulatory strategy for the Products in the Territory, considering proposed marketing and promotional plans, reviewing competitor activity and discussing any regulatory, technical, quality assurance or safety issues in relation to the Product. The Committee shall conduct its discussions in good faith with a view to operating to the mutual benefit of the Parties and in furtherance of the successful development and marketing of the Products.
- 5.3 Meetings. The Committee shall meet as often as the Committee Members may determine, but in any event not less than 2 times per Calendar Year. The Committee may invite individuals with special skills to attend such meetings where considered to be relevant and appropriate. The quorum for Committee meetings shall be 2 Committee Members, comprising 1 Committee Member from each Party.
- 5.4 Marketing Plan. The Parties acknowledge that EKR has provided the Committee with its Marketing Plans for Calendar Years 2008 and 2009 pursuant to the Original Agreement. EKR shall on or before October 15<sup>th</sup> 2009 and October 15<sup>th</sup> of each Calendar Year thereafter provide the Committee with its Marketing Plan for the coming Calendar Year. Each Marketing Plan shall include, without limitation, Net Sales targets and projections with respect to sales force staffing levels, market research, physician education, marketing expenditure, post-approval clinical trials and advertising. With regard to pre-marketing clinical trials, the design and conduct shall be subject to the written approval of PPI, such approval not to be unreasonably withheld or delayed.
- 5.5 Decision Making. Decisions of the Committee shall be made as follows:
- (a) The Committee may make decisions with respect to any subject matter that is subject to the Committee's decision-making authority. Except as expressly provided in this Agreement, all decisions of the Committee

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shall be made by unanimous vote or written consent, with EKR and PPI each having, collectively, one vote in all decisions. The Committee shall use commercially reasonable efforts to resolve the matters within its roles and functions or otherwise referred to it.

- (b) If, with respect to a matter that is subject to the Committee's decision-making authority, the Committee cannot reach consensus within 15 days after it has met and attempted to reach such consensus or the Parties cannot reach consensus on whether the Committee has decision-making authority regarding a matter within 15 days after such matter was first raised by either Party, the dispute in question shall be referred to the Chief Executive Officer of PPI, on behalf of PPI, or such other person holding a similar position designated by PPI from time to time, and the Chief Executive Officer of EKR, or such other person holding a similar position designated by the EKR from time to time (such officers collectively, the “**Executive Officers**”), for resolution. The Executive Officers shall use reasonable efforts to resolve the matter referred to them.
- (c) If the Executive Officers cannot resolve the matter in accordance with Section 5.5(b) within 30 days of the reference of the matter to them, then EKR shall have the final decision-making authority if the matter relates to the sale or marketing of the Product in any country of the Territory and PPI shall have the final decision-making authority if the matter relates to the development, manufacture or Trademarks of the Product.

6. **Fees, Milestones and Royalties.**

- 6.1 **Up-Front Payment.** In consideration for work previously undertaken by PPI in respect of the Product, the Parties acknowledge that EKR has paid a non-refundable, non-creditable up front payment of \$[\*\*] to PPI pursuant to the Original Agreement.
- 6.2 **Deferred Milestone Payments.** As further consideration for the work previously undertaken by PPI and in consideration for the license and grant of the Distribution Rights to EKR under this Agreement, EKR shall pay to PPI the following milestone payments (the “**Deferred Milestone Payments**”) on the date when due:

<u>Deferred Milestone</u>	<u>Due Date</u>
\$[**] (the “First Deferred Milestone”)	The Parties acknowledge that EKR has paid the First Deferred Milestone to PPI prior to the Agreement Date.
\$[**] (the “Second Deferred Milestone”)	Within three (3) days of the Agreement Date, EKR shall pay the Second Deferred Milestone.

6.3 **Advanced Royalty Payment to PPI.**

- (a) Within three (3) days of the Agreement Date, EKR shall make an advanced Royalty payment to PPI of \$[\*\*] (the “**Advanced Royalty Payment**”), which will be offset against EKR’s payment obligations or otherwise repaid to EKR as set forth below in this **Section 6.3.**
- (b) Offsets and/or repayment of the Advanced Royalty Payment shall commence on [\*\*] and shall continue, unless sooner paid, through [\*\*] (the “**Royalty Offset Period**”) and such offsets will be taken by EKR (and such repayment will be made by PPI) as follows:
- (i) by a reduction in Royalties due under **Section 6.4** of this Agreement of \$[\*\*] for each [\*\*] mg vial of Product sold during the Royalty Offset Period and \$[\*\*] for each [\*\*] mg Vial of Product sold during the Royalty Offset Period (collectively the “**Royalty Offset**”) which amounts shall be deducted by EKR from any Royalty payments due PPI and reflected in the quarterly and annual reports required in **Section 6.5** of this Agreement;

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- (ii) by payment to EKR of [\*\*] percent ([\*\*]%) of any purchase price payments, license fees, other access fees or royalties received by PPI or any of its Affiliates after the Agreement Date in connection with the license (to the extent permitted hereunder) or transfer of any rights to the Product (and/or any underlying intellectual property rights) in the Field in the Territory to a Third Party (other than pursuant to any transaction described in Section 6.3(b)(iii) below), which payment shall be made by PPI to EKR within ten (10) days of PPI's receipt of such payments; and
  - (iii) upon any Change of Control (as defined in Section 20.4) of PPI, by repayment to EKR in full of the balance of the Advanced Royalty Payment not previously used for offsets, which payment shall be made to EKR by PPI within ten (10) days after the closing date (without any conditions) of any such Change of Control.



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- (c) Notwithstanding Section 6.3(b), effective July 1, 2013, the balance of the Advanced Royalty Payment that is available for subsequent offsets and/or repayments under Section 6.3(b) above shall be reduced to the lesser of (x) \$[\*\*] or (y) the actual amount of such balance as calculated based upon any payments and offsets deducted to date from the beginning Advanced Royalty Payment balance of \$[\*\*], as outlined in clauses (i) and (ii) of Section 6.3(b) above. As of [\*\*] the balance of the Advanced Royalty Payment shall have been deemed repaid in full by PPI and no additional offsets to or repayments of the Royalties shall thereafter be applied for any reason.
- (d) Notwithstanding anything to the contrary, in the event EKR exercises its right of termination pursuant to Section 16.3(b) of this Agreement or PPI terminates this Agreement pursuant to Section 16.1(a): (i) EKR will sell the Transferred Equipment back to PPI, subject to payment by PPI to EKR (within five (5) days of the date of termination) of \$[\*\*] in cash and cancellation of any remaining obligation of EKR under the Promissory Note, (ii) the Advanced Royalty Payment shall be deemed to have been repaid in full, and EKR shall not have the right to the Royalty Offset between the date of notice of such termination and the termination date of the Agreement and (iii) EKR shall promptly transfer the Marketing Authorizations to PPI or its nominee in accordance with Section 17.1(e) below.

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- (e) Notwithstanding anything to the contrary, during the Royalty Offset Period, or until such time that the Advanced Royalty Payment balance has been fully repaid, the combined Royalty and Supply Price (as defined in the Supply Agreement) shall not exceed [\*\*] percent ([\*\*]%) of the net average selling price of the Product.
  - (f) For the avoidance of doubt, the Royalty Offset described in clause (i) of Section 6.3(b) shall not be applied against any Additional Royalty due PPI pursuant to Section 6.4.

6.4 Royalties. As further consideration for the license and grant of Distribution Rights and other rights under this Agreement, EKR shall pay to PPI a royalty (“**Royalty**”) equal to (a) \$[\*\*] for each [\*\*] mg Vial of Product sold during the Term and \$[\*\*] for each [\*\*] mg Vial of Product sold during the Term (the “**Minimum Royalty**”) plus (b) an additional [\*\*]% of any post Effective Date incremental price increase implemented by EKR over the Current Base Price of \$[\*\*] for the [\*\*] mg Vial and \$[\*\*] for the [\*\*] mg Vial (the “**Additional Royalty**”); provided, however, that Additional Royalty shall not be payable to the extent that the sum of (i) the Minimum Royalty and Additional Royalty payable hereunder and (ii) the Supply Price (as defined in the Supply Agreement) shall at any time during the Term exceed [\*\*] percent ([\*\*]%) of the net average selling price of the Product (the “**Royalty Cap**”); provided, however, that the Royalty Cap shall be [\*\*] percent ([\*\*]%) of the net average selling price of the Product during certain periods as described in Section 6.3(e) above. EKR shall be entitled to offset certain amounts from Royalties payable hereunder as set forth in Section 6.3(b) above. Royalties on other presentations and dosages which hereafter receive Marketing Authorization in any country of the Territory shall be negotiated in good faith by the parties in a manner consistent with the Royalty currently being paid by EKR as of the date of the receipt of Marketing Authorization for such new presentations and dosages.

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- 6.5 Quarterly Reports and Annual Reports. Within 30 days of the end of each Quarter and within sixty (60) days of the end of each Calendar Year during the Term of this Agreement EKR shall send to PPI a statement setting out in respect of each country in the Territory in which Product is sold, details of Product sold during the previous Quarter or Calendar Year, as applicable, itemized by presentation form, quantity, total gross receipts, itemized deductions which are applied to achieve the Net Sales figure, and Net Sales of Product. The statement shall (where appropriate) show:
- (a) the total Net Sales for each country expressed both in local currency and in Dollars and the conversion rate used;
  - (b) the total number of Vials sold in each country (less properly rejected, returned or recalled Vials) for each of the [\*\*] mg Product and the [\*\*] mg Product (the “**Unit Sales**”);
  - (c) the applicable Royalty rate multiplied by the Unit Sales for each of the [\*\*]mg and [\*\*] mg Products in that Quarter (“**Prepayment**”) (or in that Calendar Year, as applicable);
  - (d) any Additional Royalties due in that Quarter (or for such Calendar Year);
  - (e) the total Royalties payable on those Unit Sales (subject to the Royalty Cap) in accordance with Section 6.4, and any deductions taken pursuant to Section 6.3.
- 6.6 Payment. EKR shall pay to PPI, any Minimum Royalties and Additional Royalties due within forty-five (45) days of the end of each Quarter as the case may be subject to reconciliation at the end of each Calendar Year as set forth in Section 6.9.
- 6.7 Reserved.
- 6.8 Reserved.
- 6.9 Reconciliation. Within forty-five (45) days of the end of each Contract Year, there shall be a reconciliation between the sums paid under Section 6.6 and the Royalties payable under Section 6.4, and any payment due (or in the event of an overpayment by EKR to PPI) such amounts shall be paid by one Party to the other within thirty (30) days of the resolution of such reconciliation.

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6.10 Withholdings. In the event that a Party is required under the laws of a country or other political subdivision of competent jurisdiction to withhold any tax to the tax or revenue authorities in such jurisdiction in connection with any payment to the other Party, such amount shall be deducted from the payment to be made by such withholding Party; provided that the withholding Party shall take reasonable and lawful actions to avoid and minimize such withholding and promptly notify the other Party so that the other Party may take lawful actions to avoid and minimize such withholding. The withholding Party shall promptly furnish the other Party with copies of any tax certificate or other documentation evidencing such withholding as necessary to satisfy the requirements of the appropriate regulatory authority related to any application by such other Party for foreign tax credit for such payment. Each Party agrees to reasonably cooperate with the other Party in claiming exemptions from such deductions or withholdings under any agreement or treaty from time to time in effect.

7. **Payment, Accounting, Audit Rights**.

7.1 Currency. Unless otherwise agreed between the Parties, all payments to be made hereunder shall be made in US Dollars. Net Sales shall be determined in the currency in which the Product was sold and shall, if necessary, be converted into US Dollars using the noon buying rate as published in the Wall Street Journal for the last day of the Quarter for which such payment is being determined.

7.2 Maintenance of Records. EKR shall maintain and shall procure the maintenance of accurate and up to date records and books of account showing the quantity, description and value of the Products supplied in each country of the Territory during the previous six (6) Calendar Years.

7.3 Inspection. EKR shall during business hours, on no less than 14 day's notice from PPI and not more than once in any Calendar Year, make available for inspection the records

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and books referred to in Section 7.2. Such inspection shall be undertaken by an independent auditor appointed by PPI and reasonably acceptable to EKR for the purpose of verifying the accuracy of any statement or report given by EKR to PPI and/or the amount of Royalties due. Upon completion of such inspection, PPI shall not be entitled to inspect nor shall EKR be required to make available the records and books for any Calendar Year for which such inspection was previously undertaken.

- 7.4 Confidentiality. PPI shall procure that any independent auditor appointed under Section 7.4 shall maintain all information and materials received, directly or indirectly, by it from EKR in strict confidence and shall not use or disclose the same to any Third Party nor to PPI save for the sole purpose of conducting the audit pursuant to this Section.
- 7.5 Audit. In the event that an auditor appointed pursuant to this Section concludes that there has been an underpayment or overpayment, PPI shall deliver to EKR a copy of such auditor's report. Any deficit payable by EKR or any excess refundable by PPI shall be payable within 30 days of EKR's receipt of such report. The fees charged by such auditor shall be payable by PPI, provided that if the audit reveals that payments due to PPI for any Calendar Year have been understated by more than **[\*\*]**%, the fees charged by such auditor shall be payable by EKR.
- 7.6 Interest. Should any amount not be paid by either Party on or before the due date for payment interest on such unpaid amount at the rate of **[\*\*]**% above the prime lending rate of Citibank, N.A. (or its successor in interest) in effect from time to time and such interest shall be calculated and payable in respect of the period from the date such amount is due until the date payment in full is received in cleared funds.
8. **Intellectual Property and Trademarks.**
- 8.1 Limitation of License. Except as set out in this Agreement, all right, title and interest in the PPI IP or Trademarks shall belong to PPI and EKR shall not have any right, title or interest in the PPI IP or Trademarks.

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- 8.2 Trademark Standards. EKR shall use the Trademarks in a manner which conforms to the reasonable directions and standards notified to it by PPI from time to time and not do anything which could, in the PPI's reasonable opinion, bring the Trademarks or PPI into disrepute or otherwise damage the goodwill attaching to the Trademarks.
- 8.3 Maintenance of Trademarks. PPI shall, at its own cost, take all steps required to maintain those registrations for the Trademarks subsisting at the Effective Date, and prosecute any applications subsisting at the Effective Date for registration of the Trademarks through to grant (including oppositions thereto) in each country of the Territory.
- 8.4 Additional Trademark Registrations. EKR may request that PPI use reasonable efforts to obtain Trademark registrations in respect of the Trademarks, in classifications which cover the Product, in any countries in the Territory. PPI shall promptly notify EKR if it does not intend to make or pursue any such Trademark registration in any of the countries in the Territory and EKR shall thereafter be entitled to make applications for such Trademark registrations in its own name.
- 8.5 Domain Names. EKR shall have the right during the Term to register domain names in its own name specific to the countries comprised in the Territory that incorporate the Trademark.
- 8.6 Improvements. PPI Improvements shall be owned by PPI and be licensed to EKR hereunder. EKR Improvements shall be owned by EKR and upon termination of this Agreement by PPI pursuant to Section, shall be deemed be licensed to PPI on a worldwide, non-exclusive, irrevocable basis, at a royalty or for such other consideration as may be mutually agreed upon by the parties in writing. Joint Improvements shall be owned jointly by the Parties, and PPI's interest therein shall be licensed to EKR hereunder.

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9. **Representations and Warranties.**

9.1 **Representations and Warranties of Both Parties.** Each Party represents and warrants to the other Party as of the Effective Date, that:

- (a) **Organization.** Such Party is duly organized and validly existing and in good standing of the laws of the jurisdiction of its incorporation and it has full power and authority and legal right to enter into this Agreement and perform the obligations under it;
- (b) **Authorization.** Such Party has taken all corporate action such that the execution and delivery of this Agreement and the consummation of the transaction contemplated hereby has been duly authorized by all necessary actions;
- (c) **Valid Obligation.** This Agreement is a legal and valid obligation of such Party, binding on each of the Parties and enforceable in accordance with its terms;
- (d) **Execution and Delivery.** The execution and entry into and exercise of the respective rights and obligations under this Agreement including the granting of rights to the other Party pursuant to this Agreement do not, and will not conflict with, or violate any provision of any agreement or other instrument or document to which it is Party or affect or be in conflict with or result in the breach of or constitute a default under any such agreement, instrument or document or conflict with any rights granted by such Party to any Third Party or breach any obligation that such Party has to any Third Party; and
- (e) **Debarment.** It is not currently debarred, suspended or otherwise excluded by the United States, under any Federal law, including, without limitation, the Generic Drug Enforcement Act of 1992, or by any other country in the Territory under any analogous law, rule or regulation, and does not and will not use in any capacity the services of any person debarred under applicable law, rule or regulation, in the Territory in the performance of its obligations under this Agreement.

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9.2 Representations and Warranties of PPI. PPI hereby represents and warrants to EKR as of the Effective Date that:

- (a) Ownership; Validity. It is the owner of, or has exclusive rights to, all of the PPI IP and Trademarks in existence on the Effective Date, and has the exclusive right to grant the Distribution Rights and other rights granted under this Agreement. All of the PPI Patents in existence on the Effective Date are valid, enforceable, in full force and effect and have been maintained to date and are not the subject to any interference or opposition procedures. All of the PPI Patents listed in the Orange Book are properly filed in accordance with Applicable Laws;
- (b) Third Party Interests. There are no Third Party interests or rights in the PPI IP or Trademarks that may prevent, encumber or restrict the exercise by EKR of the Distribution Rights or other rights granted under this Agreement.
- (c) Third Party Infringement. No Third Party is infringing or has infringed the intellectual property rights of PPI in any of the PPI IP or Trademarks;
- (d) Distribution Rights and other Rights. That neither the Products, the exercise of EKR's Distribution Rights and other rights granted under this Agreement or the manufacture of the Products as contemplated by this Agreement or the Supply Agreement do not and will not infringe or conflict with any Third Party intellectual property rights and EKR will not incur any obligation to any Third Party by the exercise of the rights granted hereunder;
- (e) Renewal and Maintenance Fees. All renewal and maintenance fees and all steps necessary for the filing, prosecution and maintenance of the PPI



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Patents and Trademarks due and payable as of the Effective Date have been paid or taken and there are no actions due within 180 days of the Effective Date;

- (f) Trademarks. The Trademarks are the only trademarks, trade dress or service marks related to the Product that are owned by PPI or licensed by PPI (with the right to sublicense);
- (g) Adverse Events. To its knowledge and belief all information, data and Third Party notices in relation to adverse events serious adverse events or recalls with respect to the Product and of which PPI is aware have been disclosed by PPI to EKR;
- (h) Access to Documents. PPI has provided EKR or given EKR access to true, complete and unredacted copies of all (i) regulatory documentation or (ii) material agreements between PPI and any Third Party including all effective amendments to any such agreements which in any event (A) affects or may affect EKR's rights under this Agreement or (B) relates to the Product;
- (i) No Brokers. Neither PPI nor any office, director or agent of PPI has employed any broker, finder or agent with respect to this Agreement or the transactions contemplated hereby;
- (j) Right to License. PPI has the right to use and license PPI IP and Trademarks free and clear of any material liens, security, interests, licenses, obligations, transfer agreements, enforceable claims or encumbrances;
- (k) Litigation. There is no litigation, arbitration, proceeding, governmental investigation, action or claim of any Third Party or to the knowledge of PPI threatened by or against PPI relating specifically to the PPI IP, or the Trademarks which would impede, impair, restrict or interfere with the rights granted EKR hereunder or the ability of PPI to perform its obligations hereunder; and

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- (l) Customer Lists. PPI has or prior to the Effective Date will have provided EKR with complete and accurate lists of the names and addresses of all material customers and suppliers of the Products.
  - (m) Permits. PPI has and shall maintain at all times during the Term all necessary license, permits, records and authorizations required by Applicable Laws necessary to perform its obligations hereunder and shall observe and comply with all Applicable Laws, ordinances, rules and regulations including those of the applicable Regulatory Authorities and governmental entities including but not limited to DEA in the performance of its obligations hereunder.
  - (n) ICS Agreement. All amounts due under the ICS Agreement as of or prior to the Effective Date have been paid in full. PPI is not in, nor has PPI given or received notice of, any default or claimed, purported or alleged default, or facts that, with notice or lapse of time, or both, would constitute a default (or give rise to a termination right) on the part of any person in the performance of any obligation to be performed under the ICS Agreement. A true and complete copy of the ICS Agreement, including any amendments thereto, has been delivered to EKR.

10. **Liability, Insurance and Indemnities**

10.1 Indemnification of EKR. PPI shall be liable for and shall defend, indemnify and hold harmless EKR and its Affiliates and their officers, directors, agents, representatives, consultants and employees (individually an “**EKR Indemnified Party**” and collectively the “**EKR Indemnified Parties**”) and any of them from and against any and all Claims (as defined below), arising in connection with or relating to:

- (a) The development, manufacture, sale and supply of the Product prior to the Effective Date (including Claims arising after the Effective Date to the extent they are based on events occurring prior to the Effective Date);

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- (b) The manufacture of the Product by or on behalf of PPI (including, but not limited to, any manufacture of Product or any other product by EKR for the Other PPI Customers pursuant to Section 3.20(l)) except to the extent that such Claims arise from (i) the negligence or willful misconduct of EKR or its Affiliates, (ii) the breach by EKR of the terms of this Agreement or (iii) the manufacture of Product by EKR in accordance with EKR's exercise Step-in Right for supply of Product to EKR or its Affiliates;
  - (c) Claims which arise outside the Territory (except to the extent that the Claim has arisen from any act or omission by EKR);
  - (d) A breach by PPI of any representation, warranty, covenant or agreement contained in this Agreement, the Supply Agreement or the Transition Services and Inventory Agreement;
  - (e) PPI's failure to comply with any Applicable Law in connection with the performance of its obligations hereunder or under the Supply Agreement or the Transition Services and Inventory Agreement, or prior to the Effective Date; and
  - (f) Any Claims related to Product sold by parties other than EKR prior or subsequent to the Effective Date.
  - (g) Liabilities arising under the ICS Agreement prior to the Effective Date and subsequent to the Effective Date for Products sold by parties other than EKR or under the direction of EKR or arising under the Transition Services and Inventory Agreement.

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10.2 Indemnification of PPI. EKR shall be liable for and shall defend, indemnify and hold harmless PPI from and against any and all Claims arising from (i) EKR's exercise of the Distribution Rights or arising under the Transition Services and Inventory Agreement, (ii) a breach by EKR of any representation, warranty, covenant or agreement contained in this Agreement, the Supply Agreement or the Transitions Services and Inventory Agreement, or (iii) EKR's failure to comply with Applicable Laws in connection with its performance of its obligations hereunder, or (iv) Claims related to the manufacture of Products by EKR or by a Third Party Manufacturer designated by EKR pursuant to Section 11.5 of the Supply Agreement, except to the extent that such Claims:

- (a) relate to any act or circumstance occurring prior to the Effective Date;
- (b) relate to Intellectual Property infringement proceedings with Third Parties in connection with the PPI IP and Trademarks (except to the extent that the Claim has arisen from EKR's use of the PPI IP or Trademarks other than in accordance with this Agreement);
- (c) arise outside the Territory (except to the extent that the Claim has arisen from any act or omission by EKR);
- (d) relate to the development or manufacture of the Product by PPI or its Affiliates or its or their agents or sub-contractors;
- (e) Arise under the ICS Agreement after the Effective Date for Products sold by EKR.
- (f) result from the negligence, willful default or material breach of any representation or warranty given under this Agreement, the Supply Agreement, or the Transition Services and Inventory Agreement by PPI, its Affiliates or sub-contractors; or
- (g) are the responsibility of PPI under Section 10.1 above.

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- 10.3 Conditions to Indemnification. Promptly after receipt by a Party of any Claim or alleged claim or notice of the commencement of any action, administrative or legal proceeding, or investigation as to which the indemnity provided for in this Section 10 may apply, the indemnified Party shall give written notice to the indemnifying Party of such fact. The indemnifying Party shall have the option to assume the defense thereof by election in writing within thirty (30) days of receipt of such notice. If the indemnifying Party fails to make such election, the indemnified Party may assume such defense and the indemnifying Party will be liable for reasonable legal and other expenses subsequently incurred in connection with such defense. The Parties will co-operate in good faith in the conduct of any defense, provide such reasonable assistance as may be required to enable any Claim to be properly defended, and the Party with conduct of the action shall provide promptly to the other Party copies of all proceedings relating to such action.
- 10.4 Assumption of Defense. Should the indemnifying Party assume conduct of the defense:
- (a) the indemnified Party may retain separate legal advisors in the event that it reasonably concludes that it may have defenses available to it which are additional to, different from or inconsistent with those available to the indemnifying Party, in which case the indemnifying Party shall not be liable for the indemnified Party's reasonable costs and expenses so incurred; and
  - (b) the indemnifying Party will not, except with the consent of the indemnified Party (such consent not be unreasonably withheld or delayed), consent to the entry of any judgment or enter into any settlement (other than for the payment of damages by the indemnifying Party, which includes as an unconditional term a release from the claimant to the indemnified Party from all liability in respect of all claims).

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- 10.5 Settlement of Claims. The indemnified Party shall not admit liability in respect of, or compromise or settle any such action without the prior written consent of the indemnifying Party, such consent not to be unreasonably withheld or delayed.
- 10.6 Insurance. Each Party shall maintain, at its own cost, comprehensive product liability insurance, general commercial liability insurance and business interruption insurance at a level which is reasonable and customary taking into account the nature of the Product but which shall have combined limits of not less than \$[\*\*] per occurrence. Such insurance shall be with a reputable insurance company and where reasonably possible (taking into account the availability of such insurance) shall be maintained for not less than [\*\*] ([\*\*]) years following the expiry or termination of this Agreement. During the Term, neither Party shall do or omit to do any act, matter or thing which could prejudice or render voidable any such insurance. Each Party will provide to the other Party evidence of its insurance and thirty (30) days prior written notice of any cancellation of its coverage or reduction in coverage from the requirements stated herein.
- 10.7 Third Party Liability. Each of the Parties shall be liable to the other for legal liability to Third Parties in respect of all claims, actions, judgments, damages, lawsuits, costs or expenses or professional fees for death or personal injury incurred by such other Party in relation to or arising out of any breach of this Agreement, the Transition Services and Inventory Agreement or the Supply Agreement by the first Party or of any gross negligence or willful act of the first Party, or its employees in the course of their employment.
- 10.8 PPI Liability Limitation. Any and all liability of PPI to EKR howsoever arising in respect of this Agreement, the Transition Services and Inventory Agreement or the Supply Agreement and their performance, in contract tort or otherwise, shall be limited (except for death or personal injury caused by the negligence of PPI or its employees while acting in the course of their employment) to [\*\*] US Dollars (\$[\*\*]); provided

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however that such limitation shall not apply to the extent that EKR or any EKR Indemnified Party is required to pay in excess of such amount to a third party in respect of a final judgment or order obtained by the third party or as a result of PPI's breach of Section 7.2.12 of the Supply Agreement.

- 10.9 EKR Liability Limitation. Any and all liability of EKR to PPI howsoever arising in respect of this Agreement, the Transition Services and Inventory Agreement or the Supply Agreement and their performance in contract tort or otherwise shall be limited (except for death or personal injury caused by the negligence of EKR or its employees while acting in the course of their employment, and except in relation to any specified payment, lump sum, milestone or royalty payment unpaid) to [\*\*] US Dollars (\$[\*\*]); provided however that such limitation shall not apply to the extent that PPI or any PPI Indemnified Party is required to pay in excess of such amount to a third party in respect of a final judgment or order obtained by the third party.
- 10.10 Limitation of Damages. Notwithstanding anything contained in this Agreement or the Transition Services and Inventory Agreement or the Supply Agreement in no circumstance shall either Party be liable to the other in contract, tort (including negligence or breach of statutory duty) or otherwise howsoever, and whatever the cause thereof, for any special, indirect or consequential loss or damage of any nature whatsoever except in the cases of fraud or intentional misconduct or in the case of PPI as a result of PPI's breach of Section 7.2.12 of the Supply Agreement.
- 10.11 Definition of Claims. In this Section 10, "**Claims**" shall mean any and all claims, actions, demands, losses, damages, costs and reasonable expenses (including, without limitation, reasonable legal and expert fees) made or brought by Third Parties.
11. **Confidentiality, Press Releases and Publications**
- 11.1 Confidential Information. PPI and EKR undertake to each other to keep confidential, and to procure that their respective Affiliates, employees, directors, officers, contractors, lawyers and accountants (including those of their Affiliates) keep confidential, Confidential Information disclosed to it by or belonging to the other Party.

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- 11.2 Third Party Disclosure. Any Confidential Information received from the other Party shall not be disclosed to any Third Party or used for any purpose other than as provided or specifically envisaged by this Agreement or as required in connection with any securities offering, financing, merger, acquisition or other corporate transaction involving such Party provided that any Party to whom such disclosure is made is bound by obligations as to confidentiality that are at least as protective of Confidential Information as those contained herein.
- 11.3 Duration. The confidentiality and non-use obligations contained in this Agreement shall continue for the duration of this Agreement and for a period of [\*\*] ([\*\*]) years after termination for any reason of this Agreement.
- 11.4 Public Announcements. The Parties shall consult with each other, in advance, with regard to the terms of all proposed press releases, public announcements and other public statements with respect to the transactions contemplated under this Agreement. The Parties acknowledge that they have issued a joint press release in the form set out in Schedule VI of this Agreement.
- 11.5 Exceptions to Disclosure of Confidential Information. The Confidential Information may be disclosed by the other Parties to the extent that such disclosure has been ordered by a court of law or directed by a governmental authority, provided that, wherever practicable, the Party disclosing the Confidential Information has been given sufficient written notice in advance to the other Party to enable it to seek protection or confidential treatment of such Confidential Information, and may be disclosed only to the extent that such disclosure has been so ordered or directed.

12. **Patents**

- 12.1 Maintenance. PPI shall pay all costs and expenses of the filing, prosecution and maintenance of the PPI Patents in each country of the Territory so as to maintain the



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PPI Patents in full force and effect. PPI will consult with EKR with respect to any notice from or correspondence with the USPTO or any other governmental entity with respect thereto and the development, filing and prosecution of any subdivisions, continuations, continuations in part or additional applications related to the Product for use in the Field in the Territory.

13. **Infringement of Third Party Rights**

13.1 **Notice of Infringement**. In the event of a Party becoming aware that the exercise of either Party's rights and obligations pursuant to this Agreement are infringing or may infringe the rights of a Third Party, it will promptly notify the other Party and provide it with such details of the Third Party rights and the extent of the infringement as are known to it.

13.2 **Infringement of Third Party IP**. In the event a claim of infringement of a Third Party's intellectual property rights arising out of the manufacture, use, sale, promotion or distribution of the Products is brought against either Party, PPI shall defend such action at its cost and expense and take one or more of the following actions simultaneously or sequentially:

- (a) Defend the claim and indemnify and hold harmless EKR, its Affiliates, officers, directors, shareholders, employees, representations, consultants and agents (the "**EKR Infringement Indemnitees**") as set forth in Section 13.3 below.
- (b) Obtain for itself as the benefit of EKR the right through license or otherwise to utilize the technology upon which the claim of infringement was based. Such rights obtained by PPI from a Third Party under this Section 13.2 shall be licensed or sublicensed to EKR at no additional cost to EKR.

13.3 **Infringement Indemnification**. Notwithstanding any other provisions of this Agreement, PPI will defend, indemnify and hold harmless the EKR Infringement

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Indemnitees from and against all liabilities, losses, damages, actions, claims and expenses suffered or incurred by the EKR Infringement Indemnitees (including reasonable attorneys fees, court costs and expert witnesses' fees) resulting from any claims by any Third Party that EKR's exercise during the Term of the rights granted under this Agreement infringes or violates any license, patent, copyright, trademark or other intellectual property right of that Third Party.

14. **Infringement of PPI IP**

- 14.1 **Notice of Infringement.** In the event that either Party becomes aware of any actual or suspected infringement or misuse of the PPI IP or Trademarks in the Territory by a Third Party ("**Third Party Infringement**"), it shall promptly notify the other Party and provide it with all details thereof in its possession.
- 14.2 **Infringement Action.** Within a reasonable time of becoming aware of such Third Party Infringement, the Parties shall consult with each other and their respective counsel to develop a strategy for addressing the Third Party Infringement. In the event the Parties agree to the legal action to stop the Third Party Infringement, they shall agree upon legal counsel to prosecute such action and unless the Parties otherwise agree, PPI shall prosecute the action at its cost and expense. EKR shall provide all such assistance at PPI's cost and expense as PPI may reasonably require in the prosecution or defense of any such proceedings.
- 14.3 **Awards.** Any damages, award or settlement monies actually received by PPI in respect to such infringement and paid in compensation for sales lost by EKR shall be deemed Net Sales and be paid to EKR, subject to PPI deducting its costs and expenses in pursuing such infringement from such damages, award or settlement actually received. Any damages, award or settlement monies actually received by PPI in respect to such infringement and not paid in compensation for sales lost by EKR shall be shared equally by the Parties.

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- 14.4 Non Participation. Should in accordance with Section 14.2, PPI decide not to participate in any such infringement action, EKR may require PPI to bring the action, subject to reimbursement by EKR for reasonable out-of-pocket expenses incurred by PPI in connection with such action. The selection of counsel and all other material decisions with respect to such action shall be subject to EKR's prior, written approval, such approval not to be unreasonably withheld. In addition, EKR shall have the right to discontinue the prosecution of any such action at any time upon written notice to PPI. Except as provided above in this Section 14.4, PPI shall have control of such action but shall consult with EKR regarding the conduct of such action and shall not settle such action without the prior written consent of EKR, which consent shall not be unreasonably withheld, and EKR may, in such instance, retain any award or settlement in its entirety. Notwithstanding the foregoing, PPI shall offer reasonable assistance to EKR at no charge except for reimbursement of reasonable out of pocket expense including reasonable attorneys fees.
- 14.5 Cooperation. Each Party shall keep the other Party reasonably informed and consult with the other Party with regard to any infringement action under this Article 14.
15. Term
- 15.1 This Agreement shall commence on the Effective Date and, subject to earlier termination in accordance with the provisions of Section 16, shall continue in force for a period being the longer of fifteen (15) years from first Commercial Launch of the Product in the Territory or until the expiration of the last valid claim in the PPI Patents covering the Product in any country of the Territory (the "**Initial Term**"). Thereafter the term of this Agreement shall automatically renew for consecutive periods of two (2) years each. Notwithstanding the foregoing, this Agreement can be terminated by EKR at the end of the Initial Term by delivery of written notice to PPI at least one hundred eighty (180) days prior to the end of the Initial Term or any renewal term. As used herein "**Term**" refers to the Initial Term and any renewal terms.

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16. **Termination**

16.1 Prior Termination by Either Party. Either Party shall be entitled forthwith to terminate this Agreement by notice to the other if:

- (a) the other Party commits a material breach of any material obligation under this Agreement or the Supply Agreement, and in the case of a breach which is capable of remedy fails to remedy it within sixty (60) days of receipt of notice from the first Party of such breach and of its intention to exercise its rights under this Section; or
- (b) any representation or warranty made herein or in the Supply Agreement by such other Party proves to be incorrect when made which has a material adverse effect on the performance of the other Party's obligations hereunder and in the case of a breach which is capable of remedy fails to remedy it within sixty (60) days of receipt of notice from the first Party of such breach and of its intention to exercise its rights under this Section; or
- (c) the entry of a decree or order for relief by a court having jurisdiction in the premises in respect of the other Party in an involuntary case under the United States Bankruptcy Code, as now constituted or hereafter amended, or any other applicable foreign, federal or state insolvency or other similar law and the continuance of any such decree or order unstayed and in effect for a period of sixty (60) consecutive days; or
- (d) the filing by the other Party of a petition for relief under the United States Bankruptcy Code, as now constituted or hereafter amended, or any other applicable foreign, federal or state insolvency law or other similar law; or
- (e) the other Party becomes insolvent or takes the benefit of any statute for insolvent debtors or any steps are taken or proceedings commenced by any person for the dissolution, winding-up or other termination of such other Party's existence or the liquidation of its assets; or

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- (f) a trustee, receiver, receiver-manager or like person is appointed with respect to the business or assets of the other Party; or
  - (g) the other Party proposes or makes any composition or arrangement or composition with, or any assignment for the benefit of, its creditors; or
  - (h) anything analogous to any of the events described in Sections 16.1(c)-(k) – 16.1.6, inclusive, occurs under the laws of any applicable jurisdiction; or
  - (i) the other Party ceases or threatens to cease to carry on the whole or any material part of its business; or
  - (j) for reasons unrelated to any breach of either Parties' duties or obligations under or in connection with this Agreement, the other Party is prevented from performing any of its material obligations hereunder by any law, governmental or other action (other than laws of general application) and has not resumed performance in compliance with all Applicable Laws within one hundred twenty (120) days following the date on which such performance was first provided; or
  - (k) in accordance with Section 18.2 below.

16.2 Prior Termination by PPI.

- (a) Reserved.
- (b) PPI may terminate this Agreement with immediate effect in any country of the Territory where EKR is obligated to launch the Product pursuant to Section 4.5 if within [\*\*] months of the receipt of the Marketing Authorization for such country, EKR has not made its first Commercial Launch of the Product in that country.
- (c) In the event PPI has terminated the Supply Agreement pursuant to Section 10.2 thereof and EKR or its designee is manufacturing Products pursuant to Section 11.5 of the Supply Agreement, PPI shall have the right to terminate such rights of manufacture and this Agreement upon thirty (30)

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days prior, written notice to EKR only in the event Royalties and Additional Royalties paid hereunder in any one year period following the date of such termination are less than \$[\*\*], unless the difference between \$[\*\*] and the actual Royalties and Additional Royalties paid by EKR is paid to PPI within thirty (30) days of notice of such termination.

16.3 Prior Termination by EKR.

- (a) EKR may terminate this Agreement with immediate effect in any country of the Territory if the Products are withdrawn from the market in such country of the Territory as a result of regulatory action by FDA or other governmental entities or there are significant adverse reactions from use of the Products.
- (b) EKR may terminate this Agreement for convenience at any time upon [\*\*] ([\*\*]) days prior, written notice to PPI.

16.4 Effect of Termination. The termination or expiration of this Agreement shall not release either of the Parties from any liability which at the time of termination or expiry has already accrued to the other Party, nor affect in any way the survival of any other right, duty or obligation of the Parties which is expressly stated elsewhere in this Agreement to survive such termination or expiry.

17. Consequences of Termination

17.1 Upon termination of this Agreement for any reason except as set forth in Section 17.4 below (and, if applicable, in respect of that country in respect of which termination occurs):

- (a) the licenses and rights granted and appointments made under Sections 2.1, 2.2 and 2.3 shall terminate and EKR shall (and shall procure that its Affiliates, sub-distributors and sub-licensees shall) cease all activities licensed or appointed hereunder, subject to Sections 17.2 and 17.3;

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- (b) the following provisions of this Agreement shall continue in full force and effect: Article 1 (“Definitions”), Section 3.20(k), Section 3.20(l), Article 9 (“Representations and Warranties”), Article 10 (“Liability, Insurance and Indemnities”) (excluding Section 10.6 (“Insurance”)), Article 11 (“Confidentiality, Press Releases and Publications”), Article 13 (“Infringement of Third Party Rights”), Section 16.4 (“Effect of Termination”), Article 17 (“Consequences of Termination”), Article 18 (“Force Majeure”), Article 19 (“Notices”), Article 20 (“Assignment and Change of Control”) and Article 21 (“General Provisions”);
  - (c) EKR shall return to PPI all PPI IP in its possession;
  - (d) EKR shall assign to PPI free of charge any domain name registrations it has registered pursuant to Section 8.5; and
  - (e) Except in the event of termination of this Agreement by EKR pursuant to Section 16.1(a), EKR shall promptly transfer to PPI or its nominee, each and every Marketing Authorization (to the extent not held by PPI) relating to the Product, together with all communications with the relevant Regulatory Authorities, and all notes and record thereof.
- 17.2 Sale of Remaining Inventory. Where this Agreement has expired or has been terminated for any reason other than by PPI in accordance with Section 16.1 or EKR in accordance with Section 16.3(b), EKR and its Affiliates and sub-distributors and sales agents shall be entitled to continue to sell existing stocks of the Product in the Territory for a period of not longer than 12 months following the date of termination, provided that, EKR continues to make any Royalty payments due to PPI in respect of such sales in accordance with the provisions of this Agreement.
- 17.3 Other Rights upon Termination. In the event that this Agreement is terminated by PPI in accordance with Section 16.1 or EKR in accordance with Section 16.3(b), EKR and its Affiliates, sub-distributors and sub-licensees shall be entitled to continue to sell

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existing stocks of the Product in the Territory for so long as PPI deems necessary to ensure that sale of the Product is not disrupted provided that EKR and its Affiliates shall cease such sale immediately upon notification from PPI and in any event EKR shall not so sell for a period of longer than three (3) months following the date of termination. Immediately upon notification from PPI, such post termination sales shall cease.

- 17.4 Other Remedies of EKR. Notwithstanding anything contained herein to the contrary, in the event that EKR is entitled to exercise its right to terminate this Agreement pursuant to Section 16.1(a), in addition to the right to terminate as provided therein and any other remedies EKR may have hereunder, PPI shall assist EKR in the transfer of the manufacture of the Products, including the Specifications from PPI to EKR or EKR's designee. In such event, the Royalty payments payable hereunder shall continue to be paid; provided, however, that all costs incurred by EKR in the transfer of manufacturing information from PPI and obtaining FDA approval of the manufacture of the Products by EKR or EKR's designee, and any other amounts due to EKR, shall be deducted from any royalties payable to PPI. In addition, PPI shall during the remainder of the Term and for a period of up to [\*\*] ([\*\*]) years thereafter continue to manufacture and supply the Product to EKR at cost without mark-up until such time that EKR can secure an FDA approved manufacturing facility for the Product. PPI shall provide such advice as necessary for EKR to arrange for an alternative manufacturer and shall provide EKR with access to all relevant PPI Know-How, and any other information necessary for EKR to transfer such manufacturing to an alternate manufacturer. In addition, (i) PPI shall transfer to EKR any Marketing Authorizations held by PPI and (ii) the Trademark license granted under Section 2.3 shall continue in effect following such termination on a perpetual basis and EKR shall be responsible for all costs associated with the maintenance of such Trademark.



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17.5 EKR Step-In Rights.

- (a) During the Term, in the event EKR has the right to terminate this Agreement under Section 16.1(a) – (i) hereof (the “**Step-in Right Trigger Event**”), and EKR does not exercise its right to terminate this Agreement under such Section, EKR shall have the option to exercise step-in rights to manufacture the Product for the remainder of the Term (the “**Step-in Right**”) by providing PPI written notice of such election within ninety (90) days after the Step-in Right Trigger Event (or such longer period as mutually agreed by the Parties) (the “**Step-in Right Notice**”); provided that in the event such Step-in Right Trigger Event has been cured prior to EKR’s exercise of the Step-in Right, the Step-in Right shall terminate with respect to such Step-in Right Trigger Event. The Step-in Right Notice shall specify the date which EKR intends to exercise the rights associated with the Step-in Right.
- (b) In the event EKR exercises the Step-in Right, PPI shall, at EKR’s cost and expense, cooperate in the exercise of such rights and EKR shall reimburse PPI for the reasonable costs PPI incurs in assisting EKR in the exercise of such rights within thirty (30) days of EKR’s receipt of invoice.
- (c) The Step-in Right shall include, without limitation, and to the extent allowable under Applicable Law, PPI’s grant to EKR of such additional license rights, rights of access, rights of observation and rights of management, direction and control, in each case solely with respect to the manufacture and supply of Product and as reasonably necessary to enable and permit EKR (or EKR’s designee) to ensure that the supply of Product shall continue to be available to EKR under this Agreement and the Supply Agreement; provided that EKR in exercising the Step-in Right shall not (i) unreasonably interfere with PPI’s other activities at the facilities at which the Product is manufactured, tested, labeled, stored or

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otherwise handled (“**Product Facilities**”) or (ii) require PPI to take any action or fail to take any action that does or could reasonably be expected to interfere with PPI’s other activities at the Product Facilities. The foregoing rights shall apply with respect to any Product Facility to the extent necessary for EKR to preserve and protect supply of the Product as contemplated by this Agreement and the Supply Agreement. For the avoidance of doubt, (i) upon termination of the Lease Term, PPI shall maintain responsibility and control over all other products manufactured by PPI and nothing in this Section 17.5 shall give EKR any rights to direct, manage or control the manufacture of such products (ii) PPI shall maintain responsibility and control over the facilities where Product is manufactured, tested, labeled, stored or otherwise handled and nothing in this Section 17.5 shall give EKR general oversight or control of the facilities where Product is manufactured, tested, labeled, stored or otherwise handled.

- (d) In the event EKR exercises the Step-in Right, EKR shall comply with all policies applicable to the facilities where Product is manufactured, tested, labeled, stored or otherwise handled and all Applicable Laws with respect to the manufacture of the Product.

18. **Force Majeure**

- 18.1 **Obligation to Perform**. Except for payment obligations which shall not be excused or affected by any Force Majeure, neither Party shall be entitled to terminate this Agreement or shall be liable to the other under this Agreement for loss or damages attributable to any Force Majeure, provided the Party affected shall give prompt notice thereof to the other Party. Subject to Section 18.2, the Party giving such notice shall be excused from such of its obligations hereunder for so long as it continues to be affected by Force Majeure.

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18.2 Duration. If such Force Majeure continues unabated for a period of at least ninety (90) days, the Parties will meet to discuss in good faith what actions to take or what modifications should be made to this Agreement as a consequence of such Force Majeure in order to alleviate its consequences on the affected Party. If the affected Party is prevented by reason of any circumstances referred to in this Section of this Agreement from performing any of its obligations hereunder for a continuous period of six (6) months the other Party may terminate this Agreement.

19. Notices

19.1 Form. Any notice or other document given under this Agreement shall be in writing in the English language and shall be given by hand or sent by U.S. prepaid first class registered or certified mail, return receipt requested, recognized national overnight courier service, or by fax transmission to the address of the receiving Party as set out in Section 19.3 below unless a different address or fax number has been notified to the other in writing for this purpose.

19.2 Delivery. Each such notice or document shall:

- (a) if sent by hand, be deemed to have been given when delivered at the relevant address;
- (b) if sent by prepaid airmail, be deemed to have been given 7 days after posting; or
- (c) if sent by fax transmission be deemed to have been given when transmitted provided that a confirmatory copy of such facsimile transmission shall have been sent by hand, U.S. prepaid first class registered or certified mail, return receipt requested, or recognized national overnight courier service within 24 hours of such transmission.

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19.3 Notice of Parties. The address for services of notices and other documents on the Parties shall be:

**To EKR**

**Address:** 1545 Route 206 South  
Third Floor  
Bedminster, NJ 07921

**Fax:**

**Attention:** Chairman & CEO

**With a copy to:**

Lowenstein Sandler  
65 Livingston Avenue  
Roseland, New Jersey 07068

**Fax:** 973-597-6395

**Attention:** Michael J. Lerner

**To PPI**

**Address:** 10450 Science Center  
Drive, San Diego,  
California 92121 USA

**Fax:** 858 623 0376

**Attention:** President

**With a copy to:**

Wilmer Cutler Pickering Hale & Dorr LLP  
1117 S California Avenue  
Palo Alto, CA 94304 USA

**Fax:** 650-858-6100

**Attention:** Joseph K. Wyatt

20. **Assignment and Change of Control**

20.1 Assignment. Subject to Section 20.2, neither Party shall, nor shall it purport to, assign, license, transfer or change any of its rights or obligations under this Agreement without the prior written consent of the other, such consent not to be unreasonably withheld conditioned or delayed; provided, however, that except as provided in Section 20.4 either Party may assign its rights hereunder to an Affiliate or to any successor by merger, consolidation, sale of stock or other equity interests or the sale of substantially all of the assets of such Party without the consent of the other Party. For the avoidance of doubt, either Party may grant a security interest with respect to its rights under this Agreement in connection with a secured financing or similar transaction.

20.2 Sub-Distribution. EKR may appoint sub-distributors under this Agreement provided that EKR:

- (a) informs PPI of the identity of any Third Party sub-distributor (other than Affiliate companies) prior to the execution of any sub-distribution agreement;

- 
- (b) obtain a confidential nondisclosure agreement with the prospective Sub-Distributor in a form acceptable to PPI, which acceptance shall not be unreasonably withheld or delayed and containing terms at least as stringent as those terms included in Article 11 of this Agreement;
  - (c) deliver to the prospective Sub-Distributor a redacted copy of this Agreement (“**Redacted Agreement**”). Any sub-distribution agreement shall provide that such agreement is subject and subordinate to the rights of PPI under this Agreement; and
  - (d) provides PPI with a copy of written sub-distribution agreement as soon as reasonably practicable after the execution thereof by EKR.
- 20.3 Responsibility of EKR. Notwithstanding any such sub-distribution agreement, EKR shall remain primarily liable to PPI for its obligations hereunder, and for any act or omission of any sub-distributor.
- 20.4 Change of Control. Should there be a Change of Control of either Party resulting in the control of such Party by a Third Party which markets or sells a Competing Product in any part of the Territory, then the rights under this Agreement may not be assigned without the express consent of the other Party which consent shall not be unreasonably withheld. “**Change of Control**” shall mean (a) the sale, lease, exchange, license or disposition of all or substantially all of the Party’s assets in one transaction or series of related transactions or (b) a merger or consolidation with an unaffiliated Third Party as a result of which the holders of the Party’s issued and outstanding voting securities immediately before such transaction own or control less than a majority of the voting securities of the continuing or surviving entity immediately after such transaction. The issuance by either Party of securities in connection with any financing transaction or

public offering shall not be deemed a Change of Control under this Agreement. Notwithstanding the foregoing, for the purposes of Section 6.3(b)(iii): (i) references to a "Party" in the above definition of Change of Control shall be deemed to include PPI as well as any Affiliate of PPI and (ii) a Change of Control shall also include (in addition to any of the transactions described above in the definition of Change of Control), any sale of securities of PPI or its Affiliates directly by the holder (the "Holder") of such securities (other than to an Affiliate of such Holder) in which such sale results in a transfer of more than 50% of the outstanding voting stock of PPI or its Affiliates.

21. **General Provisions**

- 21.1 **Relationship of the Parties.** Nothing in this agreement is deemed to constitute a partnership, agency, employer-employee or joint venture relationship between the Parties. No Party shall incur any debts or make any commitments for the other, except to the extent, if at all, specifically provided herein.
- 21.2 **Dispute Resolution.** If there is a disagreement between the PPI and EKR on the interpretation of this Agreement or any aspect of the performance by either Party of its obligations under this Agreement, the Parties shall resolve the dispute in accordance with the dispute resolution procedure set out in Schedule VIII.
- 21.3 **Cooperation.** Each of the Parties shall do execute and perform and shall procure to be done executed and performed all such further acts deeds documents and things as the other Party may reasonably require from time to time to give full effect to the terms of this Agreement.
- 21.4 **Expenses.** Each Party shall pay its own costs, charges and expenses incurred in connection with the negotiation, preparation and completion of this agreement.
- 21.5 **Entire Agreement.** This Agreement (together with the Transition Services and Inventory Purchase Agreement and the Supply Agreement) sets out the entire agreement and understanding between the Parties in respect of the subject matter hereof and thereof. This Agreement supersedes the Original Agreement and any heads of agreement which shall cease to have any further force or effect. It is agreed that:
- (a) no Party has entered into this Agreement in reliance upon any representation, warranty or undertaking of the other Party which is not expressly set out in this Agreement;

- 
- (b) no Party shall have any remedy in respect of misrepresentation or untrue statement made by the other Party or for any breach of warranty which is not contained in this Agreement;
  - (c) this Section shall not exclude any liability for, or remedy in respect of, fraudulent misrepresentation.
- 21.6 Amendment. No amendment, change or modification of any of the terms, provisions or conditions of this Agreement shall be valid unless it is in writing and signed by or on behalf of both Parties.
- 21.7 Waiver. Unless expressly agreed, no waiver of any term, provision or condition of this Agreement shall constitute a general waiver of any provisions of this Agreement, nor shall it affect any rights, obligations or liabilities under or pursuant to this Agreement which have already accrued up to the date of variation, and the rights and obligations of the Parties under or pursuant to this Agreement shall remain in full force and effect, except and only to the extent that they are so waived.
- 21.8 Unenforceability. If and to the extent that any provision of this Agreement is held to be illegal, void or unenforceable, such provision shall be given no effect and shall be deemed not to be included in this Agreement but without invalidating any of the remaining provisions of this Agreement.
- 21.9 Delay. No failure or delay by either Party in exercising any right or remedy provided by law under or pursuant to this Agreement shall impair such right or remedy or operate or be construed as a waiver or variation of it or preclude its exercise at any subsequent time and no single or partial exercise of any such right or remedy shall preclude any other or further exercise of it or the exercise of any other right or remedy.

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- 21.10 Cumulative Rights. The rights and remedies of each of the Parties under or pursuant to this Agreement are cumulative, may be exercised as often as such Party considers appropriate and are in addition to its rights and remedies under general law.
- 21.11 Counterparts. This Agreement may be executed in any number of counterparts and by the Parties on separate counterparts, each of which is an original but all of which together constitute one and the same instrument.
- 21.12 Reserved.
- 21.13 Governing Law. This Agreement and the relationship between the Parties shall be governed by, and interpreted in accordance with New York law without regard to provisions related to conflicts of laws, and, except as provided in Section 21.2 above, the Parties agree to submit any dispute to the exclusive jurisdiction of the federal and state courts sitting in New York.
- 21.14 Successors and Assigns. Subject to Section 20.1, this Agreement shall be binding upon and shall inure to the benefit of the Parties hereto and their respective successors and assigns permitted under this Agreement.
- 21.15 Systems. Immediately upon the Effective Date, or as soon thereafter as practicable, the Parties shall implement a mutually acceptable operation plan to transfer the processing of chargebacks, federal releases, state releases and customer services from PPI to EKR.

*(signature page follows)*



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**AS WITNESS** the hands of the Parties or their duly authorized representatives effective as of the Effective Date.

SIGNED for and by behalf of )  
**PACIRA PHARMACEUTICALS, INC.** )

By: /s/ David Stack

David Stack  
**Print Name**

SIGNED for and by behalf of )  
**EKR THERAPEUTICS, INC.** )

By: /s/ Richard DeSimone

Richard DeSimone, CFO  
**Print Name**

**SCHEDULE I**

**PATENTS**

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Attorneys' Ref:	Country	Application date	Application no.	Patent/ Publication no.	Grant date	Expiry date	Status
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]

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Attorneys' Ref:	Country	Application date	Application no.	Patent/ Publication no.	Grant date	Expiry date	Status
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
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[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
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Attorneys' Ref:	Country	Application date	Application no.	Patent/ Publication no.	Grant date	Expiry date	Status
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]

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Attorneys' Ref:	Country	Application date	Application no.	Patent/ Publication no.	Grant date	Expiry date	Status
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
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Attorneys' Ref:	Country	Application date	Application no.	Patent/ Publication no.	Grant date	Expiry date	Status
[**]	[**]	[**]	[**]	[**]		[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]

\* Publication date of Application – 13 Apr 06.

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Attorneys' Ref:	Country	Application date	Application no.	Patent/ Publication no.	Grant date	Expiry date	Status
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]

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**SCHEDULE II  
TRADEMARKS**

File Date: [\*\*]  
Serial No.:  
International Class:  
First Use:  
First Use in Commerce:  
Registration Date:  
Registration No.:  
Mark:

File Date: [\*\*]  
Serial No.:  
International Class:  
First Use:  
First Use in Commerce:  
Registration Date:  
Registration No.:  
Mark:

File Date: [\*\*]  
Serial No.:  
International Class:  
First Use:  
First Use in Commerce:  
Registration Date:  
Registration No.:  
Mark:

**\*[\*\*] Trademark Application**

File Date: [\*\*]  
Serial No.:  
International Class:  
Mark:

[\*\*] – Owner of Record, United States Patent Trademark Office website. Record of Assignment from [\*\*]. to [\*\*] is in process.

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**SCHEDULE III**

**COPYRIGHTS**

**There are no recorded copyrights**

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**SCHEDULE IV**  
**DOMAIN NAMES**

DepoDur.com

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**SCHEDULE V**

**MARKETING AUTHORIZATIONS**

**United States Food and Drug Administration New Drug Application: [\*\*]**



SCHEDULE VI

PRESS RELEASE

News Release

**EKR Therapeutics Achieves Key Growth Milestone with the  
Acquisition of Rights to DepoDur®, a Novel Extended-Release Opioid  
Analgesic for Post Operative Pain**

**Cedar Knolls, N.J., August X, 2007** – EKR Therapeutics, Inc., a specialty pharmaceutical company focused on acquiring, developing, and commercializing proprietary products to enhance patient quality-of-life in the acute care setting, today announced it has acquired exclusive marketing and distribution rights to DepoDur® for the Americas from San Diego-based Pacira Pharmaceuticals who retains manufacturing rights to the product.

Formerly a business unit of SkyePharma, plc, Pacira Pharmaceuticals is an independent private company focused on developing and manufacturing controlled-release injectable products based on their DepoFoam™ and Biosphere™ drug delivery platforms.

DepoDur, which utilizes the DepoFoam technology, is a sterile injectable suspension of multivesicular liposomes formulated to provide extended release of morphine sulfate. It is the only extended-release opioid that is approved by the Food and Drug Administration for epidural use. A single injection of DepoDur into the lumbar epidural space may provide pain relief for up to 48 hours following major surgery without the restrictions and potential complications associated with an indwelling epidural catheter.

“The product characteristics of DepoDur fit exceptionally well with EKR’s acquisition model,” said Howard Weisman, EKR’s Chairman & CEO. “DepoDur is patent protected, addresses an important medical need in our market space, and has growth prospects that can be fully exploited through the application of EKR’s expertise and strengths in the acute care market.”

Mr. Weisman further noted, “EKR is commencing a number of pre-launch activities, including interacting with opinion leaders, and we expect to fully deploy our sales force in support of DepoDur early next year.” He concluded, “We are very optimistic about EKR’s growth prospects in 2008 as we foresee a ramp up in sales for both DepoDur and Gelclair® and anticipate favorable market synergies between these products.” Gelclair, which is marketed to acute care facilities and cancer centers, is indicated for the management of pain associated with oral lesions of various etiologies, including chemotherapy and radiation induced oral mucositis/stomatitis.

Tong Zhang, Ph.D., Director of Business Development for EKR, added, “Acquiring the rights to DepoDur exemplifies EKR’s strategy of focusing on building a portfolio of premier products in the acute care space.” He further noted, “Our strict acquisition criteria center on high-margin, innovative products that offer value to healthcare providers and their patients, thus, representing excellent opportunities for EKR to realize strong returns on investment.”



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“Pacira Pharmaceuticals is delighted to have EKR Therapeutics as our marketing and commercialization partner for DepoDur in the Americas,” commented Fred Middleton, Pacira’s Chairman of the Board. “This product was clinically developed as a proprietary treatment by Pacira R&D and it received FDA approval in 2004 for long-acting post surgical pain management, for which it is known to be effective.”

Mr. Middleton further noted, “EKR Therapeutics has demonstrated in the past that they possess the strengths to successfully bringing a focused marketing and clinician targeting approach to DepoDur to help it reach its full commercial potential. We look forward to working with EKR, as our partner on the expanded commercial marketing of DepoDur.”

Detailed terms of the transaction were not disclosed. However, EKR did note that in addition to royalty payments on net sales, it has agreed to an upfront payment amounting to somewhat more than [\*\*] times DepoDur’s 2006 U.S. sales. EKR has also agreed to certain milestone payments with the sum of upfront and milestone payments potentially worth up to \$[\*\*].

**About EKR Therapeutics**

EKR Therapeutics is a privately held specialty pharmaceutical company that has brought together a highly seasoned team of industry professionals. The Company focuses on the acquisition, development and commercialization of proprietary products for the acute care segment of the healthcare market, including oncology supportive care therapeutics. From its inception in late 2005, EKR has been organized to be a class leader in commercializing products to address unmet and under-satisfied medical needs or to otherwise enhance the therapeutic value of acute-care prescription products. EKR’s goal is to be the pre-eminent provider of acute-care specialty products, backed by a commitment to excellence in customer service. For additional information about EKR visit the Company’s website at <http://www.ekrtx.com>.

**About Pacira Pharmaceuticals, Inc.**

Pacira Pharmaceuticals, Inc. is a wholly owned subsidiary of Pacira Inc., a Delaware corporation, which is controlled and funded by a group of financial investors including Sanderling Ventures, HBM Bioventures (Cayman) Ltd, OrbiMed Advisors, and MPM Capital. This business is based in San Diego, CA, and focuses on formulating, developing and manufacturing controlled-release injectable products based on two proprietary drug delivery platforms: DepoFoam™ and Biosphere™. Revenues are generated from two marketed products: DepoCyt® for lymphomatous meningitis and DepoDur® for the treatment of post-surgical pain. For additional information about Pacira visit the Company’s website at <http://www.pacira.com>

####

Contact for EKR Therapeutics  
Stuart Z. Levine, Ph.D.  
Corporate Communications  
877-435-2524  
[s.levine@ekrtx.com](mailto:s.levine@ekrtx.com)

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**SCHEDULE VII**

**THE TERRITORY**

all countries in North America including the United States, its territories as possessions including Puerto Rico, South America and Central America

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## SCHEDULE VIII

### DISPUTE RESOLUTION

- 1.1 Representatives of the Parties will, within 14 days of receipt of a written request from either Party to the other, convene a meeting of the Committee to discuss in good faith and try to resolve the disagreement without recourse to legal proceedings.
- 1.2 If resolution does not occur within 7 days after meeting, the matter shall be escalated for determination by the respective Chief Executive Officer of the Parties who may resolve the matter themselves or jointly appoint a mediator or independent expert to do so.
- 1.3 Nothing in this Agreement restricts either Party's freedom to seek urgent relief to preserve a legal right or remedy, or to protect a proprietary, trade secret or other right.

#### **Appointment of an Expert**

- 1.4.1 In the event that the Chief Executive Officers are unable to resolve the dispute and the dispute has a monetary value of cost of [\*\*] dollars (\$[\*\*]) or more, the dispute shall be submitted to the federal or state courts located in the State of California, which shall have exclusive jurisdiction over such dispute.
- 1.4.2 In the event that the Chief Executive Officers are unable to resolve the dispute and the dispute has a monetary value of cost of less than [\*\*] dollars (\$[\*\*]), and the Parties do not agree on the appointment of an expert to resolve the dispute, or mediation has failed to resolve the dispute, one Party shall serve on the other a written Referral Notice requesting that the matter be referred to an expert for resolution, and the following procedure shall be followed.
  - 1.4.1 The dispute shall be determined by a single independent impartial expert who shall be agreed between the Parties or, in the absence of agreement between the Parties within 30 days of the service of a Referral Notice, be appointed by the American Arbitration Association or any successor thereto, or such other competent body agreed by the Parties.
  - 1.4.2 30 days after the appointment of the expert pursuant to paragraph 1.4.1 both Parties shall exchange simultaneously statements of case in no more than 10,000 words, in total, and each side shall simultaneously send a copy of its statement of case to the expert.
  - 1.4.3 Each Party may, within 30 days of the date of exchange of statement of case pursuant to paragraph 1.4.2, serve a reply to the other side's statement of case in no more than 10,000 words. A copy of any such reply shall be simultaneously sent to the expert.
  - 1.4.4 Subject to paragraph 1.4.6, there shall be no oral hearing. The expert shall issue his decision in writing to both Parties within 30 days of the date of service of the last reply pursuant to paragraph 1.4.3 above or, in the absence of receipt of any replies, within 60 days of the date of exchange pursuant to paragraph 1.4.2.

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- 1.4.5 The seat of the dispute resolution shall be the normal place of residence of the expert.
  - 1.4.6 The expert shall not have power to alter, amend or add to the provisions of this Agreement, except that the expert shall have the power to decide all procedural matters relating to the dispute, and may call for a one day hearing if desirable and appropriate.
  - 1.4.7 The expert shall have the power to request copies of any documents in the possession and/or control of the Parties which may be relevant to the dispute. The Parties shall forthwith provide to the expert and the other Party copies of any documents so requested by the expert.
  - 1.4.8 The decision of the expert shall be final and binding upon both Parties except in the case of manifest error. The Parties hereby exclude any rights of application or appeal to any court, to the extent that they may validly so agree, and in particular in connection with any question of law arising in the course of the reference out of the award.
  - 1.4.9 The expert shall determine the proportions in which the Parties shall pay the costs of the expert's procedure. The expert shall have the authority to order that all or a part of the legal or other costs of a Party shall be paid by the other Party.
  - 1.4.10 All documents and information disclosed in the course of the expert proceedings and the decision and award of the expert shall be kept strictly confidential by the recipient and shall not be used by the recipient for any purpose except for the purposes of the proceedings and/or the enforcement of the expert's decision and award.

**SCHEDULE IX**  
**SALES FORECAST**



Date: July 25, 2007  
From: [\*\*], EKR Therapeutics, Inc.  
To: [\*\*], Pacira  
Re: DepoDur Unit Sales Forecast, as of July 25, 2007

While we continue to work on our marketing plan and forecast, based on the current run rate of approximately [\*\*] to [\*\*] units per month, you can expect that our plan will call for the following forecast:

<u>Period</u>	<u>Unit Sales Forecast</u>
August 1 – December 31, 2007	[**]
January 1 – December 31, 2008	[**]
January 1 – December 31, 2009	[**]

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**SCHEDULE X**

**PHASE IV STUDIES**

A DepoDur study in pediatric patients. Pacira has requested a waiver and is awaiting a response from the FDA

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**SCHEDULE XI**  
**NDA TRANSFER LETTERS**

**A. Transfer Letter to be Filed by PPI**

[PACIRA PHARMACEUTICALS, INC. LETTERHEAD]

\_\_\_\_\_, 2009

VIA OVERNIGHT MAIL

[NAME AND ADDRESS OF APPROPRIATE FDA CONTACT TO BE PROVIDED]

Re: **DepoDur® NDA [\*\*]**  
**General Correspondence: Transfer of NDA Ownership**

Dear \_\_\_\_\_:

Effective \_\_\_\_\_, 2009, pursuant to 21 CFR 314.72, DepoDur® NDA [\*\*] is hereby transferred from Pacira Pharmaceuticals, Inc. to EKR Therapeutics, Inc., 1545 Route 206 South, Third Floor, Bedminster, New Jersey 07921 (Regulatory Contact: \_\_\_\_\_, telephone \_\_\_\_\_).

As a condition of this transfer of ownership, Pacira will provide to EKR Therapeutics all available information pertaining to the above-referenced NDA to be kept under 21 CFR 314.70, including all previous correspondence to and from the Agency. A signed 356h form is attached

If you have any questions or require any additional information, please do not hesitate to contact me at \_\_\_\_\_.

Sincerely,

PACIRA PHARMACEUTICALS, INC.

**B. Transfer Letter to be Filed by EKR**

[EKR THERAPEUTICS, INC. LETTERHEAD]

\_\_\_\_\_, 2009

VIA OVERNIGHT MAIL

[NAME AND ADDRESS OF APPROPRIATE FDA CONTACT TO BE PROVIDED]

**RE: NDA No. [\*\*]  
DepoDur®  
General Correspondence: Transfer of NDA Ownership**

Dear \_\_\_\_\_:

Pursuant to 21 CFR 314.72 the above-mentioned NDA has been transferred from Pacira Pharmaceuticals, Inc. to EKR Therapeutics, Inc. effective \_\_\_\_\_, 2009. EKR has received a complete copy of the approved application, including all supplements and records that are required to be kept under 21 CFR 314.81. EKR agrees to abide by all agreements, promises and conditions made by the former owner, which are contained in the application. EKR will advise the FDA about any changes in the conditions in the approved application as required by 21 CFR 314.70, or in the next annual report, if appropriate. EKR will consider the date of transfer to be the new date for annual reporting purposes. A new signed 356h form is attached.

Please contact me by phone at \_\_\_\_\_, by email at \_\_\_\_\_ or by fax at \_\_\_\_\_, if you have any questions or if you require additional information.

Sincerely,

[Name / Title]



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## SCHEDULE XII

### TRANSFERRED EQUIPMENT

DepoDur processing equipment:

1. ST-01 ([\*\*], [\*\*] rated to [\*\*], equipped with agitator used in preparation of [\*\*] prior to [\*\*])
2. ST-02 ([\*\*], [\*\*] rated to [\*\*], equipped with agitator used in preparation of [\*\*] [\*\*] prior to [\*\*])
3. ST-03 ([\*\*], [\*\*] rated to [\*\*], equipped with agitator used in preparation of [\*\*] prior to [\*\*])
4. ST-04 ([\*\*], [\*\*] rated to [\*\*], equipped with agitator used in preparation of [\*\*] [\*\*] prior to [\*\*])
5. ST-22 ([\*\*], [\*\*] rated to [\*\*], [\*\*])
6. EV-01 ([\*\*], [\*\*] rated to [\*\*], equipped with [\*\*] used to produce [\*\*] [\*\*])
7. EV-02 ([\*\*], [\*\*] rated to [\*\*], equipped with [\*\*] and [\*\*] [\*\*] used to produce [\*\*])
8. FV-01 ([\*\*], [\*\*] rated to [\*\*], used [\*\*] during [\*\*])
9. [\*\*] skid, including [\*\*] lobe pumps, [\*\*] manifold system, and [\*\*] flometers
10. Interconnective valves and piping between vessels
11. Pressure gauges, temperature probes, other small instrumentation for in-process measurements.
12. HMI / PLC / automation

**Exhibit 3.20(a)**  
**Form of Bill of Sale**

**BILL OF SALE**

**THIS BILL OF SALE**, dated October \_\_, 2009 (this "**Bill of Sale**"), is made by Pacira Pharmaceuticals, Inc. ("**Seller**"), in favor of EKR Therapeutics, Inc. ("**Purchaser**").

**WHEREAS**, Purchaser and Seller have entered into that certain Amended and Restated Strategic Licensing, Distribution and Marketing Agreement, dated as of the date hereof (the "**Agreement**"), providing, among other things, for the sale of the Transferred Equipment (as defined therein) by Seller to Purchaser.

**NOW, THEREFORE**, for good and valuable consideration, the receipt of which is hereby acknowledged, Seller and Purchaser agree as follows:

- 1. Definitions.** Capitalized terms used in this Bill of Sale and not otherwise defined in this Bill of Sale shall have the respective meanings assigned to them in the Agreement.
- 2. Conveyance.** In accordance with the terms of the Agreement, Seller hereby sells, transfers, conveys and assigns to Purchaser all right, title and interest in and to the Transferred Equipment. A list of the Transferred Equipment is set forth on **Schedule A** to this Bill of Sale.
- 3. Further Assurances.** At any time and from time to time after the date of this Bill of Sale, Seller, at the Purchaser's request and subject to reimbursement by Purchaser of any out-of-pocket expenses, will do, execute, acknowledge and deliver, or will cause to be done, executed, acknowledged and delivered, any and all further acts, conveyances, transfers, assignments and assurances as may be reasonably required by Purchaser to further evidence and effectuate the sale, transfer, conveyance and assignment to the Purchaser of the Transferred Equipment.
- 4. Relationship With Agreement.** The provisions of this Bill of Sale are subject, in all respects, to the terms and conditions of the Agreement and all of the representations, warranties, covenants and agreements contained in the Agreement. Nothing contained in this Bill of Sale shall be deemed to modify, limit or amend any such rights and obligations of the parties hereto under the Agreement. In the event of any conflict or inconsistency between this Bill of Sale and the Agreement, the Agreement shall govern.
- 5. Successors and Assigns.** This Bill of Sale shall be binding upon and inure to the benefit of and be enforceable by Seller and Purchaser and their respective successors and assigns.
- 6. Governing Law.** This Bill of Sale shall be governed by, and construed in accordance with, the laws of the State of New York, without regard to the conflicts of law principles thereof.
- 7. Counterparts; Facsimile Signature Pages.** This Bill of Sale may be executed by each of Seller and Purchaser in separate counterparts, each of which when so executed and delivered shall be deemed to be an original and which together shall constitute one and the same instrument. Any signed counterpart of this Bill of Sale which is delivered by facsimile or other printable electronic transmission shall be deemed to be executed and delivered for all purposes.

*[Signature Page Follows]*

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**IN WITNESS WHEREOF**, Seller has executed and delivered this Bill of Sale on the date first above written.

**Pacira Pharmaceuticals, Inc.**

By: \_\_\_\_\_  
Print Name: \_\_\_\_\_  
Title: \_\_\_\_\_

Acknowledged and Agreed to as  
of the date first above written.

**EKR Therapeutics, Inc.**

By: \_\_\_\_\_  
Print Name: \_\_\_\_\_  
Title: \_\_\_\_\_

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**Schedule A to Bill of Sale  
Transferred Equipment**

DepoDur processing equipment:

1. ST-01 ([\*\*], [\*\*] rated to [\*\*], equipped with agitator used in preparation of [\*\*] prior to [\*\*])
2. ST-02 ([\*\*], [\*\*] rated to [\*\*], equipped with agitator used in preparation of [\*\*] [\*\*] prior to [\*\*])
3. ST-03 ([\*\*], [\*\*] rated to [\*\*], equipped with agitator used in preparation of [\*\*] prior to [\*\*])
4. ST-04 ([\*\*], [\*\*] rated to [\*\*], equipped with agitator used in preparation of [\*\*] [\*\*] prior to [\*\*])
5. ST-22 ([\*\*] [\*\*], [\*\*] rated to [\*\*], [\*\*] [\*\*])
6. EV-01 ([\*\*], [\*\*] rated to [\*\*], equipped with [\*\*] used to produce [\*\*] [\*\*])
7. EV-02 ([\*\*], [\*\*] rated to [\*\*], equipped with [\*\*] and [\*\*] [\*\*] used to produce [\*\*])
8. FV-01 ([\*\*], [\*\*] rated to [\*\*], used [\*\*] during [\*\*])
9. [\*\*] skid, including [\*\*] lobe pumps, [\*\*] manifold system, and [\*\*] flometers
10. Interconnective valves and piping between vessels
11. Pressure gauges, temperature probes, other small instrumentation for in-process measurements.
12. HMI / PLC / automation

**Exhibit 3.20(b)**  
**Form of Promissory Note**

**PROMISSORY NOTE**

\$900,000

October \_\_, 2009

**FOR VALUE RECEIVED**, EKR Therapeutics, Inc. (“**Maker**”), having an address at 1545 Route 206 South, Third Floor, Bedminster, New Jersey 07921, hereby promises to pay to Pacira Pharmaceuticals, Inc. (“**Payee**”), having an address at 10450 Sciences Center Drive, San Diego, California 92121, the principal sum of NINE HUNDRED THOUSAND DOLLARS (\$900,000.00), plus interest computed at the rate of FIVE PERCENT (5%) per annum, in accordance with the terms and conditions set forth in this Promissory Note (this “**Note**”).

1. **Payments.** On the fifth anniversary of the date of this Note, all principal and interest (calculated according to Paragraph 3 below) accrued on this Note and not sooner paid in accordance with the terms hereof shall be payable in full (the “**Payment**”).

2. **Place of Payment.** The entire amount due hereunder shall be payable to Payee at the address set forth above, or at such other place as Payee may designate in writing to Maker at the address set forth above.

3. **Interest Calculation:** Interest shall be calculated on the basis of a 360 day year based on the number of days elapsed.

4. **Optional Prepayment.** Maker may, at its option, prepay the entire amount due hereunder in whole at any time or in part from time to time without penalty or premium. At the option of Maker, prepayments pursuant to this Paragraph 4 shall (a) be applied to the outstanding principal balance in reverse order of maturity or (b) reduce the Payment installments set forth above for the balance of the term of this Note. In the event that Maker elects to reduce the Payment installments, Maker agrees to provide to Payee written notice of its election to do so at least thirty (30) days prior to making any prepayment and to execute and deliver to Payee an amendment to this Note setting forth a revised payment schedule.

5. **Defaults.** At the option of Payee, the entire amount due hereunder shall immediately become due and payable on any of the following events of default:

(a) Maker fails to make Payment as provided for in this Note and such failure to make Payment continues for thirty (30) days after Maker’s receipt of written notice from Payee that such Payment is due;

(b) Maker makes a general assignment for the benefit of creditors;

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(c) A receiver is appointed for the assets of Maker upon request by any Person(s) other than Maker, or Maker makes a formal request for appointment of a receiver; or

(d) Any proceeding is brought by Maker in any court or under supervision of any court-appointed officer under any federal or state bankruptcy, reorganization, rearrangement, insolvency or debt readjustment law, or if any such proceedings are instituted against Maker and Maker fails to obtain dismissal of such proceeding within ninety (90) days after the same has been instituted.

6. Agreement. This Note is made pursuant to that certain Amended and Restated Strategic Licensing, Distribution and Marketing Agreement dated as of October \_\_, 2009 by and between Maker and Payee (the “**Agreement**”) and is subject to the terms thereof. This Note is subject to offset as expressly provided for in the Agreement.

7. Nonnegotiability, Nontransferability. This Note shall be nonnegotiable. Further, this Note may not be transferred by either party except to a permitted transferee under the Agreement.

8. Governing Law. This Note shall be governed by and construed in accordance with the laws of the State of New York, excluding any conflict-of-laws rule or principle that may refer the governance, construction or interpretation of this Note to the laws of another State.

**IN WITNESS WHEREOF**, the Maker has executed this promissory note as of \_\_\_\_\_.

\_\_\_\_\_  
\_\_\_\_\_, Maker

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

## AMENDED AND RESTATED SUPPLY AGREEMENT

the 10th day of August, 2007 (the “**Effective Date**”)

### BETWEEN

- (1) **PACIRA PHARMACEUTICALS, INC. (F/K/A SKYEPHARMA, INC.)** a company incorporated California whose principal place of business is 10450 Sciences Center Drive, San Diego, California 92121 USA (“**Pacira**”); and
- (2) **EKR THERAPEUTICS, INC.** a company incorporated in the state of Delaware whose principal place of business is 1545 Route 206 South, Third Floor, Bedminster, New Jersey 07921 (the “**Company**” or “**EKR**”).

Pacira and the Company may be sometimes referred to in this Agreement each individually as a “**Party**,” or collectively as the “**Parties**.”

### Recitals

- (A) Pacira and the Company are parties to that certain Supply Agreement dated as of August 10, 2007 (the “**Original Agreement**”), pursuant to which Pacira Manufactures (as defined below) the Products (as defined below) and supply the Finished Products (as defined below) to the Company.
- (B) Pacira and Company desire to amend and restate the Original Agreement in its entirety as set forth herein.

NOW THEREFORE, in consideration of the premises and mutual agreements and covenants set forth herein, and intending to be legally bound, the Parties acknowledge and agree that this Agreement shall amend and supersede in its entirety the Original Agreement and hereby agree as follows:

### 1. DEFINITIONS

1.1. As used in this Agreement, the following words and expressions have the following meanings:

“**Applicable Laws**” has the meaning specified in the License Agreement;

“**Approved Facilities**” means the approved facilities located at 10450 Science Center Drive, San Diego, CA 92121 USA (or the approved facility of a Third Party Manufacturer), comprising buildings and equipment where Pacira shall Manufacture and store or have Manufactured and stored the Product;

“**Backup Facility**” shall have the meaning set forth in Section 2.11.1 below;

“**Backup Manufacturing Plan**” shall have the meaning set forth in Section 2.11.1 below;

“**Backup Material Supplier Plan**” shall have the meaning set forth in Section 2.11.1 below;

“**Batch**” means shall mean that quantity of each Product (as set forth on Appendix 1) that is produced by a single cycle of Manufacture, such that it is expected to be of a uniform character and quality and in conformity within the Specification (including, but not limited to, as filed with the FDA and other applicable Relevant Authorities);

“**Business Day**” means a day other than a Saturday or Sunday when clearing banks are open for business;

“**Certificate of Analysis**” means a document, in such form as is mutually agreed upon by the Parties, setting out the results of analysis of a Batch confirming the Batch to be in accordance with the Specifications (as filed with the FDA and other applicable Relevant Authorities or contained in the Marketing Authorizations) and the identification of the methods by which the tests were performed;

“**cGMP**” means current Good Manufacturing Practice as set out in the United States 21 CFR 210 and 211, as amended from time to time, together with, as applicable, any analogous regulations, codes or guidelines having effect in any jurisdiction in the Territory in which Products are to be Manufactured and/or distributed;

“**Commencement Date**” means the date on which the Company notifies Pacira in writing that the Company has obtained all licenses and other approvals from the Relevant Authorities as necessary for the Company to distribute the Product in the United States, which date the Parties acknowledge has occurred prior to the Agreement Date;

“**Delivery**” means delivery of Finished Product at the loading dock of Pacira’s designated packaging facility, F.O.B., and “**Delivered**” shall be construed accordingly;

“**Delivery Date**” means the date on which the Company receives Delivery of a particular shipment of Finished Product.

“**Effective Date**” shall have the meaning set forth in the Preamble above;



**“Finished Product”** means Product which has been Manufactured under this Agreement meeting the Specifications (including, but not limited to, all manufacturing and testing Specifications) and the Packaging and Labelling Specifications and all other requirements of this Agreement, and which is Released and ready for immediate distribution by the Company to its subdistributors and/or customers;

**“Hazardous Materials”** means any material that because of its quantity, concentration, or physical or chemical characteristics may pose a real risk to human health or the environment;

**“License Agreement”** means: (i) with respect to the period from the Effective Date until the Agreement Date, that certain Strategic Licensing, Distribution and Marketing Agreement between Pacira and EKR dated August 10, 2007 and (ii) with respect to periods after the Effective Date, that certain Amended and Restated Strategic Licensing, Distribution and Marketing Agreement between Pacira and EKR dated as of the date hereof.

**“Manufacture”** means the conduct of all methods and processes used by Pacira or its Third Party Manufacturer in relation to the manufacture, filling, finishing, labelling, Packaging, storage, shipping and Quality Control of the Product in accordance with the Specifications, the Packaging and Labelling Specifications, cGMPs and all other Applicable Laws;

**“Manufacturing Approvals”** means all necessary or appropriate approvals, licences, permits, registrations and authorisations in respect of the Manufacture of the Product;

**“Manufacturing Services”** shall mean all or any part of the Manufacture, stability testing and other testing and Release of the Product in the Presentation Forms either for commercial sale or for clinical supplies in the United States and in all other applicable jurisdictions of the Territory in which the Company intends to distribute the Product;

**“Non-Conforming Product”** shall mean any Product which fails to comply with the Specifications (including, but not limited to, any manufacturing or testing Specifications) or the Packaging and Labelling Specifications;

**“Non-Conformity”** shall mean the event or failure which renders a Product Non-Conforming Product;

**“Packaging”** means all operations involved in the process of assembly and packaging of the Product into Finished Product ready for sale or supply to a third party in any country in the Territory and “Packaged” shall be construed accordingly;

“**Packaging and Labelling Specifications**” means the specifications set out in Appendix 2, as such specifications may be amended pursuant to Section 2.4 below from time to time;

“**Person**” shall include both corporate and real persons and institutions, partnerships and associations or entities of all kinds;

“**Presentation Form**” means the amount of active ingredient contained in each Vial, which initially shall be either 10mg or 15mg;

“**Product**” has the meaning set forth in the License Agreement;

“**Quality Control**” means the sampling, laboratory testing and inspection, in accordance with cGMPs, at the Approved Facilities of:

- (a) Raw Materials, in-process materials and Finished Product;
- (b) the Finished Product as necessary for Release; and
- (c) the Finished Product as necessary for stability testing.

“**Raw Materials**” means all active ingredients, other ingredients, packaging materials and other components and materials required to Manufacture and package the Finished Product;

“**Relevant Authority**” means any regulatory authority or other governmental body whose approval is necessary to Manufacture, store, market, sell and/or distribute the Product in any country in the Territory;

“**Release**” means confirmation, pursuant to Section 3.1.1 below, that the Product meets all applicable Specifications (including, but not limited to, all manufacturing and testing Specifications) and Packaging and Labelling Specifications.

“**Required Specification Change**” shall mean a Specification Change required by Applicable Laws or by a Relevant Authority;

“**Specifications**” means the specifications of the Product as set out in Appendix 1 (as may be amended from time to time pursuant to Section 2.4 below) and as filed with and approved by the FDA and/or any other Relevant Authorities, together with the manner of performance of the Manufacturing Services and specification of the related Raw Materials, components, methods and stability protocols and procedures as set forth in and in accordance with (a) the relevant Marketing Authorization, (b) the master control documents and change control documents utilized as of the Effective Date, as may be amended from time to time upon written agreement of the Parties, and (c) cGMPs;

“**Specification Change**” shall mean any change to the Specification, the Packaging and Labelling Specification or Manufacturing Services, including, but not limited to, any different or additional requirements arising out of a launch of the Product in any country in the Territory, in each case made in accordance with Section 2.4 below;

“**Supply Price**” means \$[\*\*] per Vial (for each of the 10mg and 15mg Products). The Committee shall review the Supply Price once every [\*\*] years and increase the Supply Price based upon any increase in the cost of manufacture of the Products; provided, however, that notwithstanding the foregoing, in no event shall any increase to the Supply Price exceed the lesser of: (i) [\*\*] percent ([\*\*]%) over the Supply Price in effect for the preceding [\*\*] ([\*\*]) year period or (ii) the percentage change in the Producer Price Index (Commodities) for Chemicals and Allied Products—Drugs and Pharmaceuticals (as published by the Bureau of Labor Statistics) over the preceding [\*\*] ([\*\*]) year period.

“**Term**” means the period that begins on the Effective Date, and ends upon expiration or earlier termination of this Agreement pursuant to Section 10 below;

“**Third Party**” has the meaning specified in the License Agreement;

“**Third Party Manufacturer**” means a Third Party appointed by Pacira to Manufacture the Product or any part of it on its behalf and approved by the Company pursuant to Section 2.6.5 below or by EKR in the event of a termination of this Agreement by Pacira pursuant to Section 10.2 below; and

“**Vial**” has the meaning specified in the License Agreement.

To the extent other capitalized terms contained herein are not otherwise defined, such terms shall have the meaning set forth in the License Agreement.

## 2. MANUFACTURE OF PRODUCT

2.1 **Commencement.** Notwithstanding anything to the contrary, except as expressly provided herein the Parties acknowledge that: (i) the Parties’ respective rights and obligations under this Agreement commenced as of the Commencement Date and (ii) during the period between the Effective Date and the Commencement Date, all Product supply was pursuant to the terms and conditions of the Transition Services and Inventory Agreement (as defined in the License Agreement).

2.2 **Manufacture of the Product.** Subject to the terms and conditions of this Agreement, Pacira shall perform, or procure from a Third Party Manufacturer the performance of, the Manufacturing Services in accordance with:

2.2.1 the Specifications;

- 2.2.2 all cGMPs and other regulations now in place or established during the Term by a Relevant Authority that are applicable to the performance of the Manufacturing Services;
  - 2.2.3 all Applicable Laws relating to the performance of Manufacturing Services; and
  - 2.2.4 the Packaging and Labelling Specifications.
- 2.3 **Pacira Responsibilities.** During the Term, Pacira shall be responsible for:
- 2.3.1 **Sourcing of Raw Materials.** Obtaining all Raw Materials required to Manufacture the Product in accordance with the Specification, the Packaging and Labelling Specification, Applicable Laws and cGMPs.
  - 2.3.2 **Equipment, Shipping Supplies and Personnel.** Supplying all equipment, shipping supplies, materials and personnel necessary for the performance of the Manufacturing Services and Delivery.
  - 2.3.3 **Raw Material Inventory.** Maintaining in its inventory such quantities of Raw Materials as the Parties shall reasonably deem necessary from time to time to enable it to perform its obligations under the terms and conditions of this Agreement in a timely manner.
  - 2.3.4 **Finished Product Safety Stock.** Storing at its expense safety stock of unlabeled vials (conforming to all applicable Specifications) in quantities to be agreed by the Joint Commercialization Committee as part of the Backup Plan described in Section 2.11 below (the “**Safety Stock**”). Finished Product may be Released from the Safety Stock to fill the Company’s orders under this Agreement. Pacira shall store and maintain such Safety Stock in accordance with cGMPs and all other Applicable Laws.
  - 2.3.5 **Recordkeeping.** Maintaining complete and accurate documentation of all validation data, stability testing data, Batch records, Quality Control and laboratory testing and any other data required under cGMPs and other requirements of any Relevant Authority in connection with the performance of any Manufacturing Services and Delivery hereunder. Pacira shall provide Company with copies of such documentation as reasonably necessary as quickly as possible upon Company’s reasonable

request at Company's expense. Throughout the Term, and for so long thereafter as is required by Applicable Laws, Pacira shall monitor and maintain reasonable records in compliance with cGMPs and all other requirements of any Relevant Authority, including through the establishment and implementation of such operating procedures as are reasonably necessary to assure such compliance.

- 2.3.6 **Quality of Finished Product; Expiry Dating.** Pacira shall ensure that, at the Delivery Date:
- 2.3.6.1 the Finished Product will conform to the Specifications and the Packaging and Labelling Specifications;
  - 2.3.6.2 the Finished Product shall not be adulterated or misbranded within the meaning of the FD&C Act, provided that Company has made timely provision of compliant artwork for labelling; and
  - 2.3.6.3 all Finished Product supplied to Company hereunder shall have a remaining shelf life as of the Delivery Date of at least [\*\*] ([\*\*]) months, except that to the extent Finished Product delivered hereunder constitutes Safety Stock then such Finished Product shall have a shelf life of not less than [\*\*] ([\*\*]) months or such other shelf life as may be agreed in writing between the Parties from time to time.
- 2.3.7 **Exceptions to Pacira's Obligations.** Pacira's obligations under Section 2.3.6 shall not apply to any Finished Product which:
- 2.3.7.1 has been tampered with or otherwise altered other than by Pacira after Delivery;
  - 2.3.7.2 has been subjected to misuse, negligence or accident other than by Pacira after Delivery; or
  - 2.3.7.3 has been stored, handled or used in a manner contrary to applicable requirements by Persons other than Pacira after Delivery.
- 2.3.8 **Negation of Other Terms.** No terms or conditions contained in any Purchase Order (as hereinafter defined), acknowledgement, invoice, acceptance, or any other pre-printed form issued by any Party shall be effective to the extent it is inconsistent with or modifies the terms and conditions contained herein.

2.4 **Changes to Specification; New Specifications.**

2.4.1 **Voluntary Specification Changes**

2.4.1.1 The Company may request a Specification Change but no such Specification Change shall be implemented unless both Parties agree in writing, such agreement not to be unreasonably withheld. Notwithstanding the foregoing, Pacira shall implement, at the Company's expense, all Specification Changes requested by the Company relating to Product package and label branding, artwork and other non-regulatory changes.

2.4.1.2 As soon as is reasonable after notice of the proposed Specification Change is served by the Company, the Parties' representatives will meet (either in person or by telephone conference) to discuss the proposed Specification Change. The Parties will confer in good faith as to the most cost-effective and efficient means to implement or to otherwise provide for the proposed Specification Change or to discuss any reasons as to why the proposed Specification Change cannot be made.

2.4.1.3 The Parties shall itemize in good faith best estimates of the relative costs and impacts, including capital expenses and potential impacts such expenditures will have on each Party and neither Party shall be required to implement a Specification Change (other than a Company-requested Specification Change described in Section 2.4.1.1 related to non-regulatory changes) unless agreement is reached in relation to the way in which costs, expenditures and other impacts will be apportioned between the Parties.

2.4.2 **Required Specification Changes**

2.4.2.1 If a Required Specification Change is necessary, the Parties will confer immediately and in good faith to determine the most cost-effective and efficient means to implement or to otherwise provide for the Required Specification Change.

2.4.2.2 Subject to Sections 2.4.2.3 and 2.4.2.4 below (but notwithstanding anything to the contrary in Section 2.4.1 above), Pacira shall implement such Required Specification Change as quickly as reasonably possible.

2.4.2.3 The Parties shall itemize in good faith best estimates of the respective costs and impacts, including capital expenses and potential impacts that such Required Specification Changes will have on each Party.

2.4.2.4 The Parties shall use reasonable commercial endeavours to agree the costs and expenses and how such costs and expenses should be allocated between them. In the event that the Parties cannot agree the costs and expenses or how such costs and expenses should be allocated between them either Party may refer the matter to Dispute Resolution in accordance with the terms of Schedule VIII of the License Agreement.

2.5 **Audit; Access to Records**

- 2.5.1 **Company Audit Right.** Company, at its expense, shall be permitted, but not obligated, to audit (or to have its auditors or accountants audit) the performance of the Manufacturing Services by Pacira and any Third Party Manufacturer, upon reasonable prior notice and during regular business hours and without unreasonable disruption to the conduct of business by Pacira or any Third Party Manufacturer provided that any such audit shall occur not more than once per year (or more frequently in the event any violation or deficiency is discovered during the course of any such audit, or during the course of any audit by an applicable Regulatory Authority, or with respect to the Product).
- 2.5.2 **Access to Records.** Pacira and any Third Party Manufacturer shall make all records (including batch records) regarding its performance under the terms and conditions of this Agreement reasonably available for inspection by Company at such audits, and at any other time, at the Company's costs and upon Company's prior written request, as well as any records relating to supply of the Manufacturing Services and materials or ingredients to be used in the performance of the terms and conditions of this Agreement.
- 2.5.3 **Permission to Audit Third Party Manufacturers.** Pacira shall use reasonable efforts to obtain permission for such auditing by Company from any Third Party Manufacturers performing any of the Manufacturing Services.
- 2.5.4 **Compliance with Pacira Rules and Regulations.** Employees and agents of Company who inspect any facilities shall at all times comply with the reasonable rules and regulations of Pacira or any Third Party Manufacturer (as the case may be), and Company shall assume all liability relating to or resulting from the presence of Company's employees or agents on Pacira's or the Third Party Manufacturer's premises (except for liability arising from the negligence or willful misconduct of Pacira or such Third Party Manufacturer).

2.5.5 **Pacira Audit Rights.** Pacira, at its expense, shall be permitted, but not obligated, to audit the performance and adequacy of the cold chain distribution facilities owned, used or to be used by Company in the distribution of the Product, upon reasonable prior notice and during regular business hours and without unreasonable disruption to the conduct of business of Company or any Third Party provided that any such audit shall occur not more than once per year or more frequently in the event Pacira and/or the Company receive a complaint that Finished Products have been delivered which have not been stored at the proper temperatures.

2.6 **Notifications and Remedies Concerning Manufacturing Matters; Subcontracting to Third Party Manufacturers.**

2.6.1 **Potential Adverse Events.** Pacira shall promptly notify Company of, and shall keep Company informed in relation to, any problems or unusual production, packaging or other Manufacturing situations which have, or are reasonably likely to have, a material adverse effect upon the Manufacturing Services or Delivery and shall use commercially reasonable efforts to promptly remedy or prevent any such situation.

2.6.2 **Potential Supply Issues.** Without limiting the Parties' respective rights and obligations under Section 2.11 below, in the event Pacira is or reasonably anticipates that it will be unable to Manufacture or have Manufactured and Deliver Product in sufficient quantities to satisfy Company's forecasted requirements and/or maintain the Safety Stock in accordance with Section 2.3.5, due to any cause, Pacira shall promptly inform Company of the expected duration of its inability to Manufacture or have Manufactured sufficient quantities of Product and shall keep Company informed on a timely basis of developments during any such period of time.

2.6.3 **Notice of Correspondence With and Actions by Relevant Authorities.** Pacira shall notify Company within three (3) Business Days following receipt of any notices or communications sent to Pacira by any Relevant Authority or any inspection, investigation or other inquiry, or other material governmental notice or communication, which have, or are reasonably likely to have, a material effect upon the Manufacturing Services, or which otherwise relates to the Products or the Manufacturing Services, promptly after Pacira becomes aware of such inspection, investigation, inquiry, notice or communication and shall promptly thereafter provide to Company a written summary of all findings by the Relevant Authority. Pacira shall, to the extent possible, allow upon reasonable request a representative of Company to be present during any such inspection, investigation or other inquiry.



- 2.6.4 **Responses to Relevant Authorities.** The Parties shall discuss any corrective actions to be taken, including any written responses to the Relevant Authority and each Party shall take into account in good faith the other Party's comments. Pacira shall be principally responsible for communications with any Relevant Authority in the Territory except when Company is required to communicate with the Relevant Authority by Applicable Law or to the extent the communication relates to the Products. Each Party shall use commercially reasonable efforts to communicate with the other Party in advance of any such communications with the Relevant Authority.
- 2.6.5 **Subcontracting to Third Party Manufacturers.** Pacira may subcontract any of its Manufacturing obligations under this Agreement to a Third Party Manufacturer, and shall notify the Company prior to the selection of any such Third Party Manufacturer; provided, however, that in no event shall such subcontracting relieve Pacira of any of its obligations under this Agreement. Pacira shall be responsible for ensuring that each Third Party Manufacturer has all necessary Manufacturing Approvals, is a cGMP-approved facility and is otherwise in compliance with the terms and conditions of this Agreement and all Applicable Laws.
- 2.7 **Compliance with Applicable Laws; Backup and Disaster Recovery Plans**
- 2.7.1 **Compliance with cGMP and Applicable Laws.** Each Party shall comply with all cGMP and Applicable Laws that are applicable to it in carrying out its duties and obligations under the terms and conditions of this Agreement.
- 2.7.2 **Approved Facility.** Pacira will perform (or procure the performance of) the Manufacturing Services at the Approved Facilities or, if applicable, the Backup Facility.
- 2.7.3 **Manufacturing Approvals.** Pacira shall maintain and shall require any Third Party Manufacturer to maintain in good order all Manufacturing Approvals and permits relating to the Approved Facilities, the Backup Facility, if applicable and the Manufacturing Services, as granted by any Relevant Authority, for so long and insofar as is necessary to permit Pacira to provide the Manufacturing Services as contemplated hereunder. Pacira shall, and will require any Third Party Manufacturer to, make copies of such Manufacturing Approvals and all related documents available to Company and its designees for inspection, upon reasonable request from Company.
- 2.7.4 **Backup and Disaster Recovery Plans.** Without limiting the Parties' respective rights and obligations under Section 2.11 below, Pacira will use commercially reasonable efforts to establish, maintain and execute such

backup and disaster recovery practices and procedures as are commercially reasonable under the circumstances, so as to facilitate an uninterrupted supply of Product to Company and to require the same of any Third Party Manufacturer. Upon Company's request, Pacira shall discuss such practices and procedures with Company and in good faith consider Company's suggestions with respect thereto.

- 2.7.5 **Narcotic Tracking Requirements.** Each Party shall comply with existing or future narcotic tracking requirements of any Relevant Authority that are applicable to it and, at such times as may be required under such Relevant Authority requirements, shall provide the other Party with reports containing such information regarding Product deliveries as are required by such Relevant Authority requirements. In addition, each Party shall be responsible for producing to the applicable Relevant Authorities any other product consumption reports or product tracking information (i.e., diversion) as may be required from such Party by any Relevant Authority from time to time.

2.8 **Use of Third Party Materials.**

- 2.8.1 Pacira shall not, and shall require any Third Party Manufacturer not to:

2.8.1.1 incorporate any materials that are proprietary to, or that are manufactured using any proprietary process of, any Person into any Product supplied to Company hereunder without necessary consents of such Person; or

2.8.1.2 design any process for the manufacture of Raw Materials or Product so as to require the use of any proprietary materials or processes of any Person without necessary consents of such Person.

2.9 **Handling of Hazardous Materials.**

- 2.9.1 **Hazardous Materials Notification and Training.** Pacira shall use commercially reasonable efforts (and shall require any Third Party Manufacturer to use commercially reasonable efforts) to inform its employees and contractors of any known or reasonably ascertainable Hazardous Materials associated with the Product or its raw materials or active ingredient, or any Hazardous Materials generated through performance of the Manufacturing Services, and provide such persons with reasonable training in the proper methods of handling and disposing of such items.

- 2.9.2 **Compliance with Applicable Laws.** Pacira shall (and shall require any Third Party Manufacturer) to handle, accumulate, label, package, ship and

dispose of all Hazardous Materials generated through performance of the Manufacturing Services in accordance with all Applicable Laws and other requirements of Relevant Authorities.

2.10 **Labelling.**

2.10.1 **Provision of Artwork; Changes to Labelling.** Company, at Company's cost and expense, shall provide to Pacira camera-ready artwork for the labelling of the Products. Company shall be responsible for assuring that the artwork as selected by Company complies with the requirements of Applicable Law in the Territory and for any claims that such use infringes the rights of third parties, except to the extent that such infringement is in relation to permitted use of the Trademarks (as defined in the License Agreement) under the terms of the License Agreement. Notwithstanding anything to the contrary, in the event any change to Product labelling is required by Applicable Law or requirements of Relevant Authorities, Company shall be responsible for all costs of implementing such change to the extent such change is made after the Agreement Date. The Company shall be responsible for the cost of any branding-driven Product labelling changes that the Company may elect to make from time to time (e.g., to colour, layout, etc.).

2.10.2 **Obsolete Stock Arising From Label Change.** Any stock rendered obsolete by a change in the Product labelling requested by Company or required by any Regulatory Authority in the Territory shall, at the Company's option, either be relabelled by or purchased from Pacira by Company at Pacira's actual cost.

2.11 **Back-Up Plans; Supply Failures.**

2.11.1 **Back-Up Plans.** Prior to the Agreement Date, the Parties have negotiated in good faith and finalized mutually-acceptable, detailed, written plans regarding: (i) securing of backup suppliers for five (5) key Raw Materials as further described below (the "**Backup Raw Material Supplier Plan**") and (ii) the build-out, qualification, and establishment of a back-up facility owned by Pacira and located at a site that is separate from the Approved Facility (the "**Backup Facility**," and such plan, the "**Backup Manufacturing Plan**"). The Backup Raw Material Supplier Plan and the Backup Manufacturing Plan is consistent with the provisions set forth in subsections (a) and (b) below, respectively:

(a) **Backup Raw Material Supplier Plan.** The Backup Raw Material Supplier Plan will: (i) identify cGMP-compliant backup suppliers for each of the following three (3) key Raw Materials: DOPC, Trycaprylyn and Triolein (together with the backup suppliers for

cholesterol and DPPG, the “**Backup Raw Material Suppliers**”), (ii) provide for the continued maintenance of qualifications that are in existence as of the Effective Date for the Backup Raw Material Suppliers for cholesterol and DPPG, and (iii) set forth a detailed plan of action (including timelines and a detailed breakdown of associated costs and economic triggers) for qualification of Backup Raw Material Suppliers for DOPC, Trycaprylyn and Triolein. Pacira shall perform the tasks described in the Backup Raw Material Supplier Qualification Plan; provided, however, that the provisions of the Backup Raw Material Supplier Qualification Plan regarding the qualification of Backup Raw Material Suppliers for DOPC, Trycaprylyn and Triolein will not be implemented until such time as may be requested by Company in writing following the satisfaction of the agreed upon economic triggers and any other conditions agreed upon by the parties in the Backup Raw Material Supplier Qualification Plan.

(b) **Backup Manufacturing Plan.** The Backup Manufacturing Plan will: (i) set forth plans, timelines, costs and economic triggers for the procurement, and storage of backup equipment necessary to Manufacture the Product, (ii) set forth plans, timelines, costs and economic triggers for the build-out and set up of the Backup Facility, (iii) set forth plans for the qualification of the Backup Facility, (iv) provide for the participation of appropriate Pacira personnel with knowledge relating to the Manufacture of the Product in the implementation of the Back-Up Manufacturing Plan and (v) provide for a formula for sharing of costs relating to the implementation of the Back-Up Manufacturing Plan, whereby Pacira’s share of such costs would increase as Product sales volume increases. The Back-Up Manufacturing Plan will not be implemented until such time as may be requested by Company in writing following satisfactions of the agreed upon economic triggers and any other conditions agreed upon by the parties in the Backup Manufacturing Plan.

2.12 **EKR Step-in Right.** Notwithstanding anything to the contrary herein, in the event EKR exercises its Step-in Right pursuant to Section 17.5 of the License Agreement, PPI shall not be responsible for the supply of Product to EKR hereunder during such time that EKR exercises such right and PPI shall not be responsible for the actions or omissions of EKR after exercising such Step-in Right.

3 **TESTING; RECEIPT OF PRODUCT; ACCEPTANCE**

3.1 **Testing; Certificate of Analysis; Shipment Samples.**

- 3.1.1 **Release Testing.** Pacira shall undertake, or have undertaken by the Third Party Manufacturer, Quality Control and Release of each Batch of the Finished Product using the analytical testing methodologies which are set forth in the Specifications and any Marketing Authorization and as required by cGMP and any other Applicable Laws.
- 3.1.2 **Certificate of Analysis.** Pacira shall furnish Company with a Certificate of Analysis for each Batch of the Product on or before the date on which the Product is Delivered to Company.
- 3.1.3 **Record Retention.** Pacira shall retain records pertaining to all such testing as required by Applicable Laws.
- 3.1.4 **Retention of Samples.** Pacira shall properly store and retain, or have any Third Party Manufacturer or suppliers properly store and retain, samples (identified by Batch number) of:
  - 3.1.4.1 Product that it supplies to Company; and
  - 3.1.4.2 Active ingredient and other materials used to Manufacture the Product (except water, compressed gases and highly volatile compounds),in each of the foregoing cases, in conditions, and for times required by, Applicable Laws and cGMPs.
- 3.1.5 **Qualification of Independent Testing Laboratory.** Promptly after the Effective Date, the Parties shall agree upon a qualified, independent testing laboratory to which purported Non-Conforming Product shall be submitted in accordance with [Section 3.2.8](#) below (the "[Independent Testing Laboratory](#)"). Following satisfactions of the agreed upon appropriate economic triggers and any other conditions agreed upon by the Joint Commercialization Committee, Pacira shall complete a transfer to the Independent Testing Laboratory (subject to appropriate confidentiality provisions) of all relevant analytical methods to be used for testing of the Product. Upon completion of the transfer, EKR shall reimburse Pacira for the reasonable costs and expenses of such transfer within thirty (30) days of receipt of an invoice and satisfactory documentation in support of such transfer expenses.

3.2 **Rejection/Acceptance Procedures; Non-Conforming Product.**

- 3.2.1 **Right to Reject Nonconforming Product.** Subject to the provisions of this clause, Company shall be entitled to reject any portion or all of any shipment of Finished Product (or any component thereof) that, at the time of Delivery is Nonconforming Product.

- 3.2.2 **Visual Inspection.** Within ten (10) Business Days of Delivery of a shipment of Finished Product, Company shall, at its option, inspect (or have inspected) such shipment for transport damages, completeness, and, as far as reasonably possible, any other Non-Conformity apparent from a reasonable visual inspection.
- 3.2.3 **Notification of Defects Discovered During Visual Inspection.** Company shall promptly, and in no event more than ten (10) Business Days after the end of such inspection period, notify Pacira if the Company has discovered that the shipment of Finished Product includes Nonconforming Product.
- 3.2.4 **Notification of Defects Discovered After Visual Inspection.** In the case of Product with defects that were not readily discoverable within the periods provided in Section 3.2.3, Company shall promptly, and in no event more than five (5) Business Days of discovery of such defect, notify Pacira of such defect.
- 3.2.5 **Content of Defect Notices.** Any notification by Company to Pacira of Nonconforming Product shall indicate the defect.
- 3.2.6 **Pacira Response to Defect Notice.** Pacira shall notify Company as promptly as reasonably possible, but in any event within ten (10) days after receipt of Company's notice of rejection, whether it accepts or disputes Company's assertions that certain Finished Product is a Nonconforming Product.
- 3.2.7 **Provision of Replacement Product.** Whether or not Pacira accepts Company's assertion that certain Finished Product is Nonconforming Product: (i) Pacira shall, as soon as reasonably possible, replace all such Nonconforming Product with Finished Product that complies with the requirements of the terms and conditions of this Agreement ("**Replacement Product**"), and (ii) except as provided in Section 3.2.12 below, Company shall pay the Supply Price invoiced in connection with the Replacement Product within thirty (30) days after receipt of an invoice for such Replacement Product. Except as provided in Section 3.2.10 below, in no event shall the Company have any obligation to pay any invoice for the purported Nonconforming Product.
- 3.2.8 **Dispute as to Defect; Submission to Independent Testing Laboratory.** If Pacira disputes Company's assertion that certain Product is a Nonconforming Product, then at either Party's request the Independent Testing Laboratory and subject to agreement by the Parties as to the appropriate procedures and tests to be conducted, shall analyze a sample of the allegedly Nonconforming Product and any shipment as necessary to determine whether the rejected Product is Nonconforming Product.

- 3.2.8.1 The Independent Testing Laboratory shall use such procedures and tests to reach a conclusion. Both Parties agree to cooperate with the Independent Testing Laboratory's reasonable requests for assistance in connection with its analysis hereunder.
  - 3.2.8.2 Both Parties shall be bound by the Independent Testing Laboratory's results of analysis, which, in the absence of manifest error, shall be deemed final as to any dispute over the Nonconformity.
  - 3.2.8.3 The costs of testing by the Independent Testing Laboratory together with any reasonable costs incurred by the Parties shall be borne by the losing Party, or if the laboratory or expert cannot place the fault noticed and complained about, then the Parties shall share equally the expenses in connection with such laboratory or expert and bear their own costs.
- 3.2.9 **Defect Accepted by Pacira or Determined by Independent Testing Laboratory.** If Pacira accepts Company's assertion that certain Finished Product is Nonconforming Product or if the Independent Testing Laboratory determines that such Finished Product was a Nonconforming Product: (i) Pacira shall bear (and, to the extent already paid for by Company, reimburse or refund to Company) all freight, tax, and insurance costs incurred in transporting such Replacement Product to Company's designated location and (ii) if Company has previously paid for the Nonconforming Product, Pacira shall issue a credit in accordance with Section 3.2.12 below.
- 3.2.10 **Lack of Defect Acknowledged by Company or Determined by Independent Testing Laboratory.** If the Independent Testing Laboratory determines, or if Company acknowledges the same in writing, that such Finished Product was not a Nonconforming Product, then Pacira shall provide an invoice to Company as of the earlier of such determination or acknowledgement, which invoice shall set forth:
- 3.2.10.1 the Supply Price for the purported Nonconforming Product; together with
  - 3.2.10.2 all freight, tax, and insurance costs incurred in transporting such Replacement Product to Company or its designee.

Such invoice for the purported Nonconforming Product shall be in lieu of the invoice for the original shipment of the allegedly Nonconforming Product. Company shall pay such invoice within thirty (30) days after receipt.

- 3.2.11 **Return or Destruction of Nonconforming Product.** Any Nonconforming Product shall, at Pacira's sole discretion and expense, either:
- 3.2.11.1 be returned to Pacira within a reasonable period of time and relabelled or reworked as permitted in the Marketing Authorizations and Specification, if permitted by the Relevant Authorities, or
  - 3.2.11.2 destroyed by Company in accordance with Applicable Law.
- 3.2.12 **Refund of Payments for Nonconforming Product.** In the event that Product is determined to contain a Nonconformity after Company has already remitted payment to Pacira for such Product, Pacira shall credit Company the amount for such Nonconforming Product against future payments owing by Company or, provided that Company has not already paid for the Replacement Product, provide Replacement Product at Pacira's sole cost and expense.

#### 4 **QUANTITIES FORECASTING AND PURCHASE ORDERS**

- 4.1 **Purchase Lot Size.** Company shall purchase Product from Pacira in multiples of a single Batch or such smaller quantities as the Parties shall agree. Batch quantities for each Product Presentation Form are listed in Appendix 1. Pacira will split a specific lot, upon Company's request via the Purchase Order, to create an approximately half normal batch size of the two Presentation Forms, for a fee of [\*\*] (\$[\*\*]) US dollars, in addition to the standard Product Supply Price per Vial.
- 4.2 **Batch Requirements; Packaging Requirements.** Company shall specify the Presentation Form, Packaging and labelling requirements for each Batch. It is understood and agreed by the Parties that no single Batch may contain more than one Presentation Form, unless Company has requested a split Batch via the Purchase Order. Responsibility for Packaging shall be with Pacira.
- 4.3 **Purchase Orders and Forecasts.** Company shall provide to Pacira, on a [\*\*] basis (or on a [\*\*] basis, if the Committee so determines) throughout that portion of the Term that begins on the Commencement Date, forecasts of units of Product estimated to be required by Company during the upcoming twelve (12) month period. The first [\*\*] ([\*\*]) months of each forecast specifying Company's requirements shall serve as a firm commitment for quantities of Product (for the



[\*\*]) and shall be deemed to be a “**Purchase Order**” for the purposes of this Agreement, and the remaining [\*\*] ([\*\*]) months of each forecast shall be a non-binding estimate of requirements for such period. In each Purchase Order, Company shall specify the desired Delivery Date(s) for Product to be supplied during the [\*\*] ([\*\*]) month period covered by such Purchase Order. Pacira shall provide Company with a written acknowledgement of each Purchase Order from Company within five (5) days of receipt of the Purchase Order from Company as set forth in Section 4.5 below.

- 4.4 **Purchase Orders in Excess of Forecast.** Notwithstanding the foregoing, Pacira will be required to accept Purchase Orders for Product only for quantities which are no greater than [\*\*] percent ([\*\*]%) more than the quantities of such Product reflected in the second quarter covered by the forecast provided immediately preceding the most recent forecast. Pacira will use commercially reasonable efforts to supply quantities of Product exceeding the amounts set forth in this Section 4.4.
- 4.5 **Acceptance of Purchase Orders.** Each Purchase Order shall be subject to acceptance in writing by Pacira within five (5) days of receipt, and Pacira may only reject Purchase Orders from Company to the extent that they are contrary to the provisions of this Section 4.
- 4.6 **Supply of Products.** Pacira shall supply Product in accordance with such Purchase Orders (including, but not limited to, in accordance with the quantities (by Presentation Form), Delivery Dates, and Delivery locations specified in such Purchase Orders), free from any liens or encumbrances.
- 4.7 **Delivery Date.** Pacira shall Deliver each of Company’s orders for the Product on the relevant Delivery Date or no earlier than one week prior to and no later than one week following the Delivery Date requested in the applicable Purchase Order, unless Pacira (without prejudice to the Parties’ respective rights and obligations under Section 2.11 above) has given notice in writing to Company of its inability to supply such Product within five (5) days of receipt of Company’s Purchase Order under Section 4.3 above (in which event Pacira shall use its best efforts to supply the Products as soon as possible but not later than twenty (20) days of the Delivery Date). If Pacira is unable to Deliver ordered Product within this period Pacira shall promptly notify Company of that fact, the reason for the delay and (if appropriate) give its best estimate of the likely date of delayed Delivery.
- 4.8 **Late Delivery.** Without limiting the Parties’ respective rights and obligations under Section 2.11 above, if Delivery of the Product has not taken place or is not estimated to take place within thirty (30) days of the requested Delivery Date, Pacira shall use all reasonable endeavours to:
- 4.8.1 secure alternative supplies of the Product from an Affiliate or a Third Party on the same terms as the terms and conditions of this Agreement; and

- 4.8.2 shall provide Company all reasonable co-operation and assistance in order to ensure continuity of supply.
- 4.9 **Shipping Documentation.** With each shipment of Finished Product, Pacira shall provide Company with commercially appropriate shipping documentation, including, without limitation, bills of lading and a Certificate of Analysis which shall:
- 4.9.1 identify the applicable Batch number of Finished Product;
- 4.9.2 record conformance of the shipment with the Specification and provide applicable supporting data; and
- 4.9.3 show that the Product was manufactured in accordance with cGMPs and all applicable regulatory filings, Applicable Law and all Manufacturing Approvals.
- 4.10 **Certificate of Compliance.** With the initial shipment of Finished Product and annually thereafter, Pacira shall provide Company with a Certificate of Compliance certifying that the Approved Facility is in compliance with cGMP and all other Applicable Laws.
- 4.11 **Delivery Term.** Pacira shall Deliver the Finished Products F.O.B at the loading dock of Pacira's designated packaging facility.

## 5 TITLE AND PAYMENT

- 5.1 **Payment of Supply Price.** Company shall pay to Pacira the Supply Price for each Vial of Product as is ordered by Company and supplied, Delivered and Released by Pacira in accordance with the terms and conditions of this Agreement. If Company has requested a split lot, then Company shall pay an additional \$[\*\*] to Pacira upon Delivery and in accordance with the terms and conditions of this Agreement.
- 5.2 **Passage of Title and Risk.** Legal title, risk in, and responsibility for, the Product shall pass from Pacira to Company upon Delivery of the Product. Upon Delivery, Company shall be responsible for, without limitation, arranging and maintaining proper temperature controlled handling and necessary narcotic product security for the Product.
- 5.3 **Invoicing.** Pacira shall render an invoice in respect of the Supply Price for each shipment of the Product upon Delivery. Company shall pay amounts properly due under the relevant invoice within forty-five (45) days from the actual date of Delivery. Unless otherwise agreed between the Parties, the Supply Price shall be invoiced and paid in U.S. Dollars.

- 5.4 **Taxes.** If Company is required to deduct or withhold for or on account of any tax required by Applicable Laws or regulations, Company shall:
- 5.4.1 pay to the relevant authorities the full amount required to be deducted or withheld; and
  - 5.4.2 forward to Pacira an official receipt (or certified copy) or other documentation reasonably acceptable to Pacira evidencing payment to such authorities.
- 6 **PROJECT MANAGEMENT**
- 6.1 **Project Managers.** Each Party shall from time to time by notice to the other nominate a Project Manager to co-ordinate relationships between the Parties pursuant to the supply arrangement comprised in the terms and conditions of this Agreement. The Project Manager shall be the first point of contact between the parties in relation to the placement of Product orders, the status of import and export licenses, confirmation of Delivery Dates, issues relating to Manufacturing and Manufacturing Approvals.
- 6.2 **Identification of Project Managers.** The Project Managers shall form a project team comprising relevant staff from both Pacira and Company for the co-ordination of the supply of the Product to Company. From the Effective Date the Project Managers for the parties shall be:
- For Pacira:     [\*\*]  
                    Senior Manager, Supply Operations**
- For Company: [\*\*]  
                    Vice President Manufacturing/Quality Control**
- 6.3 **Cooperation.** Pacira and Company shall diligently carry out the tasks assigned to them hereunder, and as subsequently agreed in writing during the Term. Each Party shall co-operate with the other in good faith particularly with respect to problems or contingencies that arise during the Term and shall perform its obligations in good faith and in a commercially reasonable, diligent and workmanlike manner.
- 6.4 **Disputes.** In the event of a dispute or disagreement between the Parties relating hereto such dispute or disagreement shall be referred for resolution in accordance with the Dispute Resolution procedures contained in Schedule VIII of the License Agreement.

7 **MANUFACTURE AND WARRANTIES**

7.1 **Changes to Approved Facilities.** Pacira shall notify the Company of any material change to the Approved Facilities or its (or any Third Party Manufacturer's) manufacturing environment. To the extent any such change could reasonably be expected to materially adversely affect Pacira's ability to perform its obligations under this Agreement, Pacira shall not implement such change without obtaining the prior, written consent of the Company, such consent not to be unreasonably withheld or delayed.

7.2 **Pacira Representations, Warranties and Covenants.** In addition to the representations and warranties set forth in the License Agreement (which are incorporated herein by reference), Pacira represents, warrants and covenants to Company that as of the date hereof and at all times thereafter during the Term:

7.2.1 the Approved Facilities and the Backup Facility shall comply in all respects with all cGMPs and Applicable Laws, regulations, rules and standards, and Pacira and each Third Party Manufacturer have all required Manufacturing Approvals and other requirements of the Relevant Authorities, including, but not limited to, any Manufacturing Approvals required by the FDA, the DEA, and any analogous governmental authority in the Territory;

7.2.2 the Approved Facilities currently have, and at all times during the Term shall maintain, the necessary equipment and appropriately qualified personnel required for the Manufacture the Product in compliance with cGMPs, all other Applicable Laws, Marketing Authorisation (as defined in the License Agreement) in any country in the Territory, and Pacira at all times during the Term shall maintain its leasehold interest in, or other right to occupy, the Approved Facility;

7.2.3 each Finished Product Delivered under this Agreement shall meet the Specification and the Packaging and Labelling Specifications, and shall not be adulterated or misbranded within the meaning of the FD&C Act, or be an article that may not be introduced into interstate commerce;

7.2.4 each Finished Product Delivered under this Agreement shall be Manufactured and tested and Released in strict compliance with the Specifications and each Marketing Authorization;

7.2.5 each Finished Product Delivered under this Agreement shall be Manufactured in compliance with all Applicable Laws, including, but not limited to, those promulgated by any Relevant Authority, and relevant professional standards and codes of conduct;

- 7.2.6 each Finished Product Delivered under this Agreement shall be Manufactured in compliance with cGMP;
- 7.2.7 each Finished Product Delivered under this Agreement shall at the time of Delivery be free and clear from all liens, encumbrances, and defects of title;
- 7.2.8 that it has and will at all times during the Term the requisite expertise and skill to perform its obligations hereunder;
- 7.2.9 Pacira shall notify the Company in writing immediately upon receipt of any notice of default under any lease, credit facility, loan agreement, security agreement, or other agreement relating to the Approved Facility or any other default or purported default which could reasonably be expected to affect Pacira's ability to Manufacture the Product in accordance with the terms and conditions of this Agreement, and shall provide the Company with the opportunity to cure any such default or purported default on behalf of Pacira;
- 7.2.10 the Manufacture of the Products shall not infringe, misappropriate or otherwise violate any patent, copyright, trade secret or other intellectual property right of any Third Party; and
- 7.2.11 neither Pacira, any Third Party Manufacturer, nor any person employed or engaged by any of the foregoing in connection with the work to be performed under this Agreement has been debarred under section 306(a) or 306 (b) of the Food Drug & Cosmetic Act and no debarred person will in the future be employed or engaged by any of the foregoing in connection with any work to be performed hereunder.
- 7.2.12 That Pacira or any of its Affiliates or Third Party Manufacturers shall not wilfully or intentionally disrupt or cause the disruption of Supply of Products to EKR as provided herein.
- 7.3 **Disclaimer.** Pacira makes no warranties, express or implied, other than those expressly made herein or in the License Agreement with respect to the Product. All other warranties, express or implied, including, but not limited to, the implied warranties of merchantability satisfactory quality and fitness for a particular purpose are hereby disclaimed by Pacira.
- 8 **ADVERSE EVENTS AND PRODUCT RECALL**
- 8.1 **Adverse Event.** Each of the parties shall promptly notify the other upon discovery of the occurrence of any Product complaint or adverse event concerning the Product. Each Party shall be responsible for notifications of adverse events to be made to the FDA as set forth in Section 3.5 of the License Agreement.

- 8.2 **Company Initiated Recalls.** In the event Company is required or voluntarily decides to initiate a recall, withdrawal, or field correction of the Product, Company shall notify Pacira and provide a copy of its proposal, including the recall letter, for review prior to initiation of such action and the Parties shall fully consult and cooperate with each other concerning the need for such a recall and in order to develop and execute a recall plan, as Company determines is necessary. In conjunction with such recall, Pacira shall assist in the investigation to determine the cause and extent of the problem.
- 8.3 **Pacira Initiated Recalls.** In the event that Pacira independently believes that a recall, withdrawal, or field correction of the Product may be necessary or appropriate, Pacira shall notify Company of Pacira's belief, and the Parties shall fully cooperate with each other concerning the necessity and nature of such action.
- 8.4 **Company Control of Recalls.** Following the Agreement Date, all coordination of any recall or field correction activities involving Product shall be handled by Company.
- 8.5 **Costs of Recalls.** In the event that any Product is recalled as a direct result of the negligent or intentionally wrongful acts or omissions of Company or its representatives, then Company shall bear (and reimburse Pacira for) all of the costs and expenses of such recall, including expenses related to communications and meetings with all required regulatory agencies, expenses of replacement stock, the cost of notifying customers and costs associated with shipment of recalled Product from customers and shipment of an equal amount of replacement Product to those same customers. In the event that any Product is recalled as a direct result of the negligent or intentionally wrongful acts or omissions of Pacira or its representatives (including, but not limited to, of any Third Party Manufacturer) or Product misbranding or failure to meet Specification or as a result of any other breach of this Agreement by Pacira, then Pacira shall bear (and reimburse the Company for) all of the costs and expenses of such recall, including expenses related to communications and meetings with all required Relevant Authorities, expenses of replacement stock, the cost of notifying customers and costs associated with shipment of recalled Product from customers and shipment of an equal amount of replacement Product to those same customers. To the extent that the reason for any recall of Product hereunder is in part the responsibility of Pacira and in part the responsibility of Company or is not due to the fault of either Party, then the expenses shall be allocated in an equitable manner between the Parties.

9 **LIABILITY, INSURANCE AND INDEMNITIES**

9.1 The indemnity obligations, limitations of liability, obligations to maintain insurance and all other provisions of Section 10 of the License Agreement will apply with respect to this Agreement, and are hereby incorporated herein by reference.

10 **TERM AND TERMINATION**

10.1 **Term.** This Agreement shall come into effect on the Effective Date and shall continue until expiration or earlier termination of the License Agreement.

10.2 **Termination by Pacira.** Notwithstanding Section 10.1 above, effective on January 1, 2013 and on each anniversary thereof, Pacira may terminate this Agreement (without terminating the License Agreement) on 12 months written notice to EKR, subject to the terms and conditions of Section 11.5 hereof, in the event that the total payments of the Supply Price hereunder and Royalties and Additional Royalties under the License Agreement in the previous calendar year of the Term are less than [\*\*] Dollars (\$[\*\*]). For the purposes of the preceding sentence, the full amount of Royalties that would be payable by EKR, without giving effect to any deductions taken pursuant to Section 6.3(b) of the License Agreement, shall be counted towards the [\*\*] Dollar threshold described in the preceding sentence.

11 **EVENTS ON TERMINATION**

11.1 **Pending Purchase Orders.** Upon termination or expiration of this Agreement pursuant to Section 10.1 above, Pacira shall supply, and Company shall accept Delivery of, any Products Manufactured pursuant to Purchase Orders placed prior to the date of such termination.

11.2 **Survival.** The following provisions shall survive any termination or expiration of this Agreement: Section 1 (“Definitions”), Section 3.2 (“Rejection/Acceptance Procedures; Non-Conforming Product”), Section 7.2 (“Pacira Representations, Warranties and Covenants”), Section 7.3 (“Disclaimer”), Section 8 (“Adverse Events and Product Recall”), Section 9 (“Liability, Insurance and Indemnities”), Section 11 (“Events on Termination”), Section 12 (“Assignment and Sub-Contracting”) and Section 13 (“General Provisions”).

11.3 **Retention of Records.** Following any termination or expiration of this Agreement, Pacira shall retain pharmaceutical records and samples with respect to all Products manufactured hereunder, in accordance with cGMP and all other Applicable Laws.

- 11.4 **Survival as Provided Under License Agreement.** Notwithstanding anything to the contrary, the terms and conditions of this Agreement shall survive termination of the License Agreement to the extent provided in Section 17.4 of the License Agreement.
- 11.5 **Termination by Pacira.** Upon termination of this Supply Agreement by Pacira pursuant to Section 10.2 above, in the event that a Third Party Manufacturer has not already been qualified, Pacira shall continue to manufacture Products hereunder until such time that a Third Party Manufacturer is qualified and shall assist EKR in the transfer of the manufacture of the Products at EKR's cost, including the Specifications, from Pacira to EKR or EKR's designee and grant such licenses under the PPI IP as necessary to enable the Third Party Manufacturer or EKR to manufacture and package the Products. This shall include, at EKR's request, the right to observe Pacira's manufacture of the Product(s) and review all relevant know how related to the manufacture of the Products, subject to reasonable confidentiality undertakings on behalf of such observers, and reasonable cooperation by Pacira prior to and following the effectiveness of the transfer. EKR shall receive the necessary Specifications and know-how and certain intellectual property developed in the course of this Agreement to permit EKR or EKR's designee to manufacture the Products in accordance with the Specifications in place at the time of the transfer.
- 12 **ASSIGNMENT AND SUB-CONTRACTING**
- 12.1 This Agreement may only be assigned or otherwise transferred (including, but not limited to, in connection with a Change of Control (as defined in the License Agreement)) by a Party only to a permitted successor or assignee of such Party's rights and obligations under the License Agreement.
- 13 **GENERAL PROVISIONS**
- 13.1 **Entire Agreement.** The terms and conditions of this Agreement, the License Agreement and the Transition Services and Inventory Agreement set out the entire agreement and understanding between the Parties in respect of the subject matter hereof, and supersede any other agreements or understandings with respect to such subject matter, including, but not limited to, the Original Agreement and that certain Summary of Proposed Terms of an Agreement between EKR Therapeutics, Inc. and SkyePharma, Inc. for the Acquisition of DepoDur dated as of May 15, 2007.
- 13.2 **Amendments.** No variation of the terms and conditions of this Agreement shall be valid unless it is in writing and signed by or on behalf of both Parties.



- 13.3 **Notices.** The provisions of Section 19 of the License Agreement shall apply to any notices permitted or required to be given hereunder.
- 13.4 **Relationship of the Parties.** Nothing in this Agreement is deemed to constitute a partnership, agency, employer-employee or joint venture relationship between the Parties. No Party shall incur any debts or make any commitments for the other, except to the extent, if at all, specifically provided herein.
- 13.5 **Waiver.** Unless expressly agreed, no waiver of any term, provision or condition of this Agreement shall constitute a general waiver of any provisions of this Agreement, nor shall it affect any rights, obligations or liabilities under or pursuant to this Agreement which have already accrued up to the date of variation, and the rights and obligations of the Parties under or pursuant to this Agreement shall remain in full force and effect, except and only to the extent that they are so waived.
- 13.6 **Severability.** If and to the extent that any provision of this Agreement is held to be illegal, void or unenforceable, such provision shall be given no effect and shall be deemed not to be included in this Agreement but without invalidating any of the remaining provisions of this Agreement.
- 13.7 **Delay.** No failure or delay by either party in exercising any right or remedy provided by law under or pursuant to this Agreement shall impair such right or remedy or operate or be construed as a waiver or variation of it or preclude its exercise at any subsequent time and no single or partial exercise of any such right or remedy shall preclude any other or further exercise of it or the exercise of any other right or remedy.
- 13.8 **Rights and Remedies Cumulative.** The rights and remedies of each of the parties under or pursuant to this Agreement are cumulative, may be exercised as often as such Party considers appropriate and are in addition to its rights and remedies under general law.
- 13.9 **Counterparts.** This Agreement may be executed in any number of counterparts and by the parties on separate counterparts, each of which is an original but all of which together constitute one and the same instrument.
- 13.10 **Choice of Law; Forum.** This Agreement and the relationship between the parties shall be governed by, and interpreted in accordance with New York law without regard to provisions related to conflicts of laws, and, except in respect of disputes to be resolved pursuant to the Dispute Resolution procedures set forth in Schedule VIII to the License Agreement, the Parties agree to submit any dispute to the exclusive jurisdiction of the federal and state courts sitting in New York.

- 13.11 **Binding Effect.** Subject to Section 12.1, this Agreement shall be binding upon and shall inure to the benefit of the Parties hereto and their respective successors and assigns permitted under this Agreement.
- 13.12 **Standard of Manufacture.** Notwithstanding anything to the contrary contained in this Agreement, Pacira will use at least the same diligence in its efforts to manufacture and supply Products to EKR pursuant to this Agreement that it uses to manufacture and supply other comparable products, whether the distributor or buyer is Pacira, an Affiliate of Pacira, a sublicensee or an unrelated third party.

*(signature page follows)*

**IN WITNESS WHEREOF** this Agreement has been signed on behalf of the Parties hereto effective as of the Effective Date.

**EKR THERAPEUTICS, INC.**

By: /s/ Richard DeSimone  
Print Name: Richard DeSimone  
Title: CFO

**PACIRA PHARMACEUTICALS, INC.  
(F/K/A SKYEPHARMA, INC.)**

By: /s/ David Stack  
Print Name: David Stack  
Title: CEO

**APPENDIX 1**  
**THE SPECIFICATION; BATCH SIZE**

DepoDur [\*\*] mg batch size: [\*\*] Vials

DepoDur [\*\*] mg batch size: [\*\*] Vials

**APPENDIX 2**  
**PACKAGING AND LABELLING SPECIFICATIONS**

All Products will be packaged in single cartons of five (5) Vials per carton. Included in each carton is a single Coldmark freeze indicator and a DepoDur Package Insert.

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

**Execution Copy**

**DATED SEPTEMBER 25, 2007**  
**PACIRA PHARMACEUTICALS, INC.**  
**and**  
**FLYNN PHARMA LIMITED**

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**STRATEGIC MARKETING AGREEMENT**

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**THIS AGREEMENT** is made on this 25<sup>th</sup> day of September 2007

**BETWEEN**

- (1) **PACIRA PHARMACEUTICALS, INC.**, a company incorporated in the state of California whose principal place of business is 10450 Sciences Center Drive, San Diego, California 92121 USA (“**Pacira**”); and
- (2) **FLYNN PHARMA LIMITED** a company incorporated in the Republic of Ireland under company number 210742 with its registered office at Alton House, 4 Herbert Street, Dublin 2, Republic of Ireland (“**Flynn Pharma**”).

**Recitals**

- (A) Pacira, which is formerly known as Skye Pharma, Inc., is the owner of certain Pacira IP (as defined below) and possesses expertise relating to the Product (as defined below).
- (B) Flynn Pharma has, amongst other things, specialist knowledge and expertise in relation to regulatory matters, the obtaining of pricing approval, and the marketing and sale of pharmaceutical products.
- (C) Pacira desires to grant and Flynn Pharma desires to acquire the exclusive right to market, distribute and sell the Product (as defined below) in the Territory (as defined below) in the Field (as defined below).

**Operative Provisions**

**1 Definitions**

1.1 In this agreement the following words and expressions have the following meanings:

“Affiliate” means any company, corporation, firm, individual or other entity which Controls, is Controlled by or is under common Control with a party to this Agreement.

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“Applicable Laws”	means all laws, rules and regulations (as amended from time to time) regarding the manufacture, packaging, labelling, import, export, storage, distribution, representation, promotion, marketing and sale of the Product including but not limited to the Association of the British Pharmaceutical Industry Code of Practice and the relevant provisions of the Medicines Act 1968, the principles of and guidance relating to Good Manufacturing Practice (“GMP”), Good Distribution Practice (“GDP”) and Good Laboratory Practice (“GLP”) together with any equivalent laws, rules, regulations, codes or guidelines having effect in any jurisdiction in the Territory;
“Calendar Year”	means the period of twelve months commencing on 1st January in any year, and each consecutive period of twelve months thereafter during the Term;
“Commercial Delivery”	means the date of the first sale to a Third Party customer for commercial use of Product in a country within the Territory following the grant of Marketing Authorisation(s) in that country and any necessary Pricing Approval being given in that country;
“Commercialisation Committee”	means the committee to be set up under the terms of clause 4;
“Competing Product”	means an epidurally administered morphine based analgesic product (other than the Product) available in a country in the Territory which competes or would compete with the Product;
“Confidential Information”	means all confidential information, data and materials in whatever form disclosed by or on behalf of one party or its Affiliates to the other party or its Affiliates including, without



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limitation, the terms of this Agreement, data, formulae, patent disclosures, processes, protocols, specifications, Know-How, pricing strategies, agreements with Marketing Partners, marketing plans and sales forecasts, but excluding information which either party can establish by written documentation:

- (i) at the time of disclosure, is in the public domain or is public knowledge;
- (ii) after disclosure, becomes part of the public domain by publication, except by breach of any obligation of confidentiality by a party hereto or an Affiliate of such party;
- (iii) was already in its possession at the time of its receipt and was not acquired directly or indirectly from the other party or its Affiliates; or
- (iv) received from Third Parties who were lawfully entitled to disclose such information;

“Control”

means in relation to any party or an Affiliate the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such firm, person or company, by contract or otherwise, or the ownership either directly or indirectly of 50% or more of the voting securities of such company, corporation, firm, individual or entity.

“Effective Date”

means the date upon which this Agreement commences, namely the \_\_\_ of September, 2007;

“EMEA”

means the European Medicines Evaluation Agency or any successors thereto;

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“FDA”	means The Food and Drug Administration of the United States of America or any successor thereto;
“Field”	means those indications for the management of post-operative pain as are set out in UK Product License Application numbers:  [**] - [**] mg / [**] ml vial [**] - [**] mg / [**] ml vial [**] - [**] mg / [**] ml vial
“Force Majeure”	means in relation to either party, any cause affecting the performance of this Agreement or the Supply Terms arising from or attributable to any acts, events, non-happenings, omissions or accidents beyond the reasonable control of the party to perform and in particular but without limiting the generality thereof shall include strikes or labour disturbances, lock-outs, industrial action, action or inaction of any Regulatory Authority, civil commotion, riot, invasion, war, threat of or preparation for war, terrorist activity, fire, explosion, storm, flood, earthquake, subsidence, epidemic or other natural physical disaster, impossibility of the use of railways, shipping, aircraft, motor transport, or other means of public or private transport, failure or suspension of utilities, unavailability, shortage or interruption in the supply of raw material, and political interference with the normal operation of either party;
“Major Countries”	means the United Kingdom, France, Germany, Spain and Italy, or any of them;

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“Marketing Authorisation”	means the grant of all necessary regulatory and governmental approvals by a Regulatory Authority or other governmental body required to market and sell the Product in any country of the Territory but excluding any Pricing Approval;
“Marketing Partner”	means a Third Party to whom Flynn Pharma has granted rights as a sub-distributor or sub-licensee in respect of the Products in the countries of the Territory other than the United Kingdom and the Republic of Ireland in accordance with the terms hereunder;
“Marketing Plan”	means the plan for the marketing, distribution and sale of the Product in the Territory submitted to the Commercialisation Committee in accordance with clause 4;
“Marketing Year”	means any period of twelve consecutive months;
“MHRA”	means the UK Medicines and Healthcare Products Regulatory Agency or any successor thereto;
“Milestone Event”	means an event identified in clause 6 which triggers a one-off Milestone Payment;
“Milestone Payment”	means each one-off payment by Flynn Pharma to Pacira identified in clause 6 which is triggered by a Milestone Event;
“Net Sales”	means total gross sales of Product invoiced by Flynn Pharma its Affiliates and Marketing Partners to Third Parties, less the following amounts actually deducted or allowed: <ul style="list-style-type: none"> <li>(i) transport, freight and insurance costs (including for cross border movement of bulk shipments and local distribution within any country of the Territory);</li> <li>(ii) sales and excise taxes and duties;</li> </ul>

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(iii) normal and customary trade, quantity and cash discounts and rebates; and

(iv) amounts repaid or credited for properly rejected, returned or recalled goods;

“Pacira Improvements”

means any improvement to the Pacira Patents and Pacira Know-How relating to the Product and developed by Pacira or Flynn Pharma or their respective Affiliates during the Term. Pacira Improvements shall constitute part of Pacira IP subject to Pacira’s third-party agreements if any;

“Pacira IP”

means the Pacira Know-How, Pacira Patents and Pacira Improvements;

“Pacira Know-How”

means all information, procedures, instructions, techniques, data, technical information, knowledge and experience (including, without limitation, toxicological, pharmaceutical, clinical, non-clinical and medical data, health registration data and marketing data), designs, dossiers (including, without limitation, manufacturing assay and quality control dossiers) manufacturing formulae, processing specifications, sales and marketing materials and technology owned by Pacira with respect to the Product, and the Product Data;

“Pacira Patents”

means those patents set out in Schedule I which cover the Product and such other patents as Pacira may include from time to time including additions, divisions, confirmations, continuations in part, substitutions, re-issues, re-examinations, extensions, registrations, patent terms extensions; supplementary protection certificates and renewals of any of the above;

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“Pricing Approval”	means any pricing and reimbursement approval required by a Regulatory Authority to enable sale of the Product in any country of the Territory following grant of the Marketing Authorisation in that country;
“Product”	means the DepoFoam™ formulation of morphine sulphate for epidural administration presented in vials, appropriately packaged and labelled for sale to end users in such presentations and dosages as required in each country in the Territory and as are defined in the Supply Terms;
“Product Data”	means all data, information or results generated in the performance of any clinical studies, non-clinical studies (including pharmacological and toxicological studies) or chemistry and analytical studies, market, customer research and product utilisation studies and reports in respect of the Product conducted by or on behalf of either party whether before or after the Effective Date;
“Quarter”	means a three month period ending on the last day of March, June, September or December in any Calendar Year;
“Regulatory Authority”	means any competent regulatory authority or other governmental body (for example, but not by way of limitation the EMEA or MHRA) responsible for granting a Marketing Authorisation or Pricing Approval in any country within the Territory;
“Supply Terms”	means the terms and conditions for the supply of the Product by Pacira to be negotiated by the parties pursuant to clause 5.10;
“Term”	means the term of this Agreement as set out in clause 15;

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“Territory”	means the countries listed in Schedule V;
“Third Party”	means any company, corporation, firm, individual or other entity but excluding a party to this Agreement or an Affiliate;
“Trade Marks”	means those trade marks registered or applied for set out in Schedule II and such other trade marks as are agreed between the parties from time to time;
“Vial”	means a vial containing the Product supplied to Flynn Pharma in presentations and dosages and other relevant terms set out in the Supply Terms;
“Year”	means the period of twelve months commencing on the first Commercial Delivery of the Product in the Territory, and each consecutive period of twelve months thereafter during the Term.

1.2 In this Agreement, unless the context requires otherwise:

- 1.2.1 the headings are included for convenience only and shall not affect the construction of this Agreement;
- 1.2.2 references to “persons” includes individuals, bodies corporate (wherever incorporated), unincorporated associations and partnerships;
- 1.2.3 words denoting the singular shall include the plural and vice versa;
- 1.2.4 words denoting one gender shall include each gender and all genders; and
- 1.2.5 any reference to an enactment or statutory provision is a reference to it as it may have been, or may from time to time be amended, modified, consolidated or re-enacted.

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1.3 The Schedules comprise part of and shall be construed in accordance with the terms of this Agreement. In the event of any inconsistency between the Schedules and the terms of this Agreement, the terms of this Agreement shall prevail.

**2 Grant of Rights**

2.1 Subject to the terms of this Agreement, Pacira hereby exclusively appoints Flynn Pharma in the Territory to market, distribute and sell the Product in the Field in the Territory, including for the avoidance of doubt, the right to appoint Marketing Partners in accordance with the terms and conditions of this Agreement.

2.2 Pacira hereby grants Flynn Pharma an exclusive license to the Pacira IP only to the extent necessary for the marketing, distribution and sale of Product in the Field in the Territory for the Term of this Agreement.

2.3 The term “exclusive” for the purposes of clauses 2.1 and 2.2 means to the exclusion of all others, including Pacira and its Affiliates, except to the extent necessary to enable Pacira to perform its specific obligations under this Agreement, and with respect to clause 2.2, except as may conflict with the principles of free movement of goods within the European Economic Area.

2.4 Subject to the terms of this Agreement, Pacira shall not in the Territory during the Term:

2.4.1 grant any Third Party the right to register, obtain pricing approvals, market, distribute and sell the Product and/or Competing Product in the Field; or

2.4.2 either itself or through or with any Affiliate or Third Party conduct or participate in any registration, pricing approvals, marketing, distribution or sale of the Product and/or Competing Product in the Field, except as specifically permitted by this Agreement.

2.5 Flynn Pharma may describe itself as the “Marketing Authorisation” holder or applicant (as applicable), Pricing Approval negotiator, and “Authorised Distributor” for the Product in the Territory but shall not hold itself out as being entitled to bind Pacira in any manner.

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3 **Obligations**

3.1 Pacira shall at its own cost:

- 3.1.1 use commercially reasonable efforts to (a) manufacture and supply, or procure the manufacture and supply of the Product in accordance with the Supply Terms and in accordance with all Applicable Laws and, (b) procure that (i) all packaging materials shall display where possible the trade name and logo of Pacira and Flynn Pharma, subject in all cases to the requirements of the applicable Regulatory Authority; and (ii) in all countries within the Territory where Flynn Pharma or its Marketing Partner distributes the Product all packaging shall state that “DepoDur® is distributed by Flynn Pharma Limited and/or its Marketing Partner, under an exclusive licence from Pacira Pharmaceuticals, Inc.”
- 3.1.2 provide Flynn Pharma with, or allow reference to as needed, complete copies of all applications to Regulatory Authorities in its possession including but not limited to the dossier of technical, scientific and pharmaceutical documents and any other information filed with any Regulatory Authority within the Territory by or on behalf of Pacira together with all correspondence to and from such Regulatory Authorities in relation to the Product and permit Flynn Pharma to use or cross-reference the same;
- 3.1.3 provide Flynn Pharma with all reasonable assistance, information and guidance, including where appropriate direct access to employees of and consultants to Pacira and its Affiliates and any sub-contractors of Pacira and its Affiliates (including for the avoidance of doubt any manufacturers of the Product) which is reasonably necessary in relation to the conduct of any post-marketing or Phase IV studies to be conducted by Flynn Pharma in the Territory or otherwise in connection with the discharge of Flynn Pharma’s obligations under the terms of this Agreement. Pacira shall pay a contribution in an amount not to exceed US\$[\*\*] ([\*\*] Unites States Dollars) towards the costs of any of the post-marketing or Phase IV studies required under this clause 3.1.3, within thirty (30) days of receipt of an invoice from Flynn Pharma in respect of the same.



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- 3.1.4 promptly provide Flynn Pharma with all information in its possession relating to the occurrence of a serious adverse event or an adverse event (in any jurisdiction throughout the world) in connection with the Product; and
- 3.1.5 to the extent permissible by Applicable Law, promptly take all commercially reasonable action to prevent any Third Party which is not a Marketing Partner from marketing, distributing or selling the Product in the Field in the Territory.
- 3.2 The appointment of Flynn Pharma, the acceptance of forecasts and orders for the Product and the supply of the Product by Pacira to Flynn Pharma shall at all times be conditional on the Marketing Authorisation for the Product being in force in the country of the Territory to which such appointment, acceptance and orders relates.
- 3.3 Flynn Pharma shall at its own cost:
- 3.3.1 use commercially reasonable and diligent efforts to obtain as soon as possible or as agreed by the Commercialisation Committee (but not to exceed eighteen months from the Effective Date), and thereafter maintain in full force and effect in its own name, a Marketing Authorisation for the Product in each of the countries listed in clause 6.2. Flynn Pharma shall be solely responsible for, and shall bear all costs associated with, all regulatory activities related to the Product in the Territory. Flynn Pharma will comply with all conditions and requirements attaching to such Marketing Authorisations including:
- (a) in the case of the Major Countries, the conduct of any Phase IV or post marketing studies required by any Regulatory Authority as a condition of grant or maintenance of a Marketing Authorisation in the Field. For the avoidance of doubt, Flynn Pharma will keep Pacira fully informed of Flynn Pharma's activities with respect to such clinical and other studies; and

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- (b) in the case of countries outside the Major Countries, the conduct of any Phase IV or post marketing studies required by any Regulatory Authority as a condition of grant or maintenance of a Marketing Authorisation in the Field as may be determined by the Commercialisation Committee.
- 3.3.2 liaise with the relevant Regulatory Authorities in respect of each Marketing Authorisation and Pricing Approval and notify Pacira of all material communications relating thereto;
- 3.3.3 use commercially reasonable endeavours promptly to obtain all necessary Pricing Approvals in Major Countries, where such approval is required, on terms acceptable to both parties within the time period agreed by the Commercialisation Committee on the basis of the pricing strategy within the Territory (unless any delay is caused by the relevant Regulatory Authority without fault of Flynn Pharma); provided, however, that such time period shall not exceed [\*\*] ([\*\*]) months following the grant of the Marketing Authorisation unless otherwise agreed by Pacira in writing;
- 3.3.4 carry out reasonable pre-launch market development and conduct such clinical trials (except for, and in addition to, those carried out for the purposes of obtaining or maintaining the Marketing Authorisation in each of the Major Countries or required as a condition thereof) in accordance with the Marketing Plan;
- 3.3.5 use commercially reasonable endeavours to launch and achieve Commercial Delivery of the Product in each Major Countries within six (6) months of obtaining Pricing Approval in that country;
- 3.3.6 subject to achieving a price in the country (and Pricing Approval where necessary) reasonably satisfactory to Flynn Pharma and the Commercialisation Committee, launch and achieve Commercial Delivery of the Product in countries other than the Major Countries in accordance with the Marketing Plan;

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- 3.3.7 subject to the terms of this clause 3.3, during the term of this Agreement, market, sell and distribute the Product to customers within the Territory and, subject to compliance by Pacira with the Supply Terms, to satisfy the demand for the Product throughout the Territory and use reasonable commercial endeavours to attempt to increase the demand for such Product by, among other things, servicing all customer accounts with reasonable frequency. Flynn Pharma and any Marketing Partner shall be solely responsible for, and shall bear all costs associated with, all marketing, selling and distributing activities related to the Product in the Territory;
  - 3.3.8 maintain, or use reasonable commercial efforts to procure that Marketing Partners maintain, adequate sales and, where appropriate, warehouse facilities and employ, or use reasonable commercial efforts to procure that Marketing Partners employ, a sufficient number of experienced, trained and qualified personnel to promote the sale of the Product in the Territory and perform, or procure the performance of the activities set forth in the Marketing Plan;
  - 3.3.9 maintain a sufficient inventory of Product and support material, or procure that its Marketing Partners maintain a sufficient inventory of Product and support material, to reasonably fulfil the requirements of its customers in the Territory provided that Pacira shall comply with the Supply Terms;
  - 3.3.10 maintain adequate records concerning the sale of the Product as required by this Agreement and any applicable Regulatory Authority in the Territory;
  - 3.3.11 provide the Commercialisation Committee with copies of the advertising literature proposed to be used in connection with the sale of the Product in the Territory for approval, such approval not to be unreasonably withheld. Flynn Pharma shall submit such advertising literature to Pacira at least fifteen (15) business days in advance of its intended use of same and such advertising literature shall be deemed to have received Pacira's approval unless Pacira provides Flynn Pharma with written notice of rejection within said fifteen (15) business day period;

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- 3.3.12 promptly provide Pacira with all information in its possession or otherwise coming to its attention relating to the occurrence of a serious adverse event or an adverse event (in any jurisdiction throughout the world) in connection with the Product, and promptly forward to Pacira information concerning any and all charges, complaints or claims reportable to any Regulatory Authority relating to the Product that may come to Flynn Pharma's and/or its Marketing Partner's attention, and otherwise comply in all respects with the adverse drug event reporting and recall procedures set out or referred to in the Supply Terms from time to time and such other reporting and recall requirements of Applicable Law;
  - 3.3.13 obtain and maintain all necessary licenses, permits, records and Authorisations required by law and observe and comply with all Applicable Laws, ordinances, rules and regulations including, but not limited to those of the applicable Regulatory Authorities as holder of the Marketing Authorisations or under the terms of this Agreement; and,
  - 3.3.14 conduct the marketing, distribution and sale of the Product in accordance with Applicable Laws and with all due care and diligence.
- 3.4 In connection with the marketing, distribution and sale of the Product Flynn Pharma shall, without limitation:
- 3.4.1 observe and comply with such storage, stock control and operational practices and procedures as may be legally required in the Territory and/or as reasonably specified in writing by Pacira from time to time;
  - 3.4.2 from time to time consult with Pacira's representatives for the purpose of assessing the state of the market in the Territory and permit them, on reasonable prior notice, to inspect any premises or documents used in connection with the marketing, distribution and sale of the Product;
  - 3.4.3 provide the Commercialisation Committee on reasonable prior notice but not more than once in any Calendar Year, copies of its up-to-date price list for the Product together with full details of standard discounts and any special pricing arrangements entered into or proposed to be entered into;

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- 3.4.4 market the Product throughout the Territory under the Trade Marks, not remove or permit the removal of the Trade Marks, and ensure that all marketing materials for the Product shall display the Trade Marks; and
- 3.4.5 comply with all applicable regulatory and statutory requirements imposed in relation to the Product, including, without limitation, those imposed by the US Drug Enforcement Agency (“DEA”) and other equivalent agencies in the Territory.
- 3.5 Flynn Pharma and its Affiliates shall not actively market, distribute and/or sell the Product in countries outside the Territory. In addition, the parties acknowledge that since the Product is a controlled substance, the DEA and other law enforcement agencies will not permit any sale outside the Territory without relevant clearances and approvals.
- 3.6 Flynn Pharma shall not, for a period of [\*\*] ([\*\*]) years from the date of Commercial Delivery by Flynn Pharma of the Product in each country of the Territory market, distribute or sell a Competing Product in such country in the Territory. Thereafter during the Term, Flynn Pharma shall purchase no less than [\*\*] per cent ([\*\*]%) of its total requirement for Product and Competing Product in respect of each country in the Territory from Pacira.
- 3.7 Flynn Pharma shall not use in relation to the Product any packaging, labelling and Product inserts that has not been approved in writing by Pacira (such approval not to be unreasonably withheld or delayed). Flynn Pharma shall submit all packaging, labelling and Product inserts to Pacira at least fifteen (15) business days in advance of its intended use of the same. Pacira’s approval shall be deemed to have been received by Flynn Pharma unless Pacira provides Flynn Pharma with written notice of rejection within said fifteen (15) business day period.
- 3.8 If Flynn Pharma receives a request from a customer located outside the Territory and outside the European Economic Area for supply of the Product, Flynn Pharma shall promptly forward such request to Pacira.

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- 3.9 Nothing in this Agreement shall entitle Flynn Pharma to any right or remedy against Pacira if the Product is actively sold in the Territory by any person outside the Territory other than by Pacira or with Pacira's consent.
- 3.10 To the extent permissible by Applicable Law, Pacira shall use commercially reasonable efforts to ensure that in the event that Pacira grants exclusive marketing and distribution rights for the Product to a Third Party outside the Territory, provisions having equivalent effect to those contained in Clauses 3.5 and 3.8 shall be included mutatis mutandis in any agreement for such grant of rights to such Third Party.

#### **4 Commercialisation Committee**

- 4.1 The Parties shall establish a Commercialisation Committee ("Committee") consisting of 4 individuals ("Committee Members"); 2 of whom shall be nominated by Pacira; and 2 of whom shall be nominated by Flynn Pharma. The Committee Members may be replaced by notice to the other Party and shall be appropriately qualified and experienced in order to make a meaningful contribution to Committee meetings.
- 4.2 The purpose of the Committee is to provide a forum for the Parties to share information and knowledge on the on-going commercialisation of the Product including, but not limited to, monitoring progress on clinical studies, reviewing clinical trial programmes, discussing the appropriate regulatory strategy for the Product in the Territory, considering proposed marketing and promotional plans, reviewing competitor activity and discussing any regulatory, technical, quality assurance or safety issues in relation to the Product. The Committee shall conduct its discussions in good faith with a view to operating to the mutual benefit of the Parties and in furtherance of the successful development and marketing of the Product.
- 4.3 The Committee shall meet as often as the Committee Members may determine, but in any event not less than 2 times per Calendar Year. The Committee may invite individuals with special skills to attend such meetings where considered to be relevant and appropriate. The quorum for Committee meetings shall be 2 Committee Members, comprising 1 Committee Member from each Party.

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- 4.4 Flynn Pharma shall within 45 days of the Effective Date, and on or before October 15<sup>th</sup> of each Calendar Year thereafter provide the Committee with its Marketing Plan for the coming Calendar Year. Each Marketing Plan shall include, without limitation, Net Sales targets and projections with respect to sales force staffing levels, market research, physician education, marketing expenditure, post-approval clinical trials and advertising. With regard to post-marketing clinical trials, the design and conduct shall be subject to the written approval of Pacira, such approval not to be unreasonably withheld or delayed.
- 4.5 Decisions of the Committee shall be made as follows:
- 4.5.1 The Committee may make decisions with respect to any subject matter that is subject to the Committee's decision-making authority. For the avoidance of doubt, the Committee has authority to make decisions in relation to, among other things, the commercial positioning of the Product within the Territory, and such other matters as may be agreed from time to time by the Parties. Except as expressly provided in this Agreement, all decisions of the Committee shall be made by unanimous vote or written consent, with Flynn Pharma and Pacira each having, collectively, one vote in all decisions. The Committee shall use commercially reasonable efforts to resolve the matters within its roles and functions or otherwise referred to it.
- 4.5.2 If, with respect to a matter that is subject to the Committee's decision-making authority, the Committee cannot reach consensus within 15 days after it has met and attempted to reach such consensus or the parties cannot reach consensus on whether the Committee has decision-making authority regarding a matter within 15 days after such matter was first raised by either party, the dispute in question shall be referred to the Chief Executive Officer of Pacira, on behalf of Pacira, or such other person holding a similar position designated by Pacira from time to time, and an Executive Director of Flynn Pharma, or such other person holding a similar position designated by the Flynn Pharma from time to time (such officers collectively, the "Executive Officers"), for resolution. The Executive Officers shall use reasonable efforts to resolve the matter referred to them.

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4.5.3 If the Executive Officers cannot resolve the matter in accordance with clause 4.5.2 within 30 days of the reference of the matter to them, such matters in dispute shall be conclusively settled by reference to an expert as set out in Schedule VI.

**5 Product Supply, Supply Price and Supply Price Adjustment**

5.1 Subject to the other provisions of this clause, in consideration of the manufacture of the Product, Flynn Pharma shall pay to Pacira €[\*\*] (Euros) for each Vial of Product supplied to Flynn Pharma or any Marketing Partner in any country within the Territory during the Term ("Product Price"), subject to review in accordance with clause 5.9. Flynn Pharma shall pay the Product Price to Pacira within 45 days from the date of delivery of the Product by Pacira.

5.2 Within 30 days of the end of each Quarter during the Term of this Agreement Flynn Pharma shall send to Pacira a statement setting out in respect of each country in the Territory in which Product is sold, details of Product sold during the previous Quarter itemised by presentation form, quantity, total gross receipts, itemised deductions which are applied to achieve the Net Sales figure of the Product. The statement shall (where appropriate) include, without limitation:

5.2.1 the total Net Sales figure for each country expressed both in local currency and in Euros and the conversion rate used;

5.2.2 the total number of Vials sold in each country;

5.2.3 the Product Price multiplied by the number of Vials sold in that Quarter ("Prepayment"); and

5.2.4 the price adjustment payable on those Net Sales in accordance with clause 5.3 below.

5.3 Flynn Pharma shall pay to Pacira, within forty five (45) days of the end of each Quarter, an additional amount equal to the difference between (a) the Prepayment made in that Quarter, and (b) [\*\*] percent ([\*\*]%) of Net Sales of Product in the Territory in that Quarter. Within thirty (30) days of the end of each Calendar Year, there shall be



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reconciliation for the previous four (4) Quarters, and any additional payment due from Flynn Pharma to Pacira shall be paid within thirty (30) days of the resolution of such reconciliation. Notwithstanding anything contained in this Agreement to the contrary, in no event shall Flynn Pharma pay Pacira less than the Product Price for each Vial supplied by Pacira to Flynn Pharma or any Marketing Partner.

- 5.4 Subject to Pacira being able to supply Product in accordance with the Supply Terms, Flynn Pharma shall guarantee minimum Product purchases of [\*\*] Vials during the period of [\*\*] years from Commercial Delivery of the Product within the UK, with at least [\*\*] percent ([\*\*]%) (*i.e.*, [\*\*] Vials) of the total to be ordered by binding purchase orders during the first twelve (12) months following such Commercial Delivery.
- 5.5 Subject to Pacira being able to supply Product in accordance with the Supply Terms, Flynn Pharma guarantees minimum Product purchases of (a) [\*\*] Vials for each of the Major Countries excluding the UK during the first twelve months following Commercial Delivery in such Major Country, and (b) [\*\*] Vials for each of the Major Countries excluding the UK during the period commencing on the twelfth month following Commercial Delivery in such Major Country and ending on the twenty-fourth month following Commercial Delivery in such Major Country.
- 5.6 The parties also acknowledge that the minimum purchase requirements in each of the Major Countries as set forth in clauses 5.4 and 5.5 may be satisfied or deemed satisfied, in aggregate from the total sales that Flynn Pharma or its Marketing Partner(s) may realise in aggregate, from all the countries in the Territory.
- 5.7 In the event that amounts paid under clause 5.1 and 5.3 in any Year fail to meet the minimum payments set out in clauses 5.4, 5.5 and 5.6, Flynn Pharma may pay to Pacira the difference between the sums actually paid and the minimum payments specified in clauses 5.4 and 5.5. If Flynn Pharma does not make the minimum purchase and payment for any Calendar Year, Pacira shall have the right at its option to:
- 5.7.1 convert the exclusive rights granted by this Agreement into non-exclusive rights, in respect of [\*\*] ([\*\*]) Major [\*\*] for each tranche or part tranche of [\*\*] Vials which are not purchased in that Calendar Year, such Major [\*\*] to be determined by Flynn Pharma, or

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- 5.7.2 terminate this Agreement with respect to each such Major Country. For the avoidance of doubt, any and all licensing payments, as set out in clause 6, made by Flynn Pharma are excluded from the Vial sale minimum calculations set forth in this clause 5.
- 5.8 For the avoidance of doubt, Pacira shall be liable for any Third Party royalty obligations existing at the date hereof relating to the Pacira IP or in relation to the sales of Products in the Territories.
- 5.9 On the [\*\*] anniversary of the Effective Date, and each second anniversary thereafter (the “Price Revision Dates”), the parties will discuss in good faith and negotiate a mutually agreeable Product Price taking into account increases in Pacira’s labour, overhead and raw material costs from the Effective Date or last price increase, and Flynn Pharma’s concerns of securing a corresponding increase in the average in-market price of the Product. Notwithstanding the foregoing, on the Price Revision Dates, Pacira may at its sole discretion increase the Product Price by an amount up to the greater of (a) the percentage increase (if any) in the index of manufacturers other than of food, beverages, tobacco and petroleum products (“Manufacturers’ (Other) Index”), published by the UK Central Statistics Office for the immediately preceding Year (or as applicable its successor index), and (b) [\*\*] percent ([\*\*]%) ; provided that such increase will only be permitted to the extent that Flynn Pharma has been able to secure a corresponding increase in the average in- market price of the Product as reported in the Quarterly report provided pursuant to clause 5.2; provided further that Flynn Pharma shall use its reasonable commercial efforts to secure such increase in the price of the Product. Pacira shall provide Flynn Pharma no less than ninety (90) days notice of any proposed price increase.
- 5.10 Notwithstanding the above clause 5.9, if Pacira’s labour, overhead and/or raw material cost of the Product increases by more than [\*\*] percent ([\*\*]%) above the cost at the Effective Date or at the date of the last price increase, whichever is later, and the Product Price cannot be increased proportionately, then the Commercialisation Committee shall meet and

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cooperate to enter into an agreement with a third party manufacturer for whom the labour, overhead and/or raw material costs with respect to the Products are at least [\*\*] percent ([\*\*]%) lower than Pacira's labour, overhead and/or raw material costs. The Commercialisation Committee will agree on the terms of the agreement with the third party manufacturer together with a royalty payment to be made to Pacira by Flynn Pharma and/or the third party manufacturer under such agreement.

- 5.11 In the event that such agreement cannot be reached with a third party manufacturer, or an agreement cannot be reached with respect to the royalty payment to Pacira by Flynn Pharma and/or the third party manufacturer, in accordance with clause 5.10 above, within 120 days of Pacira informing Flynn Pharma that its costs have increased as set out in 5.9 above, then Pacira shall have the right at its option to terminate this Agreement on ninety (90) days written notice to Flynn Pharma.
- 5.12 The Parties shall, (a) within sixty (60) days following the Effective Date negotiate in good faith the terms of the Supply Agreement on the basis of the outline terms set out in Schedule III, and (b) within ninety (90) days following the Effective Date negotiate the terms of a Quality Technical Agreement which will specify further responsibilities for quality, compliance and regulatory matters.
- 5.13 In the event that a party is required under the laws of a country or other political subdivision of competent jurisdiction to withhold any tax to the tax or revenue authorities in such jurisdiction in connection with any payment to the other party, such amount shall be deducted from the payment to be made by such withholding party; provided that the withholding party shall take reasonable and lawful actions to avoid and minimize such withholding and promptly notify the other party so that the other party may take lawful actions to avoid and minimize such withholding. The withholding party shall promptly furnish the other party with copies of any tax certificate or other documentation evidencing such withholding as necessary to satisfy the requirements of the appropriate regulatory authority related to any application by such other party for foreign tax credit for such payment. Each party agrees to reasonably cooperate with the other party in claiming exemptions from such deductions or withholdings under any agreement or treaty from time to time in effect.

6 **Lump Sum and Milestone Payments**

6.1 In consideration of the work previously undertaken by Pacira in respect of the Product, Flynn Pharma shall pay to Pacira a non-creditable and non-refundable milestone payment of [\*\*] [\*\*] euros (€[\*\*]) on the Effective Date (the “UK Fee”).

6.2 Upon the Effective Date, Flynn will immediately initiate out-licensing activity for the purpose of identifying Marketing Partner(s) in countries of the Territory other than the UK and Republic of Ireland, with an emphasis on other countries within the European market and specifically, in those countries in the Territory set out in the Table in this clause 6.2. For each such country within the Territory Flynn will seek the highest fee possible from such Marketing Partners at least equal to the amounts set out in the table below. For the avoidance of doubt, the countries in the Territory not listed in the table below will not have minimum fee requirements for any Marketing Partners found by Flynn Pharma in those countries.

<u>Market</u>	<u>Minimum Total Fee for each country</u>	<u>[**]% payable on signing for each country</u>	<u>[**]% payable on MA approval for each country</u>
France	€ [**]	€ [**]	€ [**]
Germany	€ [**]	€ [**]	€ [**]
Italy	€ [**]	€ [**]	€ [**]
Spain	€ [**]	€ [**]	€ [**]
Belgium, the Netherlands, Luxembourg, Denmark, Norway, Sweden, Greece Poland	€ [**]	€ [**]	€ [**]

6.3 Flynn Pharma will pay [\*\*]% of such fees to Pacira, up to a total of €[\*\*] (excluding the UK Fee), with the remaining [\*\*]% of such fees payable to Flynn Pharma. Following payment of fees totalling €[\*\*] (excluding the UK Fee) to Pacira, any subsequent fees

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received from the appointment of Marketing Partners in any country within the Territory will be [\*\*] (i.e. [\*\*]%-[\*\*]%) between Flynn Pharma and Pacira and may be in the form of an upfront, milestone, fee, charge, or other financial or non-financial form of compensation. For the avoidance of doubt, the parties acknowledge that Flynn Pharma may apply separate charges and fees in order to recoup the reasonable costs directly associated with the obtaining of the Marketing Authorisation(s) in the country(ies) in the Territory. Such charges and fees shall be payable directly to Flynn Pharma, provided that such charges and fees shall be disclosed to Pacira, and Flynn Pharma shall not apply such charges and fees with the purpose of circumventing its obligations to share with Pacira fees paid by Marketing Partners as set forth herein.

- 6.4 Flynn Pharma agrees and guarantees to pay Pacira €[\*\*] in fees from appointment of Marketing Partners in each of 2008 and 2009, at a minimum. If the total fees from the Marketing Partners (not including the UK Fee) from Flynn Pharma to Pacira exceeds €[\*\*] prior to the end of 2009, then it is agreed that this minimum obligation has been met in full, but does not affect any remaining obligations under clause 6.3. If Flynn Pharma does not make the minimum payments set forth in this clause, Pacira shall have the right at its option to (a) convert the exclusive rights granted under this Agreement in respect of the countries in the Territory for which Marketing Partners have not been appointed and/or Milestone Payments, where relevant, have not been received by Pacira to non-exclusive rights, or (b) terminate this Agreement in respect of the countries in the Territory for which Marketing Partners have not been appointed and/or Milestone Payments where relevant, have not been received by Pacira.
- 6.5 Upon occurrence of each Milestone Event, Flynn Pharma shall inform Pacira in writing of the appointment of a Marketing Partner and the applicable Milestone Payment=within ten (10) business days and the corresponding non-creditable and non-refundable Milestone Payment shall become payable by Flynn Pharma to Pacira within thirty (30) days of receipt of an invoice from Pacira.
- 6.6 Each Milestone Payment shall be due once only upon the first occurrence of the given Milestone Event notwithstanding the indications developed or approved.

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7 **Payment, Accounting, Audit Rights**

- 7.1 Unless otherwise agreed between the parties, all payments to be made hereunder shall be made in Euros. Net Sales shall be determined in the currency in which the Product was sold and shall, if necessary, be converted into Euros using the noon buying rate as published in the Financial Times (London Edition) for the last day of the Quarter for which such payment is being determined.
- 7.2 Any amount payable under this Agreement shall be deemed to be exclusive of Value Added Tax, which shall, if applicable, be payable in addition.
- 7.3 Flynn Pharma shall maintain and shall procure the maintenance of accurate and up to date records and books of account showing the quantity, description and value of the Product supplied in each country of the Territory during the previous six (6) Calendar Years to a maximum of six (6) Calendar Years.
- 7.4 Flynn Pharma shall during business hours, on no less than 14 day's notice from Pacira and not more than once in any Calendar Year, make available for inspection the records and books referred to in clause 7.3. Such inspection shall be undertaken by an independent auditor appointed by Pacira and reasonably acceptable to Flynn Pharma for the purpose of verifying the accuracy of any statement or report given by Flynn Pharma to Pacira and/or the amount of royalties due.
- 7.5 Pacira shall procure that any independent auditor appointed under Clause 7.4 shall maintain all information and materials received, directly or indirectly, by it from Flynn Pharma in strict confidence and shall not use or disclose the same to any Third Party nor to Pacira save for the sole purpose of conducting the audit pursuant to this Clause.
- 7.6 In the event that an auditor appointed pursuant to Clause 7.4 concludes that there has been an underpayment or overpayment, Pacira shall deliver to Flynn Pharma a copy of such auditor's report. Any deficit payable by Flynn Pharma or any excess refundable by Pacira shall be payable within 30 days of Flynn Pharma's receipt of such report. The fees charged by such auditor shall be payable by Pacira, provided that if the audit reveals that payments due to Pacira for any Calendar Year have been understated by more than [\*\*]%, the fees charged by such auditor shall be payable by Flynn Pharma.

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7.7 Should any amount not be paid by either party on or before the due date for payment interest on such unpaid amount at the rate of [\*\*]% above the base rate shall be paid from time to time of the National Westminster Bank Plc and such interest shall be calculated and payable in respect of the period from the date such amount is due until the date payment in full is received in cleared funds.

**8 Intellectual Property and Trade Marks**

8.1 Except as set out in this Agreement, all right, title and interest in the Pacira IP and Trade Marks shall belong to Pacira and Flynn Pharma shall not have any right, title or interest in the Pacira IP or Trade Marks. If Flynn Pharma or any of its Affiliates develop, in whole or in part, any improvement to the Pacira Patents and/or Pacira Know-How, then Flynn Pharma and its Affiliates shall be deemed to automatically license to Pacira a perpetual, irrevocable, royalty free, worldwide, non-exclusive license, with the right to sublicense, to manufacture, use, market and sell such improvement, in or outside of the Field.

8.2 Flynn Pharma shall:

8.2.1 use the Trade Marks in a manner which conforms to the reasonable directions and standards notified to it by Pacira from time to time; and

8.2.2 not do anything which could, in the Pacira's reasonable opinion, bring the Trade Marks or Pacira into disrepute or otherwise damage the goodwill attaching to the Trade Marks.

8.3 Pacira shall, at its own cost, take all steps required to maintain those registrations for the Trade Marks subsisting at the Effective Date, and prosecute any applications subsisting at the Effective Date for registration of the Trade Marks through to grant (including oppositions thereto) in the Territory and thereafter take all steps required to maintain the same.

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- 8.4 Flynn Pharma may request that Pacira use reasonable efforts to obtain trade mark registrations at Pacira's cost in respect of the Trade Marks, in classifications which cover the Product, in any countries in the Territory. Pacira shall promptly notify Flynn Pharma if it does not intend to make or pursue any such trade mark registration in any of the countries in the Territory and Flynn Pharma shall thereafter be entitled to make applications for such trade mark registrations in its own name and at its cost.
- 8.5 Flynn Pharma shall have the right during the Term to register domain names specific to the countries comprised in the Territory that incorporate the Trade Mark.
- 8.6 In the event that the trade mark DepoDur® is unavailable for the Product in any country of the Territory, the parties shall, via the Commercialisation Committee consider an appropriate alternative trade mark for registration in that country or territory. Pacira's decision shall be final with respect to any such appropriate alternative trade mark. Upon registration, by Pacira at Pacira's cost, such trade marks shall comprise part of the Trade Marks hereunder. For the avoidance of doubt, in the event that Pacira refuses to register an alternative trademark, considered appropriate by Pacira and the Commercialisation Committee under this clause 8.6, Flynn Pharma shall have the option to register the agreed trade mark in that country in its name and at its cost.

## 9 Representations and Warranties

- 9.1 Each of the parties warrants and represents that:
- 9.1.1 it has full power and authority and legal right to enter into this Agreement and perform the obligations under it;
  - 9.1.2 the execution of this Agreement has been duly authorised by all necessary actions;
  - 9.1.3 this Agreement is a legal and valid obligation, binding on each of the parties and enforceable in accordance with its terms; and
  - 9.1.4 entry into and exercise of the respective rights and obligations under this Agreement do not, and will not to the best of that party's knowledge and belief, without having made due enquiry, violate any provision of any agreement or other instrument or document to which it is party or affect or be in conflict with or result in the breach of or constitute a default under any such agreement, instrument or document.



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- 9.2 Pacira represents and warrants that:
- 9.2.1 to the best of its knowledge the Pacira IP includes all intellectual property in the possession, custody or control of Pacira which is reasonably necessary for the exploitation of the Product by Flynn Pharma in accordance with the terms and conditions of this Agreement;
  - 9.2.2 to the best of its knowledge it is the owner of, or has exclusive rights to, all of the Pacira IP in existence at the Effective Date, and is exclusively entitled to grant the rights granted under this Agreement;
  - 9.2.3 to the best of its knowledge there are no Third Party interests or rights in the Pacira IP that may prevent, encumber or restrict in any way the exercise by Flynn Pharma of the rights granted under this Agreement;
  - 9.2.4 to the best of its knowledge no Third Party is infringing or has infringed the intellectual property rights in any of the Pacira IP in the Territory;
  - 9.2.5 to the best of its knowledge the exercise of Flynn Pharma's rights granted under this Agreement shall not infringe or conflict with any Third Party intellectual property rights in the Territory and to the best of its knowledge Flynn Pharma will not incur any obligation to any Third Party by the exercise of the rights granted hereunder;
  - 9.2.6 all renewal and maintenance fees and all steps necessary for the filing, prosecution and maintenance of the Pacira Patents have been paid or taken; and
  - 9.2.7 to the best of its knowledge all information, data and Third Party notices in relation to adverse events serious adverse events or recalls relating to or connected with the Product (in any jurisdiction throughout the world) and of which Pacira is aware have been disclosed by Pacira to Flynn Pharma.

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9.3 For purposes of this clause 9, any statement which is qualified as being “to the best of its knowledge” shall mean that (i) Pacira has made inquiries of its directors and of William Lambert, Sr. V.P. Product Development, and Mark Walters, V.P. Commercial Development, and (ii) nothing has come to Pacira’s attention in the course of such inquiries which causes Pacira to believe that such representation and warranty is not true and correct in all material respects.

10 **Liability, Insurance and Indemnities**

10.1 Pacira shall be liable for and shall indemnify and hold harmless Flynn Pharma and its Affiliates against any and all such Claims or part thereof arising in connection with or relating to:

10.1.1 the development, manufacture, sale and supply of the Product prior to the Effective Date (including Claims or demands arising after the Effective Date to the extent they are based on events occurring prior to the Effective Date); and

10.1.2 the manufacture, storage, or carriage of the Product by Pacira or its Affiliates except to the extent that such Claims arise from the negligence of Flynn Pharma or its Affiliates or the breach by Flynn Pharma or its Affiliates of the terms of this Agreement; and

10.1.3 Claims which arise outside the Territory (except to the extent that the Claim has arisen from any act or omission by Flynn Pharma);

10.2 Flynn Pharma shall be liable for and shall indemnify and hold harmless Pacira and its Affiliates from and against any and all Claims arising from or in connection with the use, storage, marketing, distribution, or sale of the Product by Flynn Pharma or its Marketing Partners, except to the extent that such Claims:

10.2.1 relate to any act or circumstance occurring prior to the Effective Date (except to the extent that the Claim has arisen from any act or omission by Flynn Pharma);

10.2.2 relate to Intellectual Property infringement proceedings with Third Parties in connection with the Pacira IP (except to the extent that the Claim has arisen from Flynn Pharma’s use of the Pacira IP other than in accordance with this Agreement);

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- 10.2.3 arise outside the Territory (except to the extent that the Claim has arisen from any act or omission by Flynn Pharma);
  - 10.2.4 relate to the development or manufacture of the Product by Pacira or its Affiliates or its or their agents or sub-contractors;
  - 10.2.5 result from the negligence, wilful default or material breach of any representation or warranty given under this Agreement or the Supply Terms by Pacira, its Affiliates or sub-contractors; or
  - 10.2.6 are the responsibility of Pacira under clause 10.1 above.
- 10.3 Promptly after receipt by a party of any Claim or alleged claim or notice of the commencement of any action, administrative or legal proceeding, or investigation as to which the indemnity provided for in this Clause 10 may apply, the indemnified party shall give written notice to the indemnifying party of such fact. The indemnifying party shall have the option to assume the defence thereof by election in writing within thirty (30) days of receipt of such notice. If the indemnifying party fails to make such election, the indemnified party may assume such defence and the indemnifying party will be liable for reasonable legal and other expenses subsequently incurred in connection with such defence. The parties will co-operate in good faith in the conduct of any defence, provide such reasonable assistance as may be required to enable any Claim to be properly defended, and the party with conduct of the action shall provide promptly to the other party copies of all proceedings relating to such action.
- 10.4 Should the indemnifying party assume conduct of the defence:
- 10.4.1 the indemnified party may retain separate legal advisors in the event that it reasonably concludes that it may have defences available to it which are additional to, different from or inconsistent with those available to the indemnifying party, in which case the indemnifying party shall not be liable for the indemnified party's reasonable costs and expenses so incurred; and

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- 10.4.2 the indemnifying party will not, except with the consent of the indemnified party (such consent not be unreasonably withheld or delayed), consent to the entry of any judgment or enter into any settlement (other than for the payment of damages by the indemnifying party, which includes as an unconditional term a release from the claimant to the indemnified party from all liability in respect of all claims).
- 10.5 The indemnified party shall not admit liability in respect of, or compromise or settle any such action without the prior written consent of the indemnifying party, such consent not to be unreasonably withheld or delayed.
- 10.6 Each party shall maintain, at its own cost, comprehensive product liability insurance and general commercial liability insurance at a level which is reasonable and customary taking into account the nature of the Product. Such insurance shall be with a reputable insurance company and where reasonably possible (taking into account the availability of such insurance) shall be maintained for not less than three (3) years following the expiry or termination of this Agreement.
- 10.7 Pacira shall be liable to Flynn Pharma for legal liability to Third Parties in respect of all claims, actions, judgments, damages, lawsuits, costs or expenses or professional fees for death or personal injury incurred by Flynn Pharma in relation to or arising solely out of any breach of this Agreement or the Supply Terms by Pacira or of any negligent act or omission of Pacira, or its employees in the course of their employment.
- 10.8 Any and all liability of Pacira to Flynn Pharma howsoever arising in respect of this Agreement, the Supply Agreement and the Supply Terms and their performance, in contract tort or otherwise, shall be limited (except for death or personal injury caused by the negligence of Pacira or its employees while acting in the course of their employment) to [\*\*] Euros (€[\*\*]).
- 10.9 Flynn Pharma shall be liable to Pacira for legal liability to Third Parties in respect of all claims, actions, judgments, damages, lawsuits, costs or expenses or professional fees for

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death or personal injury incurred by Pacira in relation to or arising solely out of any breach of this Agreement or the Supply Agreement or the Supply Terms by Flynn Pharma or of any negligent act or omission of Flynn Pharma, or its employees in the course of their employment. Any and all liability of Flynn Pharma to Pacira howsoever arising in respect of this Agreement, the Supply Agreement or the Supply Terms and their performance in contract tort or otherwise shall be limited (except for death or personal injury caused by the negligence of Flynn Pharma or its employees while acting in the course of their employment, and except in relation to any specified payment, lump sum or milestone payment) to [\*\*] Euros (€[\*\*]).

- 10.10 Notwithstanding anything contained in this Agreement or the Supply Terms in no circumstance shall either party be liable to the other in contract, tort (including negligence or breach of statutory duty) or otherwise howsoever, and whatever the cause thereof, for any special, indirect or consequential loss or damage of any nature whatsoever (including loss of profit, loss of goodwill or loss of revenue).
- 10.11 Nothing in this Clause shall be construed as excluding or limiting the liability of either Party or any of its officers, employees and agents to the other party for death or personal injury of any person resulting from the negligence of such persons.
- 10.12 In this clause 10, "Claims" shall mean any and all claims, actions, demands, losses, damages, costs and reasonable expenses (including, without limitation, reasonable legal and expert fees) made or brought by Third Parties.
- 10.13 Where this Agreement provides for the indemnification of a party or the limitation of a party's liability, such indemnification and/or limitation (as the case may be) shall also apply for the benefit of such party's Affiliates and the employees, officers, directors and agents of any of them, acting in such capacity.

## **11 Confidentiality, Press Releases and Publications**

- 11.1 Pacira and Flynn Pharma undertake to each other to keep confidential, and to procure that their respective Affiliates, employees, directors, officers, contractors, lawyers and accountants (including those of their Affiliates) keep confidential, Confidential Information disclosed to it by or belonging to the other party.

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- 11.2 Any Confidential Information received from the other party shall not be disclosed to any Third Party or used for any purpose other than as provided or specifically envisaged by this Agreement.
- 11.3 The confidentiality and non-use obligations contained in this Agreement shall continue for the duration of this Agreement and for a period of [\*\*] ([\*\*]) years after termination for any reason of this Agreement.
- 11.4 The parties shall consult with each other, in advance, with regard to the terms of all proposed press releases, public announcements and other public statements with respect to the transactions contemplated under this Agreement.
- 11.5 The Confidential Information may be disclosed by the other parties to the extent that such disclosure has been ordered by a court of law or directed by a governmental authority, provided that, wherever practicable, the party disclosing the Confidential Information has been given sufficient written notice in advance to the other party to enable it to seek protection or confidential treatment of such Confidential Information, and may be disclosed only to the extent that such disclosure has been so ordered or directed.

## 12 **Patents**

- 12.1 Pacira shall meet all costs and expenses of the filing, prosecution and maintenance of the Pacira Patents.

## 13 **Infringement of Third Party Rights**

- 13.1 In the event of a party becoming aware that the exercise of either party's rights and obligations pursuant to this Agreement are infringing or may infringe the rights of a Third Party, it will promptly so notify the other party and provide it with such details of the Third Party rights and the extent of the infringement as are known to it. Pacira shall defend such action if Pacira determines it is legally advisable and commercial reasonable to do so (taking into account the likelihood of success and relative cost/benefits). No later than 120

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days from becoming aware of or receiving notification in relation to any infringement of the rights of a Third Party, Pacira shall inform Flynn Pharma whether it intends to contest the claim or take such other steps necessary to terminate any infringement (including the negotiation of a Third Party licence agreement). If Pacira informs Flynn Pharma that it does not intend to take steps to contest the claim or take such other steps necessary to terminate any infringement Flynn Pharma may request Pacira to contest any such Third Party claim or proceedings, at Flynn Pharma's cost, using counsel of Flynn Pharma's choice. Any damages, award or settlement monies actually received in respect to such infringement and paid in compensation for sales lost by Flynn Pharma shall be deemed Net Sales. Any damages, award or settlement monies actually received in respect to such infringement and not paid in compensation for sales lost by Flynn Pharma shall belong to Pacira, save that Flynn Pharma shall be entitled to set off its reasonable costs in pursuing such infringement against such damages, award or settlement actually received. In this case, Flynn Pharma shall pay all damages awarded as a result of the action relating to the Product as well as expenses reasonably incurred by Pacira in maintaining such action.

13.2 Where Flynn Pharma's requests that Pacira contest a Third Party claim or proceedings in accordance with clause 13, Pacira shall keep Flynn Pharma informed of its actions in this regard, and Flynn Pharma shall provide Pacira with all reasonable cooperation in connection with such action, including being named as a co-plaintiff or co-defendant in the action or any counterclaim. Flynn Pharma shall be entitled to set off any Third Party royalties or license fees incurred in this regard against payments due to Pacira pursuant to clause 5.3.

14 **Infringement of Pacira IP**

14.1 In the event that Flynn Pharma becomes aware of any actual or suspected infringement or misuse of the Pacira IP in the Territory it shall promptly notify Pacira and provide it with all details thereof in its possession.

14.2 No later than 120 days from becoming aware of or receiving notification of any actual or suspected infringement or misuse of the Pacira IP in the Territory, Pacira shall inform Flynn Pharma whether it intends to institute proceedings against the infringer.

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- 14.3 Pacira shall be entitled at its discretion to take such action to seek an abatement of such infringement as it sees fit, which may include the institution of proceedings against the infringer. Flynn Pharma shall provide all such assistance at Pacira's cost and expense as Pacira may reasonably require in the prosecution or defence of any such proceedings including being named as a co-plaintiff or co-defendant in the action or any counterclaim.
- 14.4 Any damages, award or settlement monies actually received by Pacira in respect to such infringement and paid in compensation for sales lost by Flynn Pharma shall be deemed Net Sales, subject to Pacira deducting its reasonable costs (save to the extent paid by the infringer) in pursuing such infringement from such damages, award or settlement actually received. Any damages, award or settlement monies actually received by Pacira in respect to such infringement and paid otherwise than in compensation for sales lost by Flynn Pharma shall belong to Pacira.
- 14.5 Should in accordance with clause 14.2 Pacira decide not to pursue any such infringement, it shall notify Flynn Pharma of such decision no later than 3 days from the decision, and Flynn Pharma may request Pacira to pursue such infringement at Flynn Pharma's cost using counsel of Flynn Pharma's choice, and in such case Pacira shall keep Flynn Pharma informed of its actions in this regard, and Flynn Pharma will provide Pacira with all reasonable cooperation in connection with such action. Any damages, award or settlement monies actually received in respect to such infringement and paid in compensation for sales lost by Flynn Pharma shall be deemed Net Sales. Any damages, award or settlement monies actually received in respect to such infringement and not paid in compensation for sales lost by Flynn Pharma shall belong to Pacira, save that Flynn Pharma shall be entitled to set off its reasonable costs in pursuing such infringement against such damages, award or settlement actually received.

15 **Term**

- 15.1 This Agreement commences on the Effective Date and, subject to earlier termination in accordance with the provisions of clause 16, shall continue in force for a period being the longer of:
- 15.1.1 five years from first Commercial Delivery of the Product in the Territory; or



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- 15.1.2 until the expiration of the last valid claim in the Pacira Patents covering the Product for a maximum term of 15 years from the date of first Commercial Delivery of the Product in the Territory.

## 16 Termination

- 16.1 Either party shall be entitled forthwith to terminate this Agreement by notice to the other if:
- 16.1.1 the other party commits a material or persistent breach of any obligation under this Agreement or the Supply Terms, and in the case of a breach which is capable of remedy fails to remedy it within ninety (90) days of receipt of notice from the first party of such breach and of its intention to exercise its rights under this Clause; or
  - 16.1.2 a petition is presented, or a meeting is convened for the purpose of considering a resolution, or other steps are taken, for making an administration order against or for the winding up of the other party or an administration order or a winding up order is made against or a provisional liquidator is appointed with respect to the other party; or
  - 16.1.3 an encumbrancer takes possession of, or a trustee or administrative receiver or similar officer is appointed in respect of, all or any material part of the business or assets of the other party, or distress or any form of execution is levied or enforced upon or sued out against any such assets and is not discharged within fourteen (14) days of being levied, enforced or sued out; or
  - 16.1.4 the other party is unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986 or becomes unable to pay its debts as they fall due or suspends or threatens to suspend making payments with respect to all or any class of its debts; or
  - 16.1.5 any voluntary arrangement is proposed under section 1 of the Insolvency Act 1986 in respect of the other party; or

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- 16.1.6 the other party proposes or makes any composition or arrangement or composition with, or any assignment for the benefit of, its creditors; or
  - 16.1.7 anything analogous to any of the events described in Clauses 16.1.2 - 16.1.6, inclusive, occurs under the laws of any applicable jurisdiction.
- 16.2 Subject to Pacira having complied with the material terms of this Agreement and Supply Terms, Pacira may terminate this Agreement with immediate effect if by the first anniversary of the later of Marketing Authorisation or, if required, Pricing Approval, Flynn Pharma has not made its first Commercial Delivery of Product in any of the Major Countries.
- 16.3 Pacira may terminate this Agreement with immediate effect in any country of the Territory if within eighteen months of the receipt of Marketing Authorisation and Pricing Approval where required in that country, Flynn Pharma has not made its first Commercial Delivery of the Product in that country.
- 16.4 The termination or expiry of this Agreement shall not release either of the parties from any liability which at the time of termination or expiry has already accrued to the other party, nor affect in any way the survival of any other right, duty or obligation of the parties which is expressly stated elsewhere in this Agreement to survive such termination or expiry.

## 17 **Consequences of Termination**

- 17.1 On termination of this Agreement for any reason (and, if applicable, in respect of that country in respect of which termination occurs):
- 17.1.1 the licences and rights granted and appointments made to Flynn Pharma hereunder, including under clauses 2.1 and 2.2, shall terminate and Flynn Pharma shall (and shall procure that its Affiliates and Marketing Partners shall) cease all activities licensed or appointed hereunder, subject to clauses 17.2 and 17.3;
  - 17.1.2 the following provisions of this Agreement shall continue in full force and effect: this clause 17 and clauses 10 and 11;

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- 17.1.3 Flynn Pharma shall return to Pacira all Pacira IP in its possession;
  - 17.1.4 Flynn Pharma shall assign to Pacira free of charge (save for any Third-Party assignment and registration fees) any domain name registrations it has registered pursuant to clause 8.5 and any trade marks for which it has applied under clause 8.4 or 8.6;
  - 17.1.5 Flynn Pharma shall promptly transfer to Pacira or its nominee, each and every Marketing Authorisation (to the extent not held by Pacira) (together with each Pricing Approval) relating to the Product, together with all communications with the relevant Regulatory Authorities, and all notes and record thereof.
  - 17.1.6 Pacira shall reimburse Flynn Pharma for all Marketing Authorisation filing fees previously paid by Flynn for any country in the Territory where the Product is subsequently relicensed by Pacira and sold under the same Marketing Authorisation.
- 17.2 Where this Agreement has expired or has been terminated for any reason other than by Pacira in accordance with clause 16.1.1, Flynn Pharma and its Affiliates and Marketing Partners and sales agents shall be entitled to continue to sell existing stocks of the Product in the Territory for a period of not longer than 12 months following the date of termination, provided that, Flynn Pharma continues to make any payments due to Pacira in respect of such sales in accordance with the provisions of this Agreement.
- 17.3 In the event that this Agreement is terminated by Pacira in accordance with clauses 16.1 - 16.4 inclusive, Flynn Pharma and its Affiliates and sublicensees shall be entitled to continue to sell existing stocks of the Product in the Territory for so long as Pacira deems necessary to ensure that sale of the Product is not disrupted provided that Flynn Pharma and its Affiliates shall cease such sale upon notification from Pacira and in any event Flynn Pharma shall not so sell for a period of longer than three (3) months following the date of termination. Immediately upon notification from Pacira, such post termination sales shall cease.

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**18 Force Majeure**

- 18.1 Except for payment obligations accruing prior to the Force Majeure event which shall not be affected or excused by any Force Majeure, neither Party shall be entitled to terminate this Agreement or shall be liable to the other under this Agreement for loss or damages attributable to any Force Majeure, provided the party affected shall give prompt notice thereof to the other party. Subject to Clause 18.2, the party giving such notice shall be excused from such of its obligations hereunder for so long as it continues to be affected by Force Majeure.
- 18.2 If such Force Majeure continues unabated for a period of at least ninety (90) days, the parties will meet to discuss in good faith what actions to take or what modifications should be made to this Agreement as a consequence of such Force Majeure in order to alleviate its consequences on the affected party. If the affected party is prevented by reason of any circumstances referred to in this clause 18 from performing any of its obligations hereunder for a continuous period of 180 days, then the other party may terminate this Agreement.

**19 Notices**

- 19.1 Any notice or other document given under this Agreement shall be in writing in the English language and shall be given by hand or sent by prepaid airmail, by fax transmission or e-mail to the address of the receiving Party as set out in Clauses 19.3 below unless a different address or fax number has been notified to the other in writing for this purpose.
- 19.2 Each such notice or document shall:
- 19.2.1 if sent by hand, be deemed to have been given when delivered at the relevant address;
  - 19.2.2 if sent by prepaid airmail, be deemed to have been given 7 days after posting; or

19.2.3 if sent by fax transmission be deemed to have been given when transmitted provided that a confirmatory copy of such facsimile transmission shall have been sent by prepaid airmail within 24 hours of such transmission.

19.3 The address for services of notices and other documents on the parties shall be:

**To Flynn Pharma**

2nd Floor  
The Makings  
Bridge Street  
Hitchin  
Hertfordshire  
SG5 2DE

**Fax:** +44 146 245 0755

**Attention:** President

**with a copy to:**

Roiter Zucker Solicitors  
Regent House  
5-7 Broadhurst Gardens  
Swiss Cottage, London NW6 3RZ  
ENGLAND

**Fax:** +44 20 7328 9111

**Attention:** Alia Hares

**To Pacira**

10450 Sciences Center Drive,  
San Diego, California 92121  
USA

**Fax:** + 858 623 0376

**Attention:** President

**with a copy to:**

Cohen Tauber Spievack & Wagner LLP  
420 Lexington Ave., Suite 2400  
New York, NY 10170  
USA

**Fax:** + 212 586 5095

**Attention:** Y. Jerry Cohen, Esq.

**20 Assignment and Change of Control**

20.1 Subject to clause 20.2, neither party shall, nor shall it purport to, assign, license, transfer or charge any of its rights or obligations under this Agreement without the prior written consent of the other, such consent not to be unreasonably withheld or delayed.

20.2 Flynn Pharma may appoint Marketing Partners under this Agreement, subject to Pacira's prior written consent which shall not be unreasonably withheld or delayed, provided that Flynn Pharma:

20.2.1 informs Pacira of the identity of any Marketing Partner (other than Affiliate companies) prior to the execution of any agreement with such Marketing Partner; and

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- 20.2.2 provides Pacira with a copy of written sub-distribution agreement as soon as reasonably practicable after the execution thereof by Flynn Pharma. Any sub- license granted hereunder shall (a) be on the same terms mutatis mutandis as the terms of this Agreement insofar as they are applicable, but excluding the right to grant a sub-license, and (b) provide that such agreement is subject and subordinate to the rights of Pacira under this Agreement.
- 20.3 Each party enters into this Agreement on its own behalf and not on behalf of any other person or entity.
- 20.4 Flynn Pharma shall not appoint a Third Party as a Marketing Partner that manufactures, markets or sells a Competing Product in the Territory. Notwithstanding any sub- distribution agreement, Flynn Pharma shall remain primarily liable to Pacira for its obligations hereunder, and for any act or omission of any Marketing Partner including with respect to safeguarding the confidentiality of Confidential Information.
- 20.5 Should there be a change of Control of Flynn Pharma resulting in the ownership of Flynn Pharma by a Third Party which manufactures, markets or sells a Competing Product in any part of the Territory, Pacira may terminate this Agreement by not less than ninety (90) days written notice to Flynn Pharma.

21 **General Provisions**

- 21.1 Nothing in this agreement is deemed to constitute a partnership between the parties nor constitute either party the agent of the other party for any purpose.
- 21.2 If there is a disagreement between the Pacira and Flynn Pharma on the interpretation of this Agreement or any aspect of the performance by either party of its obligations under this Agreement, the parties shall resolve the dispute in accordance with the dispute resolution procedure set out in Schedule VI.

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- 21.3 Each of the Parties shall do execute and perform and shall procure to be done executed and performed all such further acts deeds documents and things as the other party may reasonably require from time to time to give full effect to the terms of this Agreement.
- 21.4 In performing any respective obligations under this agreement, each party shall comply with the Data Protection Act 1998, any notification requirements under the Data Protection Act 1998 and the Data Protection Principles specified in that Act.
- 21.5 Each party shall pay its own costs, charges and expenses incurred in connection with the negotiation, preparation and completion of this Agreement.
- 21.6 This agreement and the Supply Terms sets out the entire agreement and understanding between the parties in respect of the subject matter of this Agreement. This Agreement supersedes any heads of agreement which shall cease to have any further force or effect. It is agreed that:
- 21.6.1 no Party has entered into this Agreement in reliance upon any representation, warranty or undertaking of the other party which is not expressly set out in this Agreement;
  - 21.6.2 no Party shall have any remedy in respect of misrepresentation or untrue statement made by the other party or for any breach of warranty which is not contained in this Agreement;
  - 21.6.3 this Clause shall not exclude any liability for, or remedy in respect of, fraudulent misrepresentation.
- 21.7 No variation of this Agreement shall be valid unless it is in writing and signed by or on behalf of both parties.
- 21.8 Unless expressly agreed, no variation shall constitute a general waiver of any provisions of this Agreement, nor shall it affect any rights, obligations or liabilities under or pursuant to this Agreement which have already accrued up to the date of variation, and the rights and obligations of the parties under or pursuant to this Agreement shall remain in full force and effect, except and only to the extent that they are so varied.

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- 21.9 If and to the extent that any provision of this Agreement is held to be illegal, void or unenforceable, such provision shall be given no effect and shall be deemed not to be included in this Agreement but without invalidating any of the remaining provisions of this Agreement.
- 21.10 No failure or delay by either party in exercising any right or remedy provided by law under or pursuant to this Agreement shall impair such right or remedy or operate or be construed as a waiver or variation of it or preclude its exercise at any subsequent time and no single or partial exercise of any such right or remedy shall preclude any other or further exercise of it or the exercise of any other right or remedy.
- 21.11 The rights and remedies of each of the parties under or pursuant to this Agreement are cumulative, may be exercised as often as such party considers appropriate and are in addition to its rights and remedies under general law.
- 21.12 This Agreement may be executed in any number of counterparts and by the parties on separate counterparts, each of which is an original but all of which together constitute one and the same instrument.
- 21.13 A person who is not a party to this Agreement shall have no right under the Contracts (Rights of Third Parties) Act 1999 to enforce any of its terms, but this does not affect any right or remedy of a third party which exists or is available apart from the Act.
- 21.14 Each party shall have and maintain insurance (including general and product liability coverage) and upon such terms (including coverages, deductible limits and self-insured retentions) as is customary for the activities to be conducted by it under this Agreement and is appropriate to cover its indemnification obligations hereunder. Each party shall furnish to the other party evidence of such insurance, upon request.
- 21.15 This Agreement and the relationship between the parties shall be governed by, and interpreted in accordance with English law.

**SIGNATURES ON NEXT PAGE**



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**AS WITNESS** the hands of the parties or their duly authorised representatives the day and the year first above written.

SIGNED for and by behalf of  
**PACIRA PHARMACEUTICALS, INC.**

)  
)  
)

/s/ Mark A. Walters

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Mark A. Walters  
V.P. Business & Commercial Development

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**Print Name and Title**

SIGNED for and by behalf of  
**FLYNN PHARMA LIMITED**

)  
)  
)

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Print Name and Title

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**AS WITNESS** the hands of the parties or their duly authorised representatives the day and the year first above written.

SIGNED for and by behalf of  
**PACIRA PHARMACEUTICALS, INC.**

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SIGNED for and by behalf of  
**FLYNN PHARMA LIMITED**

)  
)  
)

/s/ David Fakes

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D W Fakes, Director  
\_\_\_\_\_

Print Name and Title

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**SCHEDULE I**  
**PACIRA PATENTS**

Granted Patents

<b>Number</b>	<b>Country</b>	<b>Matter</b>
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]

Patent Applications

<b>Number</b>	<b>Country</b>	<b>Matter</b>
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]

**SCHEDULE II**  
**TRADE MARKS**

<b>Trademark</b>	<b>Country</b>	<b>Class</b>	<b>Status</b>	<b>Trademark No.</b>	<b>Registration Date</b>
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]

<b>Trademark</b>	<b>Country</b>	<b>Class</b>	<b>Status</b>	<b>Trademark No.</b>	<b>Registration Date</b>
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]

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## SCHEDULE III

### DRAFT MANUFACTURE AND SUPPLY TERMS AND CONDITIONS

#### Proposed Language for EU DepoDur Supply Terms

A full draft is to be supplied but please note the following:

##### **Forecasting and Ordering (part)**

Detailed Forecast. Within thirty (30) days of the Effective Date of the Supply Agreement or twelve (12) months before the anticipated Commercial Delivery, whichever is later, Licensee shall provide to Pacira a written estimate of its monthly unit requirements (by country) for the Finished Product for the next succeeding twelve (12) months (this forecast and each succeeding forecast, a "Forecast"). Each Forecast shall be updated monthly on the tenth (10th) day of the month on a twelve (12)-month rolling basis. Each Forecast shall include, during the relevant periods, the quantities necessary for commercial launch, ramp-up, and pipeline fill.

Firm Purchase Requirement. The forecast of the most current three (3) month period shall be binding on the Parties and shall be deemed a firm purchase order for which Licensee shall provide a written purchase order stating in detail the required quantities (by country) of the Product and the required delivery dates. The forecast for the remaining nine (9) month period of each rolling forecast is for planning purposes and shall not constitute a commitment to purchase or supply Product.

Unless otherwise mutually agreed upon by the Parties, all Purchase Orders submitted by Licensee for delivery of Product in any given month shall not be less than [\*\*]% of the amount forecast for such month in the Forecast immediately preceding the Forecast that is deemed to be a firm purchase order for such month.

In the event that Licensee submits any Purchase Order to purchase Product in any given month in an amount in excess of [\*\*]% of the amount forecasted for such month in the Forecast immediately preceding the Forecast that is deemed to be a firm purchase order for such month, Pacira shall use its commercially reasonable efforts to deliver the quantity ordered by Licensee; provided however, Pacira shall not be liable to Licensee for any inability to deliver the amount of Products ordered by Licensee in excess of such amount.

##### **Supply, Delivery, Title and Payment (part)**

Title and risk of loss and/or damage of the Product shall pass to Licensee upon delivery FOB (Incoterms 2000) Pacira's EU release site, or other location designated by Pacira. Upon assumption of Product title, Licensee shall be responsible for arranging and maintaining proper temperature controlled handling and necessary narcotic product security through out the Supply Chain, to the delivery of the product to end customer.

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Licensee will provide to Pacira on a quarterly basis, or more frequently if required by regulators such as the DEA, a report designating Product deliveries, by unit, by country, and by customer, in accordance with either existing or negotiated narcotic tracking requirements from the U.S. or EU. In addition, Licensee will be responsible for producing other product consumption reports or product tracking information (i.e. diversion) as may be required by a U.S. and/or EU regulatory authority from time to time.

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**SCHEDULE V**

**THE TERRITORY**

Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Republic of Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, United Kingdom, Norway, Romania, Switzerland, Turkey, South Africa, Bahrain, Jordan, Kuwait, Lebanon, Oman, Qatar, Saudi Arabia, Sudan, Syria, United Arab Emirates, Iraq

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## SCHEDULE VI

### DISPUTE RESOLUTION

- 1.1 Representatives of the parties will, within 14 days of receipt of a written request from either party to the other, convene a meeting of the Commercialisation Committee to discuss in good faith and try to resolve the disagreement without recourse to legal proceedings.
- 1.2 If resolution does not occur within 7 days after meeting, the matter shall be escalated for determination by the respective Chief Executive Officer of the parties who may resolve the matter themselves or jointly appoint a mediator or independent expert to do so.
- 1.3 Nothing in this Agreement restricts either party's freedom to seek from a court of competent jurisdiction urgent or equitable relief in the form of preliminary injunction to preserve a legal right or remedy, to avoid irreparable harm, or to protect a proprietary, trade secret or other right.

#### **Appointment of an Expert**

- 1.4 In the event that the Chief Executive Officers are unable to resolve the dispute or agree to appoint an expert, one party shall serve on the other a written Referral Notice requesting that the matter be referred to an expert for resolution, and the following procedure shall be followed.
  - 1.4.1 The dispute shall be determined by a single independent impartial expert who shall be agreed between the parties. In the absence of agreement between the parties within 30 days of the service of a Referral Notice, the expert shall be appointed (a) by the President for the time being of the Institute of Arbitrators-or any successor thereto if the Referral Notice was served by Pacira, (b) by the American Arbitration Association sitting in New York City if the Referral Notice was served by Flynn Pharma, or (c) such other competent body agreed by the parties.
  - 1.4.2 30 days after the appointment of the expert pursuant to paragraph 1.4.1 both parties shall exchange simultaneously statements of case in no more than 10,000 words, in total, and each side shall simultaneously send a copy of its statement of case to the expert.
  - 1.4.3 Each party may, within 30 days of the date of exchange of statement of case pursuant to paragraph 1.4.2, serve a reply to the other side's statement of case in no more than 10,000 words. A copy of any such reply shall be simultaneously sent to the expert.



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- 1.4.4 Subject to paragraph 1.4.6, there shall be no oral hearing. The expert shall issue his decision in writing to both parties within 30 days of the date of service of the last reply pursuant to paragraph 1.4.3 above or, in the absence of receipt of any replies, within 60 days of the date of exchange pursuant to paragraph 1.4.2.
- 1.4.5 Except for disputes predominantly related to intellectual property which may be brought in any jurisdiction, the seat of the dispute resolution shall be London, England if the Referral Notice was served by Pacira, and New York City if the Referral Notice was served by Flynn.
- 1.4.6 The expert shall not have power to alter, amend or add to the provisions of this Agreement, except that the expert shall have the power to decide all procedural matters relating to the dispute, and may call for a one day hearing if desirable and appropriate.
- 1.4.7 The expert shall have the power to request copies of any documents in the possession and/or control of the parties which may be relevant to the dispute. The parties shall forthwith provide to the expert and the other party copies of any documents so requested by the expert.
- 1.4.8 The decision of the expert shall be final and binding upon both parties except in the case of manifest error. The parties hereby exclude any rights of application or appeal to any court, to the extent that they may validly so agree, and in particular in connection with any question of law arising in the course of the reference out of the award.
- 1.4.9 The expert shall determine the proportions in which the parties shall pay the costs of the expert's procedure. The expert shall have the authority to order that all or a part of the legal or other costs of a party shall be paid by the other party.
- 1.4.10 All documents and information disclosed in the course of the expert proceedings and the decision and award of the expert shall be kept strictly confidential by the recipient and shall not be used by the recipient for any purpose except for the purposes of the proceedings and/or the enforcement of the expert's decision and award.

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

### SUPPLY AGREEMENT

**THIS SUPPLY AGREEMENT** is made effective as of the 5<sup>th</sup> day of December, 2007 (the “**Effective Date**”).

#### **BETWEEN**

- (1) **PACIRA PHARMACEUTICALS, INC. (F/K/A SKYEPHARMA, INC.)** a company incorporated in California whose principal place of business is 10450 Sciences Center Drive, San Diego, California 92121 USA (“**Pacira**”); and
- (2) **FLYNN PHARMA LIMITED** a company incorporated in the Republic of Ireland under company number 210742 with its registered office at Alton House, 4 Herbert Street, Dublin 2, Republic of Ireland (the “**Company**” or “**Flynn Pharma**”).

#### **Recitals**

- (A) On September 25, 2007 the Parties entered into a Strategic Marketing Agreement (the “Marketing Agreement”) relating to DepoFoam™.
- (B) By clause 5.12 of the Marketing Agreement the Parties agreed to negotiate in good faith the terms of the Supply Terms on the basis of the outline terms set out in Schedule III of the Marketing Agreement.
- (C) This Supply Agreement records the terms agreed between the Parties relating to the manufacture of DepoFoam™ and its supply to Flynn Pharma by Pacira.

NOW THEREFORE, in consideration of the premises and mutual agreements and covenants set forth herein, and intending to be legally bound, the Parties hereby agree as follows:

#### **1. DEFINITIONS**

**1.1.** As used in this Agreement, the following words and expressions have the following meanings:

“**Affiliate**” means any company, corporation, firm, individual or other entity which Controls, is Controlled by or is under common Control with a party to this Agreement;

“**Applicable Laws**” means all laws, rules and regulations regarding the Manufacture, Packaging, promotion, marketing and sale of the Finished Products including but not limited to the relevant laws, rules, regulations, codes or guidelines having effect in any jurisdiction in the Territory;

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“**Approved Facilities**” means the facilities located at 10450 Science Center Drive, San Diego, CA 92121 USA (or such other facility designated by Pacira), comprising buildings and equipment where Pacira shall Manufacture and store or have Manufactured and stored the Product;

“**Batch**” means shall mean that quantity of each Product (as set forth on [Appendix 1](#)) that is produced by a single cycle of Manufacture;

“**Business Day**” means a day other than a Saturday or Sunday when clearing banks are open for business;

“**Certificate of Analysis**” means a document, in such form as is mutually agreed upon by the Parties, setting out the results of analysis of a Batch confirming the Batch to be in accordance with the Specifications;

“**Commencement Date**” means the date on which the Company notifies Pacira in writing that the Company has obtained licenses and other approvals from the Relevant Authorities as necessary for the Company to distribute the Finished Product in a country in the Territory;

“**Control**” means in relation to any Party or an Affiliate the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such firm, person or company, by contract or otherwise, or the ownership either directly or indirectly of 50% or more of the voting securities of such company, corporation, firm, individual or entity

“**cGMP**” means current Good Manufacturing Practice as set out in the United States 21 CFR 210 and 211, as amended from time to time, together with, as applicable, any analogous regulations, codes or guidelines having effect in the Territory;

“**Delivery**” means delivery of Finished Product FOB (Incoterms 2000) Pacira’s EU release site or other location designated by Pacira, and “Delivered” shall be construed accordingly;

“**Delivery Date**” means the date on which the Company receives Delivery of a particular shipment of Finished Product.

“**Effective Date**” shall have the meaning set forth in the Preamble above;

“**Finished Product**” means Product which has been Manufactured and Delivered by Pacira to the Company under this Agreement for sale to end users;

“**Manufacture**” means the conduct of methods and processes used by Pacira or its Third Party Manufacturer in relation to the manufacture, filling, finishing, labelling, packaging, storage, shipping and Quality Control of the Product;

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“**Manufacturing Approvals**” means the grant of necessary approvals by Relevant Authorities required to Manufacture the Product;

“**Marketing Authorization**” means the grant of necessary approvals by Relevant Authorities required to market, distribute and sell the Finished Product in the Territory but excluding pricing approvals.

“**Manufacturing Services**” shall mean the Manufacture, stability testing and Release of the Product in the Presentation Forms conducted by Pacira;

“**Non-Conforming Product**” shall mean any Finished Product which fails to comply with the Specifications or the Packaging and Labelling Specifications;

“**Non-Conformity**” shall mean the event or failure which renders a Finished Product Non-Conforming Product;

“**Packaging**” means the operations involved in the process of assembly and packaging of the Product into Finished Product and “**Packaged**” shall be construed accordingly;

“**Packaging and Labelling Specifications**” means the specifications set out in Appendix 2, as such specifications may be amended pursuant to Section 2.4 below from time to time;

“**Party**” shall mean either Pacira or the Company, as the case may be, and “**Parties**” shall mean both Pacira and the Company.

“**Person**” shall include both corporate and real persons and institutions, partnerships and associations or entities of all kinds;

“**Presentation Form**” means the amount of active ingredient contained in each Vial, which initially shall be [\*\*] mg;

“**Product**” means the DepoFoam™ formulation of morphine sulphate for epidural administration;

“**Quality Control**” means the sampling, laboratory testing and inspection, in accordance with cGMPs, at the Approved Facilities of:

- (a) Raw Materials, in-process materials and Finished Product;
- (b) the Finished Product as necessary for Release; and
- (c) the Finished Product as necessary for stability testing.

“**Raw Materials**” means active ingredients, packaging materials, components and materials required to Manufacture and package the Finished Product;

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“**Release**” means confirmation, pursuant to Section 3.1.1 below, that the Finished Product meets all applicable Specifications and Packaging and Labelling Specifications.

“**Relevant Authority**” means any regulatory authority or other governmental body whose approval is necessary to Manufacture, store, market, sell and/or distribute the Finished Product in any country in the Territory;

“**Required Specification Change**” shall mean a Specification Change required by Applicable Laws or by a Relevant Authority;

“**Specifications**” means the specifications of the Product as set out in Appendix 1 (as may be amended from time to time pursuant to Section 2.4 below) and as filed with and approved by the Relevant Authorities;

“**Specification Change**” shall mean any change to the Specification, the Packaging and Labelling Specification or Manufacturing Services, including, but not limited to, any different or additional requirements arising out of a launch of the Finished Product in any country in the Territory, in each case made in accordance with Section 2.3 below;

“**Territory**” shall mean the countries listed on Appendix 3;

“**Third Party**” means any company, corporation, firm, individual or other entity but excluding a party to this Agreement or an Affiliate or any approved sales agent or sub-distributor appointed by Flynn Pharma under the Marketing Agreement;

“**Third Party Manufacturer**” means a Third Party appointed by Pacira to Manufacture the Product or any part of it on its behalf; and

“**Vial**” means a [\*\*] ml vial containing [\*\*] milligrams of the Finished Product.

## 2. MANUFACTURE OF PRODUCT

**2.1 Manufacture of the Product.** Subject to the terms and conditions of this Agreement, Pacira shall use reasonable commercial efforts to (a) perform the Manufacturing Services and (b) supply such quantities of the Finished Product to the Company as the Company shall order pursuant to Section 4 hereto.

**2.2 Pacira Responsibilities.** During the Term, Pacira shall be responsible for:

**2.2.1 Sourcing of Raw Materials.** Obtaining Raw Materials required to Manufacture the Product in accordance with the Specifications, the Packaging and Labelling Specifications, Applicable Laws and cGMPs.

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- 2.2.2 Equipment, Shipping Supplies and Personnel.** Supplying equipment, shipping supplies, materials and personnel reasonably necessary for the performance of the Manufacturing Services and Delivery.
- 2.2.3 Recordkeeping.** Maintaining documentation of validation data, stability testing data, Batch records, Quality Control and laboratory testing and other data required under cGMPs in connection with the performance of the Manufacturing Services and Delivery hereunder. Pacira shall provide Company with copies of such documentation as reasonably necessary upon Company's reasonable written request at Company's expense.
- 2.2.4 Negation of Other Terms.** No terms or conditions contained in any Purchase Order (as hereinafter defined), acknowledgement, invoice, acceptance, or any other preprinted form issued by any Party shall be effective to the extent it is inconsistent with or modifies the terms and conditions contained herein.
- 2.3 Changes to Specification; New Specifications.**
- 2.3.1 Voluntary Specification Changes**
- 2.3.1.1** Flynn Pharma may request a Specification Change but no such Specification Change shall be implemented unless both Parties agree in writing, such agreement not to be unreasonably withheld. Notwithstanding the foregoing, Pacira shall implement, at the Company's expense, Specification Changes reasonably requested by the Company relating to Product package and label branding, artwork and other non-regulatory changes.
- 2.3.1.2** As soon as is reasonable after notice of the proposed Specification Change is served by the Company, the Parties' representatives will meet (either in person or by telephone conference) to discuss the proposed Specification Change. The Parties will confer in good faith as to the most cost-effective and efficient means to implement or to otherwise provide for the proposed Specification Change or to discuss any reasons as to why the proposed Specification Change cannot be made.
- 2.3.1.3** The Parties shall itemize in good faith best estimates of the relative costs and impacts, including capital expenses and potential impacts such expenditures will have on each Party and neither Party shall be

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required to implement a Specification Change (other than a Company-requested Specification Change described in Section 2.3.1.1 related to non-regulatory changes) unless agreement is reached in relation to the way in which costs, expenditures and other impacts will be apportioned between the Parties.

**2.3.2 Required Specification Changes**

- 2.3.2.1** If a Required Specification Change is necessary, the Parties will confer immediately and in good faith to determine the most cost-effective and efficient means to implement or to otherwise provide for the Required Specification Change.
- 2.3.2.2** Subject to Sections 2.3.2.3 and 2.3.2.4 below, Pacira shall implement such Required Specification Change as quickly as reasonably possible.
- 2.3.2.3** The Parties shall itemize in good faith best estimates of the respective costs and impacts, including capital expenses and potential impacts that such Required Specification Changes will have on each Party.
- 2.3.2.4** The Parties shall use reasonable commercial endeavours to agree the costs and expenses and how such costs and expenses should be allocated between them. In the event that the Parties cannot agree the costs and expenses or how such costs and expenses should be allocated between them either Party may refer the matter to Dispute Resolution in accordance with the terms of Schedule VI of the Marketing Agreement.

**2.4 Audit; Access to Records**

- 2.4.1 Company Audit Right.** Company, at its expense, shall be permitted, but not obligated, to audit (or to have its auditors or accountants reasonably acceptable to Pacira audit) the performance of the Manufacturing Services by Pacira, upon reasonable prior written notice and during regular business hours and without unreasonable disruption to the conduct of business by Pacira provided that any such audit shall occur not more than once per year.
- 2.4.2 Access to Records.** Pacira shall make records (including batch records) regarding its performance under the terms and conditions of this Agreement reasonably available for

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inspection by Company at such audits, at the Company's costs and upon Company's prior written request. For the avoidance of doubt, such records shall be subject to the Confidentiality provisions under this Agreement.

**2.4.3 Permission to Audit Third Party Manufacturers.** Pacira shall use reasonable efforts to obtain permission for such auditing by Company from any Third Party Manufacturers performing any of the Manufacturing Services.

**2.4.4 Compliance with Pacira Rules and Regulations.** Employees and agents of Company who inspect any facilities shall at all times comply with the reasonable rules and regulations of Pacira or any Third Party Manufacturer (as the case may be) and the Confidentiality provisions hereunder, and Company shall assume all liability relating to or resulting from the presence of Company's employees or agents on Pacira's or the Third Party Manufacturer's premises and their respective acts and omissions.

**2.4.5 Pacira Audit Rights.** Pacira, at its expense, shall be permitted, but not obligated, to audit the performance and adequacy of the storage and distribution facilities owned, used or to be used by Company in the storage and distribution of the Finished Product, upon reasonable prior notice and during regular business hours and without unreasonable disruption to the conduct of business of Company or any Third Party provided that any such audit shall occur not more than once per year or more frequently in the event Pacira and/or the Company receive notice or complaint that Finished Products have been improperly stored or delivered, including if Finished Products have not been stored at the proper temperatures.

**2.5 Notifications and Remedies Concerning Manufacturing Matters; Subcontracting to Third Party Manufacturers.**

**2.5.1 Adverse Supply Events.** Pacira shall notify Company of any problem that to its knowledge has a material adverse effect upon the Manufacturing Services or Delivery and shall use commercially reasonable efforts to promptly remedy any such problem.

**2.5.2 Potential Supply Issues.** In the event Pacira is aware that it will be unable to Manufacture or have Manufactured and Deliver Finished Product in sufficient quantities to satisfy Company's forecasted requirements in accordance with Section 4.3, Pacira shall inform Company of the expected duration of its inability to Manufacture or have Manufactured sufficient quantities of Finished Product and shall keep Company reasonably informed on a timely basis of developments during any such period of time.



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- 2.5.3 Notice of Correspondence with and Actions by Relevant Authorities .** Pacira shall notify Company following receipt of any written notices or communications sent to Pacira by any Relevant Authority or any inspection or investigation, which have a material effect upon the Manufacturing Services, and shall thereafter provide to Company a written summary of findings by the Relevant Authority.
- 2.5.4 Responses to Relevant Authorities .** The Parties shall discuss any corrective actions to be taken, including any written responses to the Relevant Authority and each Party shall take into account in good faith the other Party's comments. Pacira shall be responsible for communications with any Relevant Authority in the Territory except when Flynn Pharma is required to communicate with the Relevant Authority by Applicable Law. Each Party shall use commercially reasonable efforts to communicate with the other Party in advance of any such communications with the Relevant Authority.
- 2.5.5 Subcontracting to Third Party Manufacturers .** Pacira may subcontract any of its Manufacturing obligations under this Agreement to a Third Party Manufacturer, and shall notify Flynn Pharma prior to the selection of any such Third Party Manufacturer; provided, however, that in no event shall such subcontracting relieve Pacira of any of its obligations under this Agreement.

**2.6 Compliance with Applicable Laws; Backup and Disaster Recovery Plans**

- 2.6.1 Compliance with cGMP and Applicable Laws .** Each Party shall comply with all cGMP and Applicable Laws that are applicable to it in carrying out its duties and obligations under the terms and conditions of this Agreement.
- 2.6.2 Approved Facility.** Pacira will perform (or procure the performance of) the Manufacturing Services at the Approved Facilities, or at a Third Party Manufacturer.
- 2.6.3 Manufacturing Approvals.** Pacira shall maintain and shall require any Third Party Manufacturer to maintain all Manufacturing Approvals and permits relating to the Approved Facilities and the Manufacturing Services, as granted by any Relevant Authority, for so long and insofar as are necessary to permit Pacira to provide the Manufacturing Services as contemplated hereunder. Pacira shall, and will request any

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Third Party Manufacturer to, make copies of such Manufacturing Approvals and all related documents available to Flynn Pharma and its designees for inspection, upon reasonable written request from Company.

**2.6.4 Narcotic Tracking Requirements.** Each Party shall comply with existing or future narcotic tracking requirements of any Relevant Authority that are applicable to it and, at such times as may be required under such Relevant Authority requirements, shall provide the other Party with reports containing such information regarding Product deliveries as are required by such Relevant Authority requirements. In addition, each Party shall be responsible for producing to the applicable Relevant Authorities any other product consumption reports or product tracking information (i.e., diversion) as may be required from such Party by any Relevant Authority from time to time.

**2.7 Labelling.**

**2.7.1 Provision of Artwork; Changes to Labelling.** Flynn Pharma, at its cost and expense, shall provide to Pacira camera-ready artwork for the labelling of the Products. Company shall be responsible for assuring that the artwork as selected by Company complies with the requirements of Applicable Law, Marketing Authorizations, requirements of Relevant Authorities, and for any claims that such use infringes the rights of Third Parties. Notwithstanding anything to the contrary, in the event any change to Product labelling is required by Applicable Law or requirements of Relevant Authorities, Flynn Pharma shall be responsible for all costs of implementing such change. The Company shall be responsible for the cost of any Product labelling changes that the Company may elect to make from time to time.

**2.7.2 Obsolete Stock Arising From Label Change.** Any stock rendered obsolete by a change in the Product labelling requested by Company or required by any Regulatory Authority in the Territory shall, at the Company's option and expense, either be relabelled by Pacira or purchased from Pacira by Company at Pacira's actual cost.

**3. TESTING; RECEIPT OF PRODUCT; ACCEPTANCE**

**3.1 Testing; Certificate of Analysis; Shipment Samples.**

**3.1.1 Release Testing.** Pacira shall undertake, or have undertaken by the Third Party Manufacturer, Quality Control and Release of each Batch of the Finished Product using the analytical testing methodologies which are set forth in the Specifications and any Marketing Authorization and as required by cGMP and any other Applicable Laws.

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- 3.1.2 Certificate of Analysis.** Pacira shall furnish Company with a Certificate of Analysis for each Batch of the Finished Product on or before the date on which the Finished Product is Delivered to Company.
- 3.1.3 Record Retention.** Pacira shall retain records pertaining to all such testing as required by Applicable Laws.
- 3.1.4 Retention of Samples.** Pacira shall properly store and retain samples (identified by Batch number) of:
- 3.1.4.1** Finished Product that it supplies to Company; and
  - 3.1.4.2** Active ingredient and other materials used to Manufacture the Product (except water, compressed gases and highly volatile compounds),
- in each of the foregoing cases, in conditions, and for times required by, Applicable Laws and cGMPs.
- 3.2 Rejection/Acceptance Procedures; Non-Conforming Product.**
- 3.2.1 Right to Reject Nonconforming Product.** Subject to the provisions of this clause, Flynn Pharma shall be entitled to reject Finished Product that, at the time of Delivery, is Nonconforming Product.
  - 3.2.2 Visual Inspection.** Within ten (10) Business Days of Delivery of a shipment of Finished Product, Company shall inspect (or have inspected) such shipment for transport damages, completeness, and, as far as reasonably possible, any other Non-Conformity apparent from a reasonable visual inspection.
  - 3.2.3 Notification of Defects Discovered During Visual Inspection.** Flynn Pharma shall promptly, and in no event more than ten (10) days after the end of such inspection period, notify Pacira if the Company has discovered that the shipment of Finished Product includes Nonconforming Product. If the Company fails to notify Pacira of such Nonconformity within the applicable time period, then the Company shall be deemed to have accepted such Finished Products.
  - 3.2.4 Content of Defect Notices.** Any notification by Company to Pacira of Nonconforming Product shall be in writing and indicate the defect in reasonable detail.

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- 3.2.5 Pacira Response to Defect Notice.** Pacira shall notify Company as promptly as reasonably possible, but in any event within ten (10) Business Days after receipt of Company's notice of rejection, whether it accepts or disputes Company's assertions that certain Finished Product is a Nonconforming Product.
- 3.2.6 Provision of Replacement Product.** Whether or not Pacira accepts Company's assertion that certain Finished Product is Nonconforming Product: (i) Pacira shall, as soon as reasonably possible, replace all such Nonconforming Product with Finished Product that complies with the requirements of the terms and conditions of this Agreement ("**Replacement Product**"), and (ii) except as provided in Section 3.2.9 below, Company shall pay the price invoiced in connection with the Replacement Product within thirty (30) days after receipt of an invoice for such Replacement Product.
- 3.2.7 Dispute as to Defect; Submission to Independent Testing Laboratory.** If Pacira disputes Company's assertion that certain Finished Product is a Nonconforming Product, then at either Party's request a mutually agreeable independent testing laboratory ("Independent Testing Laboratory") shall analyze a sample of the allegedly Nonconforming Product and any shipment as necessary to determine whether the rejected Finished Product is Nonconforming Product.
- 3.2.7.1** Both Parties agree to cooperate with the Independent Testing Laboratory's reasonable requests for assistance in connection with its analysis hereunder.
- 3.2.7.2** Both Parties shall be bound by the Independent Testing Laboratory's results of analysis, which, in the absence of manifest error, shall be deemed final as to any dispute over the Nonconformity.
- 3.2.7.3** The costs of testing by the Independent Testing Laboratory shall be borne by the losing Party, or if the Independent Testing Laboratory cannot place the fault noticed and complained about, then the Parties shall share equally the expenses in connection with such Independent Testing Laboratory.
- 3.2.8 Return or Destruction of Nonconforming Product.** Any Nonconforming Product shall, at Pacira's sole discretion and expense, either:

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**3.2.8.1** be returned to Pacira within a reasonable period of time and relabelled or reworked as permitted in the Marketing Authorizations and Specification, if permitted by the Relevant Authorities, or

**3.2.8.2** destroyed by Company in accordance with Applicable Law.

**3.2.9 Refund of Payments for Nonconforming Product.** In the event that Finished Product is determined to contain a Nonconformity after Company has already remitted payment to Pacira for such Finished Product, Pacira shall credit Company the amount for such Nonconforming Product against future payments owing by Company.

#### **4. QUANTITIES FORECASTING AND PURCHASE ORDERS**

**4.1 Purchase Lot Size.** Company shall purchase Finished Product from Pacira in multiples of a single Batch quantities for each Product Presentation Form are listed in Appendix 1.

**4.2 Batch Requirements; Packaging Requirements.** Company shall specify the Presentation Form, Packaging and labelling requirements for each Batch. It is understood and agreed by the Parties that no single Batch may contain more than one Presentation Form, unless Company has requested a reduced Batch via the Purchase Order. Notwithstanding anything contained in this Agreement to the contrary, Company agrees that no more than three (3) country packaging may be ordered per each Batch. Responsibility for Packaging shall be with Pacira.

**4.3 Purchase Orders and Forecasts.** Company shall provide to Pacira, on a quarterly basis throughout that portion of the Term that begins on the Commencement Date, forecasts of units of Finished Product estimated to be required by Company during the upcoming twelve (12) month period. The first three (3) months of each forecast specifying Company's requirements shall serve as a firm commitment for quantities of Finished Product (for the first quarter) and shall be deemed to be a "**Purchase Order**" for the purposes of this Agreement, and the remaining nine (9) months of each forecast shall be a non-binding estimate of requirements for such period. In each Purchase Order, Company shall specify the desired Delivery Date(s) for Finished Product to be supplied during the three (3) month period covered by such Purchase Order, which shall not be less than ninety (90) day "lead time." Pacira shall provide Company with a written acknowledgement of each Purchase Order from Company within ten (10) days of receipt of the Purchase Order from Company as set forth in Section 4.5 below and shall use reasonable commercial efforts to supply Finished Product in accordance therewith.

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- 4.4 **Purchase Orders in Excess of Forecast.** Unless otherwise mutually agreed upon by the Parties, all Purchase Orders shall be at least [\*\*] ([\*\*]%) of the amount of the immediately preceding forecast that is deemed to be a firm Purchase Order. Under no circumstances shall Pacira be required to accept Purchase Orders for Finished Product for quantities which are greater than [\*\*] percent ([\*\*]%) of the quantities of such Finished Product reflected in the forecast provided immediately preceding the most recent forecast. Pacira will use commercially reasonable efforts to supply quantities of Finished Product exceeding the amounts set forth in this Section 4.4; provided however, that Pacira shall not be liable to the Company for any inability to deliver the amount of Finished Products ordered by the Company in excess of such amount.
- 4.5 **Acceptance of Purchase Orders.** Each Purchase Order shall be subject to acceptance in writing by Pacira within ten (10) days of receipt as set forth herein, or Pacira shall indicate what portion of the amounts covered by the Purchase Order Pacira is willing to accept as a binding Purchase Order.
- 4.6 **Late Delivery.** If Delivery of the Finished Product has not taken place or is not estimated to take place within ninety (90) days of the requested Delivery Date, Pacira shall use reasonable endeavours to secure alternative supplies of the Finished Product from an Affiliate or a Third Party on the same terms as the terms and conditions of this Agreement; provided that Pacira shall not be obligated to transfer or license any proprietary information or intellectual property to such Third Party.
- 4.7 **Shipping Documentation.** With each shipment of Finished Product, Pacira shall provide Company with commercially appropriate shipping documentation such as bills of lading and a Certificate of Analysis.
- 4.8 **Certificate of Compliance.** With the initial shipment of Finished Product and annually thereafter, Pacira shall provide Company with a Certificate of Compliance stating that to its knowledge the Approved Facility is in compliance with cGMP and all other Applicable Laws.
- 4.9 **Delivery Term.** Pacira shall deliver the Finished Products FOB (Incoterms 2000) Pacira's EU release site or other location designated by Pacira. Company shall pay all freight, insurance charges, taxes, import and export duties, inspection fees and other charges applicable to the sale and transport of Finished Product purchased by the Company hereunder.
- 4.10 **Company Report.** Company will provide to Pacira on a quarterly basis, or more frequently if required by Relevant Authorities including the DEA, a report designating Finished Product deliveries, by unit, by

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country, and by customer, in accordance with either existing or negotiated narcotic tracking requirements from the Relevant Authorities and in accordance with Applicable Law. In addition, Company will be responsible for producing other product consumption reports or product tracking information (i.e. diversion) as may be required by a Relevant Authority from time to time.

**5. TITLE AND PAYMENT**

**5.1 Payment of Supply Price.**

**5.1.1** Company shall pay to Pacira for each Vial of Finished Product in accordance with the terms and conditions of the Marketing Agreement and this Agreement.

**5.2 Passage of Title and Risk.** Legal title, risk in, and responsibility for, the Finished Product shall pass from Pacira to Company upon Delivery of the Finished Product. Upon Delivery, Company shall be responsible for, without limitation, arranging and maintaining proper temperature controlled handling and necessary narcotic product security for the Finished Product.

**5.3 Invoicing.** All amounts payable by the Company to Pacira under this Agreement shall, if delinquent, accrue interest at the rate of [\*\*] ([\*\*]%) percent per month from the date of delinquency.

**5.4 Taxes.** The price for the Finished Product is exclusive of any and all national, state or local sales, use, value added or other taxes, customs duties and similar tariffs and fees which the Company may be required to pay or collect upon the delivery of the Finished Products, or otherwise.

**6. PROJECT MANAGEMENT**

**6.1 Project Managers.** Each Party shall from time to time by notice to the other nominate a Project Manager to co-ordinate relationships between the Parties pursuant to the supply arrangement comprised in the terms and conditions of this Agreement. The Project Manager shall be the first point of contact between the parties in relation to the placement of Finished Product orders, the status of import and export licenses, confirmation of Delivery Dates, issues relating to Manufacturing and Manufacturing Approvals.

**6.2 Identification of Project Managers.** The Project Managers shall form a project team comprising relevant staff from both Pacira and Company for the co-ordination of the supply of the Finished Product to Company. From the Effective Date the Project Managers for the parties shall be:

**For Pacira: Patricia Brady**  
**Senior Manager, Supply Operations**

**For Flynn Pharma:**

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- 6.3 Cooperation.** Each Party shall co-operate with the other in good faith particularly with respect to problems or contingencies that arise during the Term and shall perform its obligations in good faith and in a commercially reasonable manner.
- 6.4 Disputes.** In the event of a dispute or disagreement between the Parties relating hereto such dispute or disagreement shall be referred for resolution in accordance with the Dispute Resolution procedures contained in Schedule VI of the Marketing Agreement.

**7. REPRESENTATIONS AND WARRANTIES**

- 7.1 Company and Pacira.** Each of Pacira and the Company represents and warrants to the other as follows:
- 7.1.1** It has full corporate power and authority to enter into this Agreement and consummate the transactions contemplated hereby.
  - 7.1.2** It has such permits, licenses and authorizations of governmental or regulatory authorities as are necessary to own its respective properties, conduct its business and consummate the transactions contemplated hereby.
  - 7.1.3** It is not currently debarred, suspended or otherwise excluded under any Applicable Law, and does not and will not use in any capacity the services of any person debarred under Applicable Law, in the performance of its obligations under this Agreement.
- 7.2 Pacira.** Pacira represents and warrants to the Company as follows: At the Delivery Date:
- 7.2.1** the Finished Product will conform to the Specifications and the Packaging and Labelling Specifications;
  - 7.2.2** the Finished Product shall not be adulterated or misbranded within the meaning of the FD&C Act, provided that Company has made timely provision of compliant artwork for labelling; and
  - 7.2.3** all Finished Product supplied to Company hereunder shall have a remaining shelf life as of the Delivery Date of at least



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eighteen (18) months, or such other shelf life as may be agreed in writing between the Parties from time to time (provided that Company takes Delivery in accordance with the terms and conditions of this Agreement).

- 7.3 Exceptions to Pacira's Obligations.** Pacira's obligations under Section 7.2 shall not apply to any Finished Product which:
- 7.3.1** has been tampered with or otherwise altered other than by Pacira, after Delivery;
  - 7.3.2** has been subjected to misuse, negligence or accident other than by Pacira, after Delivery; or
  - 7.3.3** has been stored, handled or used in a manner contrary to applicable requirements by Persons other than Pacira, after Delivery.
- 7.4** PACIRA MAKES NO WARRANTIES, EXPRESS OR IMPLIED, OTHER THAN THOSE EXPRESSLY MADE HEREIN. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY SATISFACTORY QUALITY AND FITNESS FOR A PARTICULAR PURPOSE ARE HEREBY DISCLAIMED BY PACIRA.

## **8 ADVERSE EVENTS AND PRODUCT RECALL**

- 8.1 Adverse Event.** Each of the Parties shall promptly notify the other upon discovery of the occurrence of any Product complaint or adverse event concerning the Product. Pacira shall be responsible for any notifications of adverse events to be made to the Relevant Authority.
- 8.2 Pacira Initiated Recalls.** In the event Pacira is required or voluntarily decides to initiate a recall, withdrawal, or field correction of the Product, Pacira shall notify Company and provide a copy of its proposal, including the recall letter, for review prior to initiation of such action and the Parties shall fully consult and cooperate with each other concerning the need for such a recall and in order to develop and execute a recall plan, as necessary. In conjunction with such recall, Company shall assist in the investigation to determine the cause and extent of the problem.
- 8.3 Company Initiated Recalls.** In the event that Company independently believes that a recall, withdrawal, or field correction of the Product may be necessary or appropriate, Company shall notify Pacira of Company's belief, and the Parties shall fully cooperate with each other concerning the necessity and nature of such action.

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- 8.4 Pacira Control of Recalls.** All coordination of any recall or field correction activities involving Product shall be handled by Pacira, in cooperation with Company, whether or not such action was initially requested by Company.
- 8.5 Costs of Recalls.** In the event that any Product is recalled as a direct result of the negligent or intentionally wrongful acts or omissions of Company or its representatives or as a result of any other breach of this Agreement by Company, then Company shall bear (and reimburse Pacira for) all of the costs and expenses of such recall, including expenses related to communications and meetings with all required regulatory agencies, expenses of replacement stock, the cost of notifying customers and costs associated with shipment of recalled Product from customers and shipment of an equal amount of replacement Product to those same customers. In the event that any Product is recalled as a direct result of the negligent or intentionally wrongful acts or omissions of Pacira or as a result of any other breach of this Agreement by Pacira, then Pacira shall bear (and reimburse the Company for) all of the costs and expenses of such recall, including expenses related to communications and meetings with all required Relevant Authorities, expenses of replacement stock, the cost of notifying customers and costs associated with shipment of recalled Product from customers and shipment of an equal amount of replacement Product to those same customers. To the extent that the reason for any recall of Product hereunder is in part the responsibility of Pacira and in part the responsibility of Company or is not due to the fault of either Party, then the expenses shall be allocated in an equitable manner between the Parties.

**9. INDEMNITIES, INSURANCE, AND CONFIDENTIALITY**

- 9.1** The indemnity obligations, limitations of liability, obligations to maintain insurance, confidentiality, and all other terms, conditions, covenants and provisions of Sections 10 and 11 of the Marketing Agreement (including any corresponding definitions) shall apply with respect to this Agreement, and are hereby incorporated herein by reference and made a part hereof; provided that, all capitalized terms in Sections 10 and 11 of the Marketing Agreement that are defined in this Agreement shall have the meanings given to them in this Agreement.
- 9.2** FOR THE AVOIDANCE OF DOUBT, NEITHER PARTY HEREUNDER SHALL BE LIABLE TO THE OTHER FOR CONSEQUENTIAL, INCIDENTAL, INDIRECT, OR PUNITIVE DAMAGES, INCLUDING WITHOUT LIMITATION, LOSS OF PROFITS, LOST OPPORTUNITY OR USE OF ANY KIND, SUFFERED BY THE OTHER PARTY, WHETHER IN CONTRACT, TORT OR OTHERWISE, REGARDLESS AS TO WHETHER THE PARTY WAS ADVISED OF THE POSSIBILITY OF ANY SUCH LOSS.

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**10. TERM AND TERMINATION**

**10.1 Term.** This Agreement shall come into effect on the Effective Date and shall continue until expiration or earlier termination of the Marketing Agreement.

**11. EVENTS ON TERMINATION**

**11.1 Termination.**

11.1.1 This Agreement may be terminated in its entirety immediately upon written notice of termination given by:

(a) The non-defaulting Party in the event that the other Party shall: (A) commit a material breach or default under this Agreement, which breach or default shall not be remedied within sixty (60) days after the receipt of written notice thereof by the Party in breach or default; or (B) have made a material misrepresentation of any representation or warranty contained herein; or

(b) The non-defaulting Party if the other Party fails to pay any amounts due and payable hereunder to the non-defaulting Party within ten (10) days after written notice of such failure to pay;

(c) Either Party, upon the occurrence of either of the following:

i. The entry of a decree or order for relief by a court having jurisdiction in the premises in respect of the other Party in an involuntary case under the applicable Insolvency Act or Bankruptcy Code, as now constituted or hereafter amended, or any other applicable foreign, federal or state insolvency or other similar law and the continuance of any such decree or order unstayed and in effect for a period of sixty (60) consecutive days; or

ii. The filing by the other Party of a petition for relief under the applicable Insolvency Act or Bankruptcy Code, as now constituted or hereafter amended, or any other applicable foreign, federal or state insolvency law or other similar law.

**11.2 Effects of Termination.** Termination of this Agreement (whether under this section, on expiration of the Term or otherwise) shall be without prejudice to any rights of either Party against the other that may have accrued to the date of such termination. Upon termination of this Agreement, the Company shall purchase from Pacira and pay Pacira for all Finished Product for which Company has outstanding Purchase Orders that have been accepted by Pacira and shall reimburse Pacira for the cost of materials obtained by Pacira due to the forecast provided by the Company.

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**11.3 Survival.** The following provisions shall survive any termination or expiration of this Agreement: Section 1 (“Definitions”), Section 8 (“Adverse Events and Product Recall”), Section 9 (“Indemnitees, Insurance and Confidentiality”), Section 11 (“Events on Termination”), Section 12 (“Assignment and Sub-Contracting”) and Section 14 (“General Provisions”).

**11.4 Retention of Records.** Following any termination or expiration of this Agreement, the Parties shall retain pharmaceutical records and samples with respect to all Products manufactured hereunder, in accordance with cGMP and Applicable Laws.

**11.5 Survival as Provided Under Marketing Agreement.** Notwithstanding anything to the contrary, the terms and conditions of this Agreement shall survive termination of the Marketing Agreement to the extent provided in Section 17 of the Marketing Agreement.

## **12. ASSIGNMENT AND SUB-CONTRACTING**

**12.1** This Agreement may only be assigned or otherwise transferred by a Party only to a permitted successor or assignee of such Party’s rights and obligations under the Marketing Agreement.

## **13. FORCE MAJEURE.**

**13.1** If either Pacira or the Company shall be prevented by fire; strike; lockouts; war; civil disturbances; acts of God; explosion; flood; earthquake; acts of terror, substantial unavailability, shortage or interruption in the usual supply of raw materials; severe weather; insurrection; riot; sabotage; accident; labor strike or labor disturbances; or orders or decrees of any court; or other similar events beyond the reasonable control of Pacira or the Company (“Force Majeure”) from performing its respective obligations hereunder, the obligations of such Party shall be suspended during the time and to the extent that such Party is prevented from complying therewith and such Party shall not be liable to the other Party hereto for damages for such failure to comply. The Party whose obligations hereunder have been suspended shall promptly and diligently pursue appropriate action to enable it to lift the Force Majeure situation, except that such Party shall not be obligated to settle any strike, lockout or other labor difficulty on terms contrary to its wishes. The terms of this Section shall not forgive or excuse any failure of a party hereto to make a payment to the other party or a third party when and as required under this Agreement.

**13.2** In the event that any Force Majeure circumstance cannot be removed or overcome within six (6) months (or such other period as the Parties

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jointly shall determine) from the date the Party affected first became affected, then either Party may, as the expiration of such period by notice to the other Party terminate the term of this Agreement and neither the Company nor Pacira shall be liable to the other for damages.

#### 14. GENERAL PROVISIONS

- 14.1 Entire Agreement.** The terms and conditions of this Agreement and the Marketing Agreement (other than Schedule III of the Marketing Agreement which is superseded by this Agreement) set out the entire agreement and understanding between the Parties in respect of the subject matter hereof, and supersede any other agreements or understandings with respect to such subject matter.
- 14.2 Amendments.** No variation of the terms and conditions of this Agreement shall be valid unless it is in writing and signed by or on behalf of both Parties.
- 14.3 Notices.** The provisions of Section 19 of the Marketing Agreement shall apply to any notices permitted or required to be given hereunder.
- 14.4 Relationship of the Parties.** Nothing in this Agreement is deemed to constitute a partnership, agency, employer-employee or joint venture relationship between the Parties. No Party shall incur any debts or make any commitments for the other, except to the extent, if at all, specifically provided herein.
- 14.5 Waiver.** Unless expressly agreed, no waiver of any term, provision or condition of this Agreement shall constitute a general waiver of any provisions of this Agreement, nor shall it affect any rights, obligations or liabilities under or pursuant to this Agreement which have already accrued up to the date of variation, and the rights and obligations of the Parties under or pursuant to this Agreement shall remain in full force and effect, except and only to the extent that they are so waived.
- 14.6 Severability.** If and to the extent that any provision of this Agreement is held to be illegal, void or unenforceable, such provision shall be given no effect and shall be deemed not to be included in this Agreement but without invalidating any of the remaining provisions of this Agreement.
- 14.7 Delay.** No failure or delay by either party in exercising any right or remedy provided by law under or pursuant to this Agreement shall impair such right or remedy or operate or be construed as a waiver or variation of it or preclude its exercise at any subsequent time and no single or partial exercise of any such right or remedy shall preclude any other or further exercise of it or the exercise of any other right or remedy.

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- 14.8 Rights and Remedies Cumulative.** The rights and remedies of each of the parties under or pursuant to this Agreement are cumulative, may be exercised as often as such Party considers appropriate and are in addition to its rights and remedies under general law.
- 14.9 Counterparts.** This Agreement may be executed in any number of counterparts and by the parties on separate counterparts, each of which is an original but all of which together constitute one and the same instrument.
- 14.10 Choice of Law; Forum.** This Agreement and the relationship between the parties shall be governed by, and interpreted in accordance with English law. If there is a disagreement between the Pacira and Flynn Pharma on the interpretation of this Agreement or any aspect of the performance by either party of its obligations under this Agreement, the parties shall resolve the dispute in accordance with the dispute resolution procedure set out in Schedule VI of the Marketing Agreement. The Parties specifically waive any rights and obligations under any applicable provisions of the United Nations Convention for the International Sale of Goods.
- 14.11 Binding Effect.** Subject to Section 12.1, this Agreement shall be binding upon and shall inure to the benefit of the Parties hereto and their respective successors and assigns permitted under this Agreement.

*(signature page follows)*

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**IN WITNESS WHEREOF** this Agreement has been signed on behalf of the Parties hereto effective as of the Effective Date.

**FLYNN PHARMA THERAPEUTICS,  
INC.**

By: /s/ D.W. Fakes  
Print Name: D.W. Fakes  
Title: Director

**PACIRA PHARMACEUTICALS, INC.  
(F/K/A SKYEPHARMA, INC.)**

By: /s/ Mark Walters  
Print Name: Mark Walters  
Title: V.P. Business & Commercial Development

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**APPENDIX 1**

**THE SPECIFICATION; BATCH SIZE**

DepoDur [\*\*] mg batch size: [[\*\*] Vials]



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**APPENDIX 2**

**PACKAGING AND LABELLING SPECIFICATIONS**

All Products will be packaged in single cartons of [\*\*] ([\*\*]) Vials per carton. Included in each carton is a single Coldmark freeze indicator and a DepoDur Package Insert.

**SERVICES AGREEMENT**

This **SERVICES AGREEMENT** (this "Agreement"), is effective as of October 28, 2010, by and among Pacira Pharmaceuticals, Inc. (the "Company"), MPM Asset Management LLC ("MPM"), and Gary Patou ("Consultant").

**RECITALS**

**WHEREAS**, the Company desires that MPM and Consultant perform certain professional services for it as more specifically set forth herein;

**WHEREAS**, MPM and Consultant are in the business of providing such services and have agreed to provide such services pursuant to the terms and conditions set forth in this Agreement;

**WHEREAS**, Consultant is an employee of MPM, and MPM and the Company desire that Consultant perform the services for the Company and serve in the capacity as the Company's Chief Medical Officer;

**WHEREAS**, the Company, MPM and Consultant previously entered into a Consulting Agreement, dated March 1, 2009, as amended and restated on March 5, 2010 (the "Prior Agreement");

**WHEREAS**, the Prior Agreement has been terminated; and

**WHEREAS**, the Company, MPM and Consultant desire to enter into a new consulting relationship on the terms and subject to the conditions as set forth herein.

**AGREEMENT**

**NOW, THEREFORE**, in consideration of the premises and covenants set forth herein, the parties hereto, intending to be legally bound, the parties agree that the Prior Agreement has been terminated and shall be superseded and replaced in its entirety by this Agreement and further agree as follows:

**1. Engagement.** The Company hereby engages MPM and Consultant to provide the services set forth in Section 2 hereof to the Company, and MPM and Consultant hereby accept such engagement, on the terms and conditions set forth in this Agreement.

**2. Services.** MPM and Consultant will provide the services set forth on Exhibit A hereto (collectively, the "Services") and during the term of this Agreement, MPM will use commercially reasonable efforts to cause Consultant to perform the Services. MPM and Consultant acknowledge the unique nature of the Services to be provided and hereby agree and acknowledge that the Services shall be rendered solely by Consultant.

**3. Term.** The term of MPM's and Consultant's engagement hereunder shall commence on the date hereof and continue until December 31, 2014 unless earlier terminated in accordance with Section 5.

#### 4. Compensation.

(a) Monthly Services Fee. MPM shall be paid a monthly services fee (adjusted for increases or decreases in salary, bonus payments and benefits payments) (the “Services Fee”) at the rates set forth in this Section 4(a). The monthly Services Fee shall be payable monthly in arrears, beginning with the payment for the period of October 16, 2010 through October 31, 2010 and thereafter beginning with the month ending November 30, 2010 (unless terminated in accordance with Section 5). The Services Fee may be further adjusted from time to time by the written agreement of the Company and MPM.

<u>Year(s)</u>	<u>Amount of Monthly Services Fee</u>
2010-2011	\$ 26,467.33
2012	\$ 15,880.40
2013-2014	\$ 6,352.16

(b) Equity Compensation. On September 2, 2010, the Company granted to Consultant two stock options (each an “Option” and collectively, the “Options”) to purchase an aggregate of One Million Two Hundred Seventy Thousand (1,270,000) shares of the Company’s common stock, \$0.001 par value per share (the “Option Shares”), pursuant to the Company’s 2007 Stock Option/Stock Issuance (the “Plan”). The exercise price, vesting schedule and other terms for each of the Options are set forth in the notice of grant and option agreement for each such Option. Additional equity incentives, if any, shall be determined by the Board of Directors of the Company (the “Board”) (or a committee thereof) in its sole discretion. All shares figures set forth herein shall be subject to adjustment for stock splits, stock dividends, stock combinations, recapitalizations and similar events.

(c) Additional Compensation. Consultant is eligible to receive, at the full discretion of the Board, additional compensation equal to thirty-five percent (35%) of the annual Service Fee for the applicable year (the “Additional Compensation”). The Additional Compensation shall be based on Consultant’s and the Company’s performance during the applicable fiscal year, as determined by the Board. The Additional Compensation criteria or “goals” will be determined by agreement between the Board, the Company’s Chief Executive Officer and Consultant at beginning of each fiscal year. The actual amount of the Additional Compensation, if any, may be in an amount either above or below the amount specified by the Board at the beginning of each fiscal year based on the Board’s sole determination. The Additional Compensation for the 2011 fiscal year, if payable, shall be paid directly to Consultant and no later than March 15, 2012. Additional Compensation for subsequent years shall be determined by the Board in its sole discretion.

(d) Reimbursement of Expenses. The Company shall reimburse MPM for an amount equal to the expenses, consistent with MPM’s expense reimbursement policy, that are incurred in the performance of the services by MPM and Consultant.

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(e) Entire Compensation. Notwithstanding anything to the contrary set forth herein, the compensation provided for in this Section 4 shall constitute full payment for the Services to be rendered by MPM and Consultant to the Company.

## **5. Termination and Related Matters.**

(a) Termination. Each of the Company, MPM and Consultant may terminate this Agreement for any reason or for no reason upon at least thirty (30) days' prior written notice to the other party. The date of termination of this Agreement pursuant to this Section 5 is referred to herein as the "Termination Date".

(b) General Obligations upon Termination. In the event that the Company shall terminate this provision of Services by MPM and the Consultant, the Company shall not have any further obligation or liability under this Agreement, except (i) as specifically set forth herein, (ii) the payment of any accrued and unpaid Service Fees and (iii) for the reimbursement of reimbursable expenses (in accordance with Section 4(d)) incurred prior to the Termination Date. Upon any termination of this Agreement, Consultant shall immediately tender his written resignation from any office of the Company then held.

(c) Termination without "Cause" or for "Good Reason". In the event that the Company terminates the provision of Services by MPM and the Consultant without Cause (as defined below) or, in the event that MPM and the Consultant terminate the provision of Services for Good Reason (as defined below), in each case, (i) MPM shall be entitled to receive continuing payments of the Services Fee then in effect for a period of nine (9) months beginning on the Payment Commencement Date (as defined below), and (ii) Consultant shall be entitled to acceleration of vesting of such number of Option Shares as would have vested in the nine (9) month period following the Termination Date had Consultant continued to provide Services to the Company for such period, *provided, however* that in each case, the receipt of such payments and benefits is expressly contingent upon Consultant's execution of a release and waiver of claims in a form acceptable to the Company (the "Release") which Release must be executed and become effective within sixty (60) days following the date of termination of the provision of Services. The payments and benefits shall be paid within ten (10) days following the date the Release becomes effective (the "Payment Commencement Date"). Notwithstanding the foregoing, if the 60<sup>th</sup> day following the date of termination of Services occurs in the calendar year following the termination, then the Payment Commencement Date shall be no earlier than January 1<sup>st</sup> of such subsequent calendar year. The provision of payments and benefits pursuant to this Section 5 shall be subject to the terms and conditions set forth on Exhibit B.

(d) Termination without "Cause" or for "Good Reason" Prior to or Following a Change of Control. In the event that the Company terminates the provision of Services by MPM and the Consultant without Cause (as defined below) or, in the event that MPM and the Consultant terminate the provision of Services for Good Reason (as defined below), in each case, within thirty (30) days prior to, or twelve (12) months following, the consummation of a Change of Control, then (i) MPM shall be entitled to receive continuing payments of the Services Fee then in effect for a period of nine (9) months beginning on the Payment Commencement Date, and (ii) the Consultant shall be entitled to acceleration of vesting of one hundred percent (100%) of the then unvested Option Shares, provided, however that in each case, the receipt of such

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payments and benefits is expressly contingent the Release which Release must be executed by Consultant and become effective within sixty (60) days following the date of termination of the provision of Services. The provision of payments and benefits pursuant to this Section 5 shall be subject to the terms and conditions set forth on Exhibit B.

(e) Definitions. For purposes of this Agreement, the following terms shall have the following definitions:

(i) "Change of Control" means (A) a merger or consolidation of either the Company or Pacira, Inc., a Delaware corporation (" Parent") into another entity in which the stockholders of the Company or Parent (as applicable) do not control fifty percent (50%) or more of the total voting power of the surviving entity (other than a reincorporation merger); (B) the sale, transfer or other disposition of all or substantially all of the Company's assets in liquidation or dissolution of the Company; or (C) the sale or transfer of more than fifty percent (50%) of the outstanding voting stock of the Company. In the case of each of the foregoing clauses (A), (B) and (C), a Change of Control as a result of a financing transaction of the Company or Parent shall not constitute a Change of Control for purposes of this Agreement.

(ii) "Cause" means (A) Consultant's failure to substantially perform his duties to the Company after there has been delivered to Consultant written notice setting forth in detail the specific respects in which the Board believes that Consultant has not substantially performed his duties and, if the Company reasonably considers the situation to be correctable, a demand for substantial performance and opportunity to cure, giving Consultant thirty (30) calendar days after he receives such notice to correct the situation; (B) Consultant's having engaged in fraud, misconduct, dishonesty, gross negligence or having otherwise acted in a manner injurious to the Company or in intentional disregard for the Company's best interests; (C) Consultant's failure to follow reasonable and lawful instructions from the Board and Consultant's failure to cure such failure after receiving twenty (20) days advance written notice; (D) Consultant's material breach of the terms of this Agreement or the Confidentiality Agreement (as defined herein) or any other similar agreement that may be in effect from time to time; or (E) Consultant's conviction of, or pleading guilty or nolo contendere to, any misdemeanor involving dishonesty or moral turpitude or related to the Company's business, or any felony.

(iii) "Good Reason" means the occurrence of any one or more of the following events without the prior written consent of MPM and the Consultant: (A) any material reduction of the then effective Services Fee other than in accordance with this Agreement or which reduction is not related to a cross-executive team salary reduction; (B) any material breach by the Company of this Agreement; or (C) a material reduction in Consultant's responsibilities or duties other than in connection with a reduction in the percentage of time that Consultant is devoting to the Company, provided that in the case of clause (C), a mere reassignment following a Change of Control to a position that is substantially similar to the position held prior to the Change of Control transaction shall not constitute a material reduction in job responsibilities or duties; provided, however, that no such event or condition shall constitute Good Reason unless (x) MPM and the Consultant give the Company a written notice of termination of the provision of Services for Good Reason not more than ninety (90) days after the initial existence of the condition, (y) the grounds for termination (if susceptible to correction) are not corrected by the Company within thirty (30) days of its receipt of such notice and (z) the termination of the provision of Services occurs within one year following the Company's receipt of such notice.

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**6. Non-Disclosure, Inventions and Non-Solicitation Agreement.** Consultant has executed a Non-Disclosure, Inventions and Non-Solicitation Agreement with MPM (the “Confidentiality Agreement”) that protects the disclosure of confidential information of the Company. MPM shall take all commercially reasonable actions necessary to ensure that each of its other employees, agents or affiliates who may perform the Services for or on behalf of the Company or may have any access to the Company’s confidential or proprietary information pursuant to this Agreement signs a Non-Disclosure, Inventions and Non-Solicitation Agreement substantially similar to the Confidentiality Agreement executed by Consultant.

**7. Representations and Warranties.**

(a) Representations of the Company. As an inducement to MPM and Consultant to enter into this Agreement, the Company represents and warrants to MPM and Consultant as follows:

(i) The Company is duly organized and validly existing under the laws of the State of California and has all requisite corporate power to enter into this Agreement.

(ii) Neither the execution and delivery of this Agreement nor the consummation of the transactions contemplated herein nor compliance by the Company with any of the provisions hereof will: (a) violate any order, writ, injunction, decree, law, statute, rule or regulation applicable to it or (b) require the consent, approval, permission or other authorization of, or qualification or filing with or notice to, any court, arbitrator or other tribunal or any governmental, administrative, regulatory or self-regulatory agency or any other third party.

(iii) This Agreement has been duly executed and delivered by the Company and constitutes a valid and binding agreement of the Company, enforceable against the Company in accordance with its terms.

(b) Representations of MPM and Consultant. As an inducement to the Company to enter into this Agreement, MPM and Consultant represent and warrant to the Company that neither MPM nor Consultant is a party to or otherwise subject to any agreements or restrictions that would prohibit MPM or Consultant from entering into this Agreement and carrying out the transactions contemplated by this Agreement in accordance with the terms hereof, and this Agreement and the transactions contemplated hereby will not infringe or conflict with, and are not inconsistent with, the rights of any other person or entity. The parties to this Agreement acknowledge that Consultant’s services are provided in connection with Consultant’s employment relationship with MPM.

**8. Survival of Representations, Warranties and Covenants.** The provisions of Sections 5, 6 and 8 hereof shall survive the termination of this Agreement.

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**9. Supersedes Other Agreements.** This Agreement supersedes and is in lieu of any and all other consulting and compensation arrangements among MPM, Consultant and the Company including without the limitation the Prior Agreement.

**10. No Employment Relationship.** The parties hereto acknowledge and agree that Consultant is an employee of MPM and not an employee of the Company, and nothing herein shall be construed to be inconsistent with this relationship or status. Neither MPM nor Consultant shall be entitled to any benefits which the Company may make available to its employees from time to time. Except as expressly set forth herein, MPM shall have sole responsibility for the payment of all compensation due to Consultant, for the maintaining of adequate workers' compensation insurance coverage for Consultant, and for the withholding of all applicable federal, state or local taxes or contributions imposed under any unemployment insurance, social security, income tax or other tax law or regulation with respect to MPM's or Consultant's performance of Services hereunder.

**11. Amendments.** Any amendment to this Agreement shall be made in writing and signed by the parties hereto.

**12. Enforceability.** If any provision of this Agreement shall be invalid or unenforceable, in whole or in part, then such provision shall be deemed to be modified or restricted to the extent and in the manner necessary to render the same valid and enforceable, or shall be deemed excised from this Agreement, as the case may require, and this Agreement shall be construed and enforced to the maximum extent permitted by law as if such provision had been originally incorporated herein as so modified or restricted or as if such provision had not been originally incorporated herein, as the case may be.

**13. Governing Law.** This Agreement shall be construed and interpreted in accordance with the internal laws of the state of California, without reference to conflicts of laws principles thereunder.

**14. Assignment.**

**(a) By the Company.** The rights and obligations of the Company under this Agreement shall inure to the benefit of, and shall be binding upon, the successors and assigns of the Company.

**(b) By MPM or Consultant.** This Agreement and the obligations created hereunder may not be assigned by MPM or Consultant and any such purported assignment shall be null and void *ab initio*.

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**15. Notices.** All notices, requests, consents and other communications hereunder to any party shall be deemed to be sufficient if contained in a written instrument delivered in person or duly sent by certified mail, postage prepaid; by an overnight delivery service, charges prepaid; or by confirmed facsimile; addressed to such party at the address set forth below or such other address as may hereafter be designated in writing by the addressee to the addressor:

If to the Company:

Pacira Pharmaceuticals, Inc.  
10450 Science Center Drive  
San Diego, CA 92121  
Attention: James Scibetta, Chief Financial Officer  
Facsimile: (858) 625-2439

If to MPM or Consultant:

MPM Asset Management LLC  
200 Clarendon Street  
Boston, Massachusetts 02116  
Attention: John W. Vander Vort, Managing Director and COO and  
Dana K. O'Brien,  
Director of Operations and Legal Affairs  
Facsimile: (617) 425-9201

Any party may from time to time change its address for the purpose of notices to that party by a similar notice specifying a new address, but no such change shall be deemed to have been given until it is actually received by the party sought to be charged with its contents.

**16. Waivers.** No claim or right arising out of a breach or default under this Agreement shall be discharged in whole or in part by a waiver of that claim or right unless the waiver is supported by consideration and is in writing and executed by the aggrieved party hereto or its duly authorized agent. A waiver by any party hereto of a breach or default by the other party hereto of any provision of this Agreement shall not be deemed a waiver of future compliance therewith, and such provisions shall remain in full force and effect.

**17. Counterparts.** This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and all of which together shall be deemed to be one and the same instrument.



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**IN WITNESS WHEREOF**, this Amended and Restated Services Agreement has been executed by the parties as of the date first above written.

**PACIRA PHARMACEUTICALS, INC.**

By: /s/ Dave Stack  
Name: Dave Stack  
Title: Chief Executive Officer

**MPM ASSET MANAGEMENT LLC**

By: /s/ John W. Vander Vort  
Name: John W. Vander Vort  
Title: Managing Director and Chief Operating Officer

**CONSULTANT**

/s/ Dr. Gary Patou  
Dr. Gary Patou

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**EXHIBIT A**

**SERVICES**

Consultant will perform all the duties customarily expected of a Chief Medical Officer and related duties as requested by the Company's Chief Executive Officer from time to time. Such duties shall include (i) obtaining FDA approval for the EXPAREL New Drug Application in the United States, (ii) filing the EXPAREL dossier in the European Union, (iii) clinical development of EXPAREL for nerve block, epidural administration and any additional clinical development recommended by the Company's Chief Executive Officer or the Board of Directors of the Company, (iv) assist in marketplace presentations and questions where Consultant's expertise and title are of value and (v) assist with the Company's product pipeline development.

Consultant shall devote to the Company the percentage of his business time to the Company as follows:

Years 2010 - 2011:      approximately 80%

Year 2012:              approximately 50%

Years 2013 - 2014:    approximately 20%

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**Exhibit B**

**Payments Subject to Section 409A**

1. Subject to this Exhibit B, any severance payments or benefits that may be due under the Agreement shall begin only upon the date of MPM's and the Consultant's "separation from service" (determined as set forth below) which occurs on or after the termination of the provision of Services. The following rules shall apply with respect to distribution of the severance payments and benefits, if any, to be provided to the MPM and the Consultant under the Agreement, as applicable:

- (a) It is intended that each installment of the severance payments and benefits under the Agreement provided under shall be treated as a separate "payment" for purposes of Section 409A. Neither the Company nor MPM nor the Consultant shall have the right to accelerate or defer the delivery of any such payments or benefits except to the extent specifically permitted or required by Section 409A.
- (b) If, as of the date of Consultant's "separation from service" from the Company, Consultant is not a "specified employee" (within the meaning of Section 409A), then each installment of the severance payments and benefits shall be made on the dates and terms set forth in the Agreement.
- (c) If, as of the date of Consultant's "separation from service" from the Company, Consultant is a "specified employee" (within the meaning of Section 409A), then:
  - (i) Each installment of the severance payments and benefits due under the Agreement that, in accordance with the dates and terms set forth herein, will in all circumstances, regardless of when the separation from service occurs, be paid within the short-term deferral period (as defined under Section 409A) shall be treated as a short-term deferral within the meaning of Treasury Regulation Section 1.409A-1(b)(4) to the maximum extent permissible under Section 409A and shall be paid at the time set forth in the Agreement; and
  - (ii) Each installment of the severance payments and benefits due under the Agreement that is not described in this Exhibit B, Section 1(c)(i) and that would, absent this subsection, be paid within the six-month period following Consultant's "separation from service" from the Company shall not be paid until the date that is six months and one day after such separation from service (or, if earlier, Consultant's death), with any such installments that are required to be delayed being accumulated during the six-month period and paid in a lump sum on the date that is six months and one day following the separation from service and any subsequent installments, if any, being paid in accordance with the dates and terms set forth herein; provided, however, that the preceding provisions of this sentence shall not apply to any installment of payments if and to the maximum extent that that such installment is deemed to be paid under a separation pay plan that does not provide for a deferral of compensation by reason of the application of

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Treasury Regulation 1.409A-1(b)(9)(iii) (relating to separation pay upon an involuntary separation from service). Any installments that qualify for the exception under Treasury Regulation Section 1.409A-1(b)(9)(iii) must be paid no later than the last day of Consultant's second taxable year following the taxable year in which the separation from service occurs.

2. The determination of whether and when the separation from service from the Company has occurred shall be made and in a manner consistent with, and based on the presumptions set forth in, Treasury Regulation Section 1.409A-1(h). Solely for purposes of this Exhibit B, Section 2, "Company" shall include all persons with whom the Company would be considered a single employer under Section 414(b) and 414(c) of the Code.

3. The Company makes no representation or warranty and shall have no liability to MPM or Consultant or to any other person if any of the provisions of the Agreement (including this Exhibit) are determined to constitute deferred compensation subject to Section 409A but that do not satisfy an exemption from, or the conditions of, that section.

**PACIRA PHARMACEUTICALS, INC.**  
Stack Pharmaceuticals, Inc. Services Agreement

This Service Agreement (the "Agreement") is entered into effect as of September 15, 2010 (the "Effective Date") between PACIRA PHARMACEUTICALS, INC. (the "Company"), a Delaware corporation with its principal offices at 10450 Science Center Drive, San Diego, California 92121, and Stack Pharmaceuticals, Inc. ("Stack"), a Delaware corporation with its principal offices at 5 Sylvan Way, Parsippany, New Jersey 07054.

**RECITALS**

WHEREAS the Company desires use of the offices of Stack Pharmaceuticals for the support of commercialization and development of the Company's health care assets upon the terms and conditions set forth below.

The parties further acknowledge and agree that retroactive to May 1, 2009, the Company has paid Stack Pharmaceuticals \$10,500, on a monthly basis for services under this agreement and that such monthly payment represents the entire payment obligation of the Company and that the company obligations under the Agreement have been fully paid as of the effective date.

**Services to be Provided by Stack Pharmaceuticals, Inc.**

- Furnished office workspace for nine Pacira employees on a 60%-100% allocation of time basis of a 40 hr workweek
- Use of conference rooms for meetings
- Use of the kitchen
- Use of phone system
- Use of printers
- Fax and wireless and wired high speed internet connection

**Service Costs**

Company shall pay Stack Pharmaceuticals, Inc., \$10,500 per month for the services provided. Each month shall be paid by the first day of the month in which services are to be provided.

**Term**

The term of this agreement shall be one year renewable upon consent of both parties.

**Complete Agreement**

This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and may not be modified or amended except in writing by both parties. This agreement supersedes any prior agreement.

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**Governing Law**

This Agreement shall be governed by and construed in accordance with the laws of The State of New Jersey, without regard to its conflicts of law provisions.

**Notices**

Any notice to be given hereunder shall be in writing, mailed

to PACIRA PHARMACEUTICALS:

PACIRA PHARMACEUTICALS, INC.  
10450 Science Center Drive  
San Diego, California 92121  
Attn: James Scibetta

and to STACK

Stack Pharmaceuticals, Inc.  
5 Sylvan Way  
Parsippany, New Jersey 07054  
Attn: Fred Ryan

Or to such other address as may have been furnished at the date of mailing or emailing either by PACIRA PHARMACEUTICALS or Stack in writing

IN WITNESS WHEREOF, the Company and Stack have duly executed and delivered this Agreement as of September 16, 2010.

PACIRA PHARMACEUTICALS, INC.

By: /s/ James Scibetta  
Name: James Scibetta  
Title: CFO

STACK PHARMACEUTICALS, INC

By: /s/ Fred M. Ryan  
Names: Fred M. Ryan

**EXECUTIVE EMPLOYMENT AGREEMENT**

This Executive Employment Agreement (the "Agreement"), is entered into as of October 27, 2010 (the "Effective Date"), by and between Pacira Pharmaceuticals, Inc., a California corporation (the "Company"), and David Stack (the "Executive").

**RECITALS**

**WHEREAS**, the Company wishes to continue to employ the Executive, and the Executive desires to continue to be employed by the Company, for such purpose and upon the terms and conditions hereinafter provided; and

**WHEREAS**, the parties wish to establish the terms of the Executive's future employment with the Company and set out fully their respective rights, obligations and duties.

**AGREEMENT**

In consideration of the promises and the terms and conditions set forth in this Agreement, the parties agree as follows:

1. Title and Capacity. The Company hereby agrees to continue to employ the Executive, and the Executive hereby accepts continued employment with the Company, under the terms set forth in this Agreement. The Executive will serve as the President and Chief Executive Officer of the Company and shall perform such duties as are ordinary, customary and necessary in such role. The Executive will report directly to the Board of Directors of the Company (the "Board"). During the period of the Executive's employment as the President and Chief Executive Officer of the Company, the Company shall nominate (and re-nominate, as appropriate) the Executive and, if elected by the Company's stockholders, the Executive shall serve as a member of the Board.

2. Compensation and Benefits.

(a) Salary. The Company agrees to pay the Executive an annual base salary of Four Hundred Thousand Dollars and Twelve Cents (\$400,000.12) payable in accordance with Company's customary payroll practice (the "Base Salary"). The Executive's Base Salary shall be reviewed periodically by the Board; *provided, however*, that any such review will not necessarily result in an adjustment to the Executive's Base Salary. Any change in the Executive's Base Salary must be approved by the Board.

(b) Bonus. The Executive is eligible to receive, in addition to the Base Salary and subject to the terms hereof and at the full discretion of the Board, a targeted incentive bonus of fifty percent (50%) of Base Salary (the "Targeted Incentive Bonus"). The Targeted Incentive Bonus shall be based on the Executive's and the Company's performance during the applicable fiscal year, as determined by the Board. The Targeted Incentive Bonus criteria or "goals" will be determined by agreement between the Board and the Executive at beginning of each fiscal year. The award of the Target Incentive Bonus may be in an amount either above or below the amount specified by the Board at the beginning of each fiscal year based on the ultimate performance assessed by the Board.

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The Targeted Incentive Bonus, if awarded, shall be payable in the first payroll period in 2012, but in no event later than March 15, 2012. Targeted Incentive Bonuses for subsequent years shall be determined and approved by the Board in its sole discretion.

All salary and bonuses shall be subject to all applicable withholdings and deductions.

(c) Stock Options. On September 2, 2010, the Company granted to the Executive two stock options (each an “Option” and collectively, the “Options”) to purchase an aggregate of four million seven hundred and fifty thousand (4,750,000) shares of the Company’s common stock, \$0.001 par value per share (the “Option Shares”), pursuant to the Company’s 2007 Stock Option/Stock Issuance (the “Plan”). The exercise price, vesting schedule and other terms for each of the Options are set forth in the notice of grant and option agreement for each such Option and the Options are subject to accelerated vesting as set forth in Section 3 hereof. Additional equity incentives, if any, shall be determined by the Board (or a committee thereof) in its sole discretion. All share figures set forth herein shall be subject to adjustment for stock splits, stock dividends, stock combinations, recapitalizations and similar events.

(d) Benefits. The Executive (and, where applicable, the Executive’s qualified dependents) will be eligible to participate in health insurance and other employee benefit plans and policies established by the Company for its executive team from time to time on substantially the same terms as are made available to other such employees of the Company generally. The Executive’s participation (and the participation of the Executive’s qualified dependents) in the Company’s benefit plans and policies will be subject to the terms of the applicable plan documents and the Company’s generally applied policies, and the Company in its sole discretion may from time to time adopt, modify, interpret or discontinue such plans or policies.

(e) Expenses. The Company will reimburse the Executive for all reasonable and necessary expenses incurred by the Executive in connection with the Company’s business, in accordance with the applicable Company policy as may be amended from time to time.

(f) Vacation and Holidays. The Executive shall be eligible for thirty (30) days’ paid vacation/flexible time off per calendar year subject to the applicable terms and conditions of the Company’s vacation policy and applicable law.

(g) Termination of Benefits. Except as set forth in Section 3 or as otherwise specified herein or in any other agreement between the Executive and the Company, if the Executive’s employment is terminated by the Company for any reason, with or without Cause (as defined below), or if the Executive resigns the Executive’s employment voluntarily, with or without Good Reason (as defined below), no compensation or other payments will be paid or provided to the Executive for periods following the date when such a termination of employment is effective, provided that any rights the Executive may have under the Company’s benefit plans shall be determined under the provisions of such plans. If the Executive’s employment terminates as a result of the Executive’s death or disability, no compensation or payments will be made to the Executive other than those to which the Executive may otherwise be entitled under the benefit plans of the Company.



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3. Compensation and Benefits Upon Termination of Employment. Upon termination of the Executive's employment (such date of termination being referred to as the "Termination Date"), the Company will pay the Executive the compensation and benefits as described in this Section 3.

(a) General Benefits Upon Termination. The Company will pay the Executive on or about the Termination Date all salary and vacation/personal time off pay, if any, that has been earned or accrued through the Termination Date and that has not been previously paid.

(b) Termination without "Cause" or for "Good Reason". In the event that the Company terminates the Executive's employment without Cause (as defined below) or, in the event the Executive terminates his employment for Good Reason (as defined below), in each case, (i) the Executive shall be entitled to receive (A) continuing payments of the then effective Base Salary for a period of twelve (12) months beginning on the Payment Commencement Date and payable in accordance with the Company's payroll policies and (B) the benefits set forth in Section 3(e), and (ii) the Executive shall be entitled to acceleration of vesting of such number of Option Shares as would have vested in the twelve (12) month period following the Termination Date had the Executive continued to be employed by the Company for such period, *provided, however* that in each case the receipt of such payments and benefits is expressly contingent upon the Executive's execution and delivery of a severance and release of claims agreement drafted by and satisfactory to counsel for the Company (the "Release") which Release must be executed and become effective within sixty (60) days following the Termination Date. The payments and benefits shall be paid or commence on the first payroll period following the date the Release becomes effective (the "Payment Commencement Date"). Notwithstanding the foregoing, if the 60<sup>th</sup> day following the Termination Date occurs in the calendar year following the termination, then the Payment Commencement Date shall be no earlier than January 1st of such subsequent calendar year. The provision of payments and benefits pursuant to this Section shall be subject to the terms and conditions set forth on Exhibit A.

(c) Termination without "Cause" or for "Good Reason" Prior to or Following a Change of Control. In the event that the Company terminates the Executive's employment without Cause (as defined below) or, in the event the Executive terminates his employment for Good Reason (as defined below), in each case, within thirty (30) days prior to, or twelve (12) months following, the consummation of a Change of Control, then (i) the Executive shall be entitled to (A) receive continuing payments of the then effective Base Salary for a period of twelve (12) months beginning on the Payment Commencement Date and payable in accordance with the Company's payroll policies and (B) the benefits set forth in Section 3(e), and (ii) acceleration of vesting of one hundred percent (100%) of the then unvested Option Shares, provided, however that in each case: (x), the receipt of such payments and benefits is expressly contingent upon the Executive's execution and delivery of a Release as described above drafted by and satisfactory to counsel for the Company, which Release must be executed and become effective within sixty (60) days following the Termination Date. The provision of payments and benefits pursuant to this Section shall be subject to the terms and conditions set forth in Exhibit A.

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(d) Definitions.

(i) “Change of Control” means (A) a merger or consolidation of either the Company or Pacira, Inc., a Delaware corporation (“Parent”) into another entity in which the stockholders of the Company or Parent (as applicable) do not control fifty percent (50%) or more of the total voting power of the surviving entity (other than a reincorporation merger); (B) the sale, transfer or other disposition of all or substantially all of the Company’s assets in liquidation or dissolution of the Company; or (C) the sale or transfer of more than fifty percent (50%) of the outstanding voting stock of the Company. In the case of each of the foregoing clauses (A), (B) and (C), a Change of Control as a result of a financing transaction of the Company or Parent shall not constitute a Change of Control for purposes of this Agreement

(ii) “Cause” means (A) the Executive’s failure to substantially perform his duties to the Company after there has been delivered to the Executive written notice setting forth in detail the specific respects in which the Board believes that the Executive has not substantially performed his duties and, if the Company reasonably considers the situation to be correctable, a demand for substantial performance and opportunity to cure, giving the Executive thirty (30) calendar days after he receives such notice to correct the situation; (B) the Executive’s having engaged in fraud, misconduct, dishonesty, gross negligence or having otherwise acted in a manner injurious to the Company or in intentional disregard for the Company’s best interests; (C) the Executive’s failure to follow reasonable and lawful instructions from the Board and the Executive’s failure to cure such failure after receiving twenty (20) days advance written notice; (D) the Executive’s material breach of the terms of this Agreement or the Employee Proprietary Information and Inventions Assignment Agreement or any other similar agreement that may be in effect from time to time; or (E) the Executive’s conviction of, or pleading guilty or nolo contendere to, any misdemeanor involving dishonesty or moral turpitude or related to the Company’s business, or any felony.

(iii) “Good Reason” means the occurrence of any one or more of the following events without the prior written consent of the Executive: (A) any material reduction of the then effective Base Salary other than in accordance with this Agreement or which reduction is not related to a cross-executive team salary reduction; (B) any material breach by the Company of this Agreement; or (C) a material reduction in the Executive’s responsibilities or duties, provided that in the case of clause (C), a mere reassignment following a Change of Control to a position that is substantially similar to the position held prior to the Change of Control transaction shall not constitute a material reduction in job responsibilities or duties; provided, however, that no such event or condition shall constitute Good Reason unless (x) the Executive gives the Company a written notice of termination for Good Reason not more than ninety (90) days after the initial existence of the condition, (y) the grounds for termination (if susceptible to correction) are not corrected by the Company within thirty (30) days of its receipt of such notice and (z) the Termination Date occurs within one (1) year following the Company’s receipt of such notice.

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(c) Benefits Continuation. If the Executive's employment is terminated pursuant to Section 3(b) or Section 3(c) and provided that the Executive is eligible for and elects to continue receiving group health and dental insurance pursuant to the federal "COBRA" law, 29 U.S.C. § 1161 et seq., the Company will, for a twelve (12) month period following the Payment Commencement Date (the "Benefits Continuation Period"), continue to pay the share of the premium for such coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage. The remaining balance of any premium costs shall be paid by the Executive on a monthly basis for as long as, and to the extent that, the Executive remains eligible for COBRA continuation. Notwithstanding the above, in the event the Executive becomes eligible for health insurance benefits from a new employer during the Benefits Continuation Period, the Company's obligations under this Section 3(e) shall immediately cease and the Executive shall not be entitled to any additional monthly premium payments for health insurance coverage. Similarly, in the event the Executive becomes eligible for dental insurance benefits from a new employer during the Benefits Continuation Period, the Company's obligations under this Section 3(e) shall immediately cease and the Executive shall not be entitled to any additional monthly premium payments for dental insurance. The Executive hereby represents that he will notify the Company in writing within three (3) days of becoming eligible for health or dental insurance benefits from a new employer during the Benefits Continuation Period.

(f) Death. This Agreement shall automatically terminate upon the death of the Executive and all monetary obligations of Company under Section 2 of this Agreement shall be pro rated to the date of death and paid to the Executive's estate.

(g) Disability. The Company may terminate the Executive's employment if the Executive is unable to perform any of the duties required under this Agreement for a period of three (3) consecutive months due to a "Total and Permanent Disability". The term "Total and Permanent Disability" shall mean the existence of a permanent physical or mental illness or injury, which renders the Executive incapable of performing any material obligations or terms of this Agreement. Any dispute regarding the existence of a Total and Permanent Disability shall be resolved by a panel of three (3) physicians, one selected by Company, one selected by the Executive, and the third selected by the other two physicians. A termination of employment pursuant to this Section 3(g) shall constitute a termination for Cause.

(h) Resignation Upon Termination of Employment. Upon termination of the Executive's employment for any reason (whether with or without Cause or with or without Good Reason), the Executive shall resign, in writing, from all positions held by him with the Company and its affiliates, including without limitation from the Board and all committees of the Board.

4. At-Will Employment. The Executive will be an "at-will" employee of the Company, which means the employment relationship can be terminated by either the Executive or the Company for any reason, at any time, with or without prior notice and with or without cause. The Company makes no promise that the Executive's employment will continue for any particular period of time, nor is there any promise that it will be terminated only under particular circumstances. No raise or bonus, if any, shall alter the Executive's status as an "at-will" employee or create any implied contract of employment. Discussion of possible or potential

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benefits in future years is not an express or implied promise of continued employment. No manager, supervisor or officer of the Company has the authority to change the Executive's status as an "at-will" employee. The "at-will" nature of the employment relationship with the Executive can only be altered by a written resolution approved by the Board.

5. Non-Solicitation.

(a) Non-Solicit. The Executive agrees that during the term of the Executive's employment with the Company, and for a period of twelve (12) months immediately following the termination of the Executive's employment with the Company for any reason, whether with or without Cause or Good Reason, the Executive shall not either directly or indirectly solicit, induce, recruit or encourage any of the Company's or its affiliates' employees or consultants to terminate such employee's or consultant's relationship with the Company or its affiliates, or attempt to solicit, induce, recruit, encourage or take away employees or consultants of the Company or any of its affiliates, either for the Executive or for any other person or entity. Further, during the Executive's employment with the Company or any of its affiliates and at any time following termination of the Executive's employment with the Company or any of its affiliates for any reason, with or without Cause or Good Reason, the Executive shall not use any confidential information of the Company or any of its affiliates to attempt to negatively influence any of the Company's or any of its affiliates' clients or customers from purchasing Company products or services or to solicit or influence or attempt to influence any client, customer or other person either directly or indirectly, to direct such person's or entity's purchase of products and/or services to any person, firm, corporation, institution or other entity in competition with the business of the Company or any of its affiliates. Notwithstanding the foregoing, nothing in this Section 5(a) shall prohibit the Executive from soliciting, inducing, recruiting, encouraging or taking away employees or consultants of the Company or any of its affiliates who were previously employed by, or a consultant to, Stack Pharmaceuticals, Inc. prior to becoming an employee or consultant of the Company.

(b) Specific Performance. In the event of the breach or threatened breach by the Executive of this Section 5, the Company, in addition to all other remedies available to it at law or in equity, will be entitled to seek injunctive relief and/or specific performance to enforce this Section 5.

6. Director and Officer Liability Insurance; Indemnification. During the term of the Executive's employment hereunder, the Executive shall be entitled to the same indemnification and director and officer liability insurance as the Company and its affiliates maintain for other corporate officers.

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7. Proprietary Information and Inventions Assignment Agreement. The Executive has executed and delivered the Company's standard Employee Proprietary Information and Inventions Assignment Agreement or similar agreement and the Executive represents and warrants that the Executive shall continue to be bound and abide by such Employee Proprietary Information and Inventions Assignment Agreement or similar agreement.

8. Attention to Duties; Conflict of Interest. The Executive will devote his reasonable best business efforts and attention to the performance of services to the Company in accordance with the terms hereof and as may reasonably requested by the Company. The Company acknowledges that the Executive may continue to pursue the external obligations set forth in Exhibit B hereto to the same extent as the Executive has previously pursued such external obligations during the Executive's employment with the Company and such other opportunities which may arise during the term of your employment; *provided*, however, that the Executive shall not, without the Company's prior written consent, engage in any business activity that would materially interfere with the performance of the Executive's duties under this Agreement. Other than those set forth in Exhibit B, with the Company the Executive represents that the Executive has no other outstanding commitments inconsistent with any of the terms of this Agreement or the services to be rendered to the Company. While employed by the Company, the Executive shall not, directly or indirectly, whether as a partner, employee, creditor, shareholder, or otherwise, promote, participate or engage in any activity or other business competitive with the Company's business. The Executive shall not invest in any company or business which competes in any manner with the Company, except (A) in securities that are listed on reputable securities exchanges in the United States or European Union or (B) pursuant to any direct or indirect interest held by the Executive or his affiliates in any venture capital, private equity or similar investment fund or entity.

9. Miscellaneous.

(a) Severability. If any provision of this Agreement shall be found by any arbitrator or court of competent jurisdiction to be invalid or unenforceable, then the parties hereby waive such provision to the extent that it is found to be invalid or unenforceable and to the extent that to do so would not deprive one of the parties of the substantial benefit of its bargain. Such provision shall, to the extent allowable by law and the preceding sentence, be modified by such arbitrator or court so that it becomes enforceable and, as modified, shall be enforced as any other provision hereof, all the other provisions continuing in full force and effect.

(b) No Waiver. The failure by either party at any time to require performance or compliance by the other of any of its obligations or agreements shall in no way affect the right to require such performance or compliance at any time thereafter. The waiver by either party of a breach of any provision hereof shall not be taken or held to be a waiver of any preceding or succeeding breach of such provision or as a waiver of the provision itself. No waiver of any kind shall be effective or binding, unless it is in writing and is signed by the party against whom such waiver is sought to be enforced.

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(c) Assignment. This Agreement and all rights hereunder are personal to the Executive and may not be transferred or assigned by the Executive at any time. The Company may assign its rights, together with its obligations hereunder, to any parent, subsidiary, affiliate or successor, or in connection with any sale, transfer or other disposition of all or substantially all of its business and assets; *provided, however*, that any such assignee assumes the Company's obligations hereunder.

(d) Withholding. All sums payable to the Executive hereunder shall be reduced by all federal, state, local and other withholding and similar taxes and payments required by applicable law.

(e) Entire Agreement. This Agreement, including the agreements referred to herein (which are deemed incorporated by reference herein) constitute the entire and only agreement and understanding between the parties governing the terms and conditions of employment of the Executive with the Company and this Agreement supersedes and cancels any and all previous contracts, arrangements or understandings with governing the terms and conditions of the Executive's employment by the Company. In the event of any conflict between the terms of any other agreement between the Executive and the Company entered into prior to the Effective Date, the terms of this Agreement shall control.

(f) Amendment. This Agreement may be amended, modified, superseded, cancelled, renewed or extended only by an agreement in writing executed by both parties hereto.

(g) Headings. The headings contained in this Agreement are for reference purposes only and shall in no way affect the meaning or interpretation of this Agreement. In this Agreement, the singular includes the plural, the plural included the singular, the masculine gender includes both male and female referents, and the word "or" is used in the inclusive sense.

(h) Notices. Any notices provided hereunder must be in writing and shall be deemed effective upon the earlier of personal delivery (including, personal delivery by facsimile transmission or the third day after mailing by first class mail) to the Company at its primary office location and to the Executive at his address as listed on the Company payroll (which address may be changed by written notice).

(i) Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed to be an original but all of which, taken together, constitute one and the same agreement.

(j) Governing Law, Forum Selection, Jury Waiver. This Agreement and the rights and obligations of the parties hereto shall be construed in accordance with the laws of the State of New Jersey without giving effect to the principles of conflict of laws. Any action, suit or other legal proceeding that is commenced to resolve any matter arising under or relating to any provision of this Agreement shall be commenced only in a court of the State of New Jersey (or, if appropriate, a federal court located within the District of New Jersey), and the Company and the Executive each consents to the jurisdiction of such a court. *Both the Company and the Executive expressly waive any right that any party either has or may have to a jury trial of any dispute arising out of or in any way related to the Executive's employment with or termination from the Company.*

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**IN WITNESS WHEREOF**, the Company and the Executive have executed this Executive Employment Agreement as of the date first above written.

**PACIRA PHARMACEUTICALS, INC.:**

By: /s/ Luke Evin  
Luke Evin, Director

**EXECUTIVE:**

/s/ David Stack  
David Stack

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**EXHIBIT A**

**PAYMENTS SUBJECT TO SECTION 409A**

1. Subject to this Exhibit A, any severance payments and benefits that may be due under the Agreement shall begin only upon the date of the Executive's "separation from service" (determined as set forth below) which occurs on or after the termination of the Executive's employment. The following rules shall apply with respect to distribution of the severance payments and benefits, if any, to be provided to the Executive under the Agreement, as applicable:

- (a) It is intended that each installment of the severance payments and benefits under the Agreement provided under shall be treated as a separate "payment" for purposes of Section 409A. Neither the Company nor the Executive shall have the right to accelerate or defer the delivery of any such payments or benefits except to the extent specifically permitted or required by Section 409A.
- (b) If, as of the date of the Executive's "separation from service" from the Company, the Executive is not a "specified employee" (within the meaning of Section 409A), then each installment of the severance payments or benefits shall be made on the dates and terms set forth in the Agreement.
- (c) If, as of the date of the Executive's "separation from service" from the Company, the Executive is a "specified employee" (within the meaning of Section 409A), then:
  - (i) Each installment of the severance payments and benefits due under the Agreement that, in accordance with the dates and terms set forth herein, will in all circumstances, regardless of when the Executive's separation from service occurs, be paid within the short-term deferral period (as defined under Section 409A) shall be treated as a short-term deferral within the meaning of Treasury Regulation Section 1.409A-1(b)(4) to the maximum extent permissible under Section 409A and shall be paid at the time set forth in the Agreement; and
  - (ii) Each installment of the severance payments and benefits due under the Agreement that is not described in this Exhibit A, Section 1(c)(i) and that would, absent this subsection, be paid within the six-month period following the Executive's "separation from service" from the Company shall not be paid until the date that is six months and one day after such separation from service (or, if earlier, the Executive's death), with any such installments that are required to be delayed being accumulated during the six-month period and paid in a lump sum on the date that is six months and one day following the Executive's separation from service and any subsequent installments, if any, being paid in accordance with the dates and terms set forth herein; provided, however, that the preceding provisions of this sentence shall not apply to any installment of payments and benefits if and to the maximum extent that that such installment is deemed to be paid under a



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separation pay plan that does not provide for a deferral of compensation by reason of the application of Treasury Regulation 1.409A-1(b)(9)(iii) (relating to separation pay upon an involuntary separation from service). Any installments that qualify for the exception under Treasury Regulation Section 1.409A-1(b)(9)(iii) must be paid no later than the last day of the Executive's second taxable year following the taxable year in which the separation from service occurs.

2. The determination of whether and when the Executive's separation from service from the Company has occurred shall be made and in a manner consistent with, and based on the presumptions set forth in, Treasury Regulation Section 1.409A-1(h). Solely for purposes of this Exhibit A, Section 2, "Company" shall include all persons with whom the Company would be considered a single employer under Section 414(b) and 414(c) of the Code.

3. The Company makes no representation or warranty and shall have no liability to the Executive or to any other person if any of the provisions of the Agreement (including this Exhibit) are determined to constitute deferred compensation subject to Section 409A but that do not satisfy an exemption from, or the conditions of, that section.

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**EXHIBIT B**

**EXTERNAL OBLIGATIONS APPROVED BY THE  
BOARD OF DIRECTORS OF PACIRA PHARMACEUTICALS, INC.**

1. Founder, Managing Partner – Stack Pharmaceuticals, Inc.
2. Managing Director – MPM Capital
3. Trustee – Sienna College
4. Board Positions
  - a. Bioclinica, Inc.
  - b. Molecular Insight Pharmaceuticals, Inc.
  - c. PepTx, Inc.

**EXECUTIVE EMPLOYMENT AGREEMENT**

This Executive Employment Agreement (the "Agreement"), is entered into as of October 27, 2010 (the "Effective Date"), by and between Pacira Pharmaceuticals, Inc., a California corporation (the "Company"), and James Scibetta (the "Executive").

**RECITALS**

**WHEREAS**, the Company wishes to continue to employ the Executive, and the Executive desires to continue to be employed by the Company, for such purpose and upon the terms and conditions hereinafter provided; and

**WHEREAS**, the parties wish to establish the terms of the Executive's future employment with the Company and set out fully their respective rights, obligations and duties.

**AGREEMENT**

In consideration of the promises and the terms and conditions set forth in this Agreement, the parties agree as follows:

1. Title and Capacity. The Company hereby agrees to continue to employ the Executive, and the Executive hereby accepts continued employment with the Company, under the terms set forth in this Agreement. The Executive will serve as the Chief Financial Officer of the Company and shall perform such duties as are ordinary, customary and necessary in such role. The Executive will report directly to the Chief Executive Officer of the Company. The Executive shall devote his full business time, skill and attention to the performance of his duties on behalf of the Company.

2. Compensation and Benefits.

(a) Salary. The Company agrees to pay the Executive an annual base salary of Two Hundred and Seventy Thousand Dollars (\$270,000) payable in accordance with Company's customary payroll practice (the "Base Salary"). The Executive's Base Salary shall be reviewed periodically by the Board of Directors of the Company (the "Board"); *provided, however*, that any such review will not necessarily result in an adjustment to the Executive's Base Salary. Any change in the Executive's Base Salary must be approved by the Board.

(b) Bonus. The Executive is eligible to receive, in addition to the Base Salary and subject to the terms hereof and at the full discretion of the Board, a targeted incentive bonus of thirty percent (30%) of Base Salary (the "Targeted Incentive Bonus"). The Targeted Incentive Bonus shall be based on the Executive's and the Company's performance during the applicable fiscal year, as determined by the Board. The Targeted Incentive Bonus criteria or "goals" will be determined by agreement between the Board and the Executive at beginning of each fiscal year. The award of the Target Incentive Bonus may be in an amount either above or below the amount specified by the Board at the beginning of each fiscal year based on the ultimate performance assessed by the Board.

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The Targeted Incentive Bonus, if awarded, shall be payable in the first payroll period in 2012, but in no event later than March 15, 2012. Targeted Incentive Bonuses for subsequent years shall be determined and approved by the Board in its sole discretion.

All salary and bonuses shall be subject to all applicable withholdings and deductions.

(c) Stock Options. On September 2, 2010, the Company granted to the Executive two stock options (each an “Option” and collectively, the “Options”) to purchase an aggregate of one million five hundred and eighty five thousand (1,585,000) shares of the Company’s common stock, \$0.001 par value per share (the “Option Shares”), pursuant to the Company’s 2007 Stock Option/Stock Issuance (the “Plan”). The exercise price, vesting schedule and other terms for each of the Options are set forth in the notice of grant and option agreement for each such Option and the Options are subject to accelerated vesting as set forth in Section 3 hereof. Additional equity incentives, if any, shall be determined by the Board (or a committee thereof) in its sole discretion. All share figures set forth herein shall be subject to adjustment for stock splits, stock dividends, stock combinations, recapitalizations and similar events.

(d) Benefits. The Executive (and, where applicable, the Executive’s qualified dependents) will be eligible to participate in health insurance and other employee benefit plans and policies established by the Company for its executive team from time to time on substantially the same terms as are made available to other such employees of the Company generally. The Executive’s participation (and the participation of the Executive’s qualified dependents) in the Company’s benefit plans and policies will be subject to the terms of the applicable plan documents and the Company’s generally applied policies, and the Company in its sole discretion may from time to time adopt, modify, interpret or discontinue such plans or policies.

(e) Expenses. The Company will reimburse the Executive for all reasonable and necessary expenses incurred by the Executive in connection with the Company’s business, in accordance with the applicable Company policy as may be amended from time to time.

(f) Vacation and Holidays. The Executive shall be eligible for thirty (30) days’ paid vacation/flexible time off per calendar year subject to the applicable terms and conditions of the Company’s vacation policy and applicable law.

(g) Termination of Benefits. Except as set forth in Section 3 or as otherwise specified herein or in any other agreement between the Executive and the Company, if the Executive’s employment is terminated by the Company for any reason, with or without Cause (as defined below), or if the Executive resigns the Executive’s employment voluntarily, with or without Good Reason (as defined below), no compensation or other payments will be paid or provided to the Executive for periods following the date when such a termination of employment is effective, provided that any rights the Executive may have under the Company’s benefit plans shall be determined under the provisions of such plans. If the Executive’s employment terminates as a result of the Executive’s death or disability, no compensation or payments will be made to the Executive other than those to which the Executive may otherwise be entitled under the benefit plans of the Company.

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3. Compensation and Benefits Upon Termination of Employment. Upon termination of the Executive's employment (such date of termination being referred to as the "Termination Date"), the Company will pay the Executive the compensation and benefits as described in this Section 3.

(a) General Benefits Upon Termination. The Company will pay the Executive on or about the Termination Date all salary and vacation/personal time off pay, if any, that has been earned or accrued through the Termination Date and that has not been previously paid.

(b) Termination without "Cause" or for "Good Reason". In the event that the Company terminates the Executive's employment without Cause (as defined below) or, in the event the Executive terminates his employment for Good Reason (as defined below), in each case, (i) the Executive shall be entitled to receive (A) continuing payments of the then effective Base Salary for a period of nine (9) months beginning on the Payment Commencement Date and payable in accordance with the Company's payroll policies and (B) the benefits set forth in Section 3(e), and (ii) the Executive shall be entitled to acceleration of vesting of such number of Option Shares as would have vested in the nine (9) month period following the Termination Date had the Executive continued to be employed by the Company for such period, *provided, however* that in each case the receipt of such payments and benefits is expressly contingent upon the Executive's execution and delivery of a severance and release of claims agreement drafted by and satisfactory to counsel for the Company (the "Release") which Release must be executed and become effective within sixty (60) days following the Termination Date. The payments and benefits shall be paid or commence on the first payroll period following the date the Release becomes effective (the "Payment Commencement Date"). Notwithstanding the foregoing, if the 60<sup>th</sup> day following the Termination Date occurs in the calendar year following the termination, then the Payment Commencement Date shall be no earlier than January 1st of such subsequent calendar year. The provision of payments and benefits pursuant to this Section shall be subject to the terms and conditions set forth on Exhibit A.

(c) Termination without "Cause" or for "Good Reason" Prior to or Following a Change of Control. In the event that the Company terminates the Executive's employment without Cause (as defined below) or, in the event the Executive terminates his employment for Good Reason (as defined below), in each case, within thirty (30) days prior to, or twelve (12) months following, the consummation of a Change of Control, then (i) the Executive shall be entitled to receive (A) continuing payments of the then effective Base Salary for a period of nine (9) months beginning on the Payment Commencement Date and payable in accordance with the Company's payroll policies and (B) the benefits set forth in Section 3(e), and (ii) acceleration of vesting of one hundred percent (100%) of the then unvested Option Shares, provided, however that in each case: (x), the receipt of such payments and benefits is expressly contingent upon the Executive's execution and delivery of a Release as described above drafted by and satisfactory to counsel for the Company, which Release must be executed and become effective within sixty (60) days following the Termination Date. The provision of payments and benefits pursuant to this Section shall be subject to the terms and conditions set forth in Exhibit A.

(d) Definitions.

(i) "Change of Control" means (A) a merger or consolidation of either the Company or Pacira, Inc., a Delaware corporation (" Parent") into another entity in which the stockholders of the Company or Parent (as applicable) do not control fifty percent (50%) or more of the total voting power of the surviving entity (other than a reincorporation merger); (B) the sale, transfer or other disposition of all or substantially all of the Company's assets in liquidation or dissolution of the Company; or (C) the sale or transfer of more than fifty percent (50%) of the outstanding voting stock of the Company. In the case of each of the foregoing clauses (A), (B) and (C), a Change of Control as a result of a financing transaction of the Company or Parent shall not constitute a Change of Control for purposes of this Agreement

(ii) "Cause" means (A) the Executive's failure to substantially perform his duties to the Company after there has been delivered to the Executive written notice setting forth in detail the specific respects in which the Board believes that the Executive has not substantially performed his duties and, if the Company reasonably considers the situation to be correctable, a demand for substantial performance and opportunity to cure, giving the Executive thirty (30) calendar days after he receives such notice to correct the situation; (B) the Executive's having engaged in fraud, misconduct, dishonesty, gross negligence or having otherwise acted in a manner injurious to the Company or in intentional disregard for the Company's best interests; (C) the Executive's failure to follow reasonable and lawful instructions from the Board and the Executive's failure to cure such failure after receiving twenty (20) days advance written notice; (D) the Executive's material breach of the terms of this Agreement or the Employee Proprietary Information and Inventions Assignment Agreement or any other similar agreement that may be in effect from time to time; or (E) the Executive's conviction of, or pleading guilty or nolo contendere to, any misdemeanor involving dishonesty or moral turpitude or related to the Company's business, or any felony.

(iii) "Good Reason" means the occurrence of any one or more of the following events without the prior written consent of the Executive: (A) any material reduction of the then effective Base Salary other than in accordance with this Agreement or which reduction is not related to a cross-executive team salary reduction; (B) any material breach by the Company of this Agreement; or (C) a material reduction in the Executive's responsibilities or duties, provided that in the case of clause (C), a mere reassignment following a Change of Control to a position that is substantially similar to the position held prior to the Change of Control transaction shall not constitute a material reduction in job responsibilities or duties; provided, however, that no such event or condition shall constitute Good Reason unless (x) the Executive gives the Company a written notice of termination for Good Reason not more than ninety (90) days after the initial existence of the condition, (y) the grounds for termination (if susceptible to correction) are not corrected by the Company within thirty (30) days of its receipt of such notice and (z) the Termination Date occurs within one (1) year following the Company's receipt of such notice.

(e) Benefits Continuation. If the Executive's employment is terminated pursuant to Section 3(b) or Section 3(c) and provided that the Executive is eligible for and elects to continue receiving group health and dental insurance pursuant to the federal "COBRA" law, 29 U.S.C. § 1161 et seq., the Company will, for a twelve (12) month period following the Payment Commencement Date (the "Benefits Continuation Period"), continue to pay the share of

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the premium for such coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage. The remaining balance of any premium costs shall be paid by the Executive on a monthly basis for as long as, and to the extent that, the Executive remains eligible for COBRA continuation. Notwithstanding the above, in the event the Executive becomes eligible for health insurance benefits from a new employer during the Benefits Continuation Period, the Company's obligations under this Section 3(e) shall immediately cease and the Executive shall not be entitled to any additional monthly premium payments for health insurance coverage. Similarly, in the event the Executive becomes eligible for dental insurance benefits from a new employer during the Benefits Continuation Period, the Company's obligations under this Section 3(e) shall immediately cease and the Executive shall not be entitled to any additional monthly premium payments for dental insurance. The Executive hereby represents that he will notify the Company in writing within three (3) days of becoming eligible for health or dental insurance benefits from a new employer during the Benefits Continuation Period

(f) Death. This Agreement shall automatically terminate upon the death of the Executive and all monetary obligations of Company under Section 2 of this Agreement shall be pro rated to the date of death and paid to the Executive's estate.

(g) Disability. The Company may terminate the Executive's employment if the Executive is unable to perform any of the duties required under this Agreement for a period of three (3) consecutive months due to a "Total and Permanent Disability". The term "Total and Permanent Disability" shall mean the existence of a permanent physical or mental illness or injury, which renders the Executive incapable of performing any material obligations or terms of this Agreement. Any dispute regarding the existence of a Total and Permanent Disability shall be resolved by a panel of three (3) physicians, one selected by Company, one selected by the Executive, and the third selected by the other two physicians. A termination of employment pursuant to this Section 3(f) shall constitute a termination for Cause.

4. At-Will Employment. The Executive will be an "at-will" employee of the Company, which means the employment relationship can be terminated by either the Executive or the Company for any reason, at any time, with or without prior notice and with or without cause. The Company makes no promise that the Executive's employment will continue for any particular period of time, nor is there any promise that it will be terminated only under particular circumstances. No raise or bonus, if any, shall alter the Executive's status as an "at-will" employee or create any implied contract of employment. Discussion of possible or potential benefits in future years is not an express or implied promise of continued employment. No manager, supervisor or officer of the Company has the authority to change the Executive's status as an "at-will" employee. The "at-will" nature of the employment relationship with the Executive can only be altered by a written resolution approved by the Board.

5. Non-Solicitation.

(a) Non-Solicit. The Executive agrees that during the term of the Executive's employment with the Company, and for a period of twelve (12) months immediately following the termination of the Executive's employment with the Company for any reason, whether with

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or without Cause or Good Reason, the Executive shall not either directly or indirectly solicit, induce, recruit or encourage any of the Company's or its affiliates' employees or consultants to terminate such employee's or consultant's relationship with the Company or its affiliates, or attempt to solicit, induce, recruit, encourage or take away employees or consultants of the Company or any of its affiliates, either for the Executive or for any other person or entity. Further, during the Executive's employment with the Company or any of its affiliates and at any time following termination of the Executive's employment with the Company or any of its affiliates for any reason, with or without Cause or Good Reason, the Executive shall not use any confidential information of the Company or any of its affiliates to attempt to negatively influence any of the Company's or any of its affiliates' clients or customers from purchasing Company products or services or to solicit or influence or attempt to influence any client, customer or other person either directly or indirectly, to direct such person's or entity's purchase of products and/or services to any person, firm, corporation, institution or other entity in competition with the business of the Company or any of its affiliates.

(b) Specific Performance. In the event of the breach or threatened breach by the Executive of this Section 5, the Company, in addition to all other remedies available to it at law or in equity, will be entitled to seek injunctive relief and/or specific performance to enforce this Section 5.

6. Director and Officer Liability Insurance; Indemnification. During the term of the Executive's employment hereunder, the Executive shall be entitled to the same indemnification and director and officer liability insurance as the Company and its affiliates maintain for other corporate officers.

7. Proprietary Information and Inventions Assignment Agreement. The Executive has executed and delivered the Company's standard Employee Proprietary Information and Inventions Assignment Agreement or similar agreement and the Executive represents and warrants that the Executive shall continue to be bound and abide by such Employee Proprietary Information and Inventions Assignment Agreement or similar agreement.

8. Attention to Duties; Conflict of Interest. The Executive will devote his reasonable best business efforts and attention to the performance of services to the Company in accordance with the terms hereof and as may reasonably requested by the Company. The Company acknowledges that the Executive may continue to pursue the external obligations set forth in Exhibit B hereto to the same extent as the Executive has previously pursued such external obligations during the Executive's employment with the Company and such other opportunities which may arise during the term of your employment; *provided*, however, that the Executive shall not, without the Company's prior written consent, engage in any business activity that would materially interfere with the performance of the Executive's duties under this Agreement. Other than those set forth in Exhibit B, with the Company the Executive represents that the Executive has no other outstanding commitments inconsistent with any of the terms of this Agreement or the services to be rendered to the Company. While employed by the Company, the Executive shall not, directly or indirectly, whether as a partner, employee, creditor, shareholder, or otherwise, promote, participate or engage in any activity or other business competitive with the Company's business. The Executive represents that the Executive has no other outstanding



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commitments inconsistent with any of the terms of this Agreement or the services to be rendered to the Company. While employed by the Company, the Executive shall not, directly or indirectly, whether as a partner, employee, creditor, shareholder, or otherwise, promote, participate or engage in any activity or other business competitive with the Company's business. The Executive shall not invest in any company or business which competes in any manner with the Company, except those companies whose securities are listed on reputable securities exchanges in the United States or European Union.

9. Miscellaneous.

(a) Severability. If any provision of this Agreement shall be found by any arbitrator or court of competent jurisdiction to be invalid or unenforceable, then the parties hereby waive such provision to the extent that it is found to be invalid or unenforceable and to the extent that to do so would not deprive one of the parties of the substantial benefit of its bargain. Such provision shall, to the extent allowable by law and the preceding sentence, be modified by such arbitrator or court so that it becomes enforceable and, as modified, shall be enforced as any other provision hereof, all the other provisions continuing in full force and effect.

(b) No Waiver. The failure by either party at any time to require performance or compliance by the other of any of its obligations or agreements shall in no way affect the right to require such performance or compliance at any time thereafter. The waiver by either party of a breach of any provision hereof shall not be taken or held to be a waiver of any preceding or succeeding breach of such provision or as a waiver of the provision itself. No waiver of any kind shall be effective or binding, unless it is in writing and is signed by the party against whom such waiver is sought to be enforced.

(c) Assignment. This Agreement and all rights hereunder are personal to the Executive and may not be transferred or assigned by the Executive at any time. The Company may assign its rights, together with its obligations hereunder, to any parent, subsidiary, affiliate or successor, or in connection with any sale, transfer or other disposition of all or substantially all of its business and assets; *provided, however*, that any such assignee assumes the Company's obligations hereunder.

(d) Withholding. All sums payable to the Executive hereunder shall be reduced by all federal, state, local and other withholding and similar taxes and payments required by applicable law.

(e) Entire Agreement. This Agreement, including the agreements referred to herein (which are deemed incorporated by reference herein) constitute the entire and only agreement and understanding between the parties governing the terms and conditions of employment of the Executive with the Company and this Agreement supersedes and cancels any and all previous contracts, arrangements or understandings with governing the terms and conditions of the Executive's employment by the Company. In the event of any conflict between the terms of any other agreement between the Executive and the Company entered into prior to the Effective Date, the terms of this Agreement shall control.

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(f) Amendment. This Agreement may be amended, modified, superseded, cancelled, renewed or extended only by an agreement in writing executed by both parties hereto.

(g) Headings. The headings contained in this Agreement are for reference purposes only and shall in no way affect the meaning or interpretation of this Agreement. In this Agreement, the singular includes the plural, the plural includes the singular, the masculine gender includes both male and female referents, and the word "or" is used in the inclusive sense.

(h) Notices. Any notices provided hereunder must be in writing and shall be deemed effective upon the earlier of personal delivery (including, personal delivery by facsimile transmission or the third day after mailing by first class mail) to the Company at its primary office location and to the Executive at his address as listed on the Company payroll (which address may be changed by written notice).

(i) Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed to be an original but all of which, taken together, constitute one and the same agreement.

(j) Governing Law, Forum Selection, Jury Waiver. This Agreement and the rights and obligations of the parties hereto shall be construed in accordance with the laws of the State of New Jersey without giving effect to the principles of conflict of laws. Any action, suit or other legal proceeding that is commenced to resolve any matter arising under or relating to any provision of this Agreement shall be commenced only in a court of the **State of New Jersey** (or, if appropriate, a federal court located within **District of New Jersey** ), and the Company and the Executive each consents to the jurisdiction of such a court. *Both the Company and the Executive expressly waive any right that any party either has or may have to a jury trial of any dispute arising out of or in any way related to the Executive's employment with or termination from the Company.*

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**IN WITNESS WHEREOF**, the Company and the Executive have executed this Executive Employment Agreement as of the date first above written.

**PACIRA PHARMACEUTICALS, INC.:**

By: /s/ David Stack  
David Stack  
Chief Executive Officer

**EXECUTIVE:**

/s/ James Scibetta  
James Scibetta

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**EXHIBIT A**

**PAYMENTS SUBJECT TO SECTION 409A**

1. Subject to this Exhibit A, any severance payments and benefits that may be due under the Agreement shall begin only upon the date of the Executive's "separation from service" (determined as set forth below) which occurs on or after the termination of the Executive's employment. The following rules shall apply with respect to distribution of the severance payments and benefits, if any, to be provided to the Executive under the Agreement, as applicable:

(a) It is intended that each installment of the severance payments and benefits under the Agreement provided under shall be treated as a separate "payment" for purposes of Section 409A. Neither the Company nor the Executive shall have the right to accelerate or defer the delivery of any such payments or benefits except to the extent specifically permitted or required by Section 409A.

(b) If, as of the date of the Executive's "separation from service" from the Company, the Executive is not a "specified employee" (within the meaning of Section 409A), then each installment of the severance payments or benefits shall be made on the dates and terms set forth in the Agreement.

(c) If, as of the date of the Executive's "separation from service" from the Company, the Executive is a "specified employee" (within the meaning of Section 409A), then:

(i) Each installment of the severance payments and benefits due under the Agreement that, in accordance with the dates and terms set forth herein, will in all circumstances, regardless of when the Executive's separation from service occurs, be paid within the short-term deferral period (as defined under Section 409A) shall be treated as a short-term deferral within the meaning of Treasury Regulation Section 1.409A-1(b)(4) to the maximum extent permissible under Section 409A and shall be paid at the time set forth in the Agreement; and

(ii) Each installment of the severance payments and benefits due under the Agreement that is not described in this Exhibit A, Section 1(c)(i) and that would, absent this subsection, be paid within the six-month period following the Executive's "separation from service" from the Company shall not be paid until the date that is six months and one day after such separation from service (or, if earlier, the Executive's death), with any such installments that are required to be delayed being accumulated during the six-month period and paid in a lump sum on the date that is six months and one day following the Executive's separation from service and any subsequent installments, if any, being paid in accordance with the dates and terms set forth herein; provided, however, that the preceding provisions of this sentence shall not apply to any installment of payments and benefits if and to the maximum extent that that such installment is deemed to be paid under a

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separation pay plan that does not provide for a deferral of compensation by reason of the application of Treasury Regulation 1.409A-1(b)(9)(iii) (relating to separation pay upon an involuntary separation from service). Any installments that qualify for the exception under Treasury Regulation Section 1.409A-1(b)(9)(iii) must be paid no later than the last day of the Executive's second taxable year following the taxable year in which the separation from service occurs.

2. The determination of whether and when the Executive's separation from service from the Company has occurred shall be made and in a manner consistent with, and based on the presumptions set forth in, Treasury Regulation Section 1.409A-1(h). Solely for purposes of this Exhibit A, Section 2, "Company" shall include all persons with whom the Company would be considered a single employer under Section 414(b) and 414(c) of the Code.

3. The Company makes no representation or warranty and shall have no liability to the Executive or to any other person if any of the provisions of the Agreement (including this Exhibit) are determined to constitute deferred compensation subject to Section 409A but that do not satisfy an exemption from, or the conditions of, that section.

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**EXHIBIT B**

**EXTERNAL OBLIGATIONS APPROVED BY  
PACIRA PHARMACEUTICALS, INC.**

1. Board Positions – Nephros, Inc.

**EXECUTIVE EMPLOYMENT AGREEMENT**

This Executive Employment Agreement (the "Agreement"), is entered into as of October 27, 2010 (the "Effective Date"), by and between Pacira Pharmaceuticals, Inc., a California corporation (the "Company"), and Mark Walters (the "Executive").

**RECITALS**

**WHEREAS**, the Company wishes to continue to employ the Executive, and the Executive desires to continue to be employed by the Company, for such purpose and upon the terms and conditions hereinafter provided; and

**WHEREAS**, the parties wish to establish the terms of the Executive's future employment with the Company and set out fully their respective rights, obligations and duties.

**AGREEMENT**

In consideration of the promises and the terms and conditions set forth in this Agreement, the parties agree as follows:

1. Title and Capacity. The Company hereby agrees to continue to employ the Executive, and the Executive hereby accepts continued employment with the Company, under the terms set forth in this Agreement. The Executive will serve as the Senior Vice President of Technical Operations of the Company and shall perform such duties as are ordinary, customary and necessary in such role. The Executive will report directly to the Chief Executive Officer of the Company. The Executive shall devote his full business time, skill and attention to the performance of his duties on behalf of the Company.

2. Compensation and Benefits.

(a) Salary. The Company agrees to pay the Executive an annual base salary of Two Hundred and Fifty Thousand Dollars (\$250,000) payable in accordance with Company's customary payroll practice (the "Base Salary"). The Executive's Base Salary shall be reviewed periodically by the Board of Directors of the Company (the "Board"); *provided, however*, that any such review will not necessarily result in an adjustment to the Executive's Base Salary. Any change in the Executive's Base Salary must be approved by the Board.

(b) Bonus. The Executive is eligible to receive, in addition to the Base Salary and subject to the terms hereof and at the full discretion of the Board, a targeted incentive bonus of thirty percent (30%) of Base Salary (the "Targeted Incentive Bonus"). The Targeted Incentive Bonus shall be based on the Executive's and the Company's performance during the applicable fiscal year, as determined by the Board. The Targeted Incentive Bonus criteria or "goals" will be determined by agreement between the Board and the Executive at beginning of each fiscal year. The award of the Target Incentive Bonus may be in an amount either above or below the amount specified by the Board at the beginning of each fiscal year based on the ultimate performance assessed by the Board.

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The Targeted Incentive Bonus, if awarded, shall be payable in the first payroll period in 2012, but in no event later than March 15, 2012. Targeted Incentive Bonuses for subsequent years shall be determined and approved by the Board in its sole discretion.

All salary and bonuses shall be subject to all applicable withholdings and deductions.

(c) Stock Options. On September 2, 2010, the Company granted to the Executive two stock options (each an “Option” and collectively, the “Options”) to purchase an aggregate of five hundred and fifty thousand (550,000) shares of the Company’s common stock, \$0.001 par value per share (the “Option Shares”), pursuant to the Company’s 2007 Stock Option/Stock Issuance (the “Plan”). The exercise price, vesting schedule and other terms for each of the Options are set forth in the notice of grant and option agreement for each such Option and the Options are subject to accelerated vesting as set forth in Section 3 hereof. Additional equity incentives, if any, shall be determined by the Board (or a committee thereof) in its sole discretion. All share figures set forth herein shall be subject to adjustment for stock splits, stock dividends, stock combinations, recapitalizations and similar events.

(d) Benefits. The Executive (and, where applicable, the Executive’s qualified dependents) will be eligible to participate in health insurance and other employee benefit plans and policies established by the Company for its executive team from time to time on substantially the same terms as are made available to other such employees of the Company generally. The Executive’s participation (and the participation of the Executive’s qualified dependents) in the Company’s benefit plans and policies will be subject to the terms of the applicable plan documents and the Company’s generally applied policies, and the Company in its sole discretion may from time to time adopt, modify, interpret or discontinue such plans or policies.

(e) Expenses. The Company will reimburse the Executive for all reasonable and necessary expenses incurred by the Executive in connection with the Company’s business, in accordance with the applicable Company policy as may be amended from time to time.

(f) Vacation and Holidays. The Executive shall be eligible for thirty (30 days’ paid vacation/flexible time off per calendar year subject to the applicable terms and conditions of the Company’s vacation policy and applicable law.

(g) Termination of Benefits. Except as set forth in Section 3 or as otherwise specified herein or in any other agreement between the Executive and the Company, if the Executive’s employment is terminated by the Company for any reason, with or without Cause (as defined below), or if the Executive resigns the Executive’s employment voluntarily, with or without Good Reason (as defined below), no compensation or other payments will be paid or provided to the Executive for periods following the date when such a termination of employment is effective, provided that any rights the Executive may have under the Company’s benefit plans shall be determined under the provisions of such plans. If the Executive’s employment terminates as a result of the Executive’s death or disability, no compensation or payments will be made to the Executive other than those to which the Executive may otherwise be entitled under the benefit plans of the Company.



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3. Compensation and Benefits Upon Termination of Employment. Upon termination of the Executive's employment (such date of termination being referred to as the "Termination Date"), the Company will pay the Executive the compensation and benefits as described in this Section 3.

(a) General Benefits Upon Termination. The Company will pay the Executive on or about the Termination Date all salary and vacation/personal time off pay, if any, that has been earned or accrued through the Termination Date and that has not been previously paid.

(b) Termination without "Cause" or for "Good Reason". In the event that the Company terminates the Executive's employment without Cause (as defined below) or, in the event the Executive terminates his employment for Good Reason (as defined below), in each case, (i) the Executive shall be entitled to receive (A) continuing payments of the then effective Base Salary for a period of nine (9) months beginning on the Payment Commencement Date and payable in accordance with the Company's payroll policies and (B) the benefits set forth in Section 3(e), and (ii) the Executive shall be entitled to acceleration of vesting of such number of Option Shares as would have vested in the nine (9) month period following the Termination Date had the Executive continued to be employed by the Company for such period, *provided, however* that in each case the receipt of such payments and benefits is expressly contingent upon the Executive's execution and delivery of a severance and release of claims agreement drafted by and satisfactory to counsel for the Company (the "Release") which Release must be executed and become effective within sixty (60) days following the Termination Date. The payments and benefits shall be paid or commence on the first payroll period following the date the Release becomes effective (the "Payment Commencement Date"). Notwithstanding the foregoing, if the 60<sup>th</sup> day following the Termination Date occurs in the calendar year following the termination, then the Payment Commencement Date shall be no earlier than January 1st of such subsequent calendar year. The provision of payments and benefits pursuant to this Section shall be subject to the terms and conditions set forth on Exhibit A.

(c) Termination without "Cause" or for "Good Reason" Prior to or Following a Change of Control. In the event that the Company terminates the Executive's employment without Cause (as defined below) or, in the event the Executive terminates his employment for Good Reason (as defined below), in each case, within thirty (30) days prior to, or twelve (12) months following, the consummation of a Change of Control, then (i) the Executive shall be entitled to receive (A) continuing payments of the then effective Base Salary for a period of nine (9) months beginning on the Payment Commencement Date and payable in accordance with the Company's payroll policies and (B) the benefits set forth in Section 3(e), and (ii) acceleration of vesting of one hundred percent (100%) of the then unvested Option Shares, provided, however that in each case: (x), the receipt of such payments and benefits is expressly contingent upon the Executive's execution and delivery of a Release as described above drafted by and satisfactory to counsel for the Company, which Release must be executed and become effective within sixty (60) days following the Termination Date. The provision of payments and benefits pursuant to this Section shall be subject to the terms and conditions set forth in Exhibit A.

(d) Definitions.

(i) "Change of Control" means (A) a merger or consolidation of either the Company or Pacira, Inc., a Delaware corporation (" Parent") into another entity in which the stockholders of the Company or Parent (as applicable) do not control fifty percent (50%) or more of the total voting power of the surviving entity (other than a reincorporation merger); (B) the sale, transfer or other disposition of all or substantially all of the Company's assets in liquidation or dissolution of the Company; or (C) the sale or transfer of more than fifty percent (50%) of the outstanding voting stock of the Company. In the case of each of the foregoing clauses (A), (B) and (C), a Change of Control as a result of a financing transaction of the Company or Parent shall not constitute a Change of Control for purposes of this Agreement

(ii) "Cause" means (A) the Executive's failure to substantially perform his duties to the Company after there has been delivered to the Executive written notice setting forth in detail the specific respects in which the Board believes that the Executive has not substantially performed his duties and, if the Company reasonably considers the situation to be correctable, a demand for substantial performance and opportunity to cure, giving the Executive thirty (30) calendar days after he receives such notice to correct the situation; (B) the Executive's having engaged in fraud, misconduct, dishonesty, gross negligence or having otherwise acted in a manner injurious to the Company or in intentional disregard for the Company's best interests; (C) the Executive's failure to follow reasonable and lawful instructions from the Board and the Executive's failure to cure such failure after receiving twenty (20) days advance written notice; (D) the Executive's material breach of the terms of this Agreement or the Employee Proprietary Information and Inventions Assignment Agreement or any other similar agreement that may be in effect from time to time; or (E) the Executive's conviction of, or pleading guilty or nolo contendere to, any misdemeanor involving dishonesty or moral turpitude or related to the Company's business, or any felony.

(iii) "Good Reason" means the occurrence of any one or more of the following events without the prior written consent of the Executive: (A) any material reduction of the then effective Base Salary other than in accordance with this Agreement or which reduction is not related to a cross-executive team salary reduction; (B) any material breach by the Company of this Agreement; or (C) a material reduction in the Executive's responsibilities or duties, provided that in the case of clause (C), a mere reassignment following a Change of Control to a position that is substantially similar to the position held prior to the Change of Control transaction shall not constitute a material reduction in job responsibilities or duties; provided, however, that no such event or condition shall constitute Good Reason unless (x) the Executive gives the Company a written notice of termination for Good Reason not more than ninety (90) days after the initial existence of the condition, (y) the grounds for termination (if susceptible to correction) are not corrected by the Company within thirty (30) days of its receipt of such notice and (z) the Termination Date occurs within one (1) year following the Company's receipt of such notice.

(e) Benefits Continuation. If the Executive's employment is terminated pursuant to Section 3(b) or Section 3(c) and provided that the Executive is eligible for and elects to continue receiving group health and dental insurance pursuant to the federal "COBRA" law, 29 U.S.C. § 1161 et seq., the Company will, for a twelve (12) month period following the Payment Commencement Date (the "Benefits Continuation Period"), continue to pay the share of

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the premium for such coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage. The remaining balance of any premium costs shall be paid by the Executive on a monthly basis for as long as, and to the extent that, the Executive remains eligible for COBRA continuation. Notwithstanding the above, in the event the Executive becomes eligible for health insurance benefits from a new employer during the Benefits Continuation Period, the Company's obligations under this Section 3(e) shall immediately cease and the Executive shall not be entitled to any additional monthly premium payments for health insurance coverage. Similarly, in the event the Executive becomes eligible for dental insurance benefits from a new employer during the Benefits Continuation Period, the Company's obligations under this Section 3(e) shall immediately cease and the Executive shall not be entitled to any additional monthly premium payments for dental insurance. The Executive hereby represents that he will notify the Company in writing within three (3) days of becoming eligible for health or dental insurance benefits from a new employer during the Benefits Continuation Period

(f) Death. This Agreement shall automatically terminate upon the death of the Executive and all monetary obligations of Company under Section 2 of this Agreement shall be pro rated to the date of death and paid to the Executive's estate.

(g) Disability. The Company may terminate the Executive's employment if the Executive is unable to perform any of the duties required under this Agreement for a period of three (3) consecutive months due to a "Total and Permanent Disability". The term "Total and Permanent Disability" shall mean the existence of a permanent physical or mental illness or injury, which renders the Executive incapable of performing any material obligations or terms of this Agreement. Any dispute regarding the existence of a Total and Permanent Disability shall be resolved by a panel of three (3) physicians, one selected by Company, one selected by the Executive, and the third selected by the other two physicians. A termination of employment pursuant to this Section 3(f) shall constitute a termination for Cause.

4. At-Will Employment. The Executive will be an "at-will" employee of the Company, which means the employment relationship can be terminated by either the Executive or the Company for any reason, at any time, with or without prior notice and with or without cause. The Company makes no promise that the Executive's employment will continue for any particular period of time, nor is there any promise that it will be terminated only under particular circumstances. No raise or bonus, if any, shall alter the Executive's status as an "at-will" employee or create any implied contract of employment. Discussion of possible or potential benefits in future years is not an express or implied promise of continued employment. No manager, supervisor or officer of the Company has the authority to change the Executive's status as an "at-will" employee. The "at-will" nature of the employment relationship with the Executive can only be altered by a written resolution approved by the Board.

5. Non-Solicitation.

(a) Non-Solicit. The Executive agrees that during the term of the Executive's employment with the Company, and for a period of twelve (12) months immediately following the termination of the Executive's employment with the Company for any reason, whether with

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or without Cause or Good Reason, the Executive shall not either directly or indirectly solicit, induce, recruit or encourage any of the Company's or its affiliates' employees or consultants to terminate such employee's or consultant's relationship with the Company or its affiliates, or attempt to solicit, induce, recruit, encourage or take away employees or consultants of the Company or any of its affiliates, either for the Executive or for any other person or entity. Further, during the Executive's employment with the Company or any of its affiliates and at any time following termination of the Executive's employment with the Company or any of its affiliates for any reason, with or without Cause or Good Reason, the Executive shall not use any confidential information of the Company or any of its affiliates to attempt to negatively influence any of the Company's or any of its affiliates' clients or customers from purchasing Company products or services or to solicit or influence or attempt to influence any client, customer or other person either directly or indirectly, to direct such person's or entity's purchase of products and/or services to any person, firm, corporation, institution or other entity in competition with the business of the Company or any of its affiliates.

(b) Specific Performance. In the event of the breach or threatened breach by the Executive of this Section 5, the Company, in addition to all other remedies available to it at law or in equity, will be entitled to seek injunctive relief and/or specific performance to enforce this Section 5.

6. Director and Officer Liability Insurance; Indemnification. During the term of the Executive's employment hereunder, the Executive shall be entitled to the same indemnification and director and officer liability insurance as the Company and its affiliates maintain for other corporate officers.

7. Proprietary Information and Inventions Assignment Agreement. The Executive has executed and delivered the Company's standard Employee Proprietary Information and Inventions Assignment Agreement or similar agreement and the Executive represents and warrants that the Executive shall continue to be bound and abide by such Employee Proprietary Information and Inventions Assignment Agreement or similar agreement.

8. Attention to Duties; Conflict of Interest. While employed by the Company, the Executive shall devote the Executive's full business time, energy and abilities exclusively to the business and interests of the Company, and shall perform all duties and services in a faithful and diligent manner and to the best of the Executive's abilities. The Executive shall not, without the Company's prior written consent, render to others services of any kind for compensation, or engage in any other business activity that would materially interfere with the performance of the Executive's duties under this Agreement. The Executive represents that the Executive has no other outstanding commitments inconsistent with any of the terms of this Agreement or the services to be rendered to the Company. While employed by the Company, the Executive shall not, directly or indirectly, whether as a partner, employee, creditor, shareholder, or otherwise, promote, participate or engage in any activity or other business competitive with the Company's business. The Executive shall not invest in any company or business which competes in any manner with the Company, except those companies whose securities are listed on reputable securities exchanges in the United States or European Union.

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9. Miscellaneous.

(a) Severability. If any provision of this Agreement shall be found by any arbitrator or court of competent jurisdiction to be invalid or unenforceable, then the parties hereby waive such provision to the extent that it is found to be invalid or unenforceable and to the extent that to do so would not deprive one of the parties of the substantial benefit of its bargain. Such provision shall, to the extent allowable by law and the preceding sentence, be modified by such arbitrator or court so that it becomes enforceable and, as modified, shall be enforced as any other provision hereof, all the other provisions continuing in full force and effect.

(b) No Waiver. The failure by either party at any time to require performance or compliance by the other of any of its obligations or agreements shall in no way affect the right to require such performance or compliance at any time thereafter. The waiver by either party of a breach of any provision hereof shall not be taken or held to be a waiver of any preceding or succeeding breach of such provision or as a waiver of the provision itself. No waiver of any kind shall be effective or binding, unless it is in writing and is signed by the party against whom such waiver is sought to be enforced.

(c) Assignment. This Agreement and all rights hereunder are personal to the Executive and may not be transferred or assigned by the Executive at any time. The Company may assign its rights, together with its obligations hereunder, to any parent, subsidiary, affiliate or successor, or in connection with any sale, transfer or other disposition of all or substantially all of its business and assets; *provided, however*, that any such assignee assumes the Company's obligations hereunder.

(d) Withholding. All sums payable to the Executive hereunder shall be reduced by all federal, state, local and other withholding and similar taxes and payments required by applicable law.

(e) Entire Agreement. This Agreement, including the agreements referred to herein (which are deemed incorporated by reference herein) constitute the entire and only agreement and understanding between the parties governing the terms and conditions of employment of the Executive with the Company and this Agreement supersedes and cancels any and all previous contracts, arrangements or understandings with governing the terms and conditions of the Executive's employment by the Company. In the event of any conflict between the terms of any other agreement between the Executive and the Company entered into prior to the Effective Date, the terms of this Agreement shall control.

(f) Amendment. This Agreement may be amended, modified, superseded, cancelled, renewed or extended only by an agreement in writing executed by both parties hereto.

(g) Headings. The headings contained in this Agreement are for reference purposes only and shall in no way affect the meaning or interpretation of this Agreement. In this Agreement, the singular includes the plural, the plural included the singular, the masculine gender includes both male and female referents, and the word "or" is used in the inclusive sense.

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(h) Notices. Any notices provided hereunder must be in writing and shall be deemed effective upon the earlier of personal delivery (including, personal delivery by facsimile transmission or the third day after mailing by first class mail) to the Company at its primary office location and to the Executive at his address as listed on the Company payroll (which address may be changed by written notice).

(i) Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed to be an original but all of which, taken together, constitute one and the same agreement.

(j) Governing Law, Forum Selection, Jury Waiver. This Agreement and the rights and obligations of the parties hereto shall be construed in accordance with the laws of the State of California without giving effect to the principles of conflict of laws. Any action, suit or other legal proceeding that is commenced to resolve any matter arising under or relating to any provision of this Agreement shall be commenced only in a court of the **State of California** (or, if appropriate, a federal court located within **The Southern District of California** ), and the Company and the Executive each consents to the jurisdiction of such a court. *Both the Company and the Executive expressly waive any right that any party either has or may have to a jury trial of any dispute arising out of or in any way related to the Executive's employment with or termination from the Company .*

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**IN WITNESS WHEREOF**, the Company and the Executive have executed this Executive Employment Agreement as of the date first above written.

**PACIRA PHARMACEUTICALS, INC.:**

By: /s/ David Stack  
David Stack  
Chief Executive Officer

**EXECUTIVE:**

/s/ Mark Walters  
Mark Walters

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**EXHIBIT A**

**PAYMENTS SUBJECT TO SECTION 409A**

1. Subject to this Exhibit A, any severance payments and benefits that may be due under the Agreement shall begin only upon the date of the Executive's "separation from service" (determined as set forth below) which occurs on or after the termination of the Executive's employment. The following rules shall apply with respect to distribution of the severance payments and benefits, if any, to be provided to the Executive under the Agreement, as applicable:

(a) It is intended that each installment of the severance payments and benefits under the Agreement provided under shall be treated as a separate "payment" for purposes of Section 409A. Neither the Company nor the Executive shall have the right to accelerate or defer the delivery of any such payments or benefits except to the extent specifically permitted or required by Section 409A.

(b) If, as of the date of the Executive's "separation from service" from the Company, the Executive is not a "specified employee" (within the meaning of Section 409A), then each installment of the severance payments or benefits shall be made on the dates and terms set forth in the Agreement.

(c) If, as of the date of the Executive's "separation from service" from the Company, the Executive is a "specified employee" (within the meaning of Section 409A), then:

(i) Each installment of the severance payments and benefits due under the Agreement that, in accordance with the dates and terms set forth herein, will in all circumstances, regardless of when the Executive's separation from service occurs, be paid within the short-term deferral period (as defined under Section 409A) shall be treated as a short-term deferral within the meaning of Treasury Regulation Section 1.409A-1(b)(4) to the maximum extent permissible under Section 409A and shall be paid at the time set forth in the Agreement; and

(ii) Each installment of the severance payments and benefits due under the Agreement that is not described in this Exhibit A, Section 1(c)(i) and that would, absent this subsection, be paid within the six-month period following the Executive's "separation from service" from the Company shall not be paid until the date that is six months and one day after such separation from service (or, if earlier, the Executive's death), with any such installments that are required to be delayed being accumulated during the six-month period and paid in a lump sum on the date that is six months and one day following the Executive's separation from service and any subsequent installments, if any, being paid in accordance with the dates and terms set forth herein; provided, however, that the preceding provisions of this sentence shall not apply to any installment of payments and benefits if and to the maximum extent that that such installment is deemed to be paid under a



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separation pay plan that does not provide for a deferral of compensation by reason of the application of Treasury Regulation 1.409A-1(b)(9)(iii) (relating to separation pay upon an involuntary separation from service). Any installments that qualify for the exception under Treasury Regulation Section 1.409A-1(b)(9)(iii) must be paid no later than the last day of the Executive's second taxable year following the taxable year in which the separation from service occurs.

2. The determination of whether and when the Executive's separation from service from the Company has occurred shall be made and in a manner consistent with, and based on the presumptions set forth in, Treasury Regulation Section 1.409A-1(h). Solely for purposes of this Exhibit A, Section 2, "Company" shall include all persons with whom the Company would be considered a single employer under Section 414(b) and 414(c) of the Code.

3. The Company makes no representation or warranty and shall have no liability to the Executive or to any other person if any of the provisions of the Agreement (including this Exhibit) are determined to constitute deferred compensation subject to Section 409A but that do not satisfy an exemption from, or the conditions of, that section.

**EXECUTIVE EMPLOYMENT AGREEMENT**

This Executive Employment Agreement (the "Agreement"), is entered into as of October 27, 2010 (the "Effective Date"), by and between Pacira Pharmaceuticals, Inc., a California corporation (the "Company"), and William Lambert (the "Executive").

**RECITALS**

**WHEREAS**, the Company wishes to continue to employ the Executive, and the Executive desires to continue to be employed by the Company, for such purpose and upon the terms and conditions hereinafter provided; and

**WHEREAS**, the parties wish to establish the terms of the Executive's future employment with the Company and set out fully their respective rights, obligations and duties.

**AGREEMENT**

In consideration of the promises and the terms and conditions set forth in this Agreement, the parties agree as follows:

1. Title and Capacity. The Company hereby agrees to continue to employ the Executive, and the Executive hereby accepts continued employment with the Company, under the terms set forth in this Agreement. The Executive will serve as the Senior Vice President of Pharmaceutical Development of the Company and shall perform such duties as are ordinary, customary and necessary in such role. The Executive will report directly to the Chief Executive Officer of the Company. The Executive shall devote his full business time, skill and attention to the performance of his duties on behalf of the Company.

2. Compensation and Benefits.

(a) Salary. The Company agrees to pay the Executive an annual base salary of Two Hundred and Twenty Thousand Dollars (\$220,000) payable in accordance with Company's customary payroll practice (the "Base Salary"). The Executive's Base Salary shall be reviewed periodically by the Board of Directors of the Company (the "Board"); *provided, however*, that any such review will not necessarily result in an adjustment to the Executive's Base Salary. Any change in the Executive's Base Salary must be approved by the Board.

(b) Bonus. The Executive is eligible to receive, in addition to the Base Salary and subject to the terms hereof and at the full discretion of the Board, a targeted incentive bonus of thirty percent (30%) of Base Salary (the "Targeted Incentive Bonus"). The Targeted Incentive Bonus shall be based on the Executive's and the Company's performance during the applicable fiscal year, as determined by the Board. The Targeted Incentive Bonus criteria or "goals" will be determined by agreement between the Board and the Executive at beginning of each fiscal year. The award of the Target Incentive Bonus may be in an amount either above or below the amount specified by the Board at the beginning of each fiscal year based on the ultimate performance assessed by the Board.

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The Targeted Incentive Bonus, if awarded, shall be payable in the first payroll period in 2012, but in no event later than March 15, 2012. Targeted Incentive Bonuses for subsequent years shall be determined and approved by the Board in its sole discretion.

All salary and bonuses shall be subject to all applicable withholdings and deductions.

(c) Stock Options. On September 2, 2010, the Company granted to the Executive two stock options (each an “Option” and collectively, the “Options”) to purchase an aggregate of five hundred and fifty thousand (550,000) shares of the Company’s common stock, \$0.001 par value per share (the “Option Shares”), pursuant to the Company’s 2007 Stock Option/Stock Issuance (the “Plan”). The exercise price, vesting schedule and other terms for each of the Options are set forth in the notice of grant and option agreement for each such Option and the Options are subject to accelerated vesting as set forth in Section 3 hereof. Additional equity incentives, if any, shall be determined by the Board (or a committee thereof) in its sole discretion. All share figures set forth herein shall be subject to adjustment for stock splits, stock dividends, stock combinations, recapitalizations and similar events.

(d) Benefits. The Executive (and, where applicable, the Executive’s qualified dependents) will be eligible to participate in health insurance and other employee benefit plans and policies established by the Company for its executive team from time to time on substantially the same terms as are made available to other such employees of the Company generally. The Executive’s participation (and the participation of the Executive’s qualified dependents) in the Company’s benefit plans and policies will be subject to the terms of the applicable plan documents and the Company’s generally applied policies, and the Company in its sole discretion may from time to time adopt, modify, interpret or discontinue such plans or policies.

(e) Expenses. The Company will reimburse the Executive for all reasonable and necessary expenses incurred by the Executive in connection with the Company’s business, in accordance with the applicable Company policy as may be amended from time to time.

(f) Vacation and Holidays. The Executive shall be eligible for thirty (30 days’ paid vacation/flexible time off per calendar year subject to the applicable terms and conditions of the Company’s vacation policy and applicable law.

(g) Termination of Benefits. Except as set forth in Section 3 or as otherwise specified herein or in any other agreement between the Executive and the Company, if the Executive’s employment is terminated by the Company for any reason, with or without Cause (as defined below), or if the Executive resigns the Executive’s employment voluntarily, with or without Good Reason (as defined below), no compensation or other payments will be paid or provided to the Executive for periods following the date when such a termination of employment is effective, provided that any rights the Executive may have under the Company’s benefit plans shall be determined under the provisions of such plans. If the Executive’s employment terminates as a result of the Executive’s death or disability, no compensation or payments will be made to the Executive other than those to which the Executive may otherwise be entitled under the benefit plans of the Company.

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3. Compensation and Benefits Upon Termination of Employment. Upon termination of the Executive's employment (such date of termination being referred to as the "Termination Date"), the Company will pay the Executive the compensation and benefits as described in this Section 3.

(a) General Benefits Upon Termination. The Company will pay the Executive on or about the Termination Date all salary and vacation/personal time off pay, if any, that has been earned or accrued through the Termination Date and that has not been previously paid.

(b) Termination without "Cause" or for "Good Reason". In the event that the Company terminates the Executive's employment without Cause (as defined below) or, in the event the Executive terminates his employment for Good Reason (as defined below), in each case, (i) the Executive shall be entitled to receive (A) continuing payments of the then effective Base Salary for a period of nine (9) months beginning on the Payment Commencement Date and payable in accordance with the Company's payroll policies and (B) the benefits set forth in Section 3(e), and (ii) the Executive shall be entitled to acceleration of vesting of such number of Option Shares as would have vested in the nine (9) month period following the Termination Date had the Executive continued to be employed by the Company for such period, *provided, however* that in each case the receipt of such payments and benefits is expressly contingent upon the Executive's execution and delivery of a severance and release of claims agreement drafted by and satisfactory to counsel for the Company (the "Release") which Release must be executed and become effective within sixty (60) days following the Termination Date. The payments and benefits shall be paid or commence on the first payroll period following the date the Release becomes effective (the "Payment Commencement Date"). Notwithstanding the foregoing, if the 60<sup>th</sup> day following the Termination Date occurs in the calendar year following the termination, then the Payment Commencement Date shall be no earlier than January 1st of such subsequent calendar year. The provision of payments and benefits pursuant to this Section shall be subject to the terms and conditions set forth on Exhibit A.

(c) Termination without "Cause" or for "Good Reason" Prior to or Following a Change of Control. In the event that the Company terminates the Executive's employment without Cause (as defined below) or, in the event the Executive terminates his employment for Good Reason (as defined below), in each case, within thirty (30) days prior to, or twelve (12) months following, the consummation of a Change of Control, then (i) the Executive shall be entitled to receive (A) continuing payments of the then effective Base Salary for a period of nine (9) months beginning on the Payment Commencement Date and payable in accordance with the Company's payroll policies and (B) the benefits set forth in Section 3(e), and (ii) acceleration of vesting of one hundred percent (100%) of the then unvested Option Shares, provided, however that in each case: (x), the receipt of such payments and benefits is expressly contingent upon the Executive's execution and delivery of a Release as described above drafted by and satisfactory to counsel for the Company, which Release must be executed and become effective within sixty (60) days following the Termination Date. The provision of payments and benefits pursuant to this Section shall be subject to the terms and conditions set forth in Exhibit A.

(d) Definitions.

(i) "Change of Control" means (A) a merger or consolidation of either the Company or Pacira, Inc., a Delaware corporation (" Parent") into another entity in which the stockholders of the Company or Parent (as applicable) do not control fifty percent (50%) or more of the total voting power of the surviving entity (other than a reincorporation merger); (B) the sale, transfer or other disposition of all or substantially all of the Company's assets in liquidation or dissolution of the Company; or (C) the sale or transfer of more than fifty percent (50%) of the outstanding voting stock of the Company. In the case of each of the foregoing clauses (A), (B) and (C), a Change of Control as a result of a financing transaction of the Company or Parent shall not constitute a Change of Control for purposes of this Agreement

(ii) "Cause" means (A) the Executive's failure to substantially perform his duties to the Company after there has been delivered to the Executive written notice setting forth in detail the specific respects in which the Board believes that the Executive has not substantially performed his duties and, if the Company reasonably considers the situation to be correctable, a demand for substantial performance and opportunity to cure, giving the Executive thirty (30) calendar days after he receives such notice to correct the situation; (B) the Executive's having engaged in fraud, misconduct, dishonesty, gross negligence or having otherwise acted in a manner injurious to the Company or in intentional disregard for the Company's best interests; (C) the Executive's failure to follow reasonable and lawful instructions from the Board and the Executive's failure to cure such failure after receiving twenty (20) days advance written notice; (D) the Executive's material breach of the terms of this Agreement or the Employee Proprietary Information and Inventions Assignment Agreement or any other similar agreement that may be in effect from time to time; or (E) the Executive's conviction of, or pleading guilty or nolo contendere to, any misdemeanor involving dishonesty or moral turpitude or related to the Company's business, or any felony.

(iii) "Good Reason" means the occurrence of any one or more of the following events without the prior written consent of the Executive: (A) any material reduction of the then effective Base Salary other than in accordance with this Agreement or which reduction is not related to a cross-executive team salary reduction; (B) any material breach by the Company of this Agreement; or (C) a material reduction in the Executive's responsibilities or duties, provided that in the case of clause (C), a mere reassignment following a Change of Control to a position that is substantially similar to the position held prior to the Change of Control transaction shall not constitute a material reduction in job responsibilities or duties; provided, however, that no such event or condition shall constitute Good Reason unless (x) the Executive gives the Company a written notice of termination for Good Reason not more than ninety (90) days after the initial existence of the condition, (y) the grounds for termination (if susceptible to correction) are not corrected by the Company within thirty (30) days of its receipt of such notice and (z) the Termination Date occurs within one (1) year following the Company's receipt of such notice.

(e) Benefits Continuation. If the Executive's employment is terminated pursuant to Section 3(b) or Section 3(c) and provided that the Executive is eligible for and elects to continue receiving group health and dental insurance pursuant to the federal "COBRA" law, 29 U.S.C. § 1161 et seq., the Company will, for a twelve (12) month period following the Payment Commencement Date (the "Benefits Continuation Period"), continue to pay the share of

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the premium for such coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage. The remaining balance of any premium costs shall be paid by the Executive on a monthly basis for as long as, and to the extent that, the Executive remains eligible for COBRA continuation. Notwithstanding the above, in the event the Executive becomes eligible for health insurance benefits from a new employer during the Benefits Continuation Period, the Company's obligations under this Section 3(e) shall immediately cease and the Executive shall not be entitled to any additional monthly premium payments for health insurance coverage. Similarly, in the event the Executive becomes eligible for dental insurance benefits from a new employer during the Benefits Continuation Period, the Company's obligations under this Section 3(e) shall immediately cease and the Executive shall not be entitled to any additional monthly premium payments for dental insurance. The Executive hereby represents that he will notify the Company in writing within three (3) days of becoming eligible for health or dental insurance benefits from a new employer during the Benefits Continuation Period

(f) Death. This Agreement shall automatically terminate upon the death of the Executive and all monetary obligations of Company under Section 2 of this Agreement shall be pro rated to the date of death and paid to the Executive's estate.

(g) Disability. The Company may terminate the Executive's employment if the Executive is unable to perform any of the duties required under this Agreement for a period of three (3) consecutive months due to a "Total and Permanent Disability". The term "Total and Permanent Disability" shall mean the existence of a permanent physical or mental illness or injury, which renders the Executive incapable of performing any material obligations or terms of this Agreement. Any dispute regarding the existence of a Total and Permanent Disability shall be resolved by a panel of three (3) physicians, one selected by Company, one selected by the Executive, and the third selected by the other two physicians. A termination of employment pursuant to this Section 3(f) shall constitute a termination for Cause.

4. At-Will Employment. The Executive will be an "at-will" employee of the Company, which means the employment relationship can be terminated by either the Executive or the Company for any reason, at any time, with or without prior notice and with or without cause. The Company makes no promise that the Executive's employment will continue for any particular period of time, nor is there any promise that it will be terminated only under particular circumstances. No raise or bonus, if any, shall alter the Executive's status as an "at-will" employee or create any implied contract of employment. Discussion of possible or potential benefits in future years is not an express or implied promise of continued employment. No manager, supervisor or officer of the Company has the authority to change the Executive's status as an "at-will" employee. The "at-will" nature of the employment relationship with the Executive can only be altered by a written resolution approved by the Board.

5. Non-Solicitation.

(a) Non-Solicit. The Executive agrees that during the term of the Executive's employment with the Company, and for a period of twelve (12) months immediately following the termination of the Executive's employment with the Company for any reason, whether with

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or without Cause or Good Reason, the Executive shall not either directly or indirectly solicit, induce, recruit or encourage any of the Company's or its affiliates' employees or consultants to terminate such employee's or consultant's relationship with the Company or its affiliates, or attempt to solicit, induce, recruit, encourage or take away employees or consultants of the Company or any of its affiliates, either for the Executive or for any other person or entity. Further, during the Executive's employment with the Company or any of its affiliates and at any time following termination of the Executive's employment with the Company or any of its affiliates for any reason, with or without Cause or Good Reason, the Executive shall not use any confidential information of the Company or any of its affiliates to attempt to negatively influence any of the Company's or any of its affiliates' clients or customers from purchasing Company products or services or to solicit or influence or attempt to influence any client, customer or other person either directly or indirectly, to direct such person's or entity's purchase of products and/or services to any person, firm, corporation, institution or other entity in competition with the business of the Company or any of its affiliates.

(b) Specific Performance. In the event of the breach or threatened breach by the Executive of this Section 5, the Company, in addition to all other remedies available to it at law or in equity, will be entitled to seek injunctive relief and/or specific performance to enforce this Section 5.

6. Director and Officer Liability Insurance; Indemnification. During the term of the Executive's employment hereunder, the Executive shall be entitled to the same indemnification and director and officer liability insurance as the Company and its affiliates maintain for other corporate officers.

7. Proprietary Information and Inventions Assignment Agreement. The Executive has executed and delivered the Company's standard Employee Proprietary Information and Inventions Assignment Agreement or similar agreement and the Executive represents and warrants that the Executive shall continue to be bound and abide by such Employee Proprietary Information and Inventions Assignment Agreement or similar agreement.

8. Attention to Duties; Conflict of Interest. While employed by the Company, the Executive shall devote the Executive's full business time, energy and abilities exclusively to the business and interests of the Company, and shall perform all duties and services in a faithful and diligent manner and to the best of the Executive's abilities. The Executive shall not, without the Company's prior written consent, render to others services of any kind for compensation, or engage in any other business activity that would materially interfere with the performance of the Executive's duties under this Agreement. The Executive represents that the Executive has no other outstanding commitments inconsistent with any of the terms of this Agreement or the services to be rendered to the Company. While employed by the Company, the Executive shall not, directly or indirectly, whether as a partner, employee, creditor, shareholder, or otherwise, promote, participate or engage in any activity or other business competitive with the Company's business. The Executive shall not invest in any company or business which competes in any manner with the Company, except those companies whose securities are listed on reputable securities exchanges in the United States or European Union.

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9. Miscellaneous.

(a) Severability. If any provision of this Agreement shall be found by any arbitrator or court of competent jurisdiction to be invalid or unenforceable, then the parties hereby waive such provision to the extent that it is found to be invalid or unenforceable and to the extent that to do so would not deprive one of the parties of the substantial benefit of its bargain. Such provision shall, to the extent allowable by law and the preceding sentence, be modified by such arbitrator or court so that it becomes enforceable and, as modified, shall be enforced as any other provision hereof, all the other provisions continuing in full force and effect.

(b) No Waiver. The failure by either party at any time to require performance or compliance by the other of any of its obligations or agreements shall in no way affect the right to require such performance or compliance at any time thereafter. The waiver by either party of a breach of any provision hereof shall not be taken or held to be a waiver of any preceding or succeeding breach of such provision or as a waiver of the provision itself. No waiver of any kind shall be effective or binding, unless it is in writing and is signed by the party against whom such waiver is sought to be enforced.

(c) Assignment. This Agreement and all rights hereunder are personal to the Executive and may not be transferred or assigned by the Executive at any time. The Company may assign its rights, together with its obligations hereunder, to any parent, subsidiary, affiliate or successor, or in connection with any sale, transfer or other disposition of all or substantially all of its business and assets; *provided, however*, that any such assignee assumes the Company's obligations hereunder.

(d) Withholding. All sums payable to the Executive hereunder shall be reduced by all federal, state, local and other withholding and similar taxes and payments required by applicable law.

(e) Entire Agreement. This Agreement, including the agreements referred to herein (which are deemed incorporated by reference herein) constitute the entire and only agreement and understanding between the parties governing the terms and conditions of employment of the Executive with the Company and this Agreement supersedes and cancels any and all previous contracts, arrangements or understandings with governing the terms and conditions of the Executive's employment by the Company. In the event of any conflict between the terms of any other agreement between the Executive and the Company entered into prior to the Effective Date, the terms of this Agreement shall control.

(f) Amendment. This Agreement may be amended, modified, superseded, cancelled, renewed or extended only by an agreement in writing executed by both parties hereto.

(g) Headings. The headings contained in this Agreement are for reference purposes only and shall in no way affect the meaning or interpretation of this Agreement. In this Agreement, the singular includes the plural, the plural included the singular, the masculine gender includes both male and female referents, and the word "or" is used in the inclusive sense.



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(h) Notices. Any notices provided hereunder must be in writing and shall be deemed effective upon the earlier of personal delivery (including, personal delivery by facsimile transmission or the third day after mailing by first class mail) to the Company at its primary office location and to the Executive at his address as listed on the Company payroll (which address may be changed by written notice).

(i) Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed to be an original but all of which, taken together, constitute one and the same agreement.

(j) Governing Law, Forum Selection, Jury Waiver. This Agreement and the rights and obligations of the parties hereto shall be construed in accordance with the laws of the State of California without giving effect to the principles of conflict of laws. Any action, suit or other legal proceeding that is commenced to resolve any matter arising under or relating to any provision of this Agreement shall be commenced only in a court of the **State of California** (or, if appropriate, a federal court located within **Southern District of California** ), and the Company and the Executive each consents to the jurisdiction of such a court. *Both the Company and the Executive expressly waive any right that any party either has or may have to a jury trial of any dispute arising out of or in any way related to the Executive's employment with or termination from the Company .*

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**IN WITNESS WHEREOF**, the Company and the Executive have executed this Executive Employment Agreement as of the date first above written.

**PACIRA PHARMACEUTICALS, INC.:**

By: /s/ David Stack  
David Stack  
Chief Executive Officer

**EXECUTIVE:**

/s/ William Lambert  
William Lambert

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**EXHIBIT A**

**PAYMENTS SUBJECT TO SECTION 409A**

1. Subject to this Exhibit A, any severance payments and benefits that may be due under the Agreement shall begin only upon the date of the Executive's "separation from service" (determined as set forth below) which occurs on or after the termination of the Executive's employment. The following rules shall apply with respect to distribution of the severance payments and benefits, if any, to be provided to the Executive under the Agreement, as applicable:

(a) It is intended that each installment of the severance payments and benefits under the Agreement provided under shall be treated as a separate "payment" for purposes of Section 409A. Neither the Company nor the Executive shall have the right to accelerate or defer the delivery of any such payments or benefits except to the extent specifically permitted or required by Section 409A.

(b) If, as of the date of the Executive's "separation from service" from the Company, the Executive is not a "specified employee" (within the meaning of Section 409A), then each installment of the severance payments or benefits shall be made on the dates and terms set forth in the Agreement.

(c) If, as of the date of the Executive's "separation from service" from the Company, the Executive is a "specified employee" (within the meaning of Section 409A), then:

(i) Each installment of the severance payments and benefits due under the Agreement that, in accordance with the dates and terms set forth herein, will in all circumstances, regardless of when the Executive's separation from service occurs, be paid within the short-term deferral period (as defined under Section 409A) shall be treated as a short-term deferral within the meaning of Treasury Regulation Section 1.409A-1(b)(4) to the maximum extent permissible under Section 409A and shall be paid at the time set forth in the Agreement; and

(ii) Each installment of the severance payments and benefits due under the Agreement that is not described in this Exhibit A, Section 1(c)(i) and that would, absent this subsection, be paid within the six-month period following the Executive's "separation from service" from the Company shall not be paid until the date that is six months and one day after such separation from service (or, if earlier, the Executive's death), with any such installments that are required to be delayed being accumulated during the six-month period and paid in a lump sum on the date that is six months and one day following the Executive's separation from service and any subsequent installments, if any, being paid in accordance with the dates and terms set forth herein; provided, however, that the preceding provisions of this sentence shall not apply to any installment of payments and benefits if and to the maximum extent that that such installment is deemed to be paid under a

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separation pay plan that does not provide for a deferral of compensation by reason of the application of Treasury Regulation 1.409A-1(b)(9)(iii) (relating to separation pay upon an involuntary separation from service). Any installments that qualify for the exception under Treasury Regulation Section 1.409A-1(b)(9)(iii) must be paid no later than the last day of the Executive's second taxable year following the taxable year in which the separation from service occurs.

2. The determination of whether and when the Executive's separation from service from the Company has occurred shall be made and in a manner consistent with, and based on the presumptions set forth in, Treasury Regulation Section 1.409A-1(h). Solely for purposes of this Exhibit A, Section 2, "Company" shall include all persons with whom the Company would be considered a single employer under Section 414(b) and 414(c) of the Code.

3. The Company makes no representation or warranty and shall have no liability to the Executive or to any other person if any of the provisions of the Agreement (including this Exhibit) are determined to constitute deferred compensation subject to Section 409A but that do not satisfy an exemption from, or the conditions of, that section.

## LOAN AND SECURITY AGREEMENT

THIS LOAN AND SECURITY AGREEMENT is made and dated as of November 24, 2010 and is entered into by and between PACIRA PHARMACEUTICALS, INC., a Delaware corporation, PACIRA PHARMACEUTICALS, INC., a California corporation, and each of subsidiaries that execute a Joinder from time to time, (individually, a "Borrower" and, collectively, the "Borrowers"), and HERCULES TECHNOLOGY GROWTH CAPITAL, INC., a Maryland corporation and HERCULES TECHNOLOGY III, L.P., a Delaware limited partnership (collectively, the "Lender").

## RECITALS

A. Borrowers have requested a loan in an aggregate principal amount of up to Twenty-Six Million Two Hundred Fifty Thousand Dollars (\$26,250,000) (the "Term Loan"); and

B. Lender is willing to make the Term Loan on the terms and conditions set forth in this Agreement.

## AGREEMENT

NOW, THEREFORE, Borrowers and Lender agree as follows:

**SECTION 1. DEFINITIONS AND RULES OF CONSTRUCTION**

1.1 Unless otherwise defined herein, the following capitalized terms shall have the following meanings:

"Account Control Agreement(s)" means any agreement entered into by and among the Lender, a Borrower and a third party Bank or other institution (including a Securities Intermediary) in which Borrower maintains a Deposit Account or an account holding Investment Property and which grants Lender a perfected first priority security interest in the subject account or accounts.

"ACH Authorization" means the ACH Debit Authorization Agreement in substantially the form of Exhibit H.

"Advance" means any funds advanced under this Agreement.

"Advance Date" means the funding date of any Advance.

"Advance Request" means a request for an Advance submitted by a Borrower to Lender in substantially the form of Exhibit A.

"Agreement" means this Loan and Security Agreement, as amended from time to time.

"Assignee" has the meaning given to it in Section 11.14.

"Borrower Products" means all products, software, service offerings, technical data or technology currently being designed, manufactured or sold by a Borrower or which such Borrower intends to sell, license, or distribute in the future including any products or service offerings under development, collectively, together with all products, software, service offerings, technical data or technology that have been sold, licensed or distributed by such Borrower since its incorporation.

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“Cash” means all cash and liquid funds.

“Change in Control” means any (i) reorganization, recapitalization, consolidation or merger (or similar transaction or series of related transactions) of a Borrower or any Subsidiary, sale or exchange of outstanding shares (or similar transaction or series of related transactions) of a Borrower or any Subsidiary in which the holders of a Borrower or Subsidiary’s outstanding shares immediately before consummation of such transaction or series of related transactions do not (together with any affiliates of such holders), immediately after consummation of such transaction or series of related transactions, retain shares representing more than fifty percent (50%) of the voting power of the surviving entity of such transaction or series of related transactions (or the parent of such surviving entity if such surviving entity is wholly owned by such parent), in each case without regard to whether a Borrower or Subsidiary is the surviving entity, or (ii) sale or issuance by a Borrower of new shares of Preferred Stock of a Borrower to investors, none of whom are current investors in a Borrower, shares representing more than fifty percent (50%) of the voting power of the surviving entity of such transaction or series of related transactions (or the parent of such surviving entity if such surviving entity is wholly owned by such parent); provided, however, an Initial Public Offering shall not constitute a Change in Control or (iii) any of the chief executive officer or (before an Initial Public Offering) the chief financial officer of Borrower as of the date hereof shall cease to be involved in the day to day management of the business of Borrower, and a successor of such officer reasonably acceptable to Lender is not appointed on terms reasonably acceptable to Lender within 180 days of such cessation of such involvement.

“Claims” has the meaning given to it in Section 11.10.

“Closing Date” means the date of this Agreement.

“Collateral” means the property described in Section 3.

“Commitment Fee” means \$50,000, which fee was paid to Lender prior to the Closing Date, and shall be deemed fully earned on such date regardless of the early termination of this Agreement.

“Confidential Information” has the meaning given to it in Section 11.13.

“Contingent Obligation” means, as applied to any Person, any direct or indirect liability, contingent or otherwise, of that Person with respect to (i) any indebtedness, lease, dividend, letter of credit or other obligation of another, including any such obligation directly or indirectly guaranteed, endorsed, co-made or discounted or sold with recourse by that Person, or in respect of which that Person is otherwise directly or indirectly liable; (ii) any obligations with respect to undrawn letters of credit, corporate credit cards or merchant services issued for the account of that Person; and (iii) all obligations arising under any interest rate, currency or commodity swap agreement, interest rate cap agreement, interest rate collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; provided, however, that the term “Contingent Obligation” shall not include endorsements for collection or deposit in the ordinary course of business. The amount of any Contingent Obligation shall be deemed to be an amount equal to the stated or determined amount of the primary obligation in respect of which such Contingent Obligation is made or, if not stated or determinable, the maximum reasonably anticipated liability in respect thereof as determined by such Person in good faith; provided, however, that such amount shall not in any event exceed the maximum amount of the obligations under the guarantee or other support arrangement.

“Copyright License” means any written agreement granting any right to use any Copyright or Copyright registration, now owned or hereafter acquired by a Borrower or in which a Borrower now holds or hereafter acquires any interest.

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“Copyrights” means all copyrights, whether registered or unregistered, held pursuant to the laws of the United States, any State thereof, or of any other country.

“Deposit Accounts” means any “deposit accounts,” as such term is defined in the UCC, and includes any checking account, savings account, or certificate of deposit.

“ERISA” is the Employee Retirement Income Security Act of 1974, and its regulations, as amended and in effect from time to time.

“Event of Default” has the meaning given to it in Section 9.

“Facility Charge” is a fee equal to \$328,125.

“Financial Statements” means the financial statements required to be delivered under Section 7.1.

“GAAP” means generally accepted accounting principles in the United States of America, as in effect from time to time.

“Guarantor” means, as of the Closing Date, any Person who signs the Guaranty.

“Guaranty” means the Guaranty in the form executed in connection with the Agreement by certain shareholders of a Borrower.

“Indebtedness” means (a) all indebtedness for borrowed money or the deferred purchase price of property or services (excluding trade credit entered into in the ordinary course of business and not past due more than 90 days), including reimbursement and other obligations with respect to surety bonds and letters of credit, (b) all obligations evidenced by notes, bonds, debentures or similar instruments, (c) all capital lease obligations, and (d) all Contingent Obligations.

“Initial Public Offering” means the initial firm commitment underwritten offering of Borrower’s common stock pursuant to a registration statement under the Securities Act of 1933 (the “Securities Act”) filed with, and declared effective by, the Securities and Exchange Commission.

“Insolvency Proceeding” is any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions, extensions generally with its creditors, or proceedings seeking reorganization, arrangement, or other similar relief.

“Intellectual Property” means all of a Borrower’s Copyrights; Trademarks; Patents; Licenses; trade secrets and inventions; mask works; Borrower’s applications therefor and reissues, extensions, or renewals thereof; and a Borrower’s goodwill associated with any of the foregoing, together with Borrower’s rights to sue for past, present and future infringement of Intellectual Property and the goodwill associated therewith.

“Interest Only Period” means the period from the Closing Date through August 31, 2011, provided at Borrowers’ option, confirmed in a written request by a Borrower, the Interest Only Period shall mean the period from the Closing Date through November 30, 2011 if (i) the FDA accepts the EXPAREL New Drug Application for review and (ii) a Borrower receives at least \$50,000,000 in net new cash proceeds from an Initial Public Offering, equity, convertible debt or strategic partnership financing or any combination thereof; provided, further, that at a Borrower’s option, confirmed in a written request

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by Borrower, the Interest Only Period means the period from the Closing Date through February 28, 2012 if (x) conditions (i) and (ii) of this sentence are satisfied and, in addition, (y) Borrower receives FDA approval of the EXPAREL New Drug Application on or before December 31, 2011.

“Interest Rate” means either the Term Loan A Interest Rate or the Term Loan B Interest Rate, as applicable.

“Investment” means any beneficial ownership (including stock, partnership or limited liability company interests) of or in any Person, or any loan, advance or capital contribution to any Person or the acquisition of all, or substantially all, of the assets of another Person.

“Joinder Agreements” means for each Subsidiary, a completed and executed Joinder Agreement in substantially the form attached hereto as Exhibit G.

“Lender” has the meaning given to it in the preamble to this Agreement.

“Lender Expenses” are all audit fees and expenses, costs, and expenses (including reasonable attorneys’ fees and expenses) for preparing, negotiating, administering, defending and enforcing the Loan Documents (including, without limitation, those incurred in connection with appeals or Insolvency Proceedings) or otherwise incurred with respect to a Borrower.

“License” means any Copyright License, Patent License, Trademark License or other license of rights or interests.

“Lien” means any mortgage, deed of trust, pledge, hypothecation, assignment for security, security interest, encumbrance, levy, lien or charge of any kind, whether voluntarily incurred or arising by operation of law or otherwise, against any property, any conditional sale or other title retention agreement, and any lease in the nature of a security interest.

“Loan” means the Advances made under this Agreement.

“Loan Documents” means this Agreement, the Notes, the ACH Authorization, the Account Control Agreements, the Joinder Agreements, all UCC Financing Statements, the Subordination Agreement, the Guaranty, and any other documents executed in connection with the Secured Obligations or the transactions contemplated hereby (excluding the Warrant), as the same may from time to time be amended, modified, supplemented or restated.

“Material Adverse Effect” means a material adverse effect upon: (i) the business, operations, properties, assets, or condition (financial or otherwise) of a Borrower; or (ii) the ability of a Borrower to perform the Secured Obligations in accordance with the terms of the Loan Documents, or the ability of Lender to enforce any of its rights or remedies with respect to the Secured Obligations; or (iii) the Collateral or Lender’s Liens on the Collateral or the priority of such Liens; provided, however, that for the avoidance of doubt, any actual cash burn of Borrowers that is materially consistent with the cash burn for the Borrowers described in the most recent operating plan of Borrowers delivered to Lenders as of the Closing Date and any subsequent operating plan approved by Lenders will not, in and of itself, constitute a “Material Adverse Effect”.

“Material Agreement” means (i) any agreements or instruments relating to the Subordinated Debt, (ii) the Royalty Agreements, (iii) any agreement to which a Borrower is a party involving the receipt of payment of amounts in the aggregate exceeding \$500,000 per year, and (iv) any agreement to which a Borrower is a party the termination of which would reasonably be expected to have a Material Adverse Effect.



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“Maturity Date” means the last day of the month that is 33 months after the expiration of the Interest Only Period.

“Maximum Rate” shall have the meaning assigned to such term in Section 2.2.

“Note(s)” means a Term Note.

“Patent License” means any written agreement granting any right with respect to any invention on which a Patent is in existence or a Patent application is pending, in which agreement Borrower now holds or hereafter acquires any interest.

“Patents” means all letters patent of, or rights corresponding thereto, in the United States or in any other country, all registrations and recordings thereof, and all applications for letters patent of, or rights corresponding thereto, in the United States or any other country.

“Permitted Indebtedness” means: (i) Indebtedness of a Borrower in favor of Lender arising under this Agreement or any other Loan Document; (ii) Indebtedness existing on the Closing Date which is disclosed in Schedule 1A; (iii) Indebtedness of up to \$1,000,000 in principal outstanding at any time secured by a lien described in clause (vii) of the defined term “Permitted Liens,” provided such Indebtedness does not exceed the lesser of the cost or fair market value of the Equipment financed with such Indebtedness; (iv) Indebtedness to trade creditors incurred in the ordinary course of business, including Indebtedness incurred in the ordinary course of business with corporate credit cards; (v) Indebtedness that also constitutes a Permitted Investment; (vi) Subordinated Indebtedness; (vii) reimbursement obligations in connection with letters of credit that are secured by cash or cash equivalents and issued on behalf of a Borrower or a Subsidiary thereof in an amount not to exceed \$200,000 at any time outstanding prior to an Initial Public Offering, and not to exceed \$500,000 at any time outstanding after an Initial Public Offering, (viii) other Indebtedness in an amount not to exceed \$100,000 at any time outstanding, (ix) Indebtedness owing by any Borrower to another Borrower, provided that (a) each Borrower shall have executed and delivered to the other Borrower a demand note to evidence such Indebtedness, which note shall be in form and substance reasonably satisfactory to Lenders and shall be pledged to Lenders pursuant to the Pledge Agreement and (b) such Indebtedness shall be subordinated to the Secured Obligations pursuant to the subordination terms set forth in such note, and (c) no Event of Default would occur either before or after giving effect to any such indebtedness; (x) Indebtedness incurred in connection with interest rate swaps incurred in the ordinary course of business; and (xi) extensions, refinancings and renewals of any items of Permitted Indebtedness, provided that the principal amount is not increased or the terms modified to impose materially more burdensome terms upon a Borrower or its Subsidiary, as the case may be.

“Permitted Investment” means: (i) Investments existing on the Closing Date which are disclosed in Schedule 1B; (ii) (a) marketable direct obligations issued or unconditionally guaranteed by the United States of America or any agency or any State thereof maturing within one year from the date of acquisition thereof, (b) commercial paper maturing no more than one year from the date of creation thereof and currently having a rating of at least A-2 or P-2 from either Standard & Poor’s Corporation or Moody’s Investors Service, (c) certificates of deposit issued by any bank with assets of at least \$500,000,000 maturing no more than one year from the date of investment therein, and (d) money market accounts; (iii) repurchases of stock from former employees, directors, or consultants of a Borrower under the terms of applicable repurchase agreements at the original issuance price of such securities in an aggregate amount

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not to exceed \$250,000 in any fiscal year, provided that no Event of Default has occurred, is continuing or would exist after giving effect to the repurchases; (iv) Investments accepted in connection with Permitted Transfers; (v) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of a Borrower's business; (vi) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not affiliates, in the ordinary course of business, provided that this subparagraph (vi) shall not apply to Investments of a Borrower in any Subsidiary; (vii) Investments consisting of loans not involving the net transfer on a substantially contemporaneous basis of cash proceeds to employees, officers or directors relating to the purchase of capital stock of a Borrower pursuant to employee stock purchase plans or other similar agreements approved by a Borrower's Board of Directors; (viii) Investments consisting of travel advances in the ordinary course of business; (ix) Investments in newly-formed Subsidiaries organized in the United States, provided that such Subsidiaries enter into a Joinder Agreement promptly after their formation by a Borrower and execute such other documents as shall be reasonably requested by Lender; (x) Investments in Subsidiaries organized outside of the United States approved in advance in writing by Lender; (xi) joint ventures, partnerships or strategic alliances consistent with the ordinary course of business in Borrower's industry, provided that (i) any cash Investments by Borrower therein do not exceed \$500,000 in the aggregate in any fiscal year and (ii) prior to the Borrower receiving within any 12 month period occurring after the date hereof at least \$50,000,000 in net new cash proceeds from an Initial Public Offering, equity offering convertible debt or strategic partnership financing (which strategic partnership is not related to EXPAREL or any combination thereof the Borrower may not grant an exclusive license for the use or development of technology in the United States unless the Lenders have consented to the terms thereof (or if no such consent is given, then the first proceeds arising out of the license shall be used to repay the Secured Obligations); (xii) Investments of Funds held exclusively in the Royalty Accounts, to the extent such Investments are made in accordance with the terms and conditions of the Royalty Lockbox Agreement; (xiii) Investments made pursuant to any investment policy adopted by a Borrower after the Closing Date and approved by Lenders; (xiv) Investments by a Borrower in a Borrower; and (xv) additional Investments that do not exceed \$250,000 in the aggregate.

"Permitted Liens" means any and all of the following: (i) Liens in favor of Lender; (ii) Liens existing on the Closing Date which are disclosed in Schedule 1C; (iii) Liens for taxes, fees, assessments or other governmental charges or levies, either not delinquent or being contested in good faith by appropriate proceedings; provided, that Borrower maintains adequate reserves therefor in accordance with GAAP; (iv) Liens securing claims or demands of materialmen, artisans, mechanics, carriers, warehousemen, landlords and other like Persons arising in the ordinary course of a Borrower's business and imposed without action of such parties; provided, that the payment thereof is not yet required; (v) Liens arising from judgments, decrees or attachments in circumstances which do not constitute an Event of Default hereunder; (vi) the following deposits, to the extent made in the ordinary course of business: deposits under worker's compensation, unemployment insurance, social security and other similar laws, or to secure the performance of bids, tenders or contracts (other than for the repayment of borrowed money) or to secure indemnity, performance or other similar bonds for the performance of bids, tenders or contracts (other than for the repayment of borrowed money) or to secure statutory obligations (other than liens arising under ERISA or environmental liens) or surety or appeal bonds, or to secure indemnity, performance or other similar bonds; (vii) Liens on Equipment, software or other intellectual property, or other capital assets (not including Inventory) constituting purchase money liens and liens in connection with capital leases securing Indebtedness permitted in clause (iii) of "Permitted Indebtedness"; (viii) Liens incurred in connection with Subordinated Indebtedness; (ix) leasehold interests in leases or subleases and licenses granted in the ordinary course of business and not interfering in any material respect with the business of the licensor; (x) Liens in favor of customs and revenue authorities arising as a

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matter of law to secure payment of custom duties that are promptly paid on or before the date they become due; (xi) Liens on insurance proceeds securing the payment of financed insurance premiums that are promptly paid on or before the date they become due (provided that such Liens extend only to such insurance proceeds and not to any other property or assets); (xii) statutory and common law rights of set-off and other similar rights as to deposits of cash and securities in favor of banks, other depository institutions and brokerage firms; (xiii) easements, zoning restrictions, rights-of-way and similar encumbrances on real property imposed by law or arising in the ordinary course of business so long as they do not materially impair the value or marketability of the related property; (xiv) Liens on cash or cash equivalents securing obligations permitted under clause (vii) of the definition of Permitted Indebtedness; (xv) Licenses that constitute Permitted Transfers; (xvi) Liens securing the Indebtedness permitted in clause (vii) of “Permitted Indebtedness”, and (xvii) Liens incurred in connection with the extension, renewal or refinancing of the indebtedness secured by Liens of the type described in clauses (i) through (xi) above; provided, that any extension, renewal or replacement Lien shall be limited to the property encumbered by the existing Lien and the principal amount of the indebtedness being extended, renewed or refinanced (as may have been reduced by any payment thereon) does not increase.

“Permitted Transfers” means (i) sales of Inventory in the normal course of business, (ii) the Transfer of Assigned Interests, as such term is defined in the Royalty Assignment Agreement, pursuant to the terms and conditions of the Royalty Assignment Agreement, (iii) non-exclusive and exclusive licenses for the use of Intellectual Property in the ordinary course of business of the transferor so long as, with respect to each such license (a) no Event of Default has occurred or is continuing at the time of such Transfer, (b) the license constitutes an arms-length transaction in the course of the transferor’s business (and in the case of any exclusive license, made in connection with a bona fide transaction and approved by the board of directors of the transferor) and such license (other than any exclusive license made in connection with a bona fide transaction and approved by the board of directors of the transferor) is not a sale or assignment of the transferor’s Intellectual Property and does not restrict such transferor’s ability to pledge, grant a security in or lien on, or assign or otherwise Transfer any Intellectual Property (other than an otherwise Permitted Transfer), (c) in the case of an exclusive license or a non-exclusive license that must be approved by the board of directors of the transferor, the transferor delivers 10 days prior written notice and a brief summary of the terms of the license to Lender, (d) in the case of an exclusive license or a non-exclusive license that must be approved by the board of directors of the transferor, the transferor delivers to Lender copies of the final executed licensing documents in connection with the license promptly upon consummation of the license, (e) all royalties, milestone payments or other proceeds arising from the licensing agreement are paid to a deposit account that is governed by an Account Control Agreement, and (f) in the case of an exclusive license of EXPAREL in the United States entered into before a Borrower receives at least \$50,000,000 of proceeds from an equity offering, including an Initial Public Offering or strategic partnership financing (which strategic partnership is not related to EXPAREL) or any combination thereof within a 12-month period, Lenders have consented to the terms thereof (or if no such consent is given, then the first proceeds arising out of the license shall be used to repay the Secured Obligations), (iv) dispositions of worn-out, obsolete or surplus Equipment at fair market value in the ordinary course of business, and (v) other Transfers of assets having a fair market value of not more than \$250,000 in the aggregate in any fiscal year.

“Person” means any individual, sole proprietorship, partnership, joint venture, trust, unincorporated organization, association, corporation, limited liability company, institution, other entity or government.

“Preferred Stock” means at any given time any equity security issued by a Borrower that has any rights, preferences or privileges senior to a Borrower’s common stock.

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“Prepayment Charge” shall have the meaning assigned to such term in Section 2.4.

“Prime Rate” means the Prime Rate that appears from time to time in the Western Edition of The Wall Street Journal.

“Receivables” means (i) all of a Borrower’s Accounts, Instruments, Documents, Chattel Paper, Supporting Obligations, letters of credit, proceeds of any letter of credit, and Letter of Credit Rights.

“Royalty Agreements” means, collectively, the Royalty Assignment Agreement, the Royalty Security Agreement, and the Royalty Lockbox Agreement.

“Royalty Assignment Agreement” means the Amended and Restated Royalty Interests Assignment Agreement dated as of March 23, 2007 (as in existence on the date hereof and as certified to Lender by a Borrower, or as amended after the date hereof in accordance with Section 7.4) by and between Pacira CA, as seller, and Royalty Securitization Trust I (the “Trust”) as purchaser, pursuant to which Pacira CA has sold and assigned to Trust the “Assigned Interests” (as defined in the Royalty Assignment Agreement).

“Royalty Collateral” means the “Collateral”, as defined in the Royalty Security Agreement.

“Royalty Lockbox Agreement” means the Amended and Restated Lockbox Agreement dated as of March 23, 2007 (as in existence on the date hereof and as certified to Lender by a Borrower, or as amended in accordance with Section 7.4) by and among [Borrower], Deutsche Bank Trust Company in its capacity as custodian and JPMorgan Chase Bank, N.A.

“Royalty Security Agreement” means the Amended and Restated Security Agreement dated as of March 23, 2007 (as in existence on the date hereof and as certified to Lender by a Borrower, or as amended in accordance with Section 7.4, by and between [Borrower] and Trust, pursuant to which [Borrower] has granted to Trust a security interest in the Royalty Collateral.

“SBA” shall have the meaning assigned to such term in Section 7.15.

“SBIC” shall have the meaning assigned to such term in Section 7.15.

“SBIC Act” shall have the meaning assigned to such term in Section 7.15.

“Secured Obligations” means a Borrower’s obligations under this Agreement and any Loan Document, including any obligation to pay any amount now owing or later arising.

“Subordinated Indebtedness” means Indebtedness subordinated to the Secured Obligations in amounts and on terms and conditions satisfactory to Lender in its sole discretion, including, without limitation, the Indebtedness described on Exhibit A to the Subordination Agreement.

“Subordination Agreement” means the subordination agreement among Borrower, Lender and the Creditors named therein dated as of November 24, 2010.

“Subsequent Financing” means the closing of any equity financing that becomes effective after the Closing Date and before an Initial Public Offering.

“Subsidiary” means an entity, whether corporate, partnership, limited liability company, joint venture or otherwise, in which a Borrower owns or controls 50% or more of the outstanding voting securities, including each entity listed on Schedule 1 hereto.

“Term Loan A Interest Rate” means for any day, the greater of (i) 10.25% or (ii) 10.25% plus the amount by which the Prime Rate exceeds 4.0%.; provided, however, that upon the release of the Guaranty, the Term Loan A Interest Rate will mean for any day thereafter, the greater of (y) 11.0% or (z) 11.0% plus the amount by which the Prime Rate exceeds 4.0%.

“Term Loan B Interest Rate” means for any day, the greater of (i) 12.65% or (ii) 12.65% plus the amount by which the Prime Rate exceeds 4.0%.

“Term Note” means a Promissory Note in substantially the form of Exhibits B and B-1.

“Trademark License” means any written agreement granting any right to use any Trademark or Trademark registration, now owned or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest.

“Trademarks” means all trademarks (registered, common law or otherwise) and any applications in connection therewith, including registrations, recordings and applications in the United States Patent and Trademark Office or in any similar office or agency of the United States, any State thereof or any other country or any political subdivision thereof.

“UCC” means the Uniform Commercial Code as the same is, from time to time, in effect in the State of California; provided, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection or priority of, or remedies with respect to, Lender’s Lien on any Collateral is governed by the Uniform Commercial Code as the same is, from time to time, in effect in a jurisdiction other than the State of California, then the term “UCC” shall mean the Uniform Commercial Code as in effect, from time to time, in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority or remedies and for purposes of definitions related to such provisions.

“Warrant” means the warrant entered into in connection with the Loan.

Unless otherwise specified, all references in this Agreement or any Annex or Schedule hereto to a “Section,” “subsection,” “Exhibit,” “Annex,” or “Schedule” shall refer to the corresponding Section, subsection, Exhibit, Annex, or Schedule in or to this Agreement. Unless otherwise specifically provided herein, any accounting term used in this Agreement or the other Loan Documents shall have the meaning customarily given such term in accordance with GAAP, and all financial computations hereunder shall be computed in accordance with GAAP, consistently applied. Unless otherwise defined herein or in the other Loan Documents, terms that are used herein or in the other Loan Documents and defined in the UCC shall have the meanings given to them in the UCC.

## **SECTION 2. THE LOAN**

### **2.1 Term Loan.**

(a) Advances. Subject to the terms and conditions of this Agreement, on the Closing Date, Lender shall make, and Borrowers shall draw, an Advance of \$11,250,000 (the “Term Loan A Loan”) and an Advance of \$15,000,000 (the “Term Loan B Loan”).

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(b) Advance Request. To obtain an Advance, a Borrower shall complete, sign and deliver an Advance Request and Term Note to Lender. Lender shall fund the Advance in the manner requested by the Advance Request provided that each of the conditions precedent to such Advance is satisfied as of the requested Advance Date.

(c) Interest. The principal balance of each Advance shall bear interest thereon from such Advance Date at the Interest Rate based on a year consisting of 360 days, with interest computed daily based on the actual number of days elapsed. The Interest Rate will float and change on the day the Prime Rate changes from time to time.

(d) Payment. During the Interest Only Period, Borrowers will pay interest on each Advance on the first business day of each month, beginning the month after the Advance Date. Borrowers shall repay the aggregate Term Loan principal balance that is outstanding on the date the Interest Only Period expires in 33 equal monthly installments of principal and interest beginning the first business day of the month after such expiration and continuing on the first business day of each month thereafter. The entire Term Loan principal balance and all accrued but unpaid interest hereunder, shall be due and payable on Maturity Date. Borrowers shall make all payments under this Agreement without setoff, recoupment or deduction and regardless of any counterclaim or defense. Lender will initiate debit entries to the a Borrower's account as authorized on the ACH Authorization on each payment date of all periodic obligations payable to Lender under each Term Note or Advance.

2.2 Maximum Interest. Notwithstanding any provision in this Agreement, the Notes, or any other Loan Document, it is the parties' intent not to contract for, charge or receive interest at a rate that is greater than the maximum rate permissible by law that a court of competent jurisdiction shall deem applicable hereto (which under the laws of the State of California shall be deemed to be the laws relating to permissible rates of interest on commercial loans) (the "Maximum Rate"). If a court of competent jurisdiction shall finally determine that Borrower has actually paid to Lender an amount of interest in excess of the amount that would have been payable if all of the Secured Obligations had at all times borne interest at the Maximum Rate, then such excess interest actually paid by a Borrower shall be applied as follows: first, to the payment of principal outstanding on the Notes; second, after all principal is repaid, to the payment of Lender's accrued interest, costs, expenses, professional fees and any other Secured Obligations; and third, after all Secured Obligations are repaid, the excess (if any) shall be refunded to Borrowers.

2.3 Default Interest. In the event any payment is not paid on the scheduled payment date, an amount equal to five percent (5%) of the past due amount shall be payable on demand. In addition, upon the occurrence and during the continuation of an Event of Default hereunder, all Secured Obligations, including principal, interest, compounded interest, and professional fees, shall bear interest at a rate per annum equal to the rate set forth in Section 2.1(c), plus five percent (5%) per annum. In the event any interest is not paid when due hereunder, delinquent interest shall be added to principal and shall bear interest on interest, compounded at the rate set forth in Section 2.1(c) or Section 2.2, as applicable.

2.4 Prepayment. At its option upon at least 5 business days prior notice to Lender, a Borrower may prepay any part of the outstanding Advances by paying the principal balance, all accrued and unpaid interest, together with a prepayment charge equal to 1.25% of the Advance amount being prepaid (the "Prepayment Charge"), provided (i) at any time the Guaranty is in effect, Borrowers may not prepay any part of the Term Loan A Loan without Lender's prior written consent if any amount is outstanding in respect of the Term Loan B Loan and (ii) at any time the Guaranty is not in effect, any prepayment(s) shall be applied pro rata to the outstanding balances of the Term Loan A Loan and the Term

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Loan B Loan. Borrowers shall pay the Prepayment Charge upon any prepayment of the Secured Obligations arising out of the occurrence of an Event of Default. Borrowers agree that the Prepayment Charge is a reasonable calculation of Lender's lost profits in view of the difficulties and impracticality of determining actual damages resulting from an early repayment of the Advances.

2.5 End of Term Charge. On the earliest to occur of (i) the Maturity Date, (ii) the date that Borrowers prepay the outstanding Secured Obligations in full, or (iii) the due and proper acceleration of the Secured Obligations, Borrowers shall pay Lender a charge of \$630,000. Notwithstanding the required payment date of such charge, it shall be deemed earned by Lender as of the Closing Date.

2.6 Termination of Guaranty. As long as an Event of Default is not then continuing, a Borrower may elect to terminate the Guaranty upon the earliest to occur of (a) a Borrower's receipt after the Closing Date of at least \$75,000,000 in net new cash proceeds in any 12-month period from one or more of an Initial Public Offering, an equity financing, or convertible debt financing or strategic partnership, or any combination thereof, or (b) (i) Borrower's receipt after the Closing Date of at least \$50,000,000 in net new cash proceeds from an Initial Public Offering, equity financing, convertible debt or strategic partnership, or any combination thereof, in any 12-month period, and (ii) the FDA approves EXPAREL or (c) a Borrower completes an Initial Public Offering, and after giving effect thereto, such Borrower has a market capitalization of at least \$400,000,000 and a balance of unrestricted cash (other than Permitted Liens) of at least \$50,000,000. Such termination shall be effective upon Lender's receipt of a Borrower's notice to terminate, together with such evidence as Lender may reasonably request of the satisfaction of the occurrence of any of (a), (b), or (c).

### **SECTION 3. SECURITY INTEREST**

3.1 As security for the prompt, complete payment when due (whether on the payment dates or otherwise) of all the Secured Obligations, each Borrower grants to Lender a security interest in all of such Borrower's personal property now owned or hereafter acquired, including the following (collectively, the "Collateral"): (a) Receivables; (b) Equipment; (c) Fixtures; (d) General Intangibles; (e) Inventory; (f) Investment Property; (g) Deposit Accounts; (h) Cash; (i) Goods; (j) Intellectual Property; and (k) other tangible and intangible personal property of such Borrower whether now or hereafter owned or existing, leased, consigned by or to, or acquired by, such Borrower and wherever located; and, to the extent not otherwise included, all Proceeds of each of the foregoing and all accessions to, substitutions and replacements for, and rents, profits and products of each of the foregoing. Notwithstanding the foregoing, so long as and to the extent that the terms and conditions of the Royalty Agreements prohibit a Borrower from granting a security interest in the Royalty Collateral to Lender (or so long as a default under any Royalty Agreement would result from such grant to Lender), the grant of security interest under this Agreement shall not extend to and the term "Collateral" shall not include (i) the Royalty Collateral and (ii) any deposit accounts of such Borrower that are subject to the Royalty Lockbox Agreement and are dedicated exclusively to the receipt of royalty payments resulting from the license of the DepoDur and DepoCyt products (such deposit accounts, the "Royalty Deposit Accounts"); provided, however, if (x) the Royalty Agreements are terminated or (y) the Royalty Agreements are amended to permit such Borrower to grant a security interest in the Royalty Collateral to Lender, then the grant of security interest under this Agreement shall automatically extend to, and the term "Collateral" shall automatically include, the Royalty Collateral and the Royalty Deposit Accounts. Further, notwithstanding any provision in this Agreement to the contrary, the grant of security interest herein shall not extend to and the term "Collateral" shall not include (all of the following, together with the Royalty Collateral and the Royalty Deposit Accounts, the "Excluded Assets"): (i) more than 65% of the issued and outstanding voting capital stock of any Subsidiary of Borrower that is incorporated or organized in a jurisdiction other than the United States or any state or territory thereof, to the extent that Lender's taking a security interest in more than 65% of

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such stock would cause Borrower to incur adverse tax consequences, (ii) any “intent-to-use” trademarks at all times prior to the first use thereof, whether by the actual use thereof in commerce, the recording of a statement of use with the United States Patent and Trademark Office or otherwise, and (iii) any license or contract to the extent and only to the extent that the granting of a security interest in such license or contract is expressly prohibited by any applicable statute, law, or regulation, or would constitute a default under or a breach of such license or contract, as applicable, but only to the extent that such prohibition or default is enforceable under applicable law (including without limitation Sections 9406, 9407 and 9408 of the UCC); provided that upon the termination or expiration of any such prohibition, such license or contract, as applicable, shall automatically be subject to the security interest granted in favor of Lender hereunder and become part of the “Collateral”.

#### **SECTION 4. CONDITIONS PRECEDENT TO LOAN**

The obligations of Lender to make the Loan hereunder are subject to the satisfaction by Borrowers of the following conditions:

4.1 Advances. On or prior to the Closing Date, Borrowers shall have delivered to Lender the following:

(a) executed originals of the Loan Documents, Account Control Agreements, a legal opinion of Borrowers’ counsel, and all other documents and instruments reasonably required by Lender to effectuate the transactions contemplated hereby or to create and perfect the Liens of Lender with respect to all Collateral, in all cases in form and substance reasonably acceptable to Lender;

(b) certified copy of resolutions of each Borrower’s board of directors evidencing approval of (i) the Loan and other transactions evidenced by the Loan Documents; and (ii) the Warrant and transactions evidenced thereby;

(c) certified copies of the Articles of Incorporation and Certificate of Incorporation and the Bylaws, as amended through the Closing Date, of each Borrower, as applicable;

(d) a certificate of good standing for each Borrower from its state of incorporation and similar certificates from all other jurisdictions in which it does business and where the failure to be qualified would have a Material Adverse Effect;

(e) payment of the Facility Charge and reimbursement of Lender’s current expenses reimbursable pursuant to this Agreement, which amounts may be deducted from the initial Advance;

(f) an Intellectual Property Security Agreement;

(g) the Guaranty;

(h) the Subordination Agreement; and

(i) such other documents as Lender may reasonably request.



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4.2 All Advances. On each Advance Date:

(a) Lender shall have received (i) an Advance Request and a Note for the relevant Advance as required by Section 2.1(b), as applicable, each duly executed by a Borrower's Chief Executive Officer or Chief Financial Officer, and (ii) any other documents Lender may reasonably request.

(b) The representations and warranties set forth in this Agreement and in Section 5 shall be true and correct in all material respects on and as of the Advance Date with the same effect as though made on and as of such date, except to the extent such representations and warranties expressly relate to an earlier date.

(c) Each Borrower shall be in compliance in all material respects with all the terms and provisions set forth herein and in each other Loan Document on its part to be observed or performed, and at the time of and immediately after such Advance no Event of Default shall have occurred and be continuing.

(d) Each Advance Request shall be deemed to constitute a representation and warranty by Borrowers on the relevant Advance Date as to the matters specified in paragraphs (b) and (c) of this Section 4.2 and as to the matters set forth in the Advance Request.

4.3 No Default. As of the Closing Date and each Advance Date, (i) no fact or condition exists that would (or would, with the passage of time, the giving of notice, or both) constitute an Event of Default and (ii) no event that has had or could reasonably be expected to have a Material Adverse Effect has occurred and is continuing.

## **SECTION 5. REPRESENTATIONS AND WARRANTIES OF BORROWER**

Each Borrower represents and warrants that:

5.1 Corporate Status. Such Borrower is a corporation duly organized, legally existing and in good standing under the laws of the State of its incorporation, and is duly qualified as a foreign corporation in all jurisdictions in which the nature of its business or location of its properties require such qualifications and where the failure to be qualified could reasonably be expected to have a Material Adverse Effect. Such Borrower's present name, former names (if any), locations, place of formation, tax identification number, organizational identification number and other information are correctly set forth in Exhibit C, as may be updated by such Borrower in a written notice (including any Compliance Certificate) provided to Lender after the Closing Date.

5.2 Collateral. Such Borrower owns the Collateral free of all Liens, except for Permitted Liens. Such Borrower has the power and authority to grant to Lender a Lien in the Collateral as security for the Secured Obligations.

5.3 Consents; Conflicts. Such Borrower's execution, delivery and performance of the Notes, this Agreement and all other Loan Documents, and Borrower's execution of the Warrant, (i) have been duly authorized by all necessary corporate action of Borrower, (ii) will not result in the creation or imposition of any Lien upon the Collateral, other than Permitted Liens and the Liens created by this Agreement and the other Loan Documents, (iii) do not violate any provisions of Borrower's Certificate or Articles of Incorporation (as applicable), bylaws, or any material law, regulation, order, injunction, judgment, decree or writ to which Borrower is subject and (iv) except as described on Schedule 5.3, do not violate any Material Agreement or require the consent or approval of any other Person. The individual or individuals executing the Loan Documents and the Warrant are duly authorized to do so.

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5.4 Material Adverse Effect. No event that has had or would reasonably be expected to have a Material Adverse Effect has occurred and is continuing. Such Borrower is not aware of any event likely to occur that is reasonably expected to result in a Material Adverse Effect.

5.5 Actions Before Governmental Authorities. Except as described on Schedule 5.5, there are no actions, suits or proceedings at law or in equity or by or before any governmental authority now pending or, to the knowledge of such Borrower, threatened in writing against or affecting such Borrower or its property that, if adversely determined would reasonably be expected to have a Material Adverse Effect.

5.6 Laws. Such Borrower is not in violation of any law, rule or regulation, or in default with respect to any judgment, writ, injunction or decree of any governmental authority, where such violation or default is reasonably expected to result in a Material Adverse Effect. Such Borrower is not in default in any manner under any provision of any agreement or instrument evidencing indebtedness, or any other material agreement to which it is a party or by which it is bound, and which default would reasonably be expected to have a Material Adverse Effect.

5.7 Information Correct and Current. No information, report, Advance Request, financial statement, exhibit or schedule furnished, by or on behalf of a Borrower to Lender in connection with any Loan Document or included therein or delivered pursuant thereto contained, contains or will contain any material misstatement of fact or omitted, omits or will omit to state any material fact necessary to make the statements therein, in the light of the circumstances under which they were, are or will be made, not misleading at the time such statement was made or deemed made. Additionally, any and all financial or business projections provided by such Borrower to Lender shall be (i) provided in good faith and based on the most current data and information available to Borrower, and (ii) the most current of such projections provided to such Borrower's Board of Directors.

5.8 Taxes. Except as described on Schedule 5.8, such Borrower has (a) filed all federal, state and local tax returns that it is required to file, (b) duly paid or fully reserved for all material taxes or installments thereof (including any interest or penalties) as and when due, which have or may become due pursuant to such returns, and (c) paid or fully reserved for any material tax assessment received by Borrower for the three (3) years preceding the Closing Date, if any (including any taxes being contested in good faith and by appropriate proceedings).

5.9 Intellectual Property Claims. Such Borrower is the sole owner of, or otherwise has the right to use, the Intellectual Property. Except as described on Schedule 5.9, (i) each of the material issued Copyrights, Trademarks and Patents is valid and enforceable, (ii) no material part of the Intellectual Property has been judged invalid or unenforceable, in whole or in part, and (iii) no claim has been made to such Borrower that any material part of the Intellectual Property violates the rights of any third party. Exhibit D is a true, correct and complete list of each of Borrower's Patents, registered Trademarks, registered Copyrights, and material agreements under which Borrower licenses Intellectual Property from third parties (other than shrink-wrap software licenses), together with application or registration numbers, as applicable, owned by such Borrower or any Subsidiary, in each case as of the Closing Date. Such Borrower is not in material breach of, nor has such Borrower failed to perform any material obligations under, any of the foregoing contracts, licenses or agreements and, to such Borrower's knowledge, no third party to any such contract, license or agreement is in material breach thereof or has failed to perform any material obligations thereunder.

5.10 Intellectual Property. Except as described on Schedule 5.10, such Borrower has, or in the case of any proposed business, will have, all material rights with respect to Intellectual Property

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necessary in the operation or conduct of such Borrower's business as currently conducted and proposed to be conducted by such Borrower. Without limiting the generality of the foregoing, and in the case of Licenses, except for restrictions that are unenforceable under Division 9 of the UCC, - and except as described on Schedule 5.10, Borrower has the right, to the extent required to operate such Borrower's business, to freely transfer, license or assign Intellectual Property without condition, restriction or payment of any kind (other than license payments in the ordinary course of business) to any third party, and Borrower owns or has the right to use, pursuant to valid licenses, all software development tools, library functions, compilers and all other third-party software and other items that are used in the design, development, promotion, sale, license, manufacture, import, export, use or distribution of Borrower Products.

5.11 Borrower Products. Except as described on Schedule 5.11, no Intellectual Property owned by such Borrower or Borrower Product has been or is subject to any actual or, to the knowledge of such Borrower, threatened litigation, proceeding (including any proceeding in the United States Patent and Trademark Office or any corresponding foreign office or agency) or outstanding decree, order, judgment, settlement agreement or stipulation that restricts in any manner such Borrower's use, transfer or licensing thereof or that may affect the validity, use or enforceability thereof. There is no decree, order, judgment, agreement, stipulation, arbitral award or other provision entered into in connection with any litigation or proceeding that obligates such Borrower to grant licenses or ownership interest in any future Intellectual Property related to the operation or conduct of the business of Borrower or Borrower Products. Such Borrower has not received any written notice or claim, or, to the knowledge of Borrower, oral notice or claim, challenging or questioning such Borrower's ownership in any Intellectual Property (or written notice of any claim challenging or questioning the ownership in any licensed Intellectual Property of the owner thereof) or suggesting that any third party has any claim of legal or beneficial ownership with respect thereto nor, to such Borrower's knowledge, is there a reasonable basis for any such claim. Neither such Borrower's use of its Intellectual Property nor the production and sale of Borrower Products infringes the Intellectual Property or other rights of others.

5.12 Financial Accounts. Exhibit E, as may be updated by the Borrowers in a written notice provided to Lender after the Closing Date, is a true, correct and complete list of (a) all banks and other financial institutions at which a Borrower or any Subsidiary maintains Deposit Accounts and (b) all institutions at which such Borrower or any Subsidiary maintains an account holding Investment Property, and such exhibit correctly identifies the name, address and telephone number of each bank or other institution, the name in which the account is held, a description of the purpose of the account, and the complete account number therefor.

5.13 Employee Loans. Except as permitted by Section 7.8, such Borrower has no outstanding loans to any employee, officer or director of such Borrower nor has such Borrower guaranteed the payment of any loan made to an employee, officer or director of such Borrower by a third party.

5.14 Capitalization and Subsidiaries. Each Borrower's capitalization as of the Closing Date is set forth on Schedule 5.14 annexed hereto. No Borrower owns any stock, partnership interest or other securities of any Person, except for Permitted Investments. Attached as Schedule 5.14, as may be updated by a Borrower in a written notice provided after the Closing Date, is a true, correct and complete list of each Subsidiary.

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## **SECTION 6. INSURANCE; INDEMNIFICATION**

6.1 Coverage. Each Borrower shall cause to be carried and maintained commercial general liability insurance, on an occurrence form, against risks customarily insured against in such Borrower's line of business. Such risks shall include the risks of bodily injury, including death, property damage, personal injury, advertising injury, and contractual liability per the terms of the indemnification agreement found in Section 6.3. Each Borrower shall maintain a minimum of \$2,000,000 of commercial general liability insurance for each occurrence. Each Borrower has and shall maintain a minimum of \$2,000,000 of directors and officers' insurance for each occurrence and \$5,000,000 in the aggregate. So long as there are any Secured Obligations outstanding, such Borrower shall also cause to be carried and maintained insurance upon the Collateral, insuring against all risks of physical loss or damage howsoever caused, in an amount not less than the full replacement cost of the Collateral, provided that such insurance may be subject to standard exceptions and deductibles. Borrower shall also carry and maintain a fidelity insurance policy in an amount not less than \$100,000.

6.2 Certificates. Each Borrower shall deliver to Lender certificates of insurance that evidence such Borrower's compliance with its insurance obligations in Section 6.1 and the obligations contained in this Section 6.2. Such Borrower's insurance certificate shall state Lender is an additional insured for commercial general liability, an additional insured and a loss payee for all risk property damage insurance, subject to the insurer's approval, a loss payee for fidelity insurance, and a loss payee for property insurance and additional insured for liability insurance for any future insurance that such Borrower may acquire from such insurer. Attached to the certificates of insurance will be additional insured endorsements for liability and lender's loss payable endorsements for all risk property damage insurance and fidelity. All certificates of insurance will provide for a minimum of thirty (30) days advance written notice to Lender of cancellation or any other change adverse to Lender's interests (except with respect to non-payment, in which case 10 days advance notice is sufficient). Any failure of Lender to scrutinize such insurance certificates for compliance is not a waiver of any of Lender's rights, all of which are reserved.

6.3 Indemnity. Each Borrower agrees to indemnify and hold Lender and its officers, directors, employees, agents, in-house attorneys, representatives and shareholders (each, an Indemnitee") harmless from and against any and all claims, costs, expenses, damages and liabilities (including such claims, costs, expenses, damages and liabilities based on liability in tort, including strict liability in tort), including reasonable attorneys' fees and disbursements and other costs of investigation or defense (including those incurred upon any appeal), that may be instituted or asserted against or incurred by an Indemnitee as the result of credit having been extended, suspended or terminated under this Agreement and the other Loan Documents or the administration of such credit, or in connection with or arising out of the transactions contemplated hereunder and thereunder, or any actions or failures to act in connection therewith, or arising out of the disposition or utilization of the Collateral, excluding in all cases claims resulting from the Indemnitee's gross negligence or willful misconduct, as determined by a final judgment of a court of competent jurisdiction. In no event shall any Indemnitee be liable on any theory of liability for any special, indirect, consequential or punitive damages. Borrower agrees to pay, and to save Lender harmless from, any and all liabilities with respect to, or resulting from any delay in paying, any and all excise, sales or other similar taxes (excluding taxes imposed on or measured by the net income of Lender) that may be payable or determined to be payable with respect to any of the Collateral or this Agreement; provided, however, that (i) with respect to such liabilities imposed originally and independently on Lenders, Lenders shall notify a Borrower of any such liabilities within 180 days of the initial date Lenders had actual knowledge, or should have had knowledge, of a Lender's direct exposure to such liabilities, and (ii) with respect to all other such liabilities not described in subsection (i), Lenders shall notify Borrower of any such liabilities within 180 days of the initial date a Lender has actual knowledge of its direct exposure to such liabilities.

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## **SECTION 7. COVENANTS OF BORROWER**

Each Borrower agrees as follows:

7.1 Financial Reports. Such Borrower shall furnish the following to Lender:

(a) As soon as practicable (and in any event within 30 days) after the end of each month, unaudited interim and year-to-date financial statements as of the end of such month (prepared on a consolidated and consolidating basis, if applicable), including balance sheet and related statements of income and cash flows accompanied by a report detailing any material contingencies (including the commencement of any material litigation by or against such Borrower) or any other occurrence that would reasonably be expected to have a Material Adverse Effect, all certified by such Borrower's Chief Executive Officer or Chief Financial Officer to the effect that they have been prepared in accordance with GAAP, except (i) for the absence of footnotes, (ii) that they are subject to normal year end adjustments, and (iii) they do not contain certain non-cash items that are customarily included in quarterly and annual financial statements;

(b) As soon as practicable (and in any event within 45 days) after the end of each calendar quarter, unaudited interim and year-to-date financial statements as of the end of such calendar quarter (prepared on a consolidated and consolidating basis, if applicable), including balance sheet and related statements of income and cash flows accompanied by a report detailing any material contingencies (including the commencement of any material litigation by or against such Borrower) or any other occurrence that would reasonably be expected to have a Material Adverse Effect, certified by such Borrower's Chief Executive Officer or Chief Financial Officer to the effect that they have been prepared in accordance with GAAP, except (i) for the absence of footnotes, and (ii) that they are subject to normal year end adjustments;

(c) as soon as practicable, and in any event within 150 days (90 days if Borrower is required to file reports under the Securities Exchange Act of 1934, as amended) after the end of each fiscal year, unqualified audited financial statements as of the end of such year (prepared on a consolidated and consolidating basis, if applicable), including balance sheet and related statements of income and cash flows, and setting forth in comparative form the corresponding figures for the preceding fiscal year, certified by a firm of independent certified public accountants selected by Borrower and reasonably acceptable to Lender, accompanied by any management report from such accountants;

(d) as soon as practicable (and in any event within 30 days) after the end of each calendar month and calendar quarter, a Compliance Certificate in the form of Exhibit F;

(e) promptly after the sending or filing thereof, as the case may be, copies of any proxy statements, financial statements or reports that Borrower has made available to holders of its Preferred Stock and copies of any regular, periodic and special reports or registration statements that Borrower files with the Securities and Exchange Commission or any governmental authority that may be substituted therefor, or any national securities exchange;

(f) before the Initial Public Offering, promptly following the delivery of the same to its directors, copies of all notices, minutes, consents and other materials that Borrower provides to its directors in connection with meetings of the Board of Directors, and minutes of such meeting, provided Borrower may exclude from such delivery any materials, the disclosure of which could constitute or effect a waiver of the attorney-client privilege; and

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(g) financial and business projections, as well as budgets, operating plans and other financial information reasonably requested by Lender.

The executed Compliance Certificate may be sent via facsimile to Lender at (650) 473-9194 or via e-mail to pshah@herculestech.com. All Financial Statements required to be delivered pursuant to clauses (a), (b) and (c) shall be sent via e-mail to financialstatements@herculestech.com with a copy to pshah@herculestech.com provided, that if e-mail is not available or sending such Financial Statements via e-mail is not possible, they shall be sent via facsimile to Lender at: (866) 468-8916, attention Chief Credit Officer.

7.2 Management Rights. Each Borrower shall permit any representative that Lender authorizes, including its attorneys and accountants, to inspect the Collateral and examine and make copies and abstracts of the books of account and records of such Borrower at reasonable times and upon reasonable notice during normal business hours (but in any event no more than twice in any 12-month period unless an Event of Default has occurred and is continuing). In addition, any such representative shall have the right to meet with management and officers of such Borrower to discuss such books of account and records. In addition, Lender shall be entitled at reasonable times and intervals to consult with and advise the management and officers of such Borrower concerning significant business issues affecting Borrower. Such consultations shall not unreasonably interfere with Borrower's business operations. The parties intend that the rights granted Lender shall constitute "management rights" within the meaning of 29 C.F.R Section 2510.3-101(d)(3)(ii), but that any advice, recommendations or participation by Lender with respect to any business issues shall not be deemed to give Lender, nor be deemed an exercise by Lender of, control over Borrower's management or policies.

7.3 Further Assurances. Each Borrower shall from time to time execute, deliver and file, alone or with Lender, any financing statements, security agreements, collateral assignments, notices, control agreements, or other necessary documents to perfect or give the highest priority to Lender's Lien on the Collateral (subject to Permitted Liens). Each Borrower shall from time to time procure any instruments or documents as may be requested by Lender, and take all further action that may be necessary or desirable, or that Lender may reasonably request, to perfect and protect the Liens granted hereby and thereby. In addition, and for such purposes only, such Borrower authorizes Lender to execute and deliver on behalf of Borrower and to file such financing statements, collateral assignments, notices, control agreements, security agreements and other documents without the signature of Borrower either in Lender's name or in the name of Lender as agent and attorney-in-fact for Borrower. Borrower shall, in its reasonable business judgment, protect and defend Borrower's title to the Collateral and Lender's Lien thereon against all Persons claiming any interest adverse to Borrower or Lender other than Permitted Liens.

7.4 Amendments to Other Agreements. No Borrower may amend, modify or waive any provision of (a) any Royalty Agreement to modify (i) the scope of the Royalty Collateral or (ii) Section 5.11(c)(iv) of the Royalty Assignment Agreement, (b) any of Borrower's organizational documents, unless the net effect of such amendment, modification or waiver is not adverse in any material respect to Borrower or Lender (it being agreed for the avoidance of doubt that any amendment or modification to the organization documents of Borrower to permit the issuance of equity on terms and conditions that are not prohibited under this Agreement shall not be considered adverse to Borrower or Lender), or (c) any document relating to any of the Subordinated Indebtedness, in each case, without the prior written consent of Lender. For clarity, this Section does not restrict conversion of any Subordinated Indebtedness into equity, or any amendment to the organization documents of Borrower to increase the number of authorized shares of Borrower, in each case in connection with the IPO.

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7.5 Indebtedness. Such Borrower shall not create, incur, assume, guarantee or be or remain liable with respect to any Indebtedness, or permit any Subsidiary so to do, other than Permitted Indebtedness, or prepay any Indebtedness or take any actions which impose on such Borrower an obligation to prepay any Indebtedness, except for the conversion of Indebtedness into equity securities and the payment of cash in lieu of fractional shares in connection with such conversion.

7.6 Collateral. Such Borrower shall at all times keep the Collateral and all other property and assets used in such Borrower's business or in which such Borrower now or hereafter holds any interest free and clear from any legal process or Liens whatsoever (except for Permitted Liens), and shall give Lender prompt written notice of any legal process affecting the Collateral, such other property and assets, or any Liens thereon. Such Borrower shall cause its Subsidiaries to protect and defend such Subsidiary's title to its assets from and against all Persons claiming any interest adverse to such Subsidiary, and such Borrower shall cause its Subsidiaries at all times to keep such Subsidiary's property and assets free and clear from any legal process or Liens whatsoever (except for Permitted Liens), and shall give Lender prompt written notice of any legal process affecting such Subsidiary's assets. Such Borrower shall not enter into any agreement (other than the Royalty Agreements, Permitted Licenses and Permitted Transfers) in which a negative pledge in the Intellectual Property is granted to any Person other than Lender.

7.7 Investments. Such Borrower shall not directly or indirectly acquire or own, or make any Investment in or to any Person, or permit any of its Subsidiaries so to do, other than Permitted Investments.

7.8 Restricted Payments. Such Borrower shall not, and shall not allow any Subsidiary to, (a) repurchase or redeem any class of stock or other equity interest other than pursuant to employee, director or consultant repurchase plans or other similar agreements, provided, however, in each case the repurchase or redemption price does not exceed the original consideration paid for such stock or equity interest, and in any case does not exceed \$200,000 in any fiscal year for all such repurchases or redemptions, or (b) declare or pay any cash dividend or make a cash distribution on any class of stock or other equity interest, except that a Subsidiary may pay dividends or make distributions to Borrower, or (c) lend money to any employees, officers or directors or guarantee the payment of any such loans granted by a third party in excess of \$100,000 in the aggregate or (d) waive, release or forgive any indebtedness owed by any employees, officers or directors in excess of \$100,000 in the aggregate, or (e) make any payments to the Trust other than scheduled periodic payments required to be made pursuant to the terms and conditions of the Royalty Assignment Agreement, or (f) permit any Subsidiary to be a party to, or bound by, any agreement that restricts such Subsidiary from paying dividends or otherwise distributing property to Borrower.

7.9 Transfers. Except for Permitted Transfers, such Borrower shall not voluntarily or involuntarily transfer, sell, lease, license, lend or in any other manner convey any equitable, beneficial or legal interest in any material portion of their assets.

7.10 Mergers or Acquisitions. Such Borrower shall not merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with or into any other business organization (other than mergers or consolidations of a Subsidiary into another Subsidiary or into Borrower), or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the capital stock or property of another Person.

7.11 Taxes. Such Borrower and its Subsidiaries shall pay when due all taxes, fees or other charges of any nature whatsoever (together with any related interest or penalties) now or hereafter imposed or assessed against such Borrower, Lender or the Collateral or upon Borrower's ownership,

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possession, use, operation or disposition thereof or upon Borrower's rents, receipts or earnings arising therefrom. Borrower shall file on or before the due date therefor all personal property tax returns in respect of the Collateral. Notwithstanding the foregoing, Borrower may contest, in good faith and by appropriate proceedings, taxes for which Borrower maintains adequate reserves therefor in accordance with GAAP.

7.12 Corporate Changes. Neither Borrower nor any Subsidiary shall change its corporate name, legal form or jurisdiction of formation without 10 days' prior written notice to Lender. Neither Borrower nor any Subsidiary shall suffer a Change in Control. Neither Borrower nor any Subsidiary shall relocate its chief executive office or its principal place of business unless: (i) it has provided prior written notice to Lender; and (ii) such relocation shall be within the continental United States. Neither Borrower nor any Subsidiary shall relocate any item of Collateral (other than (w) Permitted Transfers, (x) sales of Inventory in the ordinary course of business, (y) relocations of Equipment having an aggregate value of up to \$150,000 in any fiscal year, (z) relocations of Collateral from a location described on Exhibit C to another location described on Exhibit C) unless (i) it has provided prompt written notice to Lender, (ii) such relocation is within the continental United States and, (iii) if such relocation is to a third party bailee, it has delivered a bailee agreement in form and substance reasonably acceptable to Lender.

7.13 Deposit Accounts. Neither Borrower nor any Subsidiary shall maintain any Deposit Accounts, or accounts holding Investment Property, except (i) with respect to which Lender has an Account Control Agreement and (ii) constituting Royalty Accounts.

7.14 Subsidiaries. Such Borrower shall notify Lender of each Subsidiary formed subsequent to the Closing Date and, within 15 days of formation, shall cause any such Subsidiary organized under the laws of any State within the United States to execute and deliver to Lender a Joinder Agreement.

7.15 Compliance. Such Borrower shall not, and Borrower shall not permit any of its Subsidiaries to, fail to comply in any material respect with, or violate in any material respect, any law or regulation applicable to it.

7.16 SBA. Lender has received a license from the U.S. Small Business Administration ("SBA") to extend loans as a small business investment company ("SBIC") pursuant to the Small Business Investment Act of 1958, as amended, and the associated regulations (collectively, the "SBIC Act"). Portions of the loan to Borrower will be made under the SBA license and the SBIC Act. Addendum 1 to this Agreement outlines various responsibilities of Lender and Borrower associated with an SBA loan, and such Addendum 1 is hereby incorporated in this Agreement.

7.17 EXPAREL. By December 14, 2010, Borrower shall deliver to Lenders written confirmation by the FDA of its acceptance of the EXPAREL New Drug Application.

## **SECTION 8. RIGHT TO INVEST**

8.1 Subject to applicable securities laws and regulatory requirements, Lender or its assignee or nominee shall have the right, in its discretion, to participate in any Subsequent Financing in an amount of up to \$2,000,000 in the aggregate for all Subsequent Financings (provided Lender shall have the same right to participate pro rata in future financings as are granted to other investors in a Subsequent Financing in which Lender participated) on the same terms, conditions and pricing afforded to others participating in any such Subsequent Financing.



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## SECTION 9. EVENTS OF DEFAULT

The occurrence of any one or more of the following events shall be an Event of Default:

9.1 Payments. A Borrower fails to pay any amount due under this Agreement, the Notes or any of the other Loan Documents on the due date, and in each case such default continues for more than 3 business days after the due date thereof; or

9.2 Covenants. A Borrower breaches or defaults in the performance of any covenant or Secured Obligation under this Agreement, the Notes, or any of the other Loan Documents, and (a) with respect to a default under any covenant under this Agreement (other than under Sections 6, 7.5, 7.6, 7.7, 7.8 or 7.9) such default continues for more than ten (10) business days after the earlier of the date on which (i) Lender has given notice of such default to a Borrower and (ii) a Borrower has actual knowledge of such default or (b) with respect to a default under any of Sections 6, 7.5, 7.6, 7.7, 7.8 or 7.9, the occurrence of such default; or

9.3 Material Adverse Effect. A circumstance has occurred that would reasonably be expected to have a Material Adverse Effect; or

9.4 Other Loan Documents. The occurrence of any default under any Loan Document or any other agreement between Borrower and Lender and such default continues for more than ten (10) days after the earlier of (a) Lender has given notice of such default to a Borrower, or (b) a Borrower has actual knowledge of such default; or

9.5 Representations. Any representation or warranty made by a Borrower in any Loan Document or in the Warrant shall have been false or misleading in any material respect when made; or

9.6 Insolvency. A Borrower (A) (i) shall make an assignment for the benefit of creditors; or (ii) shall be unable to pay its debts as they become due, or be unable to pay or perform under the Loan Documents; or (iii) shall file a voluntary petition in bankruptcy; or (iv) shall file any petition, answer, or document seeking for itself any reorganization, arrangement, composition, readjustment, liquidation, dissolution or similar relief under any present or future statute, law or regulation pertinent to such circumstances; or (v) shall seek or consent to or acquiesce in the appointment of any trustee, receiver, or liquidator of a Borrower or of all or any substantial part (i.e., 33 1/3% or more) of the assets or property of Borrower; or (vi) shall cease operations of its business as its business has normally been conducted for 3 consecutive business days, or terminate substantially all of its employees; or (vii) a Borrower or its directors or majority shareholders shall take any action initiating any of the foregoing actions described in clauses (i) through (vi); or (B) either (i) thirty (30) days shall have expired after the commencement of an involuntary action against a Borrower seeking reorganization, arrangement, composition, readjustment, liquidation, dissolution or similar relief under any present or future statute, law or regulation, without such action being dismissed or all orders or proceedings thereunder affecting the operations or the business of a Borrower being stayed; or (ii) a stay of any such order or proceedings shall thereafter be set aside and the action setting it aside shall not be timely appealed; or (iii) a Borrower shall file any answer admitting or not contesting the material allegations of a petition filed against Borrower in any such proceedings; or (iv) the court in which such proceedings are pending shall enter a decree or order granting the relief sought in any such proceedings; or (v) thirty (30) days shall have expired after the appointment, without the consent or acquiescence of a Borrower, of any trustee, receiver or liquidator of Borrower or of all or any substantial part of the properties of Borrower without such appointment being vacated, or (C) a Borrower becomes insolvent; or

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9.7 Attachments: Judgments. Any portion of a Borrower's assets having a value in excess of \$250,000 is attached or seized, or a levy is filed against any such assets, or a judgment or judgments is/are entered for the payment of money, individually or in the aggregate, of at least \$500,000, or a Borrower is enjoined or in any way prevented by court order from conducting any material part of its business; or

9.8 Other Obligations. The occurrence of any default under any agreement or obligation of a Borrower involving any Indebtedness in excess of \$500,000, or the occurrence of any default under any agreement or obligation of Borrower that could reasonably be expected to have a Material Adverse Effect; or

9.9 Royalty Agreements. A "Purchase Option Event", as defined in the Royalty Assignment Agreement, shall have occurred and the Trust shall have commenced the exercise of the purchase option pursuant to Section 5.07 of the Royalty Assignment Agreement (or the Trust shall have given written notice to a Borrower of its intention to exercise such purchase option), or any "Event of Default", as such term is defined in the Royalty Security Agreement, shall have occurred and the Trust shall have commenced the exercise of remedies under the Royalty Security Agreement (or the Trust shall have given written notice to a Borrower of its intention to exercise such remedies); or

9.10 Guaranty: Subordination Agreement. Any of the circumstances set forth in Section 9.6 shall exist in respect of any Guarantor, or if any Guarantor breaches any of its obligations under the Guaranty (and the expiration of any cure period under this Section 9 applicable to a comparable breach), or if any provision of the Guaranty shall fail to be valid and binding on, or enforceable against, a Guarantor, or if any subordination provision set forth in the Subordination Agreement shall, in whole or in part, terminate or otherwise fail or cease to be valid and binding on, or enforceable against, any agent for or holder of the Subordinated Indebtedness (or such person shall so state in writing).

## **SECTION 10. REMEDIES**

10.1 General. Upon and during the continuance of any one or more Events of Default, (i) Lender may, at its option, accelerate and demand payment of all or any part of the Secured Obligations together with a Prepayment Charge and declare them to be immediately due and payable (provided, that upon the occurrence of an Event of Default of the type described in Section 9.6, the Notes and all of the Secured Obligations shall automatically be accelerated and made due and payable, in each case without any further notice or act), and (ii) Lender may notify any of a Borrower's account debtors to make payment directly to Lender, compromise the amount of any such account on a Borrower's behalf and endorse Lender's name without recourse on any such payment for deposit directly to Lender's account. Lender may exercise all rights and remedies with respect to the Collateral under the Loan Documents or otherwise available to it under the UCC and other applicable law, including the right to release, hold, sell, lease, liquidate, collect, realize upon, or otherwise dispose of all or any part of the Collateral and the right to occupy, utilize, process and commingle the Collateral. All Lender's rights and remedies shall be cumulative and not exclusive.

10.2 Collection: Foreclosure. Upon the occurrence and during the continuance of any Event of Default, Lender may, at any time or from time to time, apply, collect, liquidate, sell in one or more sales, lease or otherwise dispose of, any or all of the Collateral, in its then condition or following any commercially reasonable preparation or processing, in such order as Lender may elect. Any such sale may be made either at public or private sale at its place of business or elsewhere. Each Borrower agrees that any such public or private sale may occur upon ten (10) calendar days' prior written notice to Borrower. Lender may require Borrower to assemble the Collateral and make it available to Lender at a

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place designated by Lender that is reasonably convenient to Lender and Borrower. The proceeds of any sale, disposition or other realization upon all or any part of the Collateral shall be applied by Lender in the following order of priorities:

First, to Lender in an amount sufficient to pay in full Lender's costs and professionals' and advisors' fees and expenses;

Second, to Lender in an amount equal to the then unpaid amount of the Secured Obligations (including principal, interest, and the Default Rate interest), in such order and priority as Lender may choose in its sole discretion; and

Finally, after the full and final payment in Cash of all of the Secured Obligations, to any creditor holding a junior Lien on the Collateral, or to a Borrower or its representatives or as a court of competent jurisdiction may direct.

Lender shall be deemed to have acted reasonably in the custody, preservation and disposition of any of the Collateral if it complies with the obligations of a secured party under the UCC.

10.3 No Waiver. Lender shall be under no obligation to marshal any of the Collateral for the benefit of Borrower or any other Person, and each Borrower waives all rights, if any, to require Lender to marshal any Collateral.

10.4 Cumulative Remedies. The rights, powers and remedies of Lender hereunder shall be in addition to all rights, powers and remedies given by statute or rule of law and are cumulative. The exercise of any one or more of the rights, powers and remedies provided herein shall not be construed as a waiver of or election of remedies with respect to any other rights, powers and remedies of Lender.

## **SECTION 11. MISCELLANEOUS**

11.1 Severability. Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement shall be prohibited by or invalid under such law, such provision shall be ineffective only to the extent and duration of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Agreement.

11.2 Notice. Except as otherwise provided herein, any notice, demand, request, consent, approval, declaration, service of process or other communication (including the delivery of Financial Statements) that is required, contemplated, or permitted under the Loan Documents or with respect to the subject matter hereof shall be in writing, and shall be deemed to have been validly served, given, delivered, and received upon the earlier of: (i) the day of transmission by facsimile or hand delivery or delivery by an overnight express service or overnight mail delivery service; or (ii) the third calendar day after deposit in the United States mails, with proper first class postage prepaid, in each case addressed to the party to be notified as follows:

(a) If to Lender:

HERCULES TECHNOLOGY GROWTH CAPITAL, INC.  
HERCULES TECHNOLOGY III, L.P.  
Legal Department  
Attention: Chief Legal Officer and Parag Shah  
400 Hamilton Avenue, Suite 310  
Palo Alto, CA 94301  
Facsimile: 650-473-9194  
Telephone: 650-289-3068

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(b) If to a Borrower:

PACIRA PHARMACEUTICALS, INC.

Attention: Mr. James Scibetta

5 Sylvan Way

Parsippany, NJ 07054

Facsimile:

Telephone:

or to such other address as each party may designate for itself by like notice.

11.3 Entire Agreement: Amendments. This Agreement, the Notes, and the other Loan Documents constitute the entire agreement and understanding of the parties hereto in respect of the subject matter hereof and thereof, and supersede and replace in their entirety any prior proposals, term sheets, letters, negotiations or other documents or agreements, whether written or oral, with respect to the subject matter hereof or thereof (including Lender's revised proposal letter dated October 27, 2010). None of the terms of this Agreement, the Notes or any of the other Loan Documents may be amended except by an instrument executed by each of the parties hereto.

11.4 No Strict Construction. The parties hereto have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the parties hereto and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any provisions of this Agreement.

11.5 No Waiver. The powers conferred upon Lender by this Agreement are solely to protect its rights hereunder and under the other Loan Documents and its interest in the Collateral and shall not impose any duty upon Lender to exercise any such powers. No omission or delay by Lender at any time to enforce any right or remedy reserved to it, or to require performance of any of the terms, covenants or provisions hereof by a Borrower at any time designated, shall be a waiver of any such right or remedy to which Lender is entitled, nor shall it in any way affect the right of Lender to enforce such provisions thereafter.

11.6 Survival. All agreements, representations and warranties contained in this Agreement, the Notes and the other Loan Documents or in any document delivered pursuant hereto or thereto shall be for the benefit of Lender and shall survive the execution and delivery of this Agreement and the expiration or other termination of this Agreement.

11.7 Successors and Assigns. The provisions of this Agreement and the other Loan Documents shall inure to the benefit of and be binding on Borrower and its permitted assigns (if any). No Borrower may assign its obligations under this Agreement, the Notes or any of the other Loan Documents without Lender's express prior written consent, and any such attempted assignment shall be void and of no effect. Lender may assign, transfer, or endorse its rights hereunder and under the other Loan Documents without prior notice to Borrowers, and all of such rights shall inure to the benefit of Lender's successors and assigns.

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11.8 Governing Law. This Agreement, the Notes and the other Loan Documents have been negotiated and delivered to Lender in the State of California, and shall have been accepted by Lender in the State of California. Payment to Lender by a Borrower of the Secured Obligations is due in the State of California. This Agreement, the Notes and the other Loan Documents shall be governed by, and construed and enforced in accordance with, the laws of the State of California, excluding conflict of laws principles that would cause the application of laws of any other jurisdiction.

11.9 Consent to Jurisdiction and Venue. All judicial proceedings (to the extent that the reference requirement of Section 11.10 is not applicable) arising in or under or related to this Agreement, the Notes or any of the other Loan Documents may be brought in any state or federal court located in the State of California. By execution and delivery of this Agreement, each party hereto generally and unconditionally: (a) consents to nonexclusive personal jurisdiction in Santa Clara County, State of California; (b) waives any objection as to jurisdiction or venue in Santa Clara County, State of California; (c) agrees not to assert any defense based on lack of jurisdiction or venue in the aforesaid courts; and (d) irrevocably agrees to be bound by any judgment rendered thereby in connection with this Agreement, the Notes or the other Loan Documents. Service of process on any party hereto in any action arising out of or relating to this Agreement shall be effective if given in accordance with the requirements for notice set forth in Section 11.2, and shall be deemed effective and received as set forth in Section 11.2. Nothing herein shall affect the right to serve process in any other manner permitted by law or shall limit the right of either party to bring proceedings in the courts of any other jurisdiction.

11.10 Mutual Waiver of Jury Trial / Judicial Reference.

(a) Because disputes arising in connection with complex financial transactions are most quickly and economically resolved by an experienced and expert person and the parties wish applicable state and federal laws to apply (rather than arbitration rules), the parties desire that their disputes be resolved by a judge applying such applicable laws. EACH BORROWER AND LENDER SPECIFICALLY WAIVES ANY RIGHT IT MAY HAVE TO TRIAL BY JURY OF ANY CAUSE OF ACTION, CLAIM, CROSS-CLAIM, COUNTERCLAIM, THIRD PARTY CLAIM OR ANY OTHER CLAIM (COLLECTIVELY, "CLAIMS") ASSERTED BY BORROWER AGAINST LENDER OR ITS ASSIGNEE OR BY LENDER OR ITS ASSIGNEE AGAINST BORROWER. This waiver extends to all such Claims, including Claims that involve Persons other than a Borrower and Lender; Claims that arise out of or are in any way connected to the relationship between a Borrower and Lender; and any Claims for damages, breach of contract, tort, specific performance, or any equitable or legal relief of any kind, arising out of this Agreement, any other Loan Document.

(b) If the waiver of jury trial set forth in Section 11.10(a) is ineffective or unenforceable, the parties agree that all Claims shall be resolved by reference to a private judge sitting without a jury, pursuant to Code of Civil Procedure Section 638, before a mutually acceptable referee or, if the parties cannot agree, a referee selected by the Presiding Judge of the Santa Clara County, California. Such proceeding shall be conducted in Santa Clara County, California, with California rules of evidence and discovery applicable to such proceeding.

(c) In the event Claims are to be resolved by judicial reference, either party may seek from a court identified in Section 11.9, any prejudgment order, writ or other relief and have such prejudgment order, writ or other relief enforced to the fullest extent permitted by law notwithstanding that all Claims are otherwise subject to resolution by judicial reference.

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11.11 Professional Fees. Each Borrower promises to pay Lender's fees and expenses necessary to finalize the loan documentation, including but not limited to reasonable attorneys fees, UCC searches, filing costs, and other miscellaneous expenses. In addition, Borrower promises to pay any and all reasonable attorneys' and other professionals' fees and expenses (including fees and expenses of in-house counsel) incurred by Lender after the Closing Date in connection with or related to: (a) the Loan; (b) the administration, collection, or enforcement of the Loan; (c) the amendment or modification of the Loan Documents; (d) any waiver, consent, release, or termination under the Loan Documents; (e) the protection, preservation, sale, lease, liquidation, or disposition of Collateral or the exercise of remedies with respect to the Collateral; (f) any legal, litigation, administrative, arbitration, or out of court proceeding in connection with or related to Borrower or the Collateral, and any appeal or review thereof; and (g) any bankruptcy, restructuring, reorganization, assignment for the benefit of creditors, workout, foreclosure, or other action related to Borrower, the Collateral, the Loan Documents, including representing Lender in any adversary proceeding or contested matter commenced or continued by or on behalf of Borrower's estate, and any appeal or review thereof.

11.12 Publicity. Lender may use a Borrower's name and logo, and include a brief description of the relationship between such Borrower and Lender, in Lender's marketing materials provided such use does not violate the Securities Act and provided Borrower has consented to such use at all times prior to the Initial Public Offering, such consent not to be unreasonably withheld.

11.13 Confidentiality. Lender acknowledges that certain items of Collateral and information provided to Lender by a Borrower are confidential and proprietary information of Borrower, if and to the extent such information either (x) is marked as confidential by Borrower at the time of disclosure, or (y) should reasonably be understood to be confidential (the "Confidential Information"). Accordingly, Lender agrees that any Confidential Information it may obtain in the course of acquiring, administering, or perfecting Lender's security interest in the Collateral shall not be disclosed to any other person or entity in any manner whatsoever, in whole or in part, without the prior written consent of such Borrower, except that Lender may disclose any such information: (a) to its own directors, officers, employees, accountants, counsel and other professional advisors and to its affiliates if Lender in its sole discretion determines that any such party should have access to such information in connection with such party's responsibilities in connection with the Loan or this Agreement and, provided that such recipient of such Confidential Information either (i) agrees to be bound by the confidentiality provisions of this paragraph or (ii) is otherwise subject to confidentiality restrictions that reasonably protect against the disclosure of Confidential Information; (b) if such information is generally available to the public; (c) if required or appropriate in any report, statement or testimony submitted to any governmental authority having or claiming to have jurisdiction over Lender; (d) if required or appropriate in response to any summons or subpoena or in connection with any litigation, to the extent permitted or deemed advisable by Lender's counsel; (e) to comply with any legal requirement or law applicable to Lender; (f) to the extent reasonably necessary in connection with the exercise of any right or remedy under any Loan Document, including Lender's sale, lease, or other disposition of Collateral after default; (g) to any participant or assignee of Lender or any prospective participant or assignee; provided, that such participant or assignee or prospective participant or assignee agrees in writing to be bound by this Section prior to disclosure; or (h) otherwise with the prior consent of such Borrower; provided, that any disclosure made in violation of this Agreement shall not affect the obligations of Borrower or any of its affiliates or any guarantor under this Agreement or the other Loan Documents.

11.14 Assignment. Each Borrower acknowledges and understands that Lender may sell and assign all or part of its interest hereunder and under the Note(s) and Loan Documents to any person or entity (an "Assignee"). After such assignment the term "Lender" as used in the Loan Documents shall mean and include such Assignee, and such Assignee shall be vested with all rights, powers and remedies

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of Lender hereunder with respect to the interest so assigned; but with respect to any such interest not so transferred, Lender shall retain all rights, powers and remedies hereby given. No such assignment by Lender shall relieve Borrower of any of its obligations hereunder. Each Lender agrees that in the event of any transfer by it of the Note(s), it will endorse thereon a notation as to the portion of the principal of the Note(s), which shall have been paid at the time of such transfer and as to the date to which interest shall have been last paid thereon.

11.15 Revival of Secured Obligations. This Agreement and the Loan Documents shall remain in full force and effect and continue to be effective if any petition is filed by or against a Borrower for liquidation or reorganization, if a Borrower becomes insolvent or makes an assignment for the benefit of creditors, if a receiver or trustee is appointed for all or any significant part of a Borrower's assets, or if any payment or transfer of Collateral is recovered from Lender. The Loan Documents and the Secured Obligations and Collateral security shall continue to be effective, or shall be revived or reinstated, as the case may be, if at any time payment and performance of the Secured Obligations or any transfer of Collateral to Lender, or any part thereof is rescinded, avoided or avoidable, reduced in amount, or must otherwise be restored or returned by, or is recovered from, Lender or by any obligee of the Secured Obligations, whether as a "voidable preference," "fraudulent conveyance," or otherwise, all as though such payment, performance, or transfer of Collateral had not been made. In the event that any payment, or any part thereof, is rescinded, reduced, avoided, avoidable, restored, returned, or recovered, the Loan Documents and the Secured Obligations shall be deemed, without any further action or documentation, to have been revived and reinstated except to the extent of the full, final, and indefeasible payment to Lender in Cash.

11.16 Counterparts. This Agreement and any amendments, waivers, consents or supplements hereto may be executed in any number of counterparts, and by different parties hereto in separate counterparts, each of which when so delivered shall be deemed an original, but all of which counterparts shall constitute but one and the same instrument.

11.17 No Third Party Beneficiaries. No provisions of the Loan Documents are intended, nor will be interpreted, to provide or create any third-party beneficiary rights or any other rights of any kind in any person other than Lender and Borrower unless specifically provided otherwise herein, and, except as otherwise so provided, all provisions of the Loan Documents will be personal and solely between the Lender and the Borrower

11.18 Surety Waivers. Each Borrower may, acting singly, request Advances. Each Borrower appoints the other Borrower as agent for the other for all purposes hereunder, including with respect to requesting Advances hereunder. Each Borrower shall be jointly and severally obligated to repay all Advances made hereunder, regardless of which Borrower actually receives said Advance, as if each Borrower hereunder directly received all Advances. Each Borrower waives (a) any suretyship defenses available to it under the Code or any other applicable law, including, without limitation, the benefit of California Civil Code Section 2815 permitting revocation as to future transactions and the benefit of California Civil Code Sections 1432, 2809, 2810, 2819, 2839, 2845, 2847, 2848, 2849, 2850, and 2899 and 3433, and (b) any right to require Lender to: (i) proceed against any Borrower or any other person; (ii) proceed against or exhaust any security; or (iii) pursue any other remedy. Lender may exercise or not exercise any right or remedy it has against any Borrower or any security it holds (including the right to foreclose by judicial or non-judicial sale) without affecting any Borrower's liability. Notwithstanding any other provision of this Agreement or other related document, each Borrower irrevocably waives all rights that it may have at law or in equity (including, without limitation, any law subrogating Borrower to the rights of Lender under this Agreement) to seek contribution, indemnification or any other form of reimbursement from any other Borrower, or any other Person now

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or hereafter primarily or secondarily liable for any of the Obligations, for any payment made by Borrower with respect to the Obligations in connection with this Agreement or otherwise and all rights that it might have to benefit from, or to participate in, any security for the Obligations as a result of any payment made by Borrower with respect to the Obligations in connection with this Agreement or otherwise. Any agreement providing for indemnification, reimbursement or any other arrangement prohibited under this Section shall be null and void. If any payment is made to a Borrower in contravention of this Section, such Borrower shall hold such payment in trust for Lender and such payment shall be promptly delivered to Lender for application to the Obligations, whether matured or unmatured.

(SIGNATURES TO FOLLOW)



IN WITNESS WHEREOF, Borrower and Lender have duly executed and delivered this Loan and Security Agreement as of the day and year first above written.

BORROWER:

PACIRA PHARMACEUTICALS, INC., a Delaware corporation

Signature: /s/ James Scibetta

Print Name: James Scibetta

Title: Chief Financial Officer

PACIRA PHARMACEUTICALS, INC., a California corporation

Signature: /s/ James Scibetta

Print Name: James Scibetta

Title: Chief Financial Officer

Accepted in Palo Alto, California:

LENDER:

HERCULES TECHNOLOGY GROWTH CAPITAL, INC.

Signature: /s/ K. Nicholas Martitsch

Print Name: K. Nicholas Martitsch

Title: Associate General Counsel

HERCULES TECHNOLOGY III, L.P.,  
a Delaware limited partnership

By: Hercules Technology SBIC Management, LLC, its General Partner

By: Hercules Technology Growth Capital, Inc., its Manager

By: /s/ K. Nicholas Martitsch

Name: K. Nicholas Martitsch

Its: Associate General Counsel

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## ADDENDUM 1 to LOAN AND SECURITY AGREEMENT

(a) *Borrower's Business*. For purposes of this Addendum 1, Borrower shall be deemed to include its "affiliates" as defined in Title 13 Code of Federal Regulations Section 121.103. Borrower represents and warrants to Lender (as of the Closing Date and for a period of one year thereafter) and covenants to Lender as follows:

1. **Size Status.** Borrower does not have in excess of 500 employees as of the Closing Date;
2. **No Relender.** Borrower's primary business activity does not involve, directly or indirectly, providing funds to others, purchasing debt obligations, factoring, or long-term leasing of equipment with no provision for maintenance or repair;
3. **No Passive Business.** Borrower is engaged in a regular and continuous business operation (excluding the mere receipt of payments such as dividends, rents, lease payments, or royalties). Borrower's employees are carrying on the majority of day to day operations. Borrower will not pass through substantially all of the proceeds of the Loan to another entity;
4. **No Real Estate Business.** Borrower is not classified under Major Group 65 (Real Estate) or Industry No. 1531 (Operative Builders) of the SIC Manual. The proceeds of the Loan will not be used to acquire or refinance real property unless Borrower (x) is acquiring an existing property and will use at least 51 percent of the usable square footage for its business purposes; (y) is building or renovating a building and will use at least 67 percent of the usable square footage for its business purposes; or (z) occupies the subject property and uses at least 67 percent of the usable square footage for its business purposes.
5. **No Project Finance.** Borrower's assets are not intended to be reduced or consumed, generally without replacement, as the life of its business progresses, and the nature of Borrower's business does not require that a stream of cash payments be made to the business's financing sources, on a basis associated with the continuing sale of assets (e.g., real estate development projects and oil and gas wells). The primary purpose of the Loan is not to fund production of a single item or defined limited number of items, generally over a defined production period, where such production will constitute the majority of the activities of Borrower (e.g., motion pictures and electric generating plants).
6. **No Farm Land Purchases.** Borrower will not use the proceeds of the Loan to acquire farm land which is or is intended to be used for agricultural or forestry purposes, such as the production of food, fiber, or wood, or is so taxed or zoned.
7. **No Foreign Investment.** The proceeds of the Loan will not be used substantially for a foreign operation. At the time of the Loan, Borrower will not have more than 49 percent of its employees or tangible assets located outside the United States. The representation in this subsection (7) is made only as of the date hereof and shall not continue for one year as contemplated in the first sentence of this Section 1.

(b) *Small Business Administration Documentation*. Lender acknowledges that Borrower completed, executed and delivered to Lender SBA Forms 480, 652 and 1031 (Parts A and B) together with a business plan showing Borrower's financial projections (including balance sheets and income and cash flows statements) for the period described therein and a written statement (whether included in the purchase agreement or pursuant to a separate statement) from Lender regarding its intended use of proceeds from

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the sale of securities to Lender (the "Use of Proceeds Statement"). Borrower represents and warrants to Lender that the information regarding Borrower and its affiliates set forth in the SBA Form 480, Form 652 and Form 1031 and the Use of Proceeds Statement delivered as of the Closing Date is accurate and complete.

(c) *Inspection*. The following covenants contained in this Section (c) are intended to supplement and not to restrict the related provisions of the Loan Documents. Subject to the preceding sentence, Borrower will permit, for so long as Lender holds any debt or equity securities of Borrower, Lender or its representative, at Lender's expense, and examiners of the SBA to visit and inspect the properties and assets of Borrower, to examine its books of account and records, and to discuss Borrower's affairs, finances and accounts with Borrower's officers, senior management and accountants, all at such reasonable times as may be requested by Lender or the SBA.

(d) *Annual Assessment*. Promptly after the end of each calendar year (but in any event prior to February 28 of each year) and at such other times as may be reasonably requested by Lender, Borrower will deliver to Lender a written assessment of the economic impact of Lender's investment in Borrower, specifying the full-time equivalent jobs created or retained in connection with the investment, the impact of the investment on the businesses of Borrower in terms of expanded revenue and taxes, other economic benefits resulting from the investment (such as technology development or commercialization, minority business development, or expansion of exports) and such other information as may be required regarding Borrower in connection with the filing of Lender's SBA Form 468. Lender will assist Borrower with preparing such assessment. In addition to any other rights granted hereunder, Borrower will grant Lender and the SBA access to Borrower's books and records for the purpose of verifying the use of such proceeds. Borrower also will furnish or cause to be furnished to Lender such other information regarding the business, affairs and condition of Borrower as Lender may from time to time reasonably request.

(e) *Use of Proceeds*. Borrower will use the proceeds from the Loan only for general working capital purposes. Borrower will deliver to Lender from time to time promptly following Lender's request, a written report, certified as correct by Borrower's Chief Financial Officer, verifying the purposes and amounts for which proceeds from the Loan have been disbursed. Borrower will supply to Lender such additional information and documents as Lender reasonably requests with respect to its use of proceeds and will permit Lender and the SBA to have access to any and all Borrower records and information and personnel as Lender deems necessary to verify how such proceeds have been or are being used, and to assure that the proceeds have been used for the purposes specified in this Section 7.16.

(f) *Activities and Proceeds*. Neither Borrower nor any of its affiliates (if any) will engage in any activities or use directly or indirectly the proceeds from the Loan for any purpose for which a small business investment company is prohibited from providing funds by the SBIC Act, including 13 C.F.R. §107.720. Without obtaining the prior written approval of Lender, Borrower will not change within 1 year of the date hereof, Borrower's current business activity to a business activity which a licensee under the SBIC Act is prohibited from providing funds by the SBIC Act.

(g) *Redemption Provisions*. Notwithstanding any provision to the contrary contained in the Certificate of Incorporation of Borrower, as amended from time to time (the "Charter"), if, pursuant to the redemption provisions contained in the Charter, Lender is entitled to a redemption of its Warrant, such redemption (in the case of Lender) will be at a price equal to the redemption price set forth in the Charter (the "Existing Redemption Price"). If, however, Lender delivers written notice to Borrower that the then current regulations promulgated under the SBIC Act prohibit payment of the Existing Redemption Price in the case of an SBIC (or, if applied, the Existing Redemption Price would cause the Series C Preferred Stock to lose its classification as an "equity security" and Lender has determined that such classification

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is unadvisable), the amount Lender will be entitled to receive shall be the greater of (i) fair market value of the securities being redeemed taking into account the rights and preferences of such securities plus any costs and expenses of the Lender incurred in making or maintaining the Warrant, and (ii) the Existing Redemption Price where the amount of accrued but unpaid dividends payable to the Lender is limited to Borrower's earnings plus any costs and expenses of the Lender incurred in making or maintaining the Warrant; provided, however, the amount calculated in subsections (i) or (ii) above shall not exceed the Existing Redemption Price.

(h) *Cost of Money*. Notwithstanding any provision to the contrary contained in the Loan Documents, all interest and fees charged pursuant to the Loan Documents shall comply with the provisions of 13 C.F.R. § 107.855, including, without limitation, that such amounts shall not exceed the Cost of Money ceiling (as defined hereafter). The current Cost of Money ceiling for this Loan is 14.5%, not including the valuation of the Warrant.

(i) *Compliance and Resolution*. Borrower agrees that a failure to comply with Borrower's obligations under this Addendum, or any other set of facts or circumstances where it has been asserted by any governmental regulatory agency (or Lender believes that there is a substantial risk of such assertion) that Lender and its affiliates are not entitled to hold, or exercise any significant right with respect to, any securities issued to Lender by Borrower, will, subject to the provisions in the remainder of this clause (i), constitute a breach of the obligations of Borrower under the financing agreements between Borrower and Lender. In the event of (i) a failure to comply with Borrower's obligations under this Addendum; or (ii) an assertion by any governmental regulatory agency (or Lender believes that there is a substantial risk of such assertion) of a failure to comply with Borrower's obligations under this Addendum, then (A) Lender and Borrower will meet and resolve any such issue in good faith to the satisfaction of Borrower, Lender, and any governmental regulatory agency, and (B) upon request of Lender, Borrower will cooperate and assist with any assignment of the financing agreements from Hercules Technology III, L.P. to Hercules Technology Growth Capital, Inc. (the "Assignment Remedy"). Notwithstanding anything to the contrary in this Agreement, pending the completion of such resolution meeting pursuant to clause (B) above, no default or Event of Default shall have, or be deemed to have, occurred, provided that if such resolution meeting does not result in a cure or waiver of any such failure to comply, the Assignment Remedy shall be effectuated and, for clarity, no default or Event of Default shall have or be deemed to have occurred.

EXHIBIT A  
ADVANCE REQUEST

To:

November 24, 2010

Hercules Technology Growth Capital, Inc.  
Hercules Technology III, L.P.  
400 Hamilton Avenue, Suite 310  
Palo Alto, CA 94301  
Facsimile: 650-473-9194  
Attn: Parag Shah

PACIRA PHARMACEUTICALS, INC., a Delaware corporation and Pacira Pharmaceuticals, Inc., a California corporation (individually, a "Borrower" and collectively, the "Borrowers") hereby request from Hercules Technology Growth Capital, Inc. and Hercules Technology III, L.P. (collectively "Lender") two Advances in the aggregate amount of \$26,250,000 (consisting of one Term Loan A Loan of \$11,250,000 and one Term Loan B Loan of \$15,000,000 on November 24, 2010 (the "Advance Date") pursuant to the Loan and Security Agreement between Borrowers and Lender (the "Agreement"). Capitalized words and other terms used but not otherwise defined herein are used with the same meanings as defined in the Agreement.

Please:

- (a) Issue a check payable to a Borrower \_\_\_\_\_  
or
- (b) Wire Funds to a Borrower's account \_\_\_\_\_  
Bank: \_\_\_\_\_  
Address: \_\_\_\_\_  
ABA Number: \_\_\_\_\_  
Account Number: \_\_\_\_\_  
Account Name: \_\_\_\_\_

Borrowers represent that the conditions precedent to the Advance set forth in the Agreement are satisfied and shall be satisfied upon the making of such Advance, including but not limited to: (i) that no event that has had or could reasonably be expected to have a Material Adverse Effect has occurred and is continuing; (ii) that the representations and warranties set forth in the Agreement and in the Warrant are and shall be true and correct in all material respects on and as of the Advance Date with the same effect as though made on and as of such date, except to the extent such representations and warranties expressly relate to an earlier date; (iii) that Borrower is in compliance in all material respects with all the terms and provisions set forth in each Loan Document on its part to be observed or performed; and (iv) that as of the Advance Date, no fact or condition exists that would (or would, with the passage of time, the giving of notice, or both) constitute an Event of Default under the Loan Documents. Borrowers understand and acknowledge that Lender has the right to review the financial information supporting this representation and, based upon such review in its sole discretion, Lender may decline to fund the requested Advance.

Borrowers hereby represent that each Borrower's corporate status and locations have not changed since the date of the Agreement, except as otherwise permitted under the Agreement.

Borrowers agree to notify Lender promptly before the funding of the Loan if any of the matters which have been represented above shall not be true and correct on the Borrowing Date and if Lender has received no such notice before the Advance Date then the statements set forth above shall be deemed to have been made and shall be deemed to be true and correct as of the Advance Date.

Executed as of November 24, 2010.

PACIRA PHARMACEUTICALS, INC., a  
Delaware corporation

By: \_\_\_\_\_

Title: \_\_\_\_\_

Name: \_\_\_\_\_

PACIRA PHARMACEUTICALS, INC., a  
California corporation

By: \_\_\_\_\_

Title: \_\_\_\_\_

Name: \_\_\_\_\_

**EXHIBIT B**

**SECURED TERM PROMISSORY NOTE**

\$15,000,000

Advance Date: November 24, 2010

Maturity Date: May 31, 2014 (subject to extension)

FOR VALUE RECEIVED, PACIRA PHARMACEUTICALS, INC., a Delaware corporation, and PACIRA PHARMACEUTICALS, INC., a California corporation, (individually, a "Borrower" and collectively, the "Borrowers") jointly and severally promise to pay to the order of Hercules Technology Growth Capital, Inc., a Maryland corporation or the holder of this Note (the "Lender") at 400 Hamilton Avenue, Suite 310, Palo Alto, CA 94301 or such other place of payment as the holder of this Secured Term Promissory Note (this "Promissory Note") may specify from time to time in writing, in lawful money of the United States of America, the principal amount of Fifteen Million Dollars (\$15,000,000) representing the Term Loan B Loan, or such other principal amount as Lender has advanced to Borrower, together with interest as set forth in the Loan Agreement as defined below.

This Promissory Note is the Note referred to in, and is executed and delivered in connection with, that certain Loan and Security Agreement dated November 24, 2010, by and between Borrowers and Lender (as the same may from time to time be amended, modified or supplemented in accordance with its terms, the "Loan Agreement"), and is entitled to the benefit and security of the Loan Agreement and the other Loan Documents (as defined in the Loan Agreement), to which reference is made for a statement of all of the terms and conditions thereof. All payments shall be made in accordance with the Loan Agreement. All terms defined in the Loan Agreement shall have the same definitions when used herein, unless otherwise defined herein. An Event of Default under the Loan Agreement shall constitute a default under this Promissory Note.

Borrowers waive presentment and demand for payment, notice of dishonor, protest and notice of protest under the UCC or any applicable law. Borrowers shall make all payments under this Promissory Note without setoff, recoupment or deduction and regardless of any counterclaim or defense. This Promissory Note has been negotiated and delivered to Lender and is payable in the State of California. This Promissory Note shall be governed by and construed and enforced in accordance with, the laws of the State of California, excluding any conflicts of law rules or principles that would cause the application of the laws of any other jurisdiction.

PACIRA PHARMACEUTICALS, INC., a  
Delaware corporation

By: \_\_\_\_\_  
Title: \_\_\_\_\_  
Name: \_\_\_\_\_

PACIRA PHARMACEUTICALS, INC., a  
California corporation

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_



**EXHIBIT B-1**

**SECURED TERM PROMISSORY NOTE**

\$11,250,000

Advance Date: November 24, 2010

Maturity Date: May 31, 2014 (subject to extension)

FOR VALUE RECEIVED, PACIRA PHARMACEUTICALS, INC., a Delaware corporation, and PACIRA PHARMACEUTICALS, INC., a California corporation, (individually, a "Borrower" and collectively, the "Borrowers") jointly and severally promise to pay to the order of Hercules Technology III, L.P., a Delaware limited partnership or the holder of this Note (the "Lender") at 400 Hamilton Avenue, Suite 310, Palo Alto, CA 94301 or such other place of payment as the holder of this Secured Term Promissory Note (this "Promissory Note") may specify from time to time in writing, in lawful money of the United States of America, the principal amount of Eleven Million Two Hundred Fifty Thousand Dollars (\$11,250,000), representing the Term Loan A Loan or such other principal amount as Lender has advanced to Borrower, together with interest as set forth in the Loan Agreement as defined below.

This Promissory Note is the Note referred to in, and is executed and delivered in connection with, that certain Loan and Security Agreement dated November 24, 2010, by and between Borrowers and Lender (as the same may from time to time be amended, modified or supplemented in accordance with its terms, the "Loan Agreement"), and is entitled to the benefit and security of the Loan Agreement and the other Loan Documents (as defined in the Loan Agreement), to which reference is made for a statement of all of the terms and conditions thereof. All payments shall be made in accordance with the Loan Agreement. All terms defined in the Loan Agreement shall have the same definitions when used herein, unless otherwise defined herein. An Event of Default under the Loan Agreement shall constitute a default under this Promissory Note.

Borrowers waive presentment and demand for payment, notice of dishonor, protest and notice of protest under the UCC or any applicable law. Borrowers shall make all payments under this Promissory Note without setoff, recoupment or deduction and regardless of any counterclaim or defense. This Promissory Note has been negotiated and delivered to Lender and is payable in the State of California. This Promissory Note shall be governed by and construed and enforced in accordance with, the laws of the State of California, excluding any conflicts of law rules or principles that would cause the application of the laws of any other jurisdiction.

PACIRA PHARMACEUTICALS, INC., a  
Delaware corporation

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

PACIRA PHARMACEUTICALS, INC., a  
California corporation

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

**EXHIBIT C**

**NAME, LOCATIONS, AND OTHER INFORMATION FOR BORROWERS**

Borrowers represent and warrant to Lender that each Borrower's current name and organizational status as of the Closing Date is as follows:

Name: Pacira Pharmaceuticals, Inc., a Delaware corporation:  
Organization ID Number: \_\_\_\_\_

Borrower represents and warrants to Lender that for five (5) years prior to the Closing Date, Borrower did not do business under any other name or organization or form except the following:

Name: \_\_\_\_\_  
Used during dates of: \_\_\_\_\_  
Type of Organization: \_\_\_\_\_  
State of organization: \_\_\_\_\_  
Organization ID Number: \_\_\_\_\_  
Borrower's fiscal year ends on \_\_\_\_\_  
Borrower's federal employer tax identification number is: \_\_\_\_\_

Name: Pacira Pharmaceuticals, Inc., a California corporation  
Organization ID Number: \_\_\_\_\_

Borrower represents and warrants to Lender that for five (5) years prior to the Closing Date, Borrower did not do business under any other name or organization or form except the following:

Name: \_\_\_\_\_  
Used during dates of: \_\_\_\_\_  
Type of Organization: \_\_\_\_\_  
State of organization: \_\_\_\_\_  
Organization ID Number: \_\_\_\_\_  
Borrower's fiscal year ends on \_\_\_\_\_  
Borrower's federal employer tax identification number is: \_\_\_\_\_

Borrowers represent and warrant to Lender that their chief executive office is located at \_\_\_\_\_.

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**EXHIBIT D**

**BORROWER'S PATENTS, TRADEMARKS, COPYRIGHTS AND LICENSES**

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**EXHIBIT E**

**BORROWER'S DEPOSIT ACCOUNTS AND INVESTMENT ACCOUNTS**

**EXHIBIT F**  
**COMPLIANCE CERTIFICATE**

Hercules Technology Growth Capital, Inc.  
Hercules Technology III, L.P.  
400 Hamilton Avenue, Suite 310  
Palo Alto, CA 94301

Reference is made to that certain Loan and Security Agreement dated November 24, 2010 and all ancillary documents entered into in connection with such Loan and Security Agreement all as may be amended from time to time, (hereinafter referred to collectively as the "Loan Agreement") between Hercules Technology Growth Capital, Inc. and Hercules Technology III, L.P. (collectively, "Hercules") as Lender and PACIRA PHARMACEUTICALS, INC., a Delaware corporation, and PACIRA PHARMACEUTICALS, INC., a California corporation (collectively, the "Company") as Borrower. All capitalized terms not defined herein shall have the same meaning as defined in the Loan Agreement.

The undersigned is an Officer of the Company, knowledgeable of all Company financial matters, and is authorized to provide certification of information regarding the Company; hereby certifies, in such capacity, that in accordance with the terms and conditions of the Loan Agreement, the Company is in compliance in all material respects for the period ending \_\_\_\_\_ of all covenants, conditions and terms and hereby reaffirms that all representations and warranties contained therein are true and correct on and as of the date of this Compliance Certificate with the same effect as though made on and as of such date, except to the extent such representations and warranties expressly relate to an earlier date, after giving effect in all cases to any standard(s) of materiality contained in the Loan Agreement as to such representations and warranties. Attached are the required documents supporting the above certification. The undersigned further certifies, in such capacity, that these are prepared in accordance with GAAP (except for the absence of footnotes with respect to unaudited financial statement and subject to normal year end adjustments) and are consistent from one period to the next except as explained below.

REPORTING REQUIREMENT	REQUIRED	CHECK IF ATTACHED
Interim Financial Statements	Monthly within 30 days	
Interim Financial Statements	Quarterly within 45 days	
Audited Financial Statements	FYE within 150 days (90 if public company)	

Very Truly Yours,

PACIRA PHARMACEUTICALS, INC.

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

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**EXHIBIT G**

**FORM OF JOINDER AGREEMENT**

This Joinder Agreement (the "Joinder Agreement") is made and dated as of November 24, 2010, and is entered into by and between \_\_\_\_\_, a \_\_\_\_\_ corporation ("Subsidiary"), and HERCULES TECHNOLOGY GROWTH CAPITAL, INC. and Hercules Technology III, L.P., (collectively, "Lender").

**RECITALS**

A. Subsidiary's Affiliate, PACIRA PHARMACEUTICALS, INC. ("Company") has entered/desires to enter into that certain Loan and Security Agreement dated November 24, 2010, with Lender, as such agreement may be amended (the "Loan Agreement"), together with the other agreements executed and delivered in connection therewith;

B. Subsidiary acknowledges and agrees that it will benefit both directly and indirectly from Company's execution of the Loan Agreement and the other agreements executed and delivered in connection therewith;

**AGREEMENT**

NOW THEREFORE, Subsidiary and Lender agree as follows:

1. The recitals set forth above are incorporated into and made part of this Joinder Agreement. Capitalized terms not defined herein shall have the meaning provided in the Loan Agreement.

2. By signing this Joinder Agreement, Subsidiary shall be bound by the terms and conditions of the Loan Agreement the same as if it were the Borrower (as defined in the Loan Agreement) under the Loan Agreement, mutatis mutandis, provided however, that Lender shall have no duties, responsibilities or obligations to Subsidiary arising under or related to the Loan Agreement or the other agreements executed and delivered in connection therewith. Rather, to the extent that Lender has any duties, responsibilities or obligations arising under or related to the Loan Agreement or the other agreements executed and delivered in connection therewith, those duties, responsibilities or obligations shall flow only to Company and not to Subsidiary or any other person or entity. By way of example (and not an exclusive list): (a) Lender's providing notice to Company in accordance with the Loan Agreement or as otherwise agreed between Company and Lender shall be deemed provided to Subsidiary; (b) a Lender's providing an Advance to Company shall be deemed an Advance to Subsidiary; and (c) Subsidiary shall have no right to request an Advance or make any other demand on Lender.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

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[SIGNATURE PAGE TO JOINDER AGREEMENT]

SUBSIDIARY:

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By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

Address: \_\_\_\_\_  
\_\_\_\_\_

Telephone: \_\_\_\_\_  
Facsimile: \_\_\_\_\_

HERCULES TECHNOLOGY GROWTH CAPITAL, INC.

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

Address:  
400 Hamilton Ave., Suite 310  
Palo Alto, CA 94301  
Facsimile: 650-473-9194  
Telephone: 650-289-3060

**EXHIBIT H**

**ACH DEBIT AUTHORIZATION AGREEMENT**

Hercules Technology Growth Capital, Inc.  
Hercules Technology III, L.P.  
400 Hamilton Avenue, Suite 310  
Palo Alto, CA 94301

Re: Loan and Security Agreement dated November 24, 2010 between Pacira Pharmaceuticals, Inc. ("Borrower") and Hercules Technology Growth Capital, Inc. and Hercules Technology III, L.P. (collectively, "Company") (the "Agreement")

In connection with the above referenced Agreement, the Borrower hereby authorizes the Company to initiate debit entries for the periodic payments due under the Agreement to the Borrower's account indicated below. The Borrower authorizes the depository institution named below to debit to such account.

DEPOSITORY NAME	BRANCH
CITY	STATE AND ZIP CODE
TRANSIT/ABA NUMBER	ACCOUNT NUMBER

This authority will remain in full force and effect so long as any amounts are due under the Agreement.

PACIRA PHARMACEUTICAL, INC.  
a California corporation

(Borrower)(Please Print)

By: \_\_\_\_\_

Date: \_\_\_\_\_

PACIRA PHARMACEUTICAL, INC.  
a Delaware corporation

(Borrower)(Please Print)

By: \_\_\_\_\_

Date: \_\_\_\_\_



**GUARANTY**

This GUARANTY (this "Guaranty")<sub>2</sub> dated as of November 24, 2010, is entered into by and among each of the guarantors signatory hereto as specified on Schedule 2.1 hereto (each a "VC Guarantor" and collectively, the "VC Guarantors")<sub>2</sub> and HERCULES TECHNOLOGY GROWTH CAPITAL, INC. and HERCULES TECHNOLOGY III, L.P. (individually, a "Lender" and, collectively, the "Lenders").

**WITNESSETH:**

WHEREAS, pursuant to the Loan and Security Agreement, dated of even date, among Pacira Pharmaceuticals, Inc., a California corporation ( "Pacira California"), Pacira Pharmaceuticals, Inc., a Delaware corporation ( "Parent" and, together with Pacira California, the "Borrowers"), and Lender (as amended, restated, supplemented or otherwise modified from time to time, the "Loan Agreement")<sub>2</sub> the Lender has agreed to make certain Term Loans and to extend certain financial accommodations to Borrowers;

WHEREAS, Parent owns 100% of the outstanding capital stock of Pacira California, and each VC Guarantor is a shareholder of Parent, and as such each VC Guarantor will derive direct and indirect economic benefits from the making of the Term Loans and other financial accommodations provided to Borrowers pursuant to the Loan Agreement;

WHEREAS, in order to induce Lenders to enter into the Loan Agreement and the other Loan Documents and to induce Lenders to make the Term Loan A Loan as provided for in the Loan Agreement, each VC Guarantor has agreed to guarantee payment of certain of the Secured Obligations incurred in connection with the Term Loan A Loan; and

WHEREAS, each VC Guarantor acknowledges that the Lenders would not enter into the Loan Agreement but for such VC Guarantor's entering into this Guaranty;

NOW, THEREFORE, in consideration of the premises and the covenants hereinafter contained, and to induce Lenders to provide the Term Loans and other financial accommodations under the Loan Agreement, it is agreed as follows:

**1. DEFINITIONS.**

(a) Capitalized terms used herein shall have the meanings assigned to them in the Loan Agreement, unless otherwise defined herein. "Loan Party" shall mean each Borrower and each VC Guarantor.

(b) References to this "Guaranty" shall mean this Guaranty, including all amendments, restatements, modifications and supplements and any annexes, exhibits and schedules to any of the foregoing, and shall refer to this Guaranty as the same may be in effect at the time such reference becomes operative.

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2. THE GUARANTY.

2.1 Guaranty of Term Loan A Loan. Each VC Guarantor hereby unconditionally, on a several and not joint basis, (i) guarantees to Lenders, and their respective successors, endorsees, transferees and assigns, the prompt payment (whether at stated maturity, by acceleration or otherwise) and performance of such VC Guarantor's Pro Rata Portion (as defined below) of the principal amount of the Term Loan A Loan, all interest thereon, and all fees, expenses (including without limitation, costs of collection) incurred in connection with the Term Loan A Loan (collectively, the "Obligations"), provided that the aggregate liability of each VC Guarantor under this clause (i) shall be limited to a maximum amount of (1) such VC Guarantor's Pro Rata Portion of the principal amount of all Obligations plus (2) such VC Guarantor's Pro Rata Portion of all interest, fees, expenses (including, without limitation, costs of collection) and other Obligations under the Loan Documents, and provided further that for each VC Guarantor the aggregate amount of clauses (1) and (2) shall not exceed an amount equal to such VC Guarantor's Pro Rata Portion multiplied by \$11,250,000 (the aggregate amount of clauses (1) and (2), the "Maximum Amount"), (ii) agrees to pay interest on any amount due and payable under this Guaranty by such VC Guarantor after the date such payment becomes due and payable until payment in full of such amounts due and payable by such VC Guarantor at the highest rate then applicable to the Term Loan A Loan, and (iii) agrees to pay all expenses (including reasonable counsel fees and expenses) incurred by Lenders in enforcing their rights against such VC Guarantor under this Guaranty, or obtaining advice of counsel with respect to this Guaranty with respect to such VC Guarantor, and all other reasonable costs of collection against such VC Guarantor (collectively, the aggregate amount of in clauses (i), (ii) and (iii), the "Guaranteed Obligations"). No VC Guarantor shall be required to pay to the Lenders its Pro Rata Portion of the Guaranteed Obligations until the earlier of (1) the date that is thirty (30) days after a Lender has given written notice (an "Acceleration Notice") to MPM BioVentures IV-QP, L.P. that Lenders have accelerated the Obligations under the Loan Agreement and (2) the date on which any proceeding shall be instituted by or against a Borrower or any VC Guarantor seeking to adjudicate it a bankrupt or insolvent or seeking liquidation, winding up, reorganization, arrangement, adjustment, protection, relief, composition of it or its debts or any similar order under any law relating to bankruptcy, insolvency or reorganization or relief of debtors. Each VC Guarantor agrees that this Guaranty is a guaranty of payment and performance and not of collection, and that its obligations under this Guaranty shall be primary, absolute and unconditional, irrespective of, and unaffected by:

(a) the genuineness, validity, regularity, enforceability or any future amendment of, or change in this Guaranty, any other Loan Document or any other agreement, document or instrument to which any Loan Party and/or VC Guarantor is or may become a party;

(b) the absence of any action to enforce this Guaranty or any other Loan Document or the waiver or consent by a Lender with respect to any of the provisions thereof;

(c) the existence, value or condition of, or failure to perfect Lenders' Liens against, any Collateral for the Guaranteed Obligations or any action, or the absence of any action, by a Lender in respect thereof (including, without limitation, the release of any such security);

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(d) the insolvency of any Loan Party; or

(e) any other action or circumstances which might otherwise constitute a legal or equitable discharge or defense of a surety or guarantor,

it being agreed by each VC Guarantor that its obligations under this Guaranty shall not be discharged until the Termination Date. Subject to the limitations and notice provisions in this Section 2.1, each VC Guarantor shall be regarded, and shall be in the same position, as principal debtor with respect to the Guaranteed Obligations. Each VC Guarantor agrees that any notice or directive given at any time to a Lender which is inconsistent with the waiver in the immediately preceding sentence shall be null and void and may be ignored by Lenders, and, in addition, may not be pleaded or introduced as evidence in any litigation relating to this Guaranty for the reason that such pleading or introduction would be at variance with the written terms of this Guaranty, unless Lenders have specifically agreed otherwise in writing. It is agreed among each VC Guarantor and Lenders that the foregoing waivers are of the essence of the transaction contemplated by the Loan Documents and that, but for this Guaranty and such waivers, Lenders would decline to enter into the Loan Documents and to provide the Term Loan A Loan. As used in this Guaranty with respect to any VC Guarantor, the term "Pro Rata Portion" shall mean the percentage set forth opposite such VC Guarantor's name on Schedule 2.1 hereto.

2.2 Demand by Lenders. In addition to the terms of the Guaranty set forth in Section 2.1 hereof, and in no manner imposing any limitation on such terms, it is expressly understood and agreed that, if, at any time, the outstanding principal amount of the Guaranteed Obligations under the Loan Agreement (including all accrued interest thereon) is declared to be immediately due and payable in accordance with the terms thereof, then each VC Guarantor shall, without demand (other than the giving of any Acceleration Notice), pay to the Lenders (for the benefit of the holders of the Guaranteed Obligations) the entire outstanding Guaranteed Obligations due and owing by such VC Guarantor to such holders. Payment by each VC Guarantor shall be made to Lenders in United States dollars and by wire transfer or ACH transfer in immediately available funds (which shall be the exclusive means of payment hereunder) to an account, designated by Lenders and shall be credited and applied to the Guaranteed Obligations,

2.3 Enforcement of Guaranty. In no event shall a Lender have any obligation (although it is entitled, at its option) to proceed against Borrowers or any other Loan Party or any Collateral pledged to secure the Obligations or the Guaranteed Obligations before seeking satisfaction from the VC Guarantor (provided that a Lender shall have given the Notice of Acceleration pursuant to Section 2.1, if applicable), and Lender may proceed, prior or subsequent to, or simultaneously with, the enforcement of Lender's rights hereunder, to exercise any right or remedy which it may have against any Collateral, as a result of any Lien it may have as security for all or any portion of the Obligations or the Guaranteed Obligations.

2.4 Waiver. In addition to the waivers contained in Section 2.1 hereof, each VC Guarantor waives and agrees that it shall not at any time insist upon, plead or in any manner whatever claim or take the benefit or advantage of, any appraisal, valuation, stay, extension,

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marshaling of assets or redemption laws, or exemption, whether now or at any time hereafter in force, which may delay, prevent or otherwise affect the performance by such VC Guarantor of its Guaranteed Obligations under, or the enforcement by Lenders of, this Guaranty against such VC Guarantor. Each VC Guarantor hereby waives diligence, presentment and demand (whether for non-payment or protest or of acceptance, maturity, extension of time, change in nature or form of the Guaranteed Obligations, acceptance of further security, release of further security, composition or agreement arrived at as to the amount of, or the terms of, the Guaranteed Obligations, notice of adverse change in any Loan Party's financial condition or any other fact which might increase the risk to such VC Guarantor) with respect to any of the Guaranteed Obligations or all other demands whatsoever and waives the benefit of all provisions of law which are or might be in conflict with the terms of this Guaranty. Each VC Guarantor represents, warrants and agrees that, as of the date of this Guaranty, its obligations under this Guaranty are not subject to any offsets or defenses against Lenders or any Loan Party of any kind. Each VC Guarantor further agrees that its obligations under this Guaranty shall not be subject to any counterclaims, offsets or defenses against any Lender or against any Loan Party of any kind which may arise in the future. Each VC Guarantor waives the benefit of California Civil Code Sections 2815, 2809, 2810, 2819, 2839, 2845, 2848, 2849, 2850, 2899 and 1432.

2.5 Benefit of Guaranty. The provisions of this Guaranty are for the benefit of Lenders and their respective successors, transferees (to the extent such transfer is made in accordance with the terms and conditions of the Loan Agreement), endorsees and assigns, and nothing herein contained shall impair, as between any Loan Party and Lenders, the obligations of any Loan Party under the Loan Documents. In the event all or any part of the Guaranteed Obligations are transferred, indorsed or assigned by any Lender to any Person or Persons, any reference to "Lender" herein shall be deemed to refer equally to such Person or Persons.

2.6 Modification of Guaranteed Obligations, Etc. Each VC Guarantor hereby acknowledges and agrees that Lenders may at any time or from time to time, with or without the consent of, or notice to, any VC Guarantor:

(a) change or extend the manner, place or terms of payment of, or renew or alter all or any portion of, the Guaranteed Obligations;

(b) take any action under or in respect of the Loan Documents (other than actions under this Guaranty, which may only be taken by Lenders in accordance with the terms and conditions hereof) in the exercise of any remedy, power or privilege contained therein or available to it at law, equity or otherwise, or waive or refrain from exercising any such remedies, powers or privileges;

(c) amend or modify, in any manner whatsoever, the Loan Documents (other than this Guaranty, which may only be amended in accordance with the terms and conditions hereof);

(d) extend or waive the time for any Loan Party's performance of, or compliance with, any term, covenant or agreement on its part to be performed or observed under the Loan Documents, or waive such performance or compliance or consent to a failure of, or departure from, such performance or compliance;

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(e) take and hold Collateral for the payment of the Guaranteed Obligations guaranteed hereby or sell, exchange, release, dispose of, or otherwise deal with, any property pledged, mortgaged or conveyed, or in which Lenders have been granted a Lien, to secure any Obligations;

(f) release anyone who may be liable in any manner for the payment of any amounts owed by any VC Guarantor or any Loan Party to any Lender;

(g) modify or terminate the terms of any intercreditor or subordination agreement pursuant to which claims of other creditors of VC Guarantor or any Loan Party are subordinated to the claims of Lenders; and/or

(h) apply any sums by whomever paid or however realized to any amounts owing by any VC Guarantor or any Loan Party to any Lender in such manner as any Lender shall determine in its discretion;

and Lenders shall not incur any liability to any VC Guarantor as a result thereof, and no such action shall impair or release the Guaranteed Obligations of any VC Guarantor under this Guaranty.

2.7 Reinstatement. This Guaranty shall remain in full force and effect and continue to be effective should any petition be filed by or against any Loan Party or any VC Guarantor for liquidation or reorganization, should any Loan Party or any VC Guarantor become insolvent or make an assignment for the benefit of creditors or should a receiver or trustee be appointed for all or any significant part of such Loan Party's or such VC Guarantor's assets, and shall continue to be effective or be reinstated, as the case may be, if at any time payment and performance of the Guaranteed Obligations, or any part thereof, is, pursuant to applicable law, rescinded or reduced in amount, or must otherwise be restored or returned by any Lender, whether as a "voidable preference", "fraudulent conveyance", or otherwise, all as though such payment or performance had not been made (provided that (1) as any such rescission, reduction or requirement to return payments relates to a payment made by the Borrowers, such liability of the VC Guarantors under this Section 2.7 shall be reinstated against each VC Guarantor based on such VC Guarantor's Pro Rata Portion of the amount of such payment so rescinded, reduced or required to be returned, and (2) any such reinstatement or revival shall be subject to the limitation on each VC Guarantor's Guaranteed Obligations pursuant to Section 2.1 herein). In the event that any payment, or any part thereof, is rescinded, reduced, restored or returned, the Guaranteed Obligations shall be reinstated and deemed reduced only by such amount paid and not so rescinded, reduced, restored or returned.

2.8 Waiver of Subrogation, Etc. Notwithstanding anything to the contrary in this Guaranty, or in any other Loan Document, until the Termination Date each VC Guarantor hereby:

(a) expressly and irrevocably waives, on behalf of itself and its successors and assigns (including any surety), any and all rights at law or in equity to subrogation, to reimbursement, to exoneration, to contribution, to indemnification, to set off or to any other rights that could accrue to a surety against a principal, to a guarantor against a

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principal, to a guarantor against a maker or obligor, to an accommodation party against the party accommodated, to a holder or transferee against a maker, or to the holder of any claim against any Person, and which such VC Guarantor may have or hereafter acquire against any Loan Party in connection with or as a result of such VC Guarantor's execution, delivery and/or performance of this Guaranty, or any other documents to which such VC Guarantor is a party or otherwise; and

(b) acknowledges and agrees (i) that this waiver is intended to benefit Lenders and shall not limit or otherwise affect such VC Guarantor's liability hereunder or the enforceability of this Guaranty, and (ii) that Lenders and their respective successors and assigns are intended third party beneficiaries of the waivers and agreements set forth in this Section 2.8 and their rights under this Section 2.8 shall survive payment in full of the Guaranteed Obligations.

2.9 Election of Remedies. If a Lender may, under applicable law, proceed to realize benefits under any of the Loan Documents giving Lenders a Lien upon any Collateral, either by judicial foreclosure or by non-judicial sale or enforcement, such Lender may, at its sole option, determine which of such remedies or rights it may pursue without affecting any of such rights and remedies under this Guaranty. If, in the exercise of any of its rights and remedies, a Lender shall forfeit any of its rights or remedies, including its right to enter a deficiency judgment against any Loan Party, whether because of any applicable laws pertaining to "election of remedies" or the like, each VC Guarantor hereby consents to such action by such Lender and waives any claim based upon such action, even if such action by such Lender shall result in a full or partial loss of any rights of subrogation which such VC Guarantor might otherwise have had but for such action by such lender. Any election of remedies which results in the denial or impairment of the right of a Lender to seek a deficiency judgment against any Loan Party shall not impair any VC Guarantor's obligation to pay the full amount of its Guaranteed Obligations. In the event a Lender shall bid at any foreclosure or trustee's sale or at any private sale permitted by law or the Loan Documents, such Lender may bid all or less than the amount of the Guaranteed Obligations and the amount of such bid need not be paid by such Lender but shall be credited against the Guaranteed Obligations. The amount of the successful bid at any such sale shall be conclusively deemed to be the fair market value of the collateral and the difference between such bid amount and the remaining balance of the Guaranteed Obligations shall be conclusively deemed to be the amount of the Guaranteed Obligations guaranteed under this Guaranty, notwithstanding that any present or future law or court decision or ruling may have the effect of reducing the amount of any deficiency claim to which Lenders might otherwise be entitled but for such bidding at any such sale.

2.10 This Guaranty shall terminate upon the earliest to occur of the following: (a) a Borrower's receipt after the Closing Date of at least \$75,000,000 in net new cash proceeds in any 12-month period from one or more of an Initial Public Offering, an equity financing, or convertible debt financing or strategic partnership, or any combination thereof, or (b) (i) a Borrower's receipt after the Closing Date of at least \$50,000,000 in net new cash proceeds from an Initial Public Offering, equity financing, convertible debt or strategic partnership, or any combination thereof, in any 12-month period, and (ii) the FDA approves EXPAREL or (c) a Borrower completes an Initial Public Offering, and after giving effect thereto, such Borrower has a market capitalization of at least \$400,000,000 and a balance of unrestricted cash (other than

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Permitted Liens) of at least \$50,000,000. A Borrower shall provide prompt notice to the VC Guarantors of the occurrence of any such event. Such termination shall be effective upon Lender's receipt of a Borrower's notice to terminate, together with such evidence as Lender may reasonably request of the satisfaction of the occurrence of any of (a), (b), or (c).

### 3. REPRESENTATIONS AND WARRANTIES

To induce Lenders to make the Term Loans under the Loan Agreement, each VC Guarantor makes the following representations and warranties with respect to such VC Guarantor to each Lender, each and all of which shall survive the execution and delivery of this Guaranty:

3.1 Corporate Existence; Compliance with Law. Such VC Guarantor (i) is a corporation, limited partnership or other business organization duly organized or formed, validly existing and in good standing under the laws of its jurisdiction of organization; (ii) is duly qualified to do business and is in good standing under the laws of each jurisdiction where its ownership or lease of property or the conduct of its business requires such qualification; (iii) has the requisite organizational power and authority and the legal right to own, pledge, mortgage and operate its properties, to lease the property it operates under lease, and to conduct its business as now, heretofore and proposed to be conducted (including, without limitation, to execute, deliver and perform this Guaranty); (iv) has all licenses, permits, consents or approvals from or by, and has made all material filings with, and has given all notices to, all Governmental Authorities having jurisdiction, to the extent required for such ownership, operation and conduct (including, without limitation, to execute, deliver and perform this Guaranty); (v) is in compliance with its charters and bylaws, limited partnership agreement or other applicable operating agreement; (vi) has unfunded commitments from its investors in an amount equal to one and one-half (1.5) times such VC Guarantor's Maximum Amount (including, for the avoidance of doubt and as of any date of determination, the VC Guarantor's Pro Rata Portion of all Final Payment Fees that would be due and payable if all of the Term Loans were repaid on such date), in each case after taking into account all direct and contingent liabilities for indebtedness, letters of credit, deferred liabilities or similar obligations (including guarantees thereof) that may be required to be paid with proceeds of such commitments; (vii) is not subject to, nor is any of such VC Guarantor's properties subject to, any pending or threatened action, suit or proceeding before any court or other Governmental Authority or any arbitrator (a) which challenges the validity or enforceability of this Guaranty, or (b) which could reasonably be expected to have a Material Adverse Effect on such VC Guarantor, (viii) has and will continue to have an independent means of obtaining information concerning the affairs, financial condition and business of Borrowers and the other Loan Parties, and has no need of, or right to obtain from, any Lender, any credit or other information concerning the affairs, financial condition or business of Borrowers or the other Loan Parties that may come into the possession of any Lender, and (ix) is in compliance with all applicable provisions of law, except where the failure to comply, individually or in the aggregate, would not have a Material Adverse Effect on such Guarantor.

3.2 Executive Offices. Each VC Guarantor's jurisdiction of organization, federal employer identification number, organizational identification number, executive office and principal place of business are as set forth in Schedule 3.2 hereto.

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3.3 Corporate Power; Authorization; Enforceable Guaranteed Obligations. The execution, delivery and performance of this Guaranty, any other Loan Document to which each VC Guarantor is a party and all other instruments and documents to be delivered by each VC Guarantor (including, without limitation, the making of capital calls by VC Guarantor to pay the Guaranteed Obligations) are within such VC Guarantor's organizational power, have been duly authorized by all necessary or proper organizational action, including the resolution of its board of directors or similar governing body and the consent of equityholders, are not in contravention of any provision of such VC Guarantor's bylaws, limited partnership agreement, operating agreement or other applicable governing document (including, without limitation, any restrictions under such governing document that prevent a VC Guarantor from incurring or guarantying indebtedness that exceeds any specified percentage of such VC Guarantor's aggregate capital commitments or its aggregate uncalled capital commitments), do not violate any law or regulation, or any order or decree of any Governmental Authority, do not conflict with or result in the breach of, or constitute a default under, or accelerate or permit the acceleration of any performance required by, any indenture, mortgage, deed of trust, lease, agreement or other instrument to which such VC Guarantor is a party or by which such VC Guarantor or any of its property is bound, do not result in the creation or imposition of any Lien upon any of the property of such VC Guarantor, and the same do not require the consent or approval of any Governmental Authority or any other Person. On or prior to the date hereof, this Guaranty and each other Loan Document to which each VC Guarantor is a party shall have been duly executed and delivered for the benefit of or on behalf of such VC Guarantor, and each shall then constitute a legal, valid and binding obligation of such VC Guarantor, enforceable against such VC Guarantor in accordance with its terms.

4. COVENANTS.

To induce Lenders to make the Term Loan A Loan under the Loan Agreement, each VC Guarantor hereby covenants and agrees as follows:

4.1 Maintenance of Unfunded Commitments. Such VC Guarantor shall maintain at all times unfunded commitments from its investors (minus all direct and contingent liabilities for indebtedness, letters of credit, deferred liabilities or similar obligations (including guarantees thereof)) in an amount equal to one and one-half (1.5) times such VC Guarantor's Maximum Amount (including, for the avoidance of doubt and as of any date of determination, the VC Guarantor's Pro Rata Portion of all Final Payment Fees that would be due and payable if all of the Advances were repaid on such date).

4.2 Change of Control.

(a) MPM Bioventures IV GP LLC shall at all times be the (i) general partner of MPM BioVentures IV-QP, L.P., (ii) managing limited partner of MPM BioVentures IV GmbH & Co. Beteiligungs KG, and (iii) manager of MPM Asset Management Investors BV4 LLC, in each case with sole authority to direct the day-to-day operations, management and administration of the entity.



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(b) OrbiMed Capital GP III, LLC shall at all times be the general partner of OrbiMed Private Investments III, LP, with sole authority to direct the day-to-day operations, management and administration of the entity.

(c) OrbiMed Advisors, LLC shall at all times be the general partner of OrbiMed Associates III, LP, with sole authority to direct the day-to-day operations, management and administration of the entity.

(d) Middleton, McNeil, Mills & Associates VI, LLC shall at all times be the general partner of each of Sanderling Venture Partners VI, L.P., Sanderling Venture Partners VI Co-Investment, L.P., Sanderling VI Beteiligungs GmbH & Co. KG and Sanderling VI Limited Partnership, in each case with sole authority to direct the day-to-day operations, management and administration of the entity.

(e) Each of the parties hereto further agrees to provide the Lenders with prompt written notice should its respective representations in this Section 4.2 no longer be true.

4.3 No Conflicts. No VC Guarantor shall enter into any indenture, mortgage, deed of trust, lease, agreement or other instrument or modify any of its organizational documents, in each case, that restricts the ability of the VC Guarantor to use its assets (including, without limitation, unfunded commitments) to pay the VC Guarantor's obligations hereunder.

4.4 Delivery of Compliance Certificate. Each VC Guarantor shall deliver to Lenders within 30 days after the end of each calendar quarter a compliance certificate in the form attached hereto as Exhibit A signed by an authorized officer of such VC Guarantor.

5. FURTHER ASSURANCES.

Each VC Guarantor agrees, upon the written request of any Lender, to execute and deliver to such Lender, from time to time, any additional instruments or documents reasonably requested by such Lender to cause this Guaranty to be, become or remain valid and effective in accordance with its terms.

6. PAYMENTS FREE AND CLEAR OF TAXES.

All payments required to be made by any VC Guarantor hereunder shall be made to Lenders free and clear of, and without deduction for, any and all present and future taxes, withholdings, duties, impositions or other charges (other than taxes on the overall net income of any Lender and comparable taxes).

7. OTHER TERMS.

7.1 Entire Agreement. This Guaranty, together with the other Loan Documents, constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements relating to a guaranty of the Obligations under the Loan Documents.

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7.2 Headings. The headings in this Guaranty are for convenience of reference only and are not part of the substance of this Guaranty.

7.3 Severability. Whenever possible, each provision of this Guaranty shall be interpreted in such a manner to be effective and valid under applicable law, but if any provision of this Guaranty shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Guaranty.

7.4 Notices. Whenever it is provided herein that any notice, demand, request, consent, approval, declaration or other communication shall or may be given to or served upon any of the parties by any other party, or whenever any of the parties desires to give or serve upon another any such communication with respect to this Guaranty, each such notice, demand, request, consent, approval, declaration or other communication shall be in writing and shall be addressed to the party to be notified as follows:

(a) If to any Lender, at:

Hercules Technology Growth Capital, Inc.  
400 Hamilton Ave., Suite 310  
Palo Alto, CA  
Attn: Chief Legal Officer and Parag Shah  
Facsimile: (650) 473-9194

(b) If to a VC Guarantor, to the attention of such VC Guarantor at the address of MPM BioVentures IV-QP, L.P. set forth following MPM BioVentures IV-QP, L.P.'s name on the signature pages hereof, with a copy to:

Mark Tanoury, Esq.  
Cooley LLP  
3175 Hanover Street  
Palo Alto, California 94304-1130  
Facsimile: (650) 849-7400

or at such other address as may be substituted by notice given as herein provided. The giving of any notice required hereunder may be waived in writing by the party entitled to receive such notice. Every notice, demand, request, consent, approval, declaration or other communication hereunder shall be deemed to have been validly served, given or delivered (i) upon the earlier of actual receipt and four (4) Business Days after the same shall have been deposited with the United States mail, registered or certified mail, return receipt requested, with proper postage prepaid, (ii) upon receipt of confirmation of proper transmission, when sent by telecopy or other similar facsimile transmission, (iii) one (1) Business Day after deposit with a nationally recognized overnight carrier with all charges prepaid, or (iv) when delivered, if hand-delivered by messenger.

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7.5 Successors and Assigns. This Guaranty and all obligations of each VC Guarantor hereunder shall be binding upon the successors and assigns of such VC Guarantor (including a debtor-in-possession on behalf of such VC Guarantor) and shall, together with the rights and remedies of Lenders hereunder, inure to the benefit of Lenders, all future holders of any instrument evidencing any of the Obligations and their respective successors and assigns. No sales of participations, other sales, assignments, transfers or other dispositions of any agreement governing or instrument evidencing the Obligations or any portion thereof or interest therein shall in any manner affect the rights of Lenders hereunder. No VC Guarantor may assign, sell, hypothecate or otherwise transfer any interest in or obligation under this Guaranty.

7.6 No Waiver; Cumulative Remedies; Amendments. Neither Lender shall by any act, delay, omission or otherwise be deemed to have waived any of its rights or remedies hereunder, and no waiver shall be valid unless in writing, signed by Lenders and then only to the extent therein set forth. A waiver by a Lender of any right or remedy hereunder on any one occasion shall not be construed as a bar to any right or remedy which such Lender would otherwise have had on any future occasion. No failure to exercise nor any delay in exercising on the part of any Lender, any right, power or privilege hereunder, shall operate as a waiver thereof, nor shall any single or partial exercise of any right, power or privilege hereunder preclude any other or future exercise thereof or the exercise of any other right, power or privilege. The rights and remedies hereunder provided are cumulative and may be exercised singly or concurrently, and are not exclusive of any rights and remedies provided by law. None of the terms or provisions of this Guaranty may be waived, altered, modified, supplemented or amended except by an instrument in writing, duly executed by Lenders and the VC Guarantor against which such waiver, alteration, modification, supplement or amendment is applicable.

7.7 Termination. This Guaranty is a continuing guaranty and shall remain in full force and effect until the Termination Date. Upon payment and performance in full of the Guaranteed Obligations by any VC Guarantor hereunder, Lenders shall deliver to such VC Guarantor such documents, in form and substance acceptable to Lenders and such VC Guarantor, as such VC Guarantor may reasonably request to evidence the termination of this Guaranty with respect to such VC Guarantor.

7.8 Counterparts. This Guaranty may be executed in any number of counterparts and by different parties in separate counterparts, each of which when so executed shall be deemed to be an original and all of which when taken together shall constitute one and the same agreement. Delivery of an executed signature page to this Guaranty by facsimile transmission or electronic transmission shall be as effective as delivery of a manually executed counterpart hereof.

## 8. GOVERNING LAW, JURISDICTION AND WAIVER OF JURY TRIAL

8.1 Governing Law. The laws of the State of California shall govern all matters arising out of, in connection with or relating to this Guaranty, including, without limitation, its validity, interpretation, construction, performance and enforcement.

8.2 Submission to Jurisdiction. Any legal action or proceeding with respect to this Guaranty may be brought in the courts of the State of California or the United States located in Santa Clara County and, by execution and delivery of this Guaranty, each VC Guarantor hereby

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accepts for itself and in respect of its property, generally and unconditionally, the exclusive jurisdiction of the aforesaid courts. The parties hereto hereby irrevocably waive any objection, including any objection to the laying of venue or based on the grounds of forum non conveniens, that any of them may now or hereafter have to the bringing of any such action or proceeding in such jurisdictions. Each VC Guarantor hereby agrees that any process with respect to such VC Guarantor in any such action shall be duly served if mailed by registered mail, postage prepaid, to such VC Guarantor at its address described in Section 7.4 above, or if served by any other means permitted by applicable law.

8.3 Waiver of Jury Trial. EACH OF PARTIES HERETO UNCONDITIONALLY WAIVES ANY AND ALL RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS GUARANTY, ANY OF THE OTHER LOAN DOCUMENTS, ANY DEALINGS AMONG ANY GUARANTOR, AND/OR LENDERS RELATING TO THE SUBJECT MATTER OF THIS TRANSACTION OR ANY RELATED TRANSACTIONS, AND/OR THE RELATIONSHIP THAT IS BEING ESTABLISHED AMONG ANY GUARANTOR AND/OR LENDERS. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT. THIS WAIVER IS IRREVOCABLE. THIS WAIVER MAY NOT BE MODIFIED EITHER ORALLY OR IN WRITING. THE WAIVER ALSO SHALL APPLY TO ANY SUBSEQUENT AMENDMENTS, RENEWALS, SUPPLEMENTS OR MODIFICATIONS TO THIS GUARANTY, ANY OTHER LOAN DOCUMENTS, OR TO ANY OTHER DOCUMENTS OR AGREEMENTS RELATING TO THIS TRANSACTION OR ANY RELATED TRANSACTION. THIS GUARANTY MAY BE FILED AS A WRITTEN CONSENT TO A TRIAL BY THE COURT. **If the waiver of jury trial set forth in this Section is ineffective or unenforceable, the parties agree that all claims arising out of this Guaranty (“Claims”) shall be resolved by reference to a private judge sitting without a jury, pursuant to Code of Civil Procedure Section 638, before a mutually acceptable referee or, if the parties cannot agree, a referee selected by the Presiding Judge of the Santa Clara County, California. Such proceeding shall be conducted in Santa Clara County, California, with California rules of evidence and discovery applicable to such proceeding. In the event Claims are to be resolved by judicial reference, either party may seek from a court identified in Section 18.2, any prejudgment order, writ or other relief and have such prejudgment order, writ or other relief enforced to the fullest extent permitted by law notwithstanding that all Claims are otherwise subject to resolution by judicial reference.**

[Signature Pages Follow]

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IN WITNESS WHEREOF, the parties hereto have duly executed and delivered this Guaranty as of the date first above written.

**MPM BIOVENTURES IV-QP, L.P.**

By: MPM BIOVENTURES IV GP LLC, its  
General Partner

By: MPM BIOVENTURES IV LLC, its  
Managing Member

By: /s/ Luke Evinin

Name: Luke Evinin

Title: Member

Notice Address for all VC Guarantors:

\_\_\_\_\_

\_\_\_\_\_

Attn: \_\_\_\_\_

Facsimile: \_\_\_\_\_

**MPM ASSET MANAGEMENT INVESTORS BV4 LLC**

By: MPM BIOVENTURES IV LLC, its Manager

By: /s/ Luke Evinin

Name: Luke Evinin

Title: Member

[Signature Page to VC Guaranty]

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**MPM BIOVENTURES IV GMBH & CO.  
BETEILIGUNGS KG**

By: MPM Bioventures IV GP LLC, in its capacity as  
the Managing Limited Partner

By: MPM BIOVENTURES IV LLC  
Its: Managing Member

By:           /s/ Luke Evnin          

Name: Luke Evnin

Title: Member

[Signature Page to VC Guaranty]

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**ORBIMED PRIVATE INVESTMENTS III, LP**

By: /s/ Carl Gordon

Name: Carl Gordon

Title: General Partner

**ORBIMED ASSOCIATES III, LP**

By: /s/ Carl Gordon

Name: Carl Gordon

Title: General Partner

[Signature Page to VC Guaranty]

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**SANDERLING VENTURE PARTNERS VI, L.P.**

**SANDERLING VENTURE PARTNERS VI CO-  
INVESTMENT, L.P.**

**SANDERLING VI BETEILIGUNGS GMBH &  
CO. KG**

**SANDERLING VI LIMITED PARTNERSHIP**

By: Middleton, McNeil, Mills & Associates VI, LLC  
Its: General Partner

<sup>By:</sup> /s/ Fred A. Middleton  
\_\_\_\_\_  
Fred A. Middleton  
Managing Director

[Signature Page to VC Guaranty]



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**HERCULES TECHNOLOGY GROWTH CAPITAL,  
INC.**

By: /s/ K. Nicholas Martitsch  
Name: K. Nicholas Martitsch  
Title: Associate General Counsel

**HERCULES TECHNOLOGY III, L.P.,**

a Delaware limited partnership

By: Hercules Technology SBIC Management,  
LLC, its General Partner

By: Hercules Technology Growth Capital, Inc., its Manager

By: /s/ K. Nicholas Martitsch  
Name: K. Nicholas Martitsch  
Its: Associate General Counsel

SPONSOR GUARANTY SIGNATURE PAGE

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**SCHEDULE 2.1**

Pro Rata Portion of each VC Guarantor

<u>VC Guarantor</u>	<u>Pro Rata Portion</u>	<u>Maximum Amount as of the Date Hereof</u>
MPM BioVentures IV-QP, L.P.	31.24%	\$ 3,514,500
MPM BioVentures IV GmbH & Co. Beteiligungs KG	1.20%	\$ 135,000
MPM Asset Management Investors BV4 LLC	0.89%	\$ 100,125
OrbiMed Private Investments III, LP	33.01%	\$ 3,713,625
Orbimed Associates III, LP	0.32%	\$ 36,000
Sanderling Venture Partners VI, L.P.	17.65%	\$ 1,985,625
Sanderling Venture Partners VI Co-Investment, L.P.	14.45%	\$ 1,625,625
Sanderling VI Beteiligungs GmbH & Co. KG	0.56%	\$ 63,000
Sanderling VI Limited Partnership	0.68%	\$ 76,500
<b>Total</b>	<b>100%</b>	<b>\$ 11,250,000.00</b>

In no event shall the aggregate Maximum Amount of Sanderling Venture Partners VI, L.P., Sanderling Venture Partners VI Co-Investment, L.P., Sanderling VI Beteiligungs GmbH & Co. KG and Sanderling VI Limited Partnership exceed \$3,750,750.

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**SCHEDULE 3.2**

**MPM BioVentures IV-QP, L.P.:**

1. Jurisdiction of organization: Delaware
2. Federal Employee Identification Number/Organizational Identification Number: 20-4217788
3. Executive Office and Principal Place of Business: The John Hancock Tower, 200 Clarendon Street, 54<sup>th</sup> Floor, Boston, MA 02116

**MPM BioVentures IV GmbH & Co. Beteiligungs KG:**

1. Jurisdiction of organization: Germany
2. Federal Employee Identification Number/Organizational Identification Number: N/A
3. Executive Office and Principal Place of Business: The John Hancock Tower, 200 Clarendon Street, 54<sup>th</sup> Floor, Boston, MA 02116

**MPM Asset Management Investors BV4 LLC :**

1. Jurisdiction of organization: Delaware
2. Federal Employee Identification Number/Organizational Identification Number: 20-4218062
3. Executive Office and Principal Place of Business: The John Hancock Tower, 200 Clarendon Street, 54<sup>th</sup> Floor, Boston, MA 02116

**OrbiMed Private Investments III, LP:**

1. Jurisdiction of organization: Delaware
2. Federal Employee Identification Number/Organizational Identification Number: 16- 1758090
3. Executive Office and Principal Place of Business: c/o OrbiMed Advisors LLC, 767 3<sup>rd</sup> Avenue, 30<sup>th</sup> Floor, New York, NY 10017

**Orbimed Associates III, LP:**

1. Jurisdiction of organization: Delaware
2. Federal Employee Identification Number/Organizational Identification Number: 16- 1758083
3. Executive Office and Principal Place of Business: c/o OrbiMed Advisors LLC, 767 3<sup>rd</sup> Avenue, 30<sup>th</sup> Floor, New York, NY 10017

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Sanderling Venture Partners VI, L.P.:

1. Jurisdiction of organization: California
2. Federal Employee Identification Number/Organizational Identification Number: 201044833
3. Executive Office and Principal Place of Business: 400 South El Camino Real, Suite 1200, San Mateo, California 94402-1708

Sanderling Venture Partners VI Co-Investment, L.P.:

1. Jurisdiction of organization: California
2. Federal Employee Identification Number/Organizational Identification Number: 201044877
3. Executive Office and Principal Place of Business: 400 South El Camino Real, Suite 1200, San Mateo, California 94402-1708

Sanderling VI Beteiligungs GmbH & Co. KG:

1. Jurisdiction of organization: Cayman Islands
2. Federal Employee Identification Number/Organizational Identification Number: Foreign
3. Executive Office and Principal Place of Business: c/o Sanderling Ventures 400 South El Camino Real, Suite 1200, San Mateo, California 94402-1708

Sanderling VI Limited Partnership:

1. Jurisdiction of organization: Germany
2. Federal Employee Identification Number/Organizational Identification Number: Foreign
3. Executive Office and Principal Place of Business: c/o Sanderling Ventures 400 South El Camino Real, Suite 1200, San Mateo, California 94402-1708

**EXHIBIT A**

**Compliance Certificate Form**

**[DATE]**

Reference is made to the Guaranty, dated as of November \_\_, 2010 (as amended, restated, supplemented or otherwise modified from time to time, the "Agreement"), made by (the "Fund") and each of the other VC Guarantors signatory thereto in favor of Hercules Technology Growth Capital, Inc. and Hercules Technology II, L.P. ("Lenders"). Capitalized terms used but not defined herein are used with the meanings assigned to such terms in the Agreement.

I, [\_\_\_\_\_], do hereby certify in my capacity as an officer of the Fund that:

(i) I am the duly elected, qualified and acting [TITLE] of the Fund;

(ii) as of the date hereof, the Fund has unfunded commitments from its investors (minus all direct and contingent liabilities for indebtedness, letters of credit, deferred liabilities or similar obligations (including guarantees thereof)) in an amount equal to \$ \_\_\_\_, which amount is at least one and one-half (1.5) times such VC Guarantor's Maximum Amount;

(iii) the Fund is not in default of any of its obligations under the Agreement; and

(iv) all representations and warranties of the Fund stated in the Agreement are true and correct in all material respects (without duplication of any materiality qualifier contained therein) on and as of the date hereof, except to the extent such representations and warranties expressly relate to an earlier date, in which case such representations and warranties were true and correct in all material respects (without duplication of any materiality qualifier contained therein) on and as of such earlier date.

**IN WITNESS WHEREOF**, I have hereunto set my hand as of the first date written above

Name: \_\_\_\_\_

Title: \_\_\_\_\_

THIS WARRANT HAS NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR ANY STATE SECURITIES LAWS. THEY MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED, OR HYPOTHECATED IN THE ABSENCE OF AN EFFECTIVE REGISTRATION STATEMENT RELATED THERETO OR AN OPINION OF COUNSEL (WHICH MAY BE COMPANY COUNSEL) REASONABLY SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR ANY APPLICABLE STATE SECURITIES LAWS.

WARRANT AGREEMENT

To Purchase Shares of Preferred Stock of

Pacira Pharmaceuticals, Inc.

Dated as of November 24, 2010 (the "Effective Date")

WHEREAS, Pacira Pharmaceuticals, Inc., a Delaware corporation (the "Company"), has entered into a Loan and Security Agreement of even date herewith (the "Loan Agreement") with Hercules Technology Growth Capital, Inc., a Maryland corporation (the "Warrantholder") and Hercules Technology III, L.P., a Delaware limited partnership;

WHEREAS, the Company desires to grant to Warrantholder, in consideration for, among other things, the financial accommodations provided for in the Loan Agreement, the right to purchase shares of Preferred Stock (as defined below) pursuant to this Warrant Agreement (the "Agreement");

NOW, THEREFORE, in consideration of the Warrantholder executing and delivering the Loan Agreement and providing the financial accommodations contemplated therein, and in consideration of the mutual covenants and agreements contained herein, the Company and Warrantholder agree as follows:

**SECTION 1. GRANT OF THE RIGHT TO PURCHASE PREFERRED STOCK.**

For value received, the Company hereby grants to the Warrantholder, and the Warrantholder is entitled, upon the terms and subject to the conditions hereinafter set forth, to subscribe for and purchase, from the Company, One Million Nine Hundred Twenty Five Thousand (1,925,000) fully paid and non-assessable shares of the Preferred Stock (as defined below). The Exercise Price is a price equal to the lower of (a) \$1.25 per share if this Agreement is exercised for Series A Preferred Stock (as defined below) or (b) the price per Share paid in the next private institutional equity financing of the Company prior to an Initial Public Offering if this Agreement is exercised for securities sold in such private institutional equity financing. The number of shares and Exercise Price are subject to adjustment as provided in Section 8. As used herein, the following terms shall have the following meanings:

"Act" means the Securities Act of 1933, as amended.

"Charter" means the Company's Articles of Incorporation, Certificate of Incorporation or other constitutional document, as may be amended from time to time.

"Common Stock" means the Company's common stock, \$0.001 par value per share;

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“Initial Public Offering” means the initial underwritten public offering of Common Stock pursuant to a registration statement under the Act, which registration statement for the public offering has been declared effective by the Securities and Exchange Commission (“SEC”);

“Merger Event” means a merger or consolidation involving the Company in which the Company is not the surviving entity, or in which the outstanding shares of the Company’s capital stock are otherwise converted into or exchanged for shares of capital stock of another entity.

“Preferred Stock” means the Series A Preferred Stock, \$0.001 par value per share, of the Company (the “Series A Preferred Stock”) and any other stock into or for which the Series A Preferred Stock may be converted or exchanged; provided that if the Company issues its equity securities in a private institutional equity financing after the date hereof but before the date of the Initial Public Offering then, at Holder’s option, the Preferred Stock shall be of the class and type sold in such financing. Upon and after the occurrence of an event which results in the automatic or voluntary conversion, redemption or retirement of all (but not less than all) of the outstanding shares of such Preferred Stock, including, without limitation, the consummation of an Initial Public Offering of the Common Stock in which such a conversion occurs, then from and after the date upon which such outstanding shares are so converted, redeemed or retired, “Preferred Stock” shall mean such Common Stock. Notwithstanding the foregoing, in no event shall “Preferred Stock” include any debt security or other evidences of indebtedness of the Company.

“Purchase Price” means, with respect to any exercise of this Agreement, an amount equal to the Exercise Price as of the relevant time multiplied by the number of shares of Preferred Stock requested to be exercised under this Agreement pursuant to such exercise.

“Rights Agreement” means that certain Investor’s Rights Agreement, between the Company and certain of its stockholders, dated March 23, 2007.

## **SECTION 2. TERM OF THE AGREEMENT.**

Except as otherwise provided for herein, the term of this Agreement and the right to purchase Preferred Stock as granted herein (the “Warrant”) shall commence on the Effective Date and shall be exercisable for a period ending upon the earlier to occur of (i) ten (10) years from the Effective Date; or (ii) five (5) years following the effective date of the registration statement for the Initial Public Offering (the earlier of (i) and (ii), the “Expiration Date”).

## **SECTION 3. EXERCISE OF THE PURCHASE RIGHTS.**

(a) Exercise. The purchase rights set forth in this Agreement are exercisable by the Warranholder, in whole or in part, at any time, or from time to time, prior to the Expiration Date, by tendering to the Company at its principal office a notice of exercise in the form attached hereto as Exhibit I (the “Notice of Exercise”), duly completed and executed. Promptly upon receipt of the Notice of Exercise and the payment of the Purchase Price in accordance with the terms set forth below, and in no event later than three (3) days thereafter, the Company shall issue to the Warranholder a certificate for the number of shares of Preferred Stock purchased and shall execute the acknowledgment of exercise in the form attached hereto as Exhibit II (the “Acknowledgment of Exercise”) indicating the number of shares which remain subject to future exercises, if any.

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The Purchase Price may be paid at the Warrantholder's election either (i) by cash or check, or (ii) by surrender of all or a portion of the Warrant for shares of Preferred Stock to be exercised under this Agreement and, if applicable, an amended Agreement representing the remaining number of shares purchasable hereunder, as determined below ("Net Issuance"). If the Warrantholder elects the Net Issuance method of exercise, the Company will issue Preferred Stock in accordance with the following formula:

$$X = \frac{Y(A-B)}{A}$$

Where: X = the number of shares of Preferred Stock to be issued to the Warrantholder.

Y = the number of shares of Preferred Stock requested to be exercised under this Agreement.

A = the fair market value of one (1) share of Preferred Stock at the time of issuance of such shares of Preferred Stock.

B = the Exercise Price.

For purposes of the above calculation, current fair market value of Preferred Stock shall mean with respect to each share of Preferred Stock:

(i) if the exercise is in connection with an Initial Public Offering, and if the Company's Registration Statement relating to such Initial Public Offering has been declared effective by the SEC, then the fair market value per share shall be the product of (x) the initial "Price to Public" of the Common Stock specified in the final prospectus with respect to the offering and (y) the number of shares of Common Stock into which each share of Preferred Stock is convertible at the time of such exercise;

(ii) if the exercise is after, and not in connection with an Initial Public Offering,:

(A) if the Common Stock is traded on a securities exchange, then the fair market value shall be deemed to be the product of (x) the average of the closing prices over a five (5) day period ending three days before the day the current fair market value of the securities is being determined and (y) the number of shares of Common Stock into which each share of Preferred Stock is convertible at the time of such exercise; or

(B) if the Common Stock is traded over-the-counter, then the fair market value shall be deemed to be the product of (x) the average of the closing bid and asked prices quoted on the NASDAQ system (or similar system) over the five (5) day period ending three days before the day the current fair market value of the securities is being determined and (y) the number of shares of Common Stock into which each share of Preferred Stock is convertible at the time of such exercise;

(iii) if at any time the Common Stock is not listed on any securities exchange or quoted in the NASDAQ National Market or the over-the-counter market, the current fair market value of Preferred Stock shall be the product of (x) the highest price per share which the Company could obtain from a willing buyer (not a current employee or director) for shares of Common Stock sold by the Company, from authorized but unissued shares, as determined in good faith by its Board of Directors and (y) the number of shares of Common Stock into which each share of Preferred Stock is convertible at the



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time of such exercise, unless the Company shall become subject to a Merger Event, in which case the fair market value of Preferred Stock shall be deemed to be the per share value received by the holders of the Preferred Stock on an as-converted-to common stock basis pursuant to such Merger Event.

Upon partial exercise by either cash or Net Issuance, the Company shall promptly issue an amended Agreement representing the remaining number of shares of Preferred Stock purchasable hereunder. All other terms and conditions of such amended Agreement shall be identical to those contained herein, including, but not limited to the Effective Date hereof.

(b) Exercise Prior to Expiration. To the extent this Agreement is not previously exercised as to all Preferred Stock subject hereto, and if the fair market value of one share of the Preferred Stock is greater than the Exercise Price then in effect, this Agreement shall be deemed automatically exercised pursuant to Section 3(a) (even if not surrendered) immediately prior to the Expiration Date. For purposes of such automatic exercise, the fair market value of one share of the Preferred Stock upon such Expiration Date shall be determined pursuant to Section 3(a). To the extent this Agreement or any portion thereof is deemed automatically exercised pursuant to this Section 3(b), the Company agrees to promptly notify the Warrantholder of the number of shares of Preferred Stock, if any, the Warrantholder is to receive by reason of such automatic exercise.

#### **SECTION 4. RESERVATION OF SHARES.**

During the term of this Agreement, the Company will at all times have authorized and reserved a sufficient number of shares of its Series A Preferred Stock to provide for the exercise of the rights to purchase Series A Preferred Stock as provided for herein, and shall have authorized and reserved a sufficient number of shares of Common Stock to provide for the conversion of the Series A Preferred Stock available hereunder.

#### **SECTION 5. NO FRACTIONAL SHARES OR SCRIP.**

No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Agreement, but in lieu of such fractional shares the Company shall make a cash payment therefor in an amount equal to the product of (i) the Exercise Price then in effect, multiplied by (ii) the fraction of a share.

#### **SECTION 6. REGISTRATION RIGHTS; NO OTHER RIGHTS AS STOCKHOLDER.**

The Common Stock into which the Preferred Stock is convertible shall be "Registrable Securities", and Warrantholder shall have the rights of an "Investor" under the Rights Agreement. This Agreement does not entitle the Warrantholder to any voting rights or other rights as a stockholder of the Company prior to the exercise of this Agreement.

#### **SECTION 7. WARRANTHOLDER REGISTRY.**

The Company shall maintain a registry showing the name and address of the registered holder of this Agreement. Warrantholder's initial address, for purposes of such registry, is set forth below Warrantholder's signature on this Agreement. Warrantholder may change such address by giving written notice of such changed address to the Company.

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## SECTION 8. ADJUSTMENT RIGHTS.

The Exercise Price and the number of shares of Preferred Stock purchasable hereunder are subject to adjustment, as follows:

(a) Merger Event. If at any time there shall be Merger Event, then, as a part of such Merger Event, lawful provision shall be made so that the Warrantholder shall thereafter be entitled to receive, upon exercise of this Agreement, the number of shares of preferred stock or other securities or property of the successor corporation resulting from such Merger Event that would have been issuable if Warrantholder had exercised this Agreement immediately prior to the Merger Event. In any such case, appropriate adjustment (as determined in good faith by the Company's Board of Directors) shall be made in the application of the provisions of this Agreement with respect to the rights and interests of the Warrantholder after the Merger Event to the end that the provisions of this Agreement (including adjustments of the Exercise Price and number of shares of Preferred Stock purchasable) shall be applicable in their entirety, and to the greatest extent possible. Without limiting the foregoing, in connection with any Merger Event, upon the closing thereof, the successor or surviving entity shall assume the obligations of this Agreement. In connection with a Merger Event and upon Warrantholder's written election to the Company, the Company shall cause this Warrant Agreement to be exchanged for the consideration that Warrantholder would have received if Warrantholder chose to exercise its right to have shares issued pursuant to the Net Issuance provisions of this Warrant Agreement without actually exercising such right, acquiring such shares and exchanging such shares for such consideration.

(b) Reclassification of Shares. Except as set forth in Section 8(a), if the Company at any time shall, by combination, reclassification, exchange or subdivision of securities or otherwise, change any of the securities as to which purchase rights under this Agreement exist into the same or a different number of securities of the same class or any other class or classes, this Agreement shall thereafter represent the right to acquire such number and kind of securities as would have been issuable as the result of such change with respect to the securities which were subject to the purchase rights under this Agreement immediately prior to such combination, reclassification, exchange, subdivision or other change.

(c) Subdivision or Combination of Shares. If the Company at any time shall combine or subdivide its Preferred Stock, (i) in the case of a subdivision, the Exercise Price shall be proportionately decreased, and the number of shares of Preferred Stock issuable upon exercise of this Agreement shall be proportionately increased, or (ii) in the case of a combination, the Exercise Price shall be proportionately increased, and the number of shares of Preferred Stock issuable upon the exercise of this Agreement shall be proportionately decreased.

(d) Stock Dividends. If the Company at any time while this Agreement is outstanding and unexpired shall:

(i) pay a dividend with respect to the Preferred Stock payable in Preferred Stock, then the Exercise Price shall be adjusted, from and after the date of determination of stockholders entitled to receive such dividend or distribution, to that price determined by multiplying the Exercise Price in effect immediately prior to such date of determination by a fraction (A) the numerator of which shall be the total number of shares of Preferred Stock outstanding immediately prior to such dividend or distribution, and (B) the denominator of which shall be the total number of shares of Preferred Stock outstanding immediately after such dividend or distribution; or

(ii) make any other distribution with respect to Preferred Stock (or stock into which the Preferred Stock is convertible), except any distribution specifically provided for in any other clause of this Section 8, then, in each such case, provision shall be made by the Company such that the Warrantholder shall receive upon exercise or conversion of this Warrant a proportionate share of any such distribution as though it were the holder of the Preferred Stock (or other stock for which the Preferred Stock is convertible) as of the record date fixed for the determination of the stockholders of the Company entitled to receive such distribution.

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(e) Antidilution Rights. Additional antidilution rights applicable to the Preferred Stock purchasable hereunder are as set forth in the Charter and shall be applicable with respect to the Preferred Stock issuable hereunder. The Company shall promptly provide the Warrantholder with any restatement, amendment, modification or waiver of the Charter; provided, that no such amendment, modification or waiver shall impair or reduce the antidilution rights applicable to the Preferred Stock as of the date hereof unless such amendment, modification or waiver affects the rights of Warrantholder with respect to the Preferred Stock in the same manner as it affects all other holders of Preferred Stock. The Company shall provide Warrantholder with prior written notice of any issuance of its stock or other equity security to occur after the Effective Date, which notice shall include (a) the price at which such stock or security is to be sold, (b) the number of shares to be issued, and (c) such other information as is reasonably necessary for Warrantholder to determine if a dilutive event has occurred. For the avoidance of doubt, there shall be no duplicate anti-dilution adjustment pursuant to this subsection (e), the forgoing subsection (d) and the Charter.

(f) Notice of Adjustments. If: (i) the Company shall declare any dividend or distribution upon its stock, whether in stock, cash, property or other securities; (ii) the Company shall offer for subscription prorata to the holders of any class of its Preferred Stock or other convertible stock any additional shares of stock of any class or other rights; (iii) there shall be any Merger Event; (iv) there shall be an Initial Public Offering; (v) the Company shall sell, lease, exclusive license or otherwise transfer all or substantially all of its assets; or (vi) there shall be any voluntary dissolution, liquidation or winding up of the Company; then, in connection with each such event, the Company shall send to the Warrantholder: (A) at least ten (10) days' prior written notice of the date on which the books of the Company shall close or a record shall be taken for such dividend, distribution, subscription rights (specifying the date on which the holders of Preferred Stock shall be entitled thereto) or for determining rights to vote in respect of such Merger Event, dissolution, liquidation or winding up; (B) in the case of any such Merger Event, sale, lease, exclusive license or other transfer of all or substantially all assets, dissolution, liquidation or winding up, at least ten (10) days' prior written notice of the date when the same shall take place (and specifying the date on which the holders of Preferred Stock shall be entitled to exchange their Preferred Stock for securities or other property deliverable upon such Merger Event, dissolution, liquidation or winding up); and (C) in the case of an Initial Public Offering, the Company shall give the Warrantholder at least five (5) days' written notice prior to the effective date of the registration statement therefore. .

Each such written notice shall set forth, in reasonable detail, (i) the event requiring the notice, and (ii) if any adjustment is required to be made, (A) the amount of such adjustment, (B) the method by which such adjustment was calculated, (C) the adjusted Exercise Price (if the Exercise Price has been adjusted), and (D) the number of shares subject to purchase hereunder after giving effect to such adjustment. Such written notice shall be given by first class mail, postage prepaid, by reputable overnight courier with all charges prepaid or via electronic transmission, addressed to the Warrantholder at the address for Warrantholder set forth in Section 12(g).

(g) Election. At least ten (10) days prior to the consummation of any private institutional equity financing of the Company to be consummated prior to the Initial Public Offering (an "Equity Financing"), the Company shall give written notice to the Warrantholder of such Equity Financing (the "Financing Notice") setting forth a summary of the material terms of such Equity Financing. Within three (3) days following the date of such Financing Notice, the Warrantholder

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shall deliver written notice to the Company electing to have the securities set forth in the following clause (i) or (ii) be issuable upon exercise of this warrant (i) Series A Preferred Stock of the Company or (ii) the class and series of equity securities issued in such Equity Financing, be issuable upon exercise of this Warrant. From and after such election, the equity securities set forth in such notice shall be deemed "Preferred Stock" for all purposes hereof.

**SECTION 9. REPRESENTATIONS, WARRANTIES AND COVENANTS OF THE COMPANY.**

(a) Reservation of Preferred Stock. The Series A Preferred Stock issuable upon exercise of the Warrantholder's rights has been duly and validly reserved and, when the Preferred Stock is issued in accordance with the provisions of this Agreement, will be validly issued, fully paid and non-assessable, and will be free of any taxes, liens, charges or encumbrances of any nature whatsoever; provided, that the Preferred Stock issuable pursuant to this Agreement may be subject to restrictions on transfer under state and/or federal securities laws. The Company has made available to the Warrantholder true, correct and complete copies of its Charter and bylaws currently in effect. The issuance of certificates for shares of Preferred Stock upon exercise of this Agreement shall be made without charge to the Warrantholder for any issuance tax in respect thereof, or other cost incurred by the Company in connection with such exercise and the related issuance of shares of Preferred Stock; provided, that the Company shall not be required to pay any tax which may be payable in respect of any transfer and the issuance and delivery of any certificate in a name other than that of the Warrantholder.

(b) Due Authority. The execution and delivery by the Company of this Agreement and the performance of all obligations of the Company hereunder, including the issuance to Warrantholder of the right to acquire the shares of Preferred Stock and the Common Stock into which it may be converted, have been duly authorized by all necessary corporate action on the part of the Company. This Agreement: (1) does not violate the Charter or current bylaws; (2) does not contravene any law or governmental rule, regulation or order applicable to it; and (3) does not and will not contravene any provision of, or constitute a default under, any indenture, mortgage, contract or other instrument to which it is a party or by which it is bound. This Agreement constitutes a legal, valid and binding agreement of the Company, enforceable in accordance with its terms except (a) as limited by applicable bankruptcy, insolvency, reorganization, moratorium, and other laws of general application affecting enforcement of creditors' rights generally, and (b) as limited by laws relating to the availability of specific performance, injunctive relief, or other equitable remedies.

(c) Consents and Approvals. No consent or approval of, giving of notice to, registration with, or taking of any other action in respect of any state, federal or other governmental authority or agency is required with respect to the execution, delivery and performance by the Company of its obligations under this Agreement, except for the filing of notices pursuant to Regulation D under the Act and any filing required by applicable state securities law, which filings will be effective by the time required thereby.

(d) Issued Securities. All issued and outstanding shares of Common Stock, Series A Preferred Stock or any other securities of the Company have been duly authorized and validly issued and are fully paid and nonassessable. All outstanding shares of Common Stock, Series A Preferred Stock and any other securities were issued in full compliance with all federal and state securities laws. In addition, as of the date immediately preceding the date of this Agreement:

(i) The authorized capital of the Company consists of (A) 120,000,000 shares of Common Stock, of which 6,171,755 shares are issued and outstanding, and (B)

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88,000,000 shares of Series A Preferred Stock, of which 68,000,000 shares are issued and outstanding and are convertible into 68,000,000 shares of Common Stock at \$1.25 per share.

(ii) The Company has reserved 18,600,750 shares of Common Stock for issuance under its Stock Option Plan(s), under which 16,170,553 options are outstanding. Other than warrants to purchase (i) an aggregate of 1,700,000 shares of Common Stock and (ii) an aggregate of 250,000 shares of Series A Preferred Stock, there are no other options, warrants, conversion privileges or other rights presently outstanding to purchase or otherwise acquire any authorized but unissued shares of the Company's capital stock or other securities of the Company. The Company has no outstanding loans to any employee, officer or director of the Company, and the Company agrees not to enter into any such loan or otherwise guarantee the payment of any loan made to an employee, officer or director by a third party.

(iii) Except as set forth in the Rights Agreement, , no stockholder of the Company has preemptive rights to purchase new issuances of the Company's capital stock.

(e) Other Commitments to Register Securities. Except as set forth in this Agreement and the Rights Agreement, the Company is not, pursuant to the terms of any other agreement currently in existence, under any obligation to register under the Act any of its presently outstanding securities or any of its securities which may hereafter be issued.

(f) Exempt Transaction. Subject to the accuracy of the Warrantholder's representations set forth in Section 10, the issuance of the Preferred Stock upon exercise of this Agreement, and the issuance of the Common Stock upon conversion of the Preferred Stock, will each constitute a transaction exempt from (i) the registration requirements of Section 5 of the Act, in reliance upon Section 4(2) thereof, and (ii) the qualification requirements of the applicable state securities laws.

(g) Compliance with Rule 144. If the Warrantholder proposes to sell Preferred Stock issuable upon the exercise of this Agreement, or the Common Stock into which it is convertible, in compliance with Rule 144 promulgated by the SEC, then, upon Warrantholder's written request to the Company, the Company shall furnish to the Warrantholder, within ten (10) days after receipt of such request, a written statement confirming the Company's compliance with the filing requirements of the SEC as set forth in such Rule, as such Rule may be amended from time to time.

(h) Information Rights. During the term of this Warrant, Warrantholder shall be entitled to the information rights contain in Section 7.1 of the Loan Agreement, and Section 7.1 of the Loan Agreement is hereby incorporated into this Agreement by this reference as though fully set forth herein, provided, however, that the Company shall not be required to deliver a Compliance Certificate once all Indebtedness (as defined in the Loan Agreement) owed by the Company to Warrantholder has been repaid.

#### **SECTION 10. REPRESENTATIONS AND COVENANTS OF THE WARRANTHOLDER.**

This Agreement has been entered into by the Company in reliance upon the following representations and covenants of the Warrantholder:

(a) Investment Purpose. This Agreement and the Preferred Stock issuable upon exercise of the Warrantholder's rights contained herein are and will be acquired for investment

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and not with a view to the sale or distribution of any part thereof, and the Warrantholder has no present intention of selling or engaging in any public distribution of the same except pursuant to a registration or exemption.

(b) Private Issue. The Warrantholder understands (i) that the Preferred Stock issuable upon exercise of this Agreement is not registered under the Act or qualified under applicable state securities laws on the ground that the issuance contemplated by this Agreement will be exempt from the registration and qualifications requirements thereof, and (ii) that the Company's reliance on such exemption is predicated on the representations set forth in this Section 10.

(c) Financial Risk. The Warrantholder has such knowledge and experience in financial and business matters as to be capable of evaluating the merits and risks of its investment, and has the ability to bear the economic risks of its investment.

(d) Risk of No Registration. The Warrantholder understands that if the Company does not register with the SEC pursuant to Section 12 of the Securities Exchange Act of 1934 (the "1934 Act"), or file reports pursuant to Section 15(d) of the 1934 Act, or if a registration statement covering the securities under the Act is not in effect when it desires to sell (i) the rights to purchase Preferred Stock pursuant to this Agreement or (ii) the Preferred Stock issuable upon exercise of the right to purchase, it may be required to hold such securities for an indefinite period. The Warrantholder also understands that any sale of (A) its rights hereunder to purchase Preferred Stock or (B) Preferred Stock issued or issuable hereunder which might be made by it in reliance upon Rule 144 under the Act may be made only in accordance with the terms and conditions of that Rule.

(e) Accredited Investor. Warrantholder is an "accredited investor" within the meaning of the Securities and Exchange Rule 501 of Regulation D, as presently in effect.

#### **SECTION 11. TRANSFERS.**

Subject to compliance with applicable federal and state securities laws, this Agreement and all rights hereunder are transferable, in whole or in part, without charge to the holder hereof (except for transfer taxes) upon surrender of this Agreement properly endorsed. Each taker and holder of this Agreement, by taking or holding the same, consents and agrees that this Agreement, when endorsed in blank, shall be deemed negotiable, and that the holder hereof, when this Agreement shall have been so endorsed and its transfer recorded on the Company's books, shall be treated by the Company and all other persons dealing with this Agreement as the absolute owner hereof for any purpose and as the person entitled to exercise the rights represented by this Agreement. The transfer of this Agreement shall be recorded on the books of the Company upon receipt by the Company of a notice of transfer in the form attached hereto as Exhibit III (the "Transfer Notice"), at its principal offices and the payment to the Company of all transfer taxes and other governmental charges imposed on such transfer. Until the Company receives such Transfer Notice, the Company may treat the registered owner hereof as the owner for all purposes. Notwithstanding the foregoing, this Agreement shall not be transferable to any competitor of the Company prior to the Initial Public Offering (as determined in good faith by the Board of Directors of the Company).

#### **SECTION 12. MISCELLANEOUS.**

(a) Effective Date. The provisions of this Agreement shall be construed and shall be given effect in all respects as if it had been executed and delivered by the Company on the date hereof. This Agreement shall be binding upon any successors or assigns of the Company.

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(b) Remedies. In the event of any default hereunder, the non-defaulting party may proceed to protect and enforce its rights either by suit in equity and/or by action at law, including but not limited to an action for damages as a result of any such default, and/or an action for specific performance for any default where Warrantholder will not have an adequate remedy at law and where damages will not be readily ascertainable. The Company expressly agrees that it shall not oppose an application by the Warrantholder or any other person entitled to the benefit of this Agreement requiring specific performance of any or all provisions hereof or enjoining the Company from continuing to commit any such breach of this Agreement.

(c) Additional Documents. The Company, upon execution of this Agreement, shall provide the Warrantholder with certified resolutions with respect to the representations, warranties and covenants set forth in Sections 9(a) through 9(d) and 9(f). The Company shall also supply such other documents as the Warrantholder may from time to time reasonably request.

(d) Attorney's Fees. In any litigation, arbitration or court proceeding between the Company and the Warrantholder relating hereto, the prevailing party shall be entitled to attorneys' fees and expenses and all costs of proceedings incurred in enforcing this Agreement. For the purposes of this Section 12(e), attorneys' fees shall include without limitation fees incurred in connection with the following: (i) contempt proceedings; (ii) discovery; (iii) any motion, proceeding or other activity of any kind in connection with an insolvency proceeding; (iv) garnishment, levy, and debtor and third party examinations; and (v) post-judgment motions and proceedings of any kind, including without limitation any activity taken to collect or enforce any judgment.

(e) Severability. In the event any one or more of the provisions of this Agreement shall for any reason be held invalid, illegal or unenforceable, the remaining provisions of this Agreement shall be unimpaired, and the invalid, illegal or unenforceable provision shall be replaced by a mutually acceptable valid, legal and enforceable provision, which comes closest to the intention of the parties underlying the invalid, illegal or unenforceable provision.

(f) Notices. Except as otherwise provided herein, any notice, demand, request, consent, approval, declaration, service of process or other communication that is required, contemplated, or permitted under this Agreement or with respect to the subject matter hereof shall be in writing, and shall be deemed to have been validly served, given, delivered, and received upon the earlier of: (i) the day of transmission by facsimile, electronic transmission or hand delivery if such transmission or delivery occurs on a business day at or before 5:00 pm in the time zone of the recipient, or, if transmission or delivery occurs on a non-business day or after such time, the first business day thereafter, or the first business day after deposit with an overnight express service or overnight mail delivery service; or (ii) the third calendar day after deposit in the United States mails, with proper first class postage prepaid, and shall be addressed to the party to be notified as follows:

If to Warrantholder:

HERCULES TECHNOLOGY GROWTH CAPITAL, INC.  
Legal Department  
Attention: Chief Legal Officer and Manuel Henriquez  
400 Hamilton Avenue, Suite 310  
Palo Alto, CA 94301  
Facsimile: 650-473-9194  
Telephone: 650-289-3060  
Email : pshah@herculestech.com

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If to the Company:

PACIRA PHARMACEUTICALS, INC.  
5 Sylvan Way  
Parsipany, NJ 07054  
Attention: James Scibetta  
Facsimile:  
Telephone: 973-254-3570  
Email: james.scibetta@pacira.com

With a copy to:

WilmerHale LLP  
950 Page Mill Road  
Palo Alto, CA 94304  
Attention: Joe Wyatt  
Facsimile: 650-858-6100  
Telephone: 650-858-6016  
Email: joe.wyatt@wilmerhale.com

or to such other address as each party may designate for itself by like notice, provided that any notice delivered to Warrantholder or Company shall be valid notwithstanding the failure to deliver a copy of such notice to any other person or entity.

(g) No Strict Construction. The parties hereto have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the parties hereto and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any provisions of this Agreement.

(h) No Waiver. No omission or delay by Warrantholder at any time to enforce any right or remedy reserved to it, or to require performance of any of the terms, covenants or provisions hereof by the Company at any time designated, shall be a waiver of any such right or remedy to which Warrantholder is entitled, nor shall it in any way affect the right of Warrantholder to enforce such provisions thereafter.

(i) Survival. All agreements, representations and warranties contained in this Agreement or in any document delivered pursuant hereto shall be for the benefit of Warrantholder and shall survive the execution and delivery of this Agreement and the expiration or other termination of this Agreement.

(j) Governing Law. This Agreement have been negotiated and delivered to Warrantholder in the State of California, and shall have been accepted by Warrantholder in the State of California. Delivery of Preferred Stock to Warrantholder by the Company under this Agreement is due in the State of California. This Agreement shall be governed by, and construed and enforced in accordance with, the laws of the State of California, excluding conflict of laws principles that would cause the application of laws of any other jurisdiction.

(k) Consent to Jurisdiction and Venue. All judicial proceedings arising in or under or related to this Agreement may be brought in any state or federal court of competent jurisdiction located in the State of California. By execution and delivery of this Agreement, each party hereto generally and unconditionally: (a) consents to personal jurisdiction in Santa Clara County, State of California; (b) waives any objection as to jurisdiction or venue in Santa Clara County, State of California; (c) agrees not to assert any defense based on lack of jurisdiction or venue in the aforesaid courts; and (d) irrevocably agrees to be bound by any judgment rendered thereby in connection with this Agreement.



(l) Mutual Waiver of Jury Trial: Judicial Reference. Because disputes arising in connection with complex financial transactions are most quickly and economically resolved by an experienced and expert person and the parties wish applicable state and federal laws to apply (rather than arbitration rules), the parties desire that their disputes be resolved by a judge applying such applicable laws. EACH OF THE COMPANY AND WARRANTHOLDER SPECIFICALLY WAIVES ANY RIGHT IT MAY HAVE TO TRIAL BY JURY OF ANY CAUSE OF ACTION, CLAIM, CROSS-CLAIM, COUNTERCLAIM, THIRD PARTY CLAIM OR ANY OTHER CLAIM (COLLECTIVELY, "CLAIMS") ASSERTED BY THE COMPANY AGAINST WARRANTHOLDER OR ITS ASSIGNEE OR BY WARRANTHOLDER OR ITS ASSIGNEE AGAINST THE COMPANY. This waiver extends to all such Claims, including Claims that involve Persons other than the Company and Warrantholder; Claims that arise out of or are in any way connected to the relationship between the Company and Warrantholder; and any Claims for damages, breach of contract, specific performance, or any equitable or legal relief of any kind, arising out of this Agreement. If this waiver of jury trial is ineffective or unenforceable, the parties agree that all Claims shall be resolved by reference to a private judge sitting without a jury, pursuant to Code of Civil Procedure Section 638, before a mutually acceptable referee or, if the parties cannot agree, a referee selected by the Presiding Judge of the Santa Clara County, California. Such proceeding shall be conducted in Santa Clara County, California, with California rules of evidence and discovery applicable to such proceeding. In the event Claims are to be resolved by judicial reference, either party may seek from a court identified in this Section, any prejudgment order, writ or other relief and have such prejudgment order, writ or other relief enforced to the fullest extent permitted by law notwithstanding that all Claims are otherwise subject to resolution by judicial reference

(m) Counterparts. This Agreement and any amendments, waivers, consents or supplements hereto may be executed in any number of counterparts, and by different parties hereto in separate counterparts, each of which when so delivered shall be deemed an original, but all of which counterparts shall constitute but one and the same instrument.

(n) Specific Performance. The parties hereto hereby declare that it is impossible to measure in money the damages which will accrue to Warrantholder by reason of the Company's failure to perform any of the obligations under this Agreement and agree that the terms of this Agreement shall be specifically enforceable by Warrantholder. If Warrantholder institutes any action or proceeding to specifically enforce the provisions hereof, any person against whom such action or proceeding is brought hereby waives the claim or defense therein that Warrantholder has an adequate remedy at law, and such person shall not offer in any such action or proceeding the claim or defense that such remedy at law exists.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by its officers thereunto duly authorized as of the Effective Date.

COMPANY:

PACIRA PHARMACEUTICALS, INC.

By: /s/ James Scibetta

Name: James Scibetta

Title: Chief Financial Officer

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WARRANTHOLDER: HERCULES TECHNOLOGY GROWTH CAPITAL, INC.

By: /s/ K. Nicholas Martitsch  
K. Nicholas Martitsch  
Title: Associate General Counsel

EXHIBIT I

NOTICE OF EXERCISE

To: Pacira Pharmaceuticals, Inc.

- (1) The undersigned Warrantholder hereby elects to purchase [\_\_\_\_\_] shares of the Series [\_\_\_] Preferred Stock of [\_\_\_\_], pursuant to the terms of the Agreement dated the [\_\_\_] day of [\_\_\_\_, \_\_\_\_] (the "Agreement") between [\_\_\_\_] and the Warrantholder, and [CASH PAYMENT: tenders herewith payment of the Purchase Price in full, together with all applicable transfer taxes, if any.] [NET ISSUANCE: elects pursuant to Section 3(a) of the Agreement to effect a Net Issuance.]
- (2) Please issue a certificate or certificates representing said shares of Series [\_\_\_] Preferred Stock in the name of the undersigned or in such other name as is specified below.

\_\_\_\_\_  
(Name)

\_\_\_\_\_  
(Address)

WARRANTHOLDER: HERCULES TECHNOLOGY GROWTH CAPITAL, INC.

By: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

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EXHIBIT II

ACKNOWLEDGMENT OF EXERCISE

The undersigned [\_\_\_\_\_], hereby acknowledge receipt of the "Notice of Exercise" from Hercules Technology Growth Capital, Inc., [ Hercules Technology II, L.P.] to purchase [\_\_\_\_\_] shares of the Series [\_\_\_] Preferred Stock of [\_\_\_\_\_], pursuant to the terms of the Agreement, and further acknowledges that [\_\_\_\_\_] shares remain subject to purchase under the terms of the Agreement.

COMPANY:

PACIRA PHARMACEUTICALS, INC.

By: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

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EXHIBIT III  
TRANSFER NOTICE

(To transfer or assign the foregoing Agreement execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Agreement and all rights evidenced thereby are hereby transferred and assigned to

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(Please Print)

whose address is

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Dated:

Holder's Signature:

Holder's Address:

**Consent of Independent  
Registered Public Accounting Firm**

We consent to the inclusion in Amendment No. 1 to the Registration Statement on Form S-1 (File No. 333-170245) of Pacira Pharmaceuticals, Inc. of our report, which includes an explanatory paragraph relating to Pacira Pharmaceuticals, Inc.'s ability to continue as a going concern, dated November 1, 2010, except for the effects of the matter discussed in Note 1 ("Correction of Immaterial Errors") which are as of December 3, 2010, on our audits of the consolidated financial statements of Pacira Pharmaceuticals, Inc. as of December 31, 2009 and 2008, and for each of the three years in the period ended December 31, 2009. We also consent to the references to our firm under the captions "Experts" and "Selected Consolidated Financial Data."

/s/ J.H. Cohn LLP

Roseland, New Jersey  
December 3, 2010