51-0619477

(I.R.S. Employer

Identification No.)

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# Amendment No. 3

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.)

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)

Copies to:

Joseph K. Wyatt, Esq. Wilmer Cutler Pickering Hale and Dorr LLP 950 Page Mill Road Palo Alto, California 94304 (650) 858-6000

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<b>Approximate date of commencement of proposed sale to the public:</b> As soon as practicable after this Registration Statement is dec	lared 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 amended (the "Securities Act") please check the following box.	ties Act of 1933, a	S
If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the follist the Securities Act registration statement number of the earlier effective registration statement for the same offering. $\Box$	lowing box and	
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 registration statement number of the earlier effective registration statement for the same offering. $\Box$	t the Securities Ac	t
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 Act registration statement number of the earlier effective registration statement for the same offering. $\Box$	st the Securities	
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b2 of the Exchange Act.	ng company. See	
Large accelerated filer	er [	
Non-accelerated filer   (Do not check if a smaller reporting company)  Smaller report	ing 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 January 13, 2011

**PROSPECTUS** 

4,250,000 Shares



# Common Stock

This is the initial public offering of the common stock of Pacira Pharmaceuticals, Inc. We are offering 4,250,000 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 \$14.00 and \$16.00 per share.

Investing in our common stock involves risks. See "Risk Factors" beginning on page 11 of this prospectus.

	Per Snare	ıotaı
Price to the public	\$	\$
Underwriting discounts and commissions	\$	\$
Proceeds to us (before expenses)	\$	\$

We have granted the underwriters the option to purchase 637,500 additional shares of common stock on the same terms and conditions set forth above if the underwriters sell more than 4,250,000 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 , 2011.

Barclays Capital			Piper Jaffray
Wedbush PacGrow Life Sciences	Prospectus dated	, 2011.	Brean Murray, Carret & Co.

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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.

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#### 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 11, 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. Our NDA for EXPAREL was accepted by the FDA on December 10, 2010 and the PDUFA goal date for our NDA is July 28, 2011. We are also pursuing several additional indications for EXPAREL and expect to submit a supplemental NDA, or sNDA, for nerve block and epidural administration.

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
EXPAREL	Postsurgical analgesia by infiltration	PDUFA goal date: July 28, 2011	Pacira (worldwide)
	Postsurgical analgesia by nerve block	Phase 2/3 (planning)	Pacira (worldwide)
	Postsurgical analgesia by epidural administration	Phase 1 (completed)	Pacira (worldwide)
DepoCyt(e)	Lymphomatous meningitis	Marketed	Sigma-Tau Pharmaceuticals Mundipharma International
DepoDur	Post-operative pain	Marketed	EKR Therapeutics Flynn Pharmaceuticals
DepoNSAID	Acute pain	Preclinical	Pacira (worldwide)
DepoMethotrexate	Rheumatoid arthritis Oncology	Preclinical Preclinical	Pacira (worldwide) 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, which permits us to rely upon the FDA's previous findings of safety and effectiveness for an approved product. A 505(b)(2) strategy may not succeed if there are successful challenges to the FDA's interpretation of Section 505(b)(2).

#### **Recent Developments**

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. 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 December 31, 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 178,986 shares of our Series A convertible preferred stock with an exercise price of \$13.44 per share. 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.

# December 2010 Convertible Notes

On December 29, 2010, we sold \$15.0 million in aggregate principal amount of convertible promissory notes, or the December 2010 Convertible Notes, in a private placement to certain of our existing investors. 50% of the principal amount was funded on December 29, 2010. The remaining 50% of the principal amount will be funded in a second closing to occur upon written request of holders of at least 75% of the outstanding principal amount of the December 2010 Convertible Notes. In connection with the issuance and sale of the December 2010 Convertible Notes, we issued warrants to the holders of the December 2010 Convertible Notes to purchase an

aggregate of 167,361 shares of our common stock with an exercise price of \$13.44 per share. Pursuant to the terms of the agreement for the issuance and sale of the December 2010 Convertible Notes, in the event a second closing of the issuance and sale of the December 2010 Convertible Notes occurs, we will issue warrants to the holders of the December 2010 Convertible Notes to purchase an additional 167,361 shares of our common stock with an exercise price of \$13.44 per share. The December 2010 Convertible Notes will have an interest rate of 5% per year from and after March 31, 2011 and all principal and accrued and unpaid interest on the December 2010 Convertible Notes is due and payable upon 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 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.

Upon completion of this offering, all principal and interest due under the December 2010 Convertible Notes will be converted into shares of our common stock at a conversion price equal to the price per share of common stock sold in this offering. Purchasers of the December 2010 Convertible Notes included certain holders of more than 5% of our capital stock, or entities affiliated with them.

Amendment of 2007 Plan and Option Grant

In December 2010, our 2007 Stock Option/Stock Issuance Plan, or the 2007 Plan, was amended to increase the number of shares of common stock authorized for issuance under the 2007 Plan from 1,729,498 shares to 2,546,657 shares. On December 29, 2010, our board of directors granted options for an aggregate of 571,300 shares of our common stock to our employees, executive officers and directors. The options have an exercise price of \$5.49 which was the per share value of our common stock on the date of grant. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Stock Based Compensation—Options Granted on December 29, 2010."

#### **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 coinvestors, 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. 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

4,250,000 shares

Common stock to be outstanding after this offering

14,911,448 shares (15,548,948 shares in the event the underwriters elect to exercise their option to purchase additional shares from us in full)

Use of proceeds

We estimate that the net proceeds to us from this offering, after deducting estimated underwriting discounts and commissions and offering expenses, will be approximately \$57.0 million, or approximately \$65.9 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:

- approximately \$36.0 million through the fourth quarter of 2011 for the planned manufacture and commercialization of EXPAREL in the United States;
- approximately \$1.5 million through the fourth quarter of 2011 for the development of EXPAREL for nerve block; 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.

See "Use of Proceeds."

Risk factors

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.

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 December 31, 2010, and excludes:

- 360,291 shares of common stock issuable upon the exercise of warrants outstanding as of December 31, 2010, at a weighted average exercise price of \$8.73 per share;
- 2,073,864 shares of common stock issuable upon the exercise of stock options outstanding as of December 31, 2010, at a weighted average exercise price of \$2.69 per share;
- 363,662 shares of common stock available for future issuance under our equity compensation plans as of December 31, 2010; and

• 167,361 shares of common stock issuable upon the exercise of warrants outstanding as of December 31, 2010, at a weighted average exercise price of \$13.44 per share and 167,361 shares of common stock issuable upon the exercise of warrants to be outstanding in the event a second closing of the issuance and sale of the December 2010 Convertible Notes occurs, at a weighted average exercise price of \$13.44 per share.

Except as otherwise noted, all information in this prospectus:

- gives effect to a one-for-10.755 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;
- does not give effect to the occurrence of a second closing of the issuance and sale of the December 2010 Convertible Notes, which would convert into 500,000 shares of common stock at a conversion price equal to the price per share of the common stock sold in this offering based on an assumed initial public offering price of \$15.00 per share, the midpoint of the estimated price range shown on the cover of this prospectus, or the related warrants which would become exercisable for 167,361 shares of our common stock;
- gives effect to the issuance of 6,322,640 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 500,000 shares of common stock upon the conversion of the December 2010 Convertible Notes at a conversion price equal to the price per share of common stock sold in this offering based on an assumed initial public offering price of \$15.00 per share, the midpoint of the estimated price range shown on the cover of this prospectus;
- gives effect to the issuance of 3,264,777 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 \$47.5 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 \$15.00 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.

	Dradonoscov	1			Suggester			
	Predecessor January 1 to March 23					Months Ended		
	2007	2007	2008		2009	2009		2010
	(unaudited)		(audited)	nde o	xcept share and p	(unaudited)	(	unaudited)
Consolidated Statement of Operations Data:			(in thousa	mus, c.	rcept snare and p	per share data)		
Revenues	\$ 1,427	\$ 8,341	\$ 13,925	\$	15,006	\$ 10,722	\$	12,371
Operating expenses:								
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
Interest:								
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)
Net income (loss)	\$(11,041)	\$(36,193)	\$ (41,862)	\$	(31,707)	\$ (22,736)	\$	(20,105)
Net (loss) per share applicable to common stockholders								
—basic and diluted		\$ (77.85)	\$ (79.23)	\$	(55.32)	\$ (39.69)	\$	(35.02)
Weighted average number of common shares used in net								
(loss) per share calculation—basic and diluted		464,900	528,357		573,118	572,860		574,112
Pro forma net (loss) per share—basic and diluted								
(unaudited) (1)				\$	(3.60)		\$	(1.72)
Shares used in computing pro forma loss per share—basic								
and diluted (unaudited)				8	,545,094		1	0,661,448

<sup>(1)</sup> 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 (including the notes issued upon the first closing of the December 2010 Convertible Notes) and accrued interest thereon into common stock at the beginning of the period or at the original date of issuance, if later, but does not give effect to a second closing of the issuance and sale and subsequent conversion of the December 2010 Convertible Notes into 500,000 shares of our common stock at a conversion price equal to the price per share of common stock sold in this offering, based on an assumed initial public offering price of \$15.00 per share, the midpoint of the estimated price range shown on the cover of this prospectus, or the related warrants which would become exercisable for 167,361 shares of our common stock. The net losses for the years ended December 31, 2009 and the nine months ended September 30, 2010 were adjusted to reflect the elimination of interest expense associated with the assumed conversion at the beginning of each period of the convertible and secured notes in the amounts of \$0.9 million and \$1.7 million, respectively.

	As of September 30, 2010				
	Actual	Pro forma (1) (unaudited, in thousands)	Pro forma as adjusted		
Consolidated Balance Sheet Data:					
Cash and cash equivalents	\$ 13,851	\$36,351	\$ 93,339		
Working capital	6,585	29,085	86,073		
Total assets	52,756	75,256	132,244		
Long-term debt	57,312	29,660	29,660		
Convertible preferred stock, par value	6	_	_		
Common stock, par value	1	11	15		
Accumulated deficit	(129,867)	(129,867)	(129,867)		
Total stockholders' equity (deficit)	(43,038)	7,114	64,102		

<sup>(1)</sup> Pro forma includes the 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. The pro forma information also includes \$7,500,000 of the gross proceeds from the first closing of the issuance and sale of the December 2010 Convertible Notes and the subsequent conversion of the December 2010 Convertible Notes into 500,000 shares of our common stock at a conversion price equal to the price per share of common stock sold in this offering, based on an assumed initial public offering price of \$15.00 per share, the midpoint of the estimated price range shown on the cover of this prospectus. The pro forma consolidated balance sheet data do not give effect to a second closing of the issuance and sale and subsequent conversion of the December 2010 Convertible Notes into 500,000 shares of our common stock at a conversion price equal to the price per share of common stock sold in this offering, based on an assumed initial public offering price of \$15.00 per share, the midpoint of the estimated price range shown on the cover of this prospectus, or the related warrants which would become exercisable for 167,361 shares of our common stock.

#### 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, which was accepted by the FDA for review on December 10, 2010, 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

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

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.

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.

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

As of December 31, 2010, we had 83 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.

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;

- · 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.

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,

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;

- · 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.

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

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 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

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;

- · 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 f

### 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.

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

# 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;

- 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

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

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 issuance and sale of the December 2010 Convertible Notes and the application of the proceeds therefrom, we had \$73.75 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 \$47.5 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 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.

### 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 \$47.5 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.

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

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

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;

- · 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 57.8% 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 \$11.35 per share. Further, investors purchasing common stock in this offering will contribute approximately 32.0% of the total amount invested by stockholders since our inception, but will own only approximately 28.5% 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 December 31, 2010, options to purchase 2,073,864 shares of our common stock at a weighted average exercise price of \$2.69 per share, warrants exercisable for up to 325,422 shares of our common stock at weighted average exercise price of \$8.22 per share and up to 202,230 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 \$13.44 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.

## 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, 10,896,339 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;

- · 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 \$57.0 million (or approximately \$65.9 million if the underwriters exercise their option to purchase additional shares from us in full), based on an assumed initial public offering price of \$15.00 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 (decrease) in the assumed initial public offering price of \$15.00 would increase (decrease) the net proceeds to us from this offering by \$4.0 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:

- approximately \$36.0 million through the fourth quarter of 2011 for the planned manufacture and commercialization of EXPAREL in the United States;
- · approximately \$1.5 million through the fourth quarter of 2011 for the development of EXPAREL for nerve block; 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 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 cash and cash equivalents and 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 \$47.5 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-10.755 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 \$47.5 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-10.755 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 4,250,000 shares of common stock in this offering at an assumed initial public offering price of \$15.00 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."

	Actual	Pro Forma (1)	Pro Forma As Adjusted
Cash and cash equivalents	\$ 13,851	usands, except per share amou \$ 36,351	\$ 93,339
Related party debt, excluding current portion	\$ 42,652	<u> </u>	s —
Long-term debt, excluding current portion	11,250	26,250	26,250
Royalty interest obligation, excluding current portion	3,410	3,410	3,410
Total long-term debt	57,312	29,660	29,660
Series A convertible preferred stock, \$0.001 par value: actual, 88,000,000 shares authorized, 6,322,640 shares issued and outstanding; pro forma and pro forma as adjusted, no shares authorized, issued and outstanding	6	_	_
Preferred stock, \$0.001 par value: actual, no shares authorized, issued and outstanding; pro forma and pro forma as adjusted; 5,000,000 shares authorized, no shares issued and outstanding	_	_	_
Common stock, \$0.001 par value: actual, 120,000,000 shares authorized, 574,903 shares issued and 573,838 shares outstanding; pro forma, 120,000,000 shares authorized, 10,661,448 shares issued and outstanding; pro forma as adjusted, 250,000,000 shares			
authorized, 14,911,448 shares issued and outstanding	1	11	15
Additional paid-in capital	86,824	136,972	193,956
Accumulated deficit	(129,867)	(129,867)	(129,867)
Treasury stock, 1,065 shares at cost	(2)	(2)	(2)
Total stockholders' equity (deficit)	(43,038)	7,114	64,102
Total capitalization	\$ 14,274	\$ 36,774	\$ 93,762

(1) Pro forma includes the 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. The pro forma information also includes \$7,500,000 of the gross proceeds from the first closing of the issuance and sale of the December 2010 Convertible Notes and the subsequent conversion of the December 2010 Convertible Notes into 500,000 shares of our common stock at a conversion price equal to the price per share of common stock sold in this offering, based on an assumed initial public offering price of \$15.00 per share, the midpoint of the estimated price range shown on the cover of this prospectus. The pro forma information does not include the impact of a second closing of the issuance and sale and subsequent conversion of the December 2010 Convertible Notes into 500,000 shares of our common stock at a conversion price equal to the price per share of common stock sold in this offering, based on an assumed initial public offering price of \$15.00 per share, the midpoint of the estimated price range shown on the cover of this prospectus, or the related warrants which would become exercisable for 167,361 shares of our common stock.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$15.00 would increase (decrease) each of cash and cash equivalents, additional paid-in capital and total stockholders' equity in the pro forma as adjusted column by \$4.0 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:

- 181,305 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 \$4.07 per share;
- 1,504,507 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2010, at a weighted average exercise price of \$1.61 per share; and
- 116,054 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 historical net tangible book value as of September 30, 2010 was \$(52.5) million, or \$(91.52) per share of our common stock. Our historical net tangible book value per share represents our total tangible assets less total liabilities, divided by the number of shares of our common stock outstanding on September 30, 2010.

Our pro forma net tangible book value as of September 30, 2010 was \$(2.6) million, or \$(0.24) per share of our common stock. Our pro forma net tangible book value per share set forth below represents our total tangible assets less total liabilities, 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 \$47.5 million aggregate principal amount and all accrued and unpaid interest on secured and unsecured notes (including the notes issued upon the first closing of the December 2010 Convertible 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 4,250,000 shares of our common stock in this offering at an assumed initial public offering price of \$15.00 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 \$54.4 million, or \$3.65 per share. This represents an immediate increase in net tangible book value to existing stockholders of \$3.89 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 \$11.35 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		\$ 15.00
Pro forma net tangible book value per share as of September 30, 2010	\$(0.24)	
Increase per share attributable to sale of shares of common stock in this offering	3.89	
Pro forma as adjusted net tangible book value per share after the offering		
Dilution per share to new investors		3.65 \$11.35

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$15.00 per share would increase (decrease) the pro forma as adjusted net tangible book value by \$4.0 million, the pro forma as adjusted net tangible book value per share after this offering by \$0.27 per share and the dilution per share to investors in this offering by \$0.27 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 \$4.07 per share, representing an immediate increase to existing stockholders of \$4.31 per share and an immediate dilution of \$10.93 per share to new investors. If any shares are issued upon exercise of outstanding options or warrants, you will experience further dilution.

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 and the conversion of \$47.5 million aggregate principal amount and all accrued and unpaid interest on secured and unsecured notes (including the notes issued upon the first closing of the December 2010 Convertible Notes), 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 \$15.00 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:

	Shares Purcha	sed	Total Considerat	ion	Average
					Price Per
	Number	%	Amount	%	Share
Existing stockholders	10,661,448	71.5%	\$ 135,379,681	68.0%	\$12.70
New investors	4,250,000	28.5	63,750,000	32.0	\$15.00
Total	14,911,448	100%	\$199,129,681	100%	

The number of shares purchased from us by existing stockholders is based on 10,161,255 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 \$47.5 million aggregate principal amount and all accrued and unpaid interest on secured and unsecured notes (including the notes issued upon the first closing of the December 2010 Convertible Notes) held by certain of our stockholders into common stock upon the completion of this offering. This number excludes:

- 181,305 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 \$4.07 per share;
- 1,504,507 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2010, at a weighted average exercise price of \$1.61 per share; and
- 116,054 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 4,887,500, or 31.4% of the total number of shares of common stock outstanding after this offering and the percentage of shares held by existing stockholders will decrease to 68.6% 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.

		Predecessor			Ī					Successor				
							Yea	r Ended			Niı	ne Mo	nths E	nded
	Year Ended													
		ber 31, 2006		1, 2007 1 23, 2007	-	2007	Dece 20	mber 31, 08		2009	2009	Septe	mber 3	<u>0,</u> 2010
		(unaudited)						idited)				(una	udited	
Consolidated Statement of				(iı	n thousai	ıds, except sl	are and p	er share d	ata)					
Operations Data:														
Revenues:														
Supply revenue	\$ 3,647	\$ 5,800	\$	684	\$	5,444	\$ 6	,852	\$	6,324	\$ 4,2	73	\$	7,127
Royalties	1,813	2,784	Ψ	500	Ψ	2,388		3,648	Ψ	4,044	2,90		Ψ	2,693
Collaborative licensing and	1,010	2,70		200		2,200		,,,,,,		.,	_,,,	, 0		2,072
development revenue	13,630	3,088		204		509	3	3,425		4,638	3,54	43		2,551
Revenue from SkyePharma	,	,						,		,				,
PLC	1,927	702		39		_		_		_	_	-		_
Total revenues	21,017	12,374		1,427		8,341	13	,925		15,006	10,72	22		12,371
Operating expenses:								<u> </u>						
Cost of revenues	15,312	15,782		2,825		9,492	17	7,463		12,301	8,82	23		10,168
Research and development	21,280	16,060		3,251		20,665	3.	3,214		26,233	18,71	17		14,954
Selling, general and														
administrative	12,768	8,685		2,632		4,170	8	,611		5,020	3,92	20		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	31,40	50		29,063
(Loss) from operations:	(28,343)	(28,153)		(7,281)		(38,386)	(4:	5,363)		(28,548)	(20,73	38)		(16,692)
Other income (expense)	1,525	(2,713)		(13)		16		(224)		367	3:	53		100
Interest income (expense)														
Interest income	25	60		4		491		235		77		46		112
Interest (expense)	(8,485)	(11,221)		(2,265)						(1,723)	(	90)		(2,577)
Royalty interest obligation	961	4,694		(1,486)	_	1,686		3,490		(1,880)	(1,40			(1,048)
Net income (loss)	\$ (34,317)	\$ (37,333)	\$	(11,041)	\$ (	(36,193)	\$ (4)	,862)	\$	(31,707)	\$ (22,73	36)	\$	(20,105)
Net (loss) per share applicable to														
common stockholders—basic														
and diluted					\$	(77.85)	\$ (	79.23)	\$	(55.32)	\$ (39.6	59)	\$	(35.02)
Weighted average number of														
common shares used in net														
(loss) per share calculation						164,900	528	3,357		573,118	572,86	50		574,112
Pro forma net (loss) per share														
—basic and diluted									Ф	(2.60)			Ф	(1.70)
(unaudited)(1)									\$	(3.60)			\$	(1.72)
Shares used in computing pro forma loss per share—basic and														
diluted (unaudited)									Q	3,545,094			10	0.661.448
unated (unaddited)									0	,,,,,,,,,,			1 (	,,,,,,,,,,

<sup>(1)</sup> 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 (including the notes issued upon the first closing of the December 2010 Convertible Notes) and accrued interest thereon into common stock at the beginning of the period or at the original date of issuance, if later, but does not give effect to a second closing of the issuance and sale and subsequent conversion of the December 2010 Convertible Notes into 500,000 shares of our common stock at a conversion price equal to the price per share of common stock sold in this offering, based on an assumed initial public offering price of \$15.00 per share, the midpoint of the estimated price range shown on the cover of this prospectus, or the related warrants which would become exercisable for 167,361 shares of our common stock. The net losses for the years ended December 31, 2009 and the nine months ended September 30, 2010 were adjusted to reflect the elimination of interest expense associated with the assumed conversion at the beginning of each period of the convertible and secured notes in the amounts of \$0.9 million and \$1.7 million, respectively.

	Predecessor Successor							
	Decem	ber 31,		December 31,			September 30, 2010	
	2005 (unau-	2006	2007 (unaudited)	2008	2009 lited)	Actual	Pro forma (1) (unaudited)	Pro forma as adjusted
			(in thousa	inds)				
Consolidated Balance Sheet								
Data:								
Cash and cash equivalents	\$ 911	\$ 627	\$ 7,240	\$ 12,386	\$ 7,077	\$ 13,851	\$ 36,351	93,339
Working capital (deficit)	17,004	27,010	2,354	2,341	(1,868)	6,585	29,085	86,073
Total assets	61,698	63,188	39,157	50,541	43,954	52,756	75,256	132,244
Long-term debt	28,789	21,648	8,241	3,618	25,820	57,312	29,660	29,660
Convertible preferred stock, par								
value	_	_	3	6	6	6	_	_
Common stock, par value	_	_	1	1	1	1	11	15
Accumulated deficit	(282,423)	(319,756)	(36,193)	(78,055)	(109,762)	(129,867)	(129,867)	(129,867)
Total stockholders' equity (deficit)	\$(163,867)	\$ (221,541)	\$ 8,937	\$ 7,490	\$ (22,949)	\$ (43,038)	7,114	64,102

<sup>(1)</sup> Pro forma includes the 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. The pro forma information also includes \$7,500,000 of the gross proceeds from the first closing of the issuance and sale of the December 2010 Convertible Notes and the subsequent conversion of the December 2010 Convertible Notes into 500,000 shares of our common stock at a conversion price equal to the price per share of common stock sold in this offering, based on an assumed initial public offering price of \$15.00 per share, the midpoint of the estimated price range shown on the cover of this prospectus. The pro forma consolidated balance sheet data do not give effect to a second closing of the issuance and sale and subsequent conversion of the December 2010 Convertible Notes into 500,000 shares of our common stock at a conversion price equal to the price per share of common stock sold in this offering, based on an assumed initial public offering price of \$15.00 per share, the midpoint of the estimated price range shown on the cover of this prospectus, or the related warrants which would become exercisable for 167,361 shares of our common stock.

# 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, which was accepted by the FDA for review on December 10, 2010, 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. The PDUFA goal date for our NDA is July 28, 2011. 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.

ths Ended iber 30,	
2010	
\$ 6,497	
2,470	
8,967	
630	
223	
853	
9,820	
2,551	
\$12,371	

<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;

- · royalties due to third parties on our revenues;
- · packaging, testing, freight and shipping;
- · the cost of active pharmaceutical ingredients; and
- overhead costs associated with excess manufacturing capacity are charged to cost of revenue as incurred. Manufacturing, labor and overhead costs are capitalized only to the extent of actual capacity utilized. The cost of excess capacity was \$10.1 million, \$5.5 million and \$4.4 million for the years ended December 31, 2008 and 2009 and for the nine months ended September 30, 2010, respectively. Gross margins from supply revenue were -110%, -55% and -25% for the years ended December 31, 2008 and 2009, and for the nine months ended September 30, 2010, respectively. Our negative margin is primarily due to excess capacity. Excluding the cost of excess capacity, as described above, gross margin from supply revenue was 36%, 31%, and 36% for the years ended December 31, 2008 and 2009, and for the nine months ended September 30, 2010, respectively.

## 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 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 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 by outside contractors or consultants.

We recognize revenues from non-refundable up-front license 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 license fee is recognized accordingly on a prospective basis. Upon termination of a collaboration agreement, any remaining non-refundable license 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 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 \$15.00 per share, is \$25.5 million, based on 2,073,864 shares of our common stock issuable upon exercise of stock-based compensation arrangements outstanding at December 31, 2010 at a weighted average exercise price of \$2.69 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,					
	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%			

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.

	Number of Options	Per Share Exercise	Number of Options	Number of Options	Number of Options Surrendered on	Number of Options
Grant Date	Granted	Price	Exercised	Cancelled	March 24, 2009	Outstanding
7/20/2007	361,395	\$ 1.61	(51,884)(1)	(179,485)	(116,593)	14,498
10/2/2007	10,128	\$ 1.61	(6,255)	(3,484)	_	389
12/6/2007	188,767	\$ 1.61	(46,537)	(1,902)	(139,470)	858
2/1/2008	44,891	\$ 1.61	_	(27,997)	(16,736)	158
4/17/2008	225,140	\$ 1.61	(4,921)	(99,831)	(97,629)	22,759
6/19/2008	57,173	\$ 2.15	(599)	(44,210)	(10,227)	2,137
6/27/2008	15,340	\$ 2.15	_	(2,788)	(12,552)	_
6/30/2008	928	\$ 2.69	_	(657)	_	271
7/14/2008	74,384	\$ 2.69	_	_	(74,384)	_
8/15/2008	25,288	\$ 2.69	_	(18,781)	(5,113)	1,394
9/30/2008	6,041	\$ 2.69	_	(928)	(5,113)	_
12/9/2008	4,925	\$ 2.69	_	(1,394)	_	3,531
4/16/2009	370	\$ 2.69	_	_	_	370
9/23/2009	371	\$ 2.69	_	_	_	371
3/3/2010	3,343	\$ 2.69	_	_	_	3,343
5/20/2010	5,113	\$ 2.69	_	_	_	5,113
9/2/2010	1,448,301	\$ 1.61	_	(929)	_	1,447,372
12/29/2010	571,300	\$ 5.49	_	<u> </u>	_	571,300
	3,043,198		(110,196)(1)	(382,386)	(477,817)	2,073,864

<sup>(1)</sup> Includes 1,065 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;

- 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 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;
- report dated October 1, 2010 for a valuation of our common stock as of August 31, 2010, or the August 2010 Report; and
- report dated December 23, 2010 for a valuation of our common stock as of December 22, 2010, or the December 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.

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 at \$1.61 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

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 \$1.61 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 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 \$2.26, which was reduced by a discount for lack of marketability of 30.0%, resulting in an estimated value per share of \$1.61.

During this period, we granted options to purchase an aggregate of 830,321 shares of our common stock. As of December 31, 2010, options to purchase 38,662 of these shares of our common stock remain outstanding, options to purchase 109,597 of those shares were exercised and options to purchase 683,127 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 at \$2.15 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 72,513 shares of our common stock were granted. As of December 31, 2010, options to purchase only 2,137 of these shares of our common stock remain outstanding, options to purchase 599 of those shares were exercised and options to purchase 69,777 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 at \$2.69 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 discount rate of 30.0%, arrived at by using a size-adjusted CAPM. Using the PWERM method, the value of our common stock was \$2.69 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 \$1.61 per share to \$2.69 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 111,566 shares of our common stock. As of December 31, 2010, options to purchase 5,196 of these shares of our common stock remain outstanding and options to purchase 106,370 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 \$2.69 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 \$2.69 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 9,197 shares of our common stock. As of December 31, 2010, all of these options remained outstanding.

## Options Granted on September 2, 2010

Our board of directors valued our common stock at \$1.61 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 \$1.61 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 \$1.61 per share on September 2, 2010, as compared to the \$2.69 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 September 2, 2010, we granted options to purchase an aggregate of 1,448,301 shares of our common stock. As of December 31, 2010, options to purchase 1,447,372 of these shares of our common stock remain outstanding and options to purchase 929 of these shares have been cancelled or surrendered.

## Options Granted on December 29, 2010

Our board of directors valued our common stock at \$5.49 per share for options granted on December 29, 2010, based on the December 2010 Report. In the December 2010 Report, the PWERM method was used employing three scenarios: an IPO early in 2011, an IPO in late 2011, 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 20.0%, 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 \$5.49 per share. A discount for lack of marketability of 14.3% was used for these options.

The income and market approaches were also used to examine our enterprise value. For purposes of calculating our enterprise value using the income approach, we applied a discount rate of 20% to our forecasted future cash flows, as it was consistent with the weighted average cost of capital of a group of venture-backed companies of similar size and stage. We also assumed significantly increased cash flows based on the possible approval of EXPAREL. For purposes of calculating our enterprise value using the market approach, we applied multiples ranging from 2.4 to 4.0 times revenue, which we believed to be a reasonable range based on a review of the same peer group data. This peer group included the following companies: AP Pharma Inc., BioDelivery Sciences International Inc., CPEX Pharmaceuticals, Inc., NeurogesX, Inc., Anacor Pharmaceuticals, Inc., Zogenix, Inc., Ligand Pharmaceuticals Inc., POZEN, Inc., Durect Corp., Enzon Pharmaceuticals Inc. and Akorn Inc.

The change in value for our common stock to \$5.49 per share on December 29, 2010, as compared to the \$1.61 per share value as of September 2010, is primarily the result of the filing of our NDA on September 28, 2010, the acceptance of our NDA filing by the FDA and FDA establishment of a PDUFA goal date of July 28, 2011, which occurred in December 2010, the filing of this registration statement in November 2010, the completion of the \$26.25 million Hercules Credit Facility in November 2010 which provided \$15.0 million of new funding to us, the issuance and sale of the December 2010 Convertible Notes which provides up to an additional \$15.0 million of new funding to us, and, with the aforementioned resources available, the ability to assemble the commercial team to prepare for the launch of EXPAREL, and the marketplace interactions the commercial team has had with KOLs in validating the unmet medical need that may be addressed by EXPAREL.

On December 29, 2010, we granted options to purchase an aggregate of 571,300 shares of our common stock. As of December 31, 2010, all of these options remained outstanding.

On January 11, 2011, we and the underwriters determined a preliminary range for the initial public offering price. The midpoint of the range was \$15.00 per share as compared to \$5.49 per share, which was based on the December 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 and the underwriters. Among the factors considered in setting the preliminary range were prevailing market conditions and estimates of our business potential, as described below. 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 December 29, 2010 was primarily the result of the following factors:

- The contemporaneous valuation we prepared on December 23, 2010 contained multiple scenarios including two IPO scenarios with an aggregate probability of 80% and one sale scenario. If we had considered only a single scenario with 100% probability and assumed that the IPO will be completed by the middle of February 2011, the contemporaneous valuation would have resulted in an increased fair value determination.
- Our December 23, 2010 contemporaneous valuation included a scenario with a 40% probability that the IPO would not be completed until the end of
  the second quarter of 2011. However, our January 2011 discussions with the underwriters took into account our and the underwriters' perceptions
  of

significantly increased optimism regarding overall market conditions and the market for initial public offerings, and confirmed our and the underwriters' expectations that we would complete our initial public offering by the middle of February 2011.

- Our convertible preferred stock currently has substantial economic rights and preferences over our common stock. The midpoint of the estimated
  price range shown on the cover of this prospectus assumes the conversion of our preferred stock upon the completion of this offering and the
  corresponding elimination of these preferences resulting in an increased common stock valuation.
- The proceeds of a successful initial public offering would substantially strengthen our balance sheet by increasing our cash and reducing our
  outstanding indebtedness. Additionally, the completion of this offering would provide us with access to the public company debt and equity
  markets. These projected improvements in our financial position influenced the increased common stock valuation indicated by the midpoint of the
  estimated price range shown on the cover of this prospectus.
- 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 \$15.00 midpoint of the estimated price range shown on the cover of this prospectus, the intrinsic value of the options granted on December 29, 2010, the last date we granted stock options, was approximately \$5.4 million. Also based on the \$15.00 midpoint of the estimated price range shown on the cover of this prospectus, the intrinsic value of outstanding options as of December 31, 2010 was \$25.5 million, of which \$6.3 million related to vested options and \$19.2 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 End	led September 30,	Increase/	% Increase/
	2009	2010	(Decrease)	(Decrease)
		(dollars in tho	usands)	
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 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

	Year Ended D	December 31,	Increase/	% Increase/
	2008	2009	(Decrease)	(Decrease)
		(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, 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. \$5.4 million of the increase in interest expense was primarily attributable to the royalty interest obligation under the

Amended and Restated Royalty Interests Assignment Agreement and \$1.7 million was due to our debt financing activities in 2009. The interest income (expense) relating to the obligations under the Amended and Restated Royalty Interests Assignment Agreement is composed of (1) the difference in the revaluation of our obligations under the Amended and Restated Royalty Interests Assignment Agreement between each reporting period and (2) the actual royalty interest payments payable pursuant to the Amended and Restated Royalty Interests Assignment Agreement for such reporting period. In determining the amount of the royalty interest obligation, we employ estimates of future cash flows derived from our royalties payable to Paul Capital based on end user sales of DepoCyt(e) and DepoDur, discounted at a rate that reflects an estimate of the cost of capital under the Amended and Restated Royalty Interests Assignment Agreement. At December 31, 2008, our estimate of future end user sales of DepoCyt(e) and DepoDur was considerably lower than the estimate as of December 31, 2007. This lower estimate resulted in a decrease of the royalty interest obligation valuation of \$10.2 million at December 31, 2007 to \$5.0 million at December 31, 2008. As a result, \$5.2 million of the royalty interest obligation was recorded as interest income in the year ended December 31, 2008. In comparison, the valuation of the royalty interest obligation of \$5.2 million at December 31, 2009, which resulted in a \$0.2 million interest expense in the year ended December 31, 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).

	Year Ended I	December 31,	Increase/	% Increase/
	2007	2008	(Decrease)	(Decrease)
		(dollars in t	housands)	
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%

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 increase was primarily due to the impact of the periodic revaluation adjustment of our royalty interest obligation under the Amended and Restated Royalty Interests Assignment Agreement. The interest income (expense) relating to the obligations under the Amended and Restated Royalty Interests Assignment agreement is composed of (1) the difference in the revaluation of our obligations under the Amended and Restated Royalty Interests Assignment Agreement between each reporting period and (2) the actual royalty interest payments payable pursuant to the Amended and Restated Royalty Interests Assignment Agreement for such reporting period. In determining the amount of the royalty interest obligation, we employ estimates of future cash flows derived from royalties payable to Paul Capital based on end user sales of DepoCyt(e) and DepoDur, discounted at a rate that reflects an estimate of the cost of capital of the Amended and Restated Royalty Interests Assignment Agreement. At December 31, 2008, our estimate of the royalty interest obligation valuation of \$10.2 million at December 31, 2007 to \$5.0 million at December 31, 2008. As a result, \$5.2 million of the royalty interest obligation was recorded as to interest income in the year ended December 31, 2008. Our estimate of future end user sales of DepoCyt(e) and DepoDur at December 31, 2007 of \$10.2 million was also lower than the estimate as of March 24, 2007 of \$13.0 million, and resulted in a \$2.8 million lower valuation of the royalty interest obligation being recorded as interest income in the year ended December 31, 2007. The higher interest income of \$2.4 million for the year ended December 31, 2008 was partially offset by \$0.6 million higher royalty interest payment in 2008, reflecting a full year of operations in comparison to 2007, which reflected operatio

## **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:

			Nine Months		
	Ye	ar Ended December 3	1,	Ended Sep	tember 30,
	2007	2008	2009	2009	2010
			(in thousands)		
Consolidated Statement of Cash Flows Data:					
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	\$ 7,240	\$ 5,146	\$ (5,309)	\$ (7,974)	\$ 6,774

## **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. The \$3.8 million increase in the deferred revenue balance in 2009 as compared to 2008 was primarily due to the \$5.0 million license fee received from EKR in 2009, offset by approximately \$1.0 million license fee received from Amylin and the \$5.0 million license fee received from EKR in 2008, offset by approximately \$3.0 million of deferred revenue amortization in 2008.

We do not believe that the impairment of the DepoDur trademark in 2008 that resulted from revised estimates of future sales of DepoDur will have a material impact on our future operations and cash flows because (i) the cash flows from DepoDur are not material and (ii) we have already taken the impairment charge for this trademark.

As described above, as of December 31, 2008, we lowered the amount of our liability under the Amended and Restated Royalty Interests Assignment Agreement, resulting from lower estimates of future sales of DepoCyt(e) and DepoDur. We do not believe the lower estimates of future sales of DepoCyt(e) and DepoDur will have a material impact on our future operations and cash flows because (i) our revenues from DepoCyt(e) remain stable, (ii) our estimates of future capital requirements are derived, in part, on stable but not high growth DepoCyt(e) revenue and (iii) the cash flows from DepoDur are not material.

## **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 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 September 30, 2010, after giving effect to the Hercules Credit Facility and the issuance and sale of the December 2010 Convertible Notes and the application of the proceeds therefrom, we had \$73.75 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 \$43.75 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, all principal and accrued interest on the convertible and secured notes (other than the December 2010 Convertible Notes) will convert into 3,264,777 shares of our common stock upon completion of this offering at a conversion price of \$13.44, in accordance with the terms of the October 2010 agreement. 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

Debt Issue	Principal amount	Conversion Shares
Hercules Credit Facility	\$26.25 million	_
2009 Convertible Notes	10.63 million	871,635
2009 Secured Notes	10.63 million	927,881
2010 Secured Notes	15.00 million	1,156,606
HBM Secured Notes	3.75 million	308,655
December 2010 Convertible Notes	7.50 million	500.000(1)

(1) The December 2010 Convertible Notes will be converted into shares of our common stock at a conversion price equal to the price per share of common stock sold in this offering. Based on an assumed initial public offering price of \$15.00 per share, the midpoint of the estimated price range shown on the cover of this prospectus.

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 December 31, 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 December 31, 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 178,986 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 \$13.44 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 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 158,061 shares of our common stock with an exercise price of \$2.69 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 pursuant to which 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, and the holders of the 2009 Secured Notes agreed to share payments pro rata with the holders of the 2010 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 December 31, 2010, \$11.67 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 conve

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 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 December 31, 2010, \$12.32 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 927,881 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 December 31, 2010, \$15.46 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 1,156,606 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 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 December 31, 2010, \$3.94 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 308,655 shares of our common stock upon completion of this offering.

December 2010 Convertible Notes. On December 29, 2010, we sold \$15.0 million in aggregate principal amount of convertible promissory notes, or the December 2010 Convertible Notes, in a private placement to certain of our existing investors. 50% of the principal amount was funded on December 29, 2010. The remaining 50% of the principal amount will be funded in a second closing to occur upon written request of holders of at least 75% of the outstanding principal amount of the December 2010 Convertible Notes on or before the earlier of the completion of this offering or March 31, 2011. In connection with the issuance and sale of the December 2010 Convertible Notes, we issued warrants to the holders of the December 2010 Convertible Notes to purchase an aggregate of 167,361 shares of our common stock with an exercise price of \$13.44 per share. Pursuant to the terms of the agreement for the issuance and sale of the December 2010 Convertible Notes occurs, we will issue warrants to the holders of the December 2010 Convertible Notes to purchase an additional 167,361 shares of our common stock with an exercise price of \$13.44 per share. The December 2010 Convertible Notes will have an interest rate of 5% per year from and after March 31, 2011 and all principal and accrued and unpaid interest on the December 2010 Convertible Notes is due and payable upon the earliest of: (1) 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 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. Upon completion of this offering, all principal and interest due under the December 2010 Convertible Notes will be converted into shares of our common stock at a conversion price equal to the price per share of common stock sold in this offering. Purchasers of the December 2010 Convertible Notes included certain holders of more than 5% of our capital stock, or entities affiliated with them.

## 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, 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. 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.

As described above, as of December 31, 2008, we lowered the value of our liability under the Amended and Restated Royalty Interests Assignment Agreement, resulting from lower estimates of future sales of DepoCyt(e) and DepoDur. We do not believe the lower estimates of future sales of DepoCyt(e) and DepoDur will have a material impact on our future operations and cash flows because (i) our revenues from DepoCyt(e) remain stable, (ii) our estimates of future capital requirements are derived, in part, on stable but not high growth DepoCyt(e) revenue and (iii) the cash flows from DepoDur are not material.

In addition, we do not believe that the impairment of the DepoDur trademark in 2008 that resulted from revised estimates of future sales of DepoDur will have a material impact on our future operations and cash flows because (a) the cash flows from DepoDur are not material and (b) we have already taken the impairment charge for this trademark.

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.

#### **Contractual Obligations**

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

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

<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.

#### **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.

<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 (including the December 2010 Convertible Notes) and accrued interest thereon to be converted into common stock.

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

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.

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, which was accepted by the FDA for review on December 10, 2010. 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. The PDUFA goal date for our NDA is July 28, 2011. 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:

Product(s)/ Product Candidate(s)	Primary Indication(s)	Status	Commercialization Rights
EXPAREL	Postsurgical analgesia by infiltration	PDUFA goal date: July 28, 2011	Pacira (worldwide)
	Postsurgical analgesia by nerve block	Phase 2/3 (planning)	Pacira (worldwide)
	Postsurgical analgesia by epidural administration	Phase 1 (completed)	Pacira (worldwide)
DepoCyt(e)	Lymphomatous meningitis	Marketed	Sigma-Tau Pharmaceuticals Mundipharma International
DepoDur	Post-operative pain	Marketed	EKR Therapeutics Flynn Pharmaceuticals
DepoNSAID	Acute pain	Preclinical	Pacira (worldwide)
DepoMethotrexate	Rheumatoid arthritis Oncology	Preclinical Preclinical	Pacira (worldwide) Pacira (worldwide)
		70	

### **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, which permits us to rely upon the FDA's previous findings of safety and effectiveness for an approved product. A 505(b)(2) strategy may not succeed if there are successful challenges to the FDA's interpretation of Section 505(b)(2).

## 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.

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

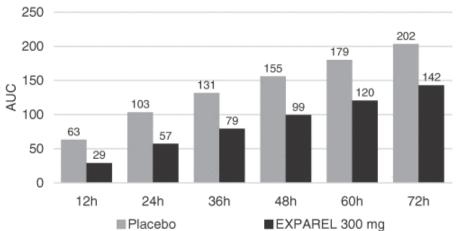
bupivacaine has been observed with EXPAREL. We conducted two thorough QTc studies that demonstrated that EXPAREL did not cause significant QTc prolongation (a measure of cardiac safety mandated by the FDA for all new products) even at the highest dose evaluated. No events of destruction of articular 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

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:

- <u>Total avoidance of opioid rescue medication</u>. 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
- <u>Delayed use of opioid rescue medication</u>. 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
- <u>Improved patient satisfaction</u>. 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:

- <u>Total avoidance of opioid rescue medication</u>. 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);
- <u>Delayed use of opioid rescue medication</u>. 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.

The EXPAREL wound infiltration program encompassed 21 dosing comparisons (a dose of EXPAREL compared to a control) throughout a total of ten clinical trials; nine of these were randomized parallel-group clinical trials, seven of which had a bupivacaine control and two of which had a placebo control. When a program-wide primary endpoint of the area under the curve of the numeric rating scale score for pain at rest from 0 through 72 hours was applied to the 19 doses in the randomized parallel-group clinical trials, 16 favored EXPAREL.

## **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, 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, which was accepted by the FDA for review on December 10, 2010, 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 FFDCA, 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 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.

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

- <u>Convenience</u>. 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;
- <u>Multiple regulatory precedents</u>. 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;
- <u>Proven manufacturing capabilities</u>. 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

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

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 DepoCyte in the European Union and certain other European countries. This agreement continues in force for 15 years, and after that term expires, continues year to year unless terminated by us or by Mundipharma upon no less than 12 months written notice.

Under the agreement, as amended, and a separate supply agreement, we receive a fixed payment for manufacturing the vials of DepoCyte, 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 up to  $\epsilon$ 10 million in milestone payments from Mundipharma upon the achievement by Mundipharma of certain milestone events, of which we have already received  $\epsilon$ 2.5 million and we do not expect to receive the remaining  $\epsilon$ 7.5 million.

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 DepoCyte in any three countries in the territory covered in the agreement by a final non-appealable judgment in respect of infringement by DepoCyte 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. Under this agreement, as amended, we received nonrefundable license fees of \$5.0 million upon execution of the agreement in August 2007, \$5.0 million in 2008, and \$5.0 million in 2009. At the time we entered into the agreement we had the right to receive aggregate milestone payments of up to \$20 million, but we do not expect any additional milestone payments under the agreement. 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 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.

### 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 preapproval 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.

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. Furthermore, a non-exclusively licensed patent of ours relating to EXPAREL was allowed in Europe with an expiration date in October 2021 and was extended in the United States until October 2023.

## 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.

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 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 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 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.

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

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 II 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, 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

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

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 or 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

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

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

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 December 31, 2010, we employed 83 employees, with 8 in research and development, 56 in operations, and 19 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 December 31, 2010 are set forth below:

Name	Age	Position(s)
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.	52	Senior Vice President, Pharmaceutical Development
Mark Walters	55	Senior Vice President, Technical Operations
Fred Middleton (2)	61	Chairman of the Board of Directors
Luke Evnin, Ph.D. (2)	47	Director
Carl Gordon, Ph.D. (1)	46	Director
John Longenecker, Ph.D. (1)(2)(3)	63	Director
Gary Pace, Ph.D. (1)(3)	63	Director
Andreas Wicki, Ph.D.	52	Director

- Member of audit committee upon completion of this offering.
- (2) Member of compensation committee upon completion of this offering.
- (3) 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

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

sectors. Dr. Evnin 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. Evnin'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 Favrille, 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

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.

### **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. 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**

## Non-Employee Director Compensation Policy

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 2,325 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.

In addition, certain of our non-employee directors received option grants to purchase 6,043 shares of our common stock and certain of our non-employee directors received option grants to purchase 4,649 shares of our common stock, each of 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 6,043 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.

# Director Compensation Table - 2010

The following table sets forth a summary of the compensation earned by our directors for the year ended December 31, 2010, with the exception of Mr. Stack, whose compensation is included in the "Summary Compensation Table" below.

	Option	
	Awards <sup>(1)</sup>	Total
Name_	(\$)	(\$)
Fred Middleton	10,464	10,464
Luke Evnin, Ph.D.	10,464	10,464
Carl Gordon, Ph.D.	10,464	10,464
John Longenecker, Ph.D.	18,614	18,614
Gary Pace, Ph.D.	18,745	18,745
Andreas Wicki, Ph.D.	<del></del>	

<sup>(1)</sup> Represents the grant date fair value of option awards granted in 2010 in accordance with ASC Topic 718, or ASC 718, formerly Statement of Financial Accounting Standards No. 123(R). Our directors will only realize compensation to the extent the fair value of our common stock is greater than the exercise price of such stock options. For information regarding assumptions underlying the valuation of equity awards, see note 11 to our financial statements included elsewhere in this prospectus.

## **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

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 2010, 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

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 2009 or 2010 and we have not paid any bonuses based on corporate goals or personal achievement goals in 2009 or 2010. Although our 2009 and 2010 corporate goals were informal, they were focused on the achievement of certain objectives. In 2009, the objectives were (1) successful completion of additional Phase 3 clinical trials of EXPAREL and (2) obtaining additional financing. In 2010, the objectives were (1) filing our NDA for EXPAREL, (2) obtaining additional financing, (3) converting our current clinical manufacturing suite to a commercial manufacturing suite and (4) filing this registration statement. For 2009 and 2010, 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 2009 or 2010 corporate goals had been achieved. We did not have additional individual performance goals for our executive officers in 2009 or 2010. Our compensation committee has the authority to award discretionary performance-based cash bonuses to our executive officers and achievements by our executives and employees, as recommended by management. No such discretionary bonuses were awarded in 2009 or 2010. 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 809,390 shares of common stock to our named executive officers. The following table sets forth the number of shares underlying stock options granted to our named executive officers in September 2010:

	Common Stock
Name_	Underlying Stock Option
David Stack, Chief Executive Officer	441,655
James Scibetta, Chief Financial Officer	147,373
Gary Patou, Chief Medical Officer	118,084
Mark Walters, Senior Vice President	51,139
William Lambert, Senior Vice President	51,139

Number of Shares of

In December 2010, our board of directors granted options to all of our employees, including our named executive officers and our non-employee directors. Options to purchase an aggregate of 290,407 shares of common stock were granted to our named executive officers. The following table sets forth the number of shares underlying stock options granted to our named executive officers in December 2010:

	Number of Shares of
	Common Stock
Name	Underlying Stock Option
David Stack, Chief Executive Officer	158,466
James Scibetta, Chief Financial Officer	52,877
Gary Patou, Chief Medical Officer	42,368
Mark Walters, Senior Vice President	18,348
William Lambert, Senior Vice President	18,348

*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.

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 809,390 shares of common stock to our named executive officers. On December 29, 2010, we granted options to purchase an aggregate of 290,407 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.
- 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 years ended December 31, 2009 and 2010. We refer to these individuals as our named executive officers.

Name and Principal Position David Stack Chief Executive Officer	<u>Year</u> 2010 2009	Salary (s) 400,000 400,000	Bonus (1) (S)	Option Awards (2) (S) 1,112,323	All Other Compensation (3) (8) 1,504 1,504	Total (\$) 1,513,827 401,504
James Scibetta Chief Financial Officer	2010 2009	270,000 270,000	_	370,735	1,504 1,504	642,239 271,504
Gary Patou Chief Medical Officer (4)	2010 2009	317,608 317,604	300,000	295,018 —		912,626 317,604
Mark Walters Senior Vice President	2010 2009	250,000 250,000	_	127,595	1,600 1,600	393,595 251,600
William Lambert Senior Vice President	2010 2009	220,000 220,000	_	127,595 —	1,487 1,483	349,082 221,483

<sup>(1)</sup> Represents a bonus paid to Dr. Patou upon the successful completion of the NDA submission for EXPAREL pursuant to the Services Agreement with MPM Asset Management LLC, or MPM AM, and Dr. Patou.

<sup>(3)</sup> Amounts represent the value of perquisites and other personal benefits which are further detailed in the table below:

	2009 Group Life	2010 Group Life
Name	Insurance (\$)	Insurance (\$)
David Stack	1,504	1,504
James Scibetta	1,504	1,504
Gary Patou	_	_
Mark Walters	1,600	1,600
William Lambert	1,483	1,487

<sup>(4)</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 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."

<sup>(2)</sup> Represents the grant date fair value of option awards granted in 2010 in accordance with ASC 718. Our named executive officers will only realize compensation to the extent the fair value of our common stock is greater than the exercise price of such stock options. For information regarding assumptions underlying the valuation of equity awards, see note 11 to our financial statements included elsewhere in this prospectus.

# Grants of Plan-Based Awards in 2010

The following table sets forth information for the year ended December 31, 2010 regarding grants of stock options made during 2010 to our named executive officers.

## 2010 Grants of Plan-Based Awards

Name_	Grant Date	All Other Option Awards: Number of Securities Underlying Options (#)	Exercise or Base Price of Option Awards (\$/Sb)	Grant Date Fair Value of Stock and Option Awards <sup>(1)</sup>
David Stack	9/02/10	441,655	\$ 1.61	\$495,195
	12/29/10	158,466	5.49	617,128
James Scibetta	9/02/10	147,373	1.61	164,809
	12/29/10	52,877	5.49	205,926
Gary Patou	9/02/10	118,084	1.61	130,018
	12/29/10	42,368	5.49	165,001
Mark Walters	9/02/10	51,139	1.61	56,138
	12/29/10	18,348	5.49	71,457
William Lambert	9/02/10	51,139	1.61	56,138
	12/29/10	18,348	5.49	71,457

<sup>(1)</sup> Represents the grant date fair value of option awards granted in 2010 in accordance with ASC 718.

## **Outstanding Equity Awards at Year End**

The following table sets forth certain information with respect to outstanding options held by our named executive officers at December 31, 2010.

<u>Name</u>	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price (S)	Option Expiration Date
David Stack	104,602	81,358(1)	\$1.61	9/2/20
	_	$255,695^{(2)}$	1.61	9/2/20
	_	158,466(3)	5.49	12/29/20
James Scibetta	41,841	32,543(1)	1.61	9/2/20
	_	72,989(2)	1.61	9/2/20
	_	52,877(3)	5.49	12/29/20
Gary Patou	33,211	25,831(1)	1.61	9/2/20
	_	59,042(2)	1.61	9/2/20
	_	42,368(3)	5.49	12/29/20
Mark Walters	30,218	$6,974^{(4)}$	1.61	9/2/20
	_	13,947(2)	1.61	9/2/20
	_	18,348(3)	5.49	12/29/20
William Lambert	30,218	6,974(4)	1.61	9/2/20
	<u> </u>	13,947(2)	1.61	9/2/20
	_	18,348(3)	5.49	12/29/20

<sup>(1)</sup> This option vested with respect to 50% of the shares subject to the option on September 2, 2010 and with respect to the remaining shares in approximately equal successive monthly installments over the next 24 months provided that the named executive officer continues to provide services to us over such period.

<sup>(2)</sup> This option vests with respect to 25% of the shares subject to the option on September 2, 2011 and will vest in approximately equal successive monthly installments over the next 36 months provided that the named executive officer continues to provide services to us over such period.

- (3) This option vests with respect to 25% of the shares subject to the option on December 29, 2011 and will vest in approximately equal successive monthly installments over the next 36 months provided that the named executive officer continues to provide services to us over such period.
- (4) This option vested with respect to 75% of the shares subject to the option on September 2, 2010 and with respect to the remaining shares in approximately equal successive monthly installments over the next 12 months provided that the named executive officer continues to provide services to us over such period.

### **Option Exercises and Stock Vested**

None of our named executive officers exercised any options during the year ended December 31, 2010.

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

The tables below summarize the potential payments to each of our named executive officers if he were to be terminated without cause or resigned for good reason on December 31, 2010, the last business day of the fiscal year ended December 31, 2010, under the following circumstances.

	Not in Connection with a Change of Control			
	Cash Severance	Value of Continuation of	Value of Stock Vesting Upon Termination	Total
<u>Name</u>	Payments (\$)	Benefits (\$)	(\$) <sup>(1)</sup>	(\$)
David Stack	400,000	9,305	894,375	1,303,680
James Scibetta	202,500	6,979	286,650	496,129
Gary Patou	238,206(2)	_	228,600(3)	466,806
Mark Walters	187,500	4,637	160,875	353,012
William Lambert	165,000	6,979	160,875	332,854

- This amount is equal to (i) the number of option shares that would vest as a direct result of the employment termination without cause or for good reason, assuming a December 31, 2010 employment termination, multiplied by (ii) the excess of fair market value of our common stock as of December 31, 2010, over the exercise price of the option. For a discussion of our methodology for determining the fair market value of our common stock, see the "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Use of Estimates—Stock Based Compensation."
- Pursuant to the Services Agreement with MPM AM and Dr. Patou, we are required to make certain payments to MPM in the case of a termination of the agreement. For more information, see "Executive Compensation—Services Agreement with MPM and Gary Patou."
- (3) Pursuant to the Services Agreement with MPM AM and Dr. Patou, Dr. Patou is entitled to accelerated vesting of his options in the case of a termination of the agreement. For more information, see "Executive Compensation—Services Agreement with MPM and Gary Patou."

	30 days Prior to, or One Year After, a Change of Control			
	Cash Severance Payments	Value of Continuation of Benefits	Value of Stock Vesting Upon Termination	Total
Name	<u>(\$)</u>	(\$)	(\$)(1)	(\$)
David Stack	400,000	9,305	1,710,000	2,119,305
James Scibetta	202,500	6,979	570,600	780,079
Gary Patou	238,206(2)	_	457,200(3)	695,406
Mark Walters	187,500	4,637	198,000	390,137
William Lambert	165,000	6,979	198,000	369,979

This amount is equal to (i) the number of option shares that would vest as a direct result of the employment termination without cause or for good reason in connection with a change in control, assuming a December 31, 2010 employment termination, multiplied by (ii) the excess of fair market value of our common stock as of December 31, 2010, over the exercise price of the option. For a discussion of our methodology for determining the fair market value of our common stock, see the "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Use of Estimates—Stock Based Compensation."

Pursuant to the Services Agreement with MPM and Dr. Patou, we are required to make certain payments to MPM in the case of a termination of the agreement. For more information, see "Executive Compensation—Services Agreement with MPM and Gary Patou."

<sup>(3)</sup> Pursuant to the Services Agreement with MPM AM and Dr. Patou is entitled to accelerated vesting of his options in the case of a termination of the agreement. For more information, see "Executive Compensation—Services Agreement with MPM and Gary Patou."

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.

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, provided that the options granted to Dr. Patou in December 2010 are subject to additional vesting. 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 650,860 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 650,860 to 1,066,946 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 1,066,946 to 1,729,498 shares of our common stock. This increase was approved by our stockholders in October 2010. In December 2010, our board of directors further amended the 2007 Plan to increase the number of authorized plan shares from 1,729,498 to 2,546,657 shares of our common stock. This increase was approved by our stockholders in December 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.

*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 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.

### 2011 Stock Incentive Plan

Our 2011 stock incentive plan, or the 2011 plan, which will become effective immediately prior to the completion of this offering, was adopted by our board of directors and approved by our stockholders in December 2010. The 2011 plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards and other stock-based awards. Upon effectiveness, the sum of (up to 2,546,657 shares) (x) the number of shares of our common stock reserved for issuance under the 2007 plan at such time, and (y) the number of shares of our common stock subject to awards granted under the 2007 plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by us pursuant to a contractual repurchase right, will be reserved for issuance under the 2011 plan. In addition, the 2011 plan contains an "evergreen" provision, which allows for an increase in the number of shares available for issuance under the 2011 plan on the first day of each calendar year from 2012 through 2015. The annual increase in the number of shares shall be equal to the lesser of:

• 557,880 shares of our common stock;

- a number of shares equal to 3% of our outstanding shares as of such date; or
- an amount determined by our board of directors.

Our employees, officers, directors, consultants and advisors are eligible to receive awards under our 2011 plan. The 2011 plan permits the grant of options, stock appreciation rights (SARs), restricted stock, restricted stock units and other stock-based awards. The exercise price of all stock options granted under the 2011 plan cannot be less than 100% of the fair market value of the common stock on the date of grant. In general, stock options granted under the 2011 plan will have a term of up to ten years. The measurement (base) price of SARs granted under the 2011 plan cannot be less than 100% of the fair market value of the common stock on the date of grant. SARs will have a term of up to ten years.

The 2011 plan is administered by the board of directors or another committee designated by the board of directors. Subject to limitations specified in the plan, the board or applicable committee to whom authority is delegated will select the recipients of awards and determine:

- the number of shares of common stock covered by options and the dates upon which the options become exercisable;
- the exercise price of options;
- · the duration of the options; and
- the number of shares of common stock subject to any SARs, restricted stock or other stock-based awards and the terms and conditions of such awards, including conditions for repurchase, issue price and repurchase price.

Upon a merger or other reorganization event, our board of directors, may, in its sole discretion, take any one or more of the following actions pursuant to the 2011 plan, as to some or all outstanding awards other than restricted stock awards:

- provide that all outstanding awards shall be assumed or substituted by the successor corporation;
- upon written notice to a participant, provide that the participant's unexercised options or awards will terminate immediately prior to the consummation of such transaction unless exercised by the participant;
- provide that outstanding awards will become exercisable, realizable or deliverable, or restrictions applicable to an award will lapse, in whole or in part, prior to or upon the reorganization event;
- in the event of a reorganization event pursuant to which holders of our common stock will receive a cash payment for each share surrendered in the reorganization event, make or provide for a cash payment to the participants equal to the excess, if any, of the acquisition price times the number of shares of our common stock subject to such outstanding awards (to the extent then exercisable (after giving effect to any acceleration of vesting) at prices not in excess of the acquisition price), over the aggregate exercise price of all such outstanding awards and any applicable tax withholdings, in exchange for the termination of such awards; and
- · provide that, in connection with a liquidation or dissolution, awards convert into the right to receive liquidation proceeds.

Upon the occurrence of a reorganization event other than a liquidation or dissolution, the repurchase and other rights under each outstanding restricted stock award will continue for the benefit of the successor company and will, unless the board of directors may otherwise determine, apply to the cash, securities or other property into which our common stock is converted pursuant to the reorganization event. Upon the occurrence of a reorganization event involving a liquidation or dissolution, all conditions on each outstanding restricted stock award will automatically be deemed terminated or satisfied, unless otherwise provided in the agreement evidencing the restricted stock award.

No award may be granted under the 2011 plan after December 29, 2020. Our board of directors may amend, suspend or terminate the 2011 plan at any time, subject to stockholder approval to the extent required by applicable law or stock market requirements.

## 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.

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 158,061 shares of our common stock with an exercise price of \$2.69 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 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 871,635 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.

	Aggregate Principal	
Purchaser	Amount of Notes	Number of Warrant Shares
HBM BioVentures	\$ 2,500,000	37,192
Entities affiliated with MPM Capital	2,500,000	37,190
Entities affiliated with OrbiMed Advisors	2,500,000	37,191
Entities affiliated with Sanderling Ventures	2.500.000	37.190

### 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.

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 927,881 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:

		Aggregate Principal Amount of
Date of Purchase	<u>Purchaser</u>	Notes Purchased on Such Date
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
september 1, 2009	Entities affiliated with MPM Capital	988,235
	1	, , , , , , , , , , , , , , , , , , ,
	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 1,156,606 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.

Date of Purchase	Purchaser	Aggregate Principal Amount of Notes Purchased on Such Date
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
		007 700
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
9 1 4 9010		025 500
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 were subordinated to the Hercules Credit Facility.

All principal and interest due under the HBM Secured Notes will be converted into 308,655 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.

# **December 2010 Convertible Notes**

On December 29, 2010, we sold \$15.0 million in aggregate principal amount of convertible promissory notes, or the December 2010 Convertible Notes, in a private placement to certain of our existing investors. 50% of the principal amount was funded on December 29, 2010. The remaining 50% of the principal amount will be

funded in a second closing to occur upon written request of holders of at least 75% of the outstanding principal amount of the December 2010 Convertible Notes on or before the earlier of the completion of this offering or March 31, 2011. In connection with the issuance and sale of the December 2010 Convertible Notes, we issued warrants to the holders of the December 2010 Convertible Notes to purchase an aggregate of 167,361 shares of our common stock with an exercise price of \$13.44 per share. Pursuant to the terms of the agreement for the issuance and sale of the December 2010 Convertible Notes, in the event a second closing of the issuance and sale of the December 2010 Convertible Notes occurs, we will issue warrants to the holders of the December 2010 Convertible Notes to purchase an additional 167,361 shares of our common stock with an exercise price of \$13.44 per share. The December 2010 Convertible Notes will have an interest rate of 5% per year from and after March 31, 2011 and all principal and accrued and unpaid interest on the December 2010 Convertible Notes is due and payable upon 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 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.

Upon completion of this offering, all principal and interest due under the December 2010 Convertible Notes will be converted into shares of our common stock at a conversion price equal to the price per share of common stock sold in this offering. Purchasers of the December 2010 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 December 2010 Convertible Notes purchased by each such holder and the warrants received in connection with the purchase of the December 2010 Convertible Notes, assuming that a second closing is not consummated.

		Number of
	Aggregate Principal	Warrant
Purchaser	Amount of Notes	Shares
HBM BioVentures	\$ 1,875,000	41,841
Entities affiliated with MPM Capital	\$ 1,875,000	41,840
Entities affiliated with OrbiMed Advisors	\$ 1,875,000	41,840
Entities affiliated with Sanderling Ventures	\$ 1,875,000	41,840

## **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 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 6,322,640 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 \$13.44 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:

	Shares of Series
	A Convertible
<u>Investor</u>	Preferred Stock
Entities affiliated with MPM Capital (1)	1,487,680
Entities affiliated with Sanderling Ventures (2)	1,487,680
Entities affiliated with OrbiMed Advisors (3)	1,487,680
Entities affiliated with HBM BioVentures (4)	1.487.680

- Consists of (i) 1,394,315 shares of Series A convertible preferred stock held by MPM BioVentures IV-QP, L.P., (ii) 53,717 shares of Series A convertible preferred stock held by MPM BioVentures IV-QP, L.P., (ii) 53,717 shares of Series A convertible preferred stock held by MPM BioVentures IV-QP, L.P., (ii) 53,717 shares of Series A convertible preferred stock held by MPM Asset Management Investors BV4 LLC. Dr. Patou is a managing director of MPM Asset Management LLC. MPM BioVentures IV-LLC is the managing member of MPM BioVentures IV-QP, L.P. and the managing limited partner of MPM BioVentures IV-QP, L.P. and the managing limited p
- Consists of (i) 736,583 shares of Series A convertible preferred stock held by Sanderling Venture Partners VI, L.P.; (ii) 24,871 shares of Series A convertible preferred stock held by Sanderling VI Limited Partnership, (iv) 681,715 shares of Series A convertible preferred stock held by Sanderling Venture Partners VI Co-Investment Fund, L.P., and (v) 14,877 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 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.
- (3) Consists of (i) 1,473,645 shares of Series A convertible preferred stock held by OrbiMed Private Investments III, LP, and (ii) 14,035 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 an 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) Consists of 1,487,680 shares of Series A convertible preferred stock 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 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.

### **Common Stock Issuances**

In connection with our formation, we issued an aggregate of 464,900 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:

	Snares of
	Common
Investor	Stock
Entities affiliated with Sanderling Ventures (1)	185,960
Entities affiliated with MPM Capital (2)	92,980
Entities affiliated with OrbiMed Advisors (3)	92,980
Entities affiliated with HBM BioVenture (4)	92,980

- Consists of (i) 125,800 shares of common stock held by Sanderling Venture Partners VI, L.P.; (ii) 1,995 shares of common stock held by Sanderling VI Beteiligungs GmbH & Co. KG, (iii) 2,377 shares of common stock held by Sanderling VI Limited Partnership, and (iv) 55,788 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 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.
- Consists of (i) 87,144 shares of common stock held by MPM BioVentures IV-QP, L.P., (ii) 3,357 shares of common stock held by MPM BioVentures IV GmbH & Co. Beteiligungs KG, and (iii) 2,479 shares of common stock held by MPM Asset Management Investors BV4 LLC. Dr. Patou is a managing director of 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 LLC, which is the general partner of MPM BioVentures IV-QP, L.P. 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.
- (3) Consists of (i) 92,103 shares of common stock held by OrbiMed Private Investments III, LP, and (ii) 877 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.
- (4) Consists of 92,980 shares of common stock 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 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.

## **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.

### **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 December 31, 2010, we paid an aggregate of \$33,999 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.

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 December 31, 2010, we have paid SPI an aggregate of \$533,452 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 December 31, 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.

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 December 31, 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 December 31, 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 10,661,448 shares outstanding as of December 31, 2010, assuming the conversion of all of the outstanding Series A convertible preferred stock and assuming the conversion of \$47.5 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.

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 December 31, 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 (\*).

	Number of Shares Beneficially	Percentage Before the	Percentage After the
Name and Address of Beneficial Owner	Owned	Offering	Offering
5% Stockholders			
HBM BioVentures (Cayman) Ltd. (1)	2,805,916	26.1%	18.7%
MPM Capital and its affiliates (2)	2,497,257	23.3%	16.7%
OrbiMed Advisors and its affiliates (3)	2,497,258	23.3%	16.7%
Sanderling Ventures and its affiliates (4).	2,590,237	24.1%	17.3%
Officers and Directors			
David Stack (5)	130,950	1.2%	*
James Scibetta (6)	44,940	*	*
Gary Patou (7)	35,671	*	*
William Lambert (8)	31,768	*	*
Mark Walters <sup>(9)</sup>	31,768	*	*
Luke Evnin (10)	2,497,257	23.3%	16.7%
Carl Gordon (11)	2,497,258	23.3%	16.7%
John Longenecker (12)	6,353	*	*
Fred Middleton (13).	2,590,237	24.1%	17.3%
Gary Pace (14)	4,494	*	*
Andreas Wicki (15)	2,805,916	26.1%	18.7%
All current executive officers and directors as a group (11 persons)	10,676,612	95.0%	57.8%

- 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) 1,487,680 shares of Series A convertible preferred stock held by HBM BioVentures (Cayman) Ltd., (ii) 29,280 shares of common stock held by HBM BioVentures (Cayman) Ltd., (iii) 79,033 shares of common stock issuable upon exercise of warrants held by HBM BioVentures (Cayman) Ltd., and (iv) 1,146,223 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 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.
- The address for funds managed by MPM Capital is 200 Clarendon St., 54th Floor, Boston, MA 02116. Consists of (i) 1,394,315 shares of Series A convertible preferred stock held by MPM BioVentures IV-QP, L.P., (ii) 53,717 shares of Series A convertible preferred stock held by MPM BioVentures IV GmbH & Co. Beteiligungs KG, (iii) 39,648 shares of Series A convertible preferred stock held by MPM BioVentures IV-QP, L.P., (v) 3,357 shares of common stock held by MPM BioVentures IV GmbH & Co. Beteiligungs KG, (vi) 2,479 shares of common stock held by MPM BioVentures IV-QP, L.P., (viii) 2,852 shares of common stock held by MPM BioVentures IV-QP, L.P., (viii) 2,852 shares of common stock issuable upon exercise of warrants held by MPM BioVentures IV-QP, L.P., (viii) 2,852 shares of common stock issuable upon exercise of warrants held by MPM BioVentures IV-QP, L.P., (viii) 2,852 shares of common stock issuable upon exercise of warrants held by MPM BioVentures IV-QP, L.P., (viii) 3,9648 shares of common stock held by MPM BioVentures IV-QP, L.P., (viii) 2,479 shares of common stock held by MPM BioVentures IV-QP, L.P., (viii) 2,479 shares of common stock issuable upon exercise of warrants held by MPM BioVentures IV-QP, L.P., (viii) 2,852 shares of common stock issuable upon exercise of warrants held by MPM Asset Management Investors BV4 LLC, (x) 785,004 shares of common stock issuable upon conversion of notes held by MPM BioVentures IV GP, L.P., (xi) 30,242 shares of common stock issuable upon exercise of warrants held by MPM BioVentures IV-QP, L.P., (xi) 30,242 shares of common stock issuable upon exercise of warrants held by MPM BioVentures IV-QP, L.P., (xi) 30,242 shares of common stock issuable upon exercise of warrants held by MPM BioVentures IV-QP, L.P., (xi) 30,242 shares of common stock issuable upon exercise of warrants held by MPM BioVentures IV-QP, L.P., (xi) 30,242 shares of common stock issuable upon exercise of warrants held by MPM BioVentures IV-QP, L.P., (xi) 30,242 shares of common stock issuable upon exercise
- (3) The address for funds managed by OrbiMed Advisors is 767 3rd Avenue, 30th Floor, New York, NY 10017. Consists of (i) 1,473,645 shares of Series A convertible preferred stock held by OrbiMed Private Investments III, LP, (ii) 14,035 shares of Series A convertible preferred stock held by OrbiMed Associates III, LP, (iii) 92,103 shares of common stock held by OrbiMed Private Investments III, LP, (iv) 877 shares of common stock held by OrbiMed Associates III, LP, (v) 78,287 shares of common stock issuable upon exercise of warrants held by OrbiMed Private Investments III, LP, (vi) 744 shares of common stock issuable upon exercise of warrants held by OrbiMed Private Investments III, LP, and (viii) 7,901 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.

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.

- The address for funds managed by Sanderling Ventures is 400 South El Camino Real, Suite 1200, San Mateo, California 94402. Consists of (i) 736,583 shares of Series A convertible preferred stock held by Sanderling Venture Partners VI, L.P., (ii) 24,871 shares of Series A convertible preferred stock held by Sanderling VI Beteiligungs GmbH & Co. KG, (iii) 29,634 shares of Series A convertible preferred stock held by Sanderling VI Limited Partnership, (iv) 681,715 shares of Series A convertible preferred stock held by Sanderling Venture Partners VI Co-Investment Fund, L.P., (v) 14,877 shares of Series A convertible preferred stock held by Sanderling Venture Partners VI, L.P., (vii) 1,995 shares of common stock held by Sanderling VI Beteiligungs GmbH & Co. KG, (viii) 2,377 shares of common stock held by Sanderling VI Beteiligungs GmbH & Co. KG, (viii) 2,377 shares of common stock held by Sanderling VI Imited Partnership, (ix) 55,788 shares of common stock held by Sanderling VI Beteiligungs GmbH & Co. KG, (viii) 1,592 shares of common stock issuable upon exercise of warrants held by Sanderling VI Imited Partnership, (xiii) 37,908 shares of common stock issuable upon exercise of warrants held by Sanderling VI Imited Partnership, (xiii) 37,908 shares of common stock issuable upon exercise of warrants held by Sanderling VI Imited Partnership, (xiii) 37,908 shares of common stock issuable upon exercise of warrants held by Sanderling VI Imited Partnership, (xiii) 343,903 shares of common stock issuable upon conversion of notes held by Sanderling VI Imited Partnership, (xvii) 343,903 shares of common stock issuable upon conversion of notes held by Sanderling VI Imited Partnership, (xviii) 343,903 shares of common stock issuable upon conversion of notes held by Sanderling VI Imited Partnership, (xviii) 343,903 shares of common stock issuable upon conversion of notes held by Sanderling VI Imited Partnership, (xviii) 343,903 shares of common stock issuable upon conversion of notes held by Sanderling VI Imited Partnership and
- (5) Consists of (i) 18,600 shares of common stock held by Stack Schroon Mohawk FLP and (ii) 112,350 shares of common stock issuable upon exercise of stock options within 60 days of December 31, 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 44,940 shares of common stock issuable upon exercise of stock options within 60 days of December 31, 2010, including options that become exercisable upon completion of this offering.
- (7) Consists of 35,671 shares of common stock issuable upon exercise of stock options within 60 days of December 31, 2010, including options that become exercisable upon completion of this offering.
- (8) Includes 31,768 shares of common stock issuable upon exercise of stock options within 60 days of December 31, 2010, including options that become exercisable upon completion of this offering.
- (9) Includes 31,768 shares of common stock issuable upon exercise of stock options within 60 days of December 31, 2010, including options that become exercisable upon completion of this offering.
- Consists of (i) 1,394,315 shares of Series A convertible preferred stock held by MPM BioVentures IV-QP, L.P., (ii) 53,717 shares of Series A convertible preferred stock held by MPM BioVentures IV-QP, L.P., (v) 87,144 shares of common stock held by MPM BioVentures IV-QP, L.P., (v) 3,357 shares of common stock held by MPM BioVentures IV-QP, L.P., (vi) 3,357 shares of common stock held by MPM BioVentures IV-QP, L.P., (vii) 74,975 shares of common stock held by MPM BioVentures IV-QP, L.P., (viii) 2,852 shares of common stock held by MPM BioVentures IV-QP, L.P., (viii) 2,852 shares of common stock issuable upon exercise of warrants held by MPM BioVentures IV-QP, L.P., (viii) 2,852 shares of common stock issuable upon exercise of warrants held by MPM Asset Management Investors BV4 LLC., (x) 785,004 shares of common stock issuable upon conversion of notes held by MPM BioVentures IV-QP, L.P., (xii) 30,242 shares of common stock issuable upon conversion of notes held by MPM BioVentures IV-QP, L.P., (xii) 30,242 shares of common stock issuable upon conversion of notes held by MPM BioVentures IV-QP, L.P., (xii) 30,242 shares of common stock issuable upon conversion of notes held by MPM BioVentures IV-QP, L.P., (xii) 30,242 shares of common stock issuable upon conversion of notes held by MPM BioVentures IV-QP, L.P., (xii) 30,242 shares of common stock issuable upon conversion of notes held by MPM BioVentures IV-QP, L.P., (xii) 30,242 shares of common stock issuable upon conversion of notes held by MPM BioVentures IV-QP, L.P., (xii) 30,242 shares of common stock issuable upon conversion of notes held by MPM BioVentures IV-QP, L.P., (xiii) 22,321 shares of common stock issuable upon conversion of notes held by MPM BioVentures IV-QP, L.P., (xiii) 22,321 shares of common stock issuable upon conversion of notes held by MPM BioVentures IV-QP, L.P., (xiii) 22,321 shares of common stock issuable upon conversion of notes held by MPM BioVentures IV-QP, L.P., (xiiii) 22,321 shares of common stock issuable upon conversion of notes hel
- (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.

- (12) Consists of 6,353 shares of common stock issuable upon exercise of stock options within 60 days of December 31, 2010, including options that become exercisable upon completion of this offering.
- Consists of (i) 736,583 shares of Series A convertible preferred stock held by Sanderling Venture Partners VI, L.P., (ii) 24,871 shares of Series A convertible preferred stock held by Sanderling VI Limited Partnership, (iv) 681,715 shares of Series A convertible preferred stock held by Sanderling VI Limited Partnership, (iv) 681,715 shares of Series A convertible preferred stock held by Sanderling Venture Partners VI Co-Investment Fund, L.P., (vi) 14,877 shares of Series A convertible preferred stock held by Sanderling Ventures Partners VI, L.P., (vii) 1,995 shares of common stock held by Sanderling VI Beteiligungs GmbH & Co. KG, (viii) 2,377 shares of common stock held by Sanderling VI Limited Partnership, (ix) 55,788 shares of common stock held by Sanderling VI Beteiligungs GmbH & Co. KG, (viii) 2,377 shares of common stock held by Sanderling VI Limited Partnership, (ix) 55,788 shares of common stock held by Sanderling VI Beteiligungs GmbH & Co. KG, (xii) 1,592 shares of common stock issuable upon exercise of warrants held by Sanderling VI Limited Partnership, (xiii) 37,908 shares of common stock issuable upon exercise of warrants held by Sanderling VI Limited Partnership, (xiii) 37,908 shares of common stock issuable upon exercise of warrants held by Sanderling VI Limited Partnership, (xiii) 37,908 shares of common stock issuable upon exercise of warrants held by Sanderling VI Limited Partnership, (xiii) 37,908 shares of common stock issuable upon exercise of warrants held by Sanderling VI Limited Partnership, (xiii) 37,908 shares of common stock issuable upon exercise of warrants held by Sanderling VI Limited Partnership, (xiii) 343,903 shares of common stock issuable upon conversion of notes held by Sanderling VI Limited Partnership, (xvii) 343,903 shares of common stock issuable upon conversion of notes held by Sanderling VI Limited Partnership, (xvii) 343,903 shares of common stock issuable upon conversion of notes held by Sanderling VI Limited Partnership, (xvii) 343,903 shares of common stock issuable
- (14) Consists of 4,494 shares of common stock issuable upon exercise of stock options within 60 days of December 31, 2010, including options that become exercisable upon completion of this offering.
- (15) Consists of (i) 1,487,680 shares of Series A convertible preferred stock held by HBM BioVentures (Cayman) Ltd., (ii) 92,980 shares of common stock held by HBM BioVentures (Cayman) Ltd., (iii) 79,033 shares of common stock issuable upon exercise of warrants held by HBM BioVentures (Cayman) Ltd., and (iv) 1,146,223 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 250,000,000 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.

#### Preferred Stock

Under the terms of our restated certificate of incorporation that will be in effect upon completion of this offering, our board of directors is authorized to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock.

### **Common Stock**

As of December 31, 2010, there were 10,661,448 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 \$47.5 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 6,322,640 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 \$13.44 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 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 2/3% 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 December 31, 2010, options to purchase 2,073,864 shares of common stock at a weighted average exercise price of \$2.69 per share were outstanding.

# Warrants

Assuming no warrants have been exercised as of December 31, 2010, upon the completion of this offering there will be outstanding 11 warrants to purchase an aggregate of 158,061 shares of common stock, each at an exercise price of \$2.69 per share and each of which expire on January 21, 2014 and two warrants to purchase an aggregate of 23,244 shares of common stock, each at an exercise price of \$13.44 per share and each of which expires 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 178,986 shares of common stock at an exercise price of \$13.44 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. Furthermore, upon the completion of this offering, there will be additional outstanding warrants to purchase 167,361 shares of common stock at an exercise price of \$13.44 per share, each of which expires on December 29, 2017.

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 11,056,725 shares of our common stock as of December 31, 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 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 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 2/3% 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 Computershare Trust Company, N.A.

# 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 14,911,448 shares of common stock, assuming the automatic conversion of all outstanding shares of our Series A convertible preferred stock and the conversion of \$47.5 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 3,264,777 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 4,250,000 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 10,661,448 shares of common stock will be "restricted securities," as that term is defined in Rule 144 under the Securities Act. Substantially all of these restricted securities will be subject to the 180-day lock-up period described below. After the 180 day lock-up period 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.

In addition, of the 2,073,864 shares of our common stock that were subject to stock options outstanding as of December 31, 2010, options to purchase 442,307 shares of common stock were exercisable as of December 31, 2010 and, upon exercise, these shares will be eligible for sale subject to the lock-up agreements and securities laws described below. The 527,652 shares of our common stock that were subject to warrants outstanding as of December 31, 2010, were exercisable as of December 31, 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 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 149,114 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 4,250,000 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 14,911,448 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 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 December 31, 2010, we had outstanding options to purchase 2,073,864 shares of common stock, of which options to purchase 442,307 shares of common stock were vested as of December 31, 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 December 31, 2010, we also had outstanding and exercisable warrants to purchase 325,422 shares of common stock and 202,230 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.

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;

- 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%, 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.

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:

	Number of
Underwriters	Shares
Barclays Capital Inc.	
Piper Jaffray & Co.	
Wedbush Securities Inc.	
Brean Murray, Carret & Co., LLC	
Total	4,250,000

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.

	No Exercise	Full Exercise
Per share		
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 \$2.3 million (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 637,500 shares at the public offering price less underwriting discounts and commissions. This option may be exercised if the underwriters sell more than 4,250,00 shares in connection with this offering. To the extent that this option is exercised, each underwriter will

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.

Our lock-up agreement permits us to offer, without the prior written consent of each of Barclays Capital Inc. and Piper Jaffray, (1) our common stock issued in this offering, (2) shares of our common stock or other securities issued pursuant to employee benefit plans, stock option plans or other employee compensation plans or arrangements existing as of the date of this prospectus or pursuant to currently outstanding options, warrants or rights whether or not issued under one of those plans, and (3) shares of our common stock or other securities issued in connection with acquisitions, strategic partnerships or lending, leasing or other commercial transactions, in each case, subject to the recipient of such shares of our common stock or other securities agreeing to be subject to substantially the same restrictions as those contained in lock-up agreements described above.

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.

## 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.

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 "PCRX."

## 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.

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 "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.

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, 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 theses 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, 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. Our website is not a part of this prospectus.

# Pacira Pharmaceuticals, Inc.

# **Index to Consolidated Financial Statements**

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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 matters discussed in Note 1
("Correction of Immaterial Errors")
which are as of December 3, 2010 and
("Reverse Stock Split") which are as of January 12, 2011

# Pacira Pharmaceuticals, Inc. Consolidated Balance Sheets as of December 31, 2009 and 2008

	Decem	
	2009	2008
	(in thousands, and per sha	
ASSETS	·	
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	\$ 43,954	\$ 50,541
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
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	66,903	43,051
Commitments and Contingencies		
Stockholders' equity (deficit):		
Preferred stock, par value \$0.001, 88,000,000 shares authorized, 6,322,640 issued and outstanding at		
December 31, 2009 and 2008 (liquidation preference of \$85,000,000)	6	6
Common stock, par value \$0.001, 120,000,000 shares authorized, 573,920 and 572,164 shares issued		
and outstanding at December 31, 2009 and 2008, respectively	1	1
Additional paid-in capital	86,806	85,538
Accumulated deficit	(109,762)	(78,055)
Total stockholders' equity (deficit)	(22,949)	7,490
Total liabilities and stockholders' equity (deficit)	\$ 43,954	\$ 50,541

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	15,006	13,925	8,341	
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	43,554	59,288	46,727	
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	<u>'</u> ) —		
Royalty interest obligation	(1,880	3,490	1,686	
Net loss	\$ (31,707	(41,862)	\$ (36,193)	
Net loss per common share:				
Basic and diluted net loss per share	\$ (55.32	2) \$ (79.23)	\$ (77.85)	
Weighted average shares outstanding—basic and diluted	573,118	528,357	464,900	

See accompanying notes to consolidated financial statements.

# Pacira Pharmaceuticals, Inc.

# Consolidated Statements of Stockholders' Equity (Deficit) Years Ended December 31, 2009, 2008, and 2007

	Preferre	d Stock	Comm	on Stock	Additional Paid-In	Accumulated	
	Shares	Amount	Shares	Amount	<u>Capital</u>	Deficit	Total
					housands)		
Balances, January 1, 2007	_	\$ —	_	\$ —	\$ —	\$ —	\$ —
Issuance of preferred stock	3,347	3			44,997		45,000
Issuance of common stock			465	1	49		50
Share-based compensation					80		80
Net loss						(36,193)	(36,193)
Balances, December 31, 2007	3,347	3	465	1	45,126	(36,193)	8,937
Issuance of preferred stock	2,975	3			39,997		40,000
Exercise of stock options			107	_	173		173
Share-based compensation					242		242
Net loss						(41,862)	(41,862)
Balances, December 31, 2008	6,322	6	572	1	85,538	(78,055)	7,490
Exercise of stock options			2	_	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	6,322	\$ 6	574	\$ 1	\$86,806	\$(109,762)	\$(22,949)

 $See\ accompanying\ notes\ to\ consolidated\ financial\ statements.$ 

# Pacira Pharmaceuticals, Inc.

# Consolidated Statements of Cash Flows Years Ended December 31, 2009, 2008, and 2007

	Years Ended December 31,			
	2009	2008	2007	
Operating activities:		(in thousands)		
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	<del>_</del>	_	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)	(2,750	
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	7,42	
Deferred rent	303	446	423	
Net cash used in operating activities	(20,838)	(29,189)	(13,435	
nvesting activities:				
Purchase of fixed assets	(5,509)	(5,840)	(2,124	
Proceeds from sale of fixed assets	(3,307)	2	(2,12	
Acquisition of intangibles	_		(1,44)	
Acquisition of SkyePharma, Inc., net of cash acquired of \$175	<u> </u>	_	(20,813	
Net cash used in investing activities	(5,509)	(5,838)	(24,375	
	(3,309)	(3,838)	(24,37,	
Financing activities:		40.000	45.000	
Proceeds from issuance of preferred stock	_	40,000	45,000	
Proceeds from exercise of stock options and issuance of common stock	10.625	173	50	
Proceeds from convertible notes	10,625	_		
Proceeds from secured promissory notes	10,625	<del>_</del>		
Financing costs	(215)			
Net cash provided by financing activities	21,038	40,173	45,050	
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	\$ 7,077	\$ 12,386	\$ 7,240	
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	s —	
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	\$ —	\$ —	
value of warranto issued to fandiord	φ 204	Ψ —	Ψ —	

 $See\ accompanying\ notes\ to\ consolidated\ financial\ statements.$ 

# 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.

# Reverse Stock Split

On January 12, 2011, the board of directors of the Company approved, and on January 12, 2011 the stockholders of the Company approved, a one-for-10.755 reverse stock split of the Company's outstanding common stock, which was effected on January 12, 2011. Stockholders entitled to fractional shares as a result of the reverse stock split will receive a cash payment for such fractional shares within 180 days following the effective date of the reverse stock split in lieu of receiving fractional shares. The reverse stock split affected all holders of the Company's preferred stock and common stock uniformly. Shares of common stock underlying outstanding stock options were proportionately reduced and the respective exercise prices were proportionately increased in accordance with the terms of the agreements governing such securities. Shares of common stock reserved for issuance upon the conversion of the Company's series A preferred stock and convertible notes were proportionately reduced and the respective conversion prices were proportionately increased. All references to preferred and common stock and per share information, except par value and authorized shares, in these consolidated financial statements and notes have been adjusted to reflect the effects of the reverse stock split.

## 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

# Pacira Pharmaceuticals, Inc.

# Notes to Consolidated Financial Statements—(continued)

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.

# 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

# Pacira Pharmaceuticals, Inc.

# Notes to Consolidated Financial Statements—(continued)

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 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. Overhead costs associated with excess manufacturing capacity are charged to cost of revenue, as incurred

## 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:

 Asset Category
 Years

 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.

# Pacira Pharmaceuticals, Inc.

# Notes to Consolidated Financial Statements—(continued)

# 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.

# 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.

# Pacira Pharmaceuticals, Inc. Notes to Consolidated Financial Statements—(continued)

# 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 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 license 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 license fee is recognized accordingly on a prospective basis. Upon termination of a collaboration agreement, any remaining non-refundable license 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.

# Pacira Pharmaceuticals, Inc.

# Notes to Consolidated Financial Statements—(continued)

## 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 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 7.2 million, 6.6 million and 3.3 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.

# Pacira Pharmaceuticals, Inc.

## Notes to Consolidated Financial Statements—(continued)

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.

# 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

# Pacira Pharmaceuticals, Inc.

# Notes to Consolidated Financial Statements—(continued)

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.

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:

Purchase consideration:	
(in thousands)	
Cash paid to SkyePharma Holding, Inc.	\$19,632
Acquisition costs	1,355
Contingent purchase liability	2,042
Total purchase consideration	\$ 23,029
Allocation of purchase price:	
(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	(1,959)
	\$ 23,029

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.

# Pacira Pharmaceuticals, Inc.

# Notes to Consolidated Financial Statements—(continued)

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 milestones following the Acquisition. According to this agreement, Pacira would pay SkyePharma Holding, Inc. royalty payments based on the net revenues of EXPAREL and certain other products from the future yet-to-be-developed biologics product line and milestone payments of up to an aggregate of \$62 million upon the occurrence of the following events: a) first commercial sale in the United States; b) first commercial sale in a major EU country (UK, France, Germany, Italy, or Spain); c) annual net sales reach \$100 million; d) annual net sales reach \$250 million and e) annual net sales reach \$500 million. Additionally, the Company agreed to pay to SkyePharma Holding, Inc. a 3% royalty of its 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:

(in thousands, except per share data)	(Unaudited)
Revenue	\$ 9,860
Net loss	\$(48,165)
Basic and diluted net loss per common share	\$ (103.60)
Basic and diluted weighted average shares	464,900

# 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.

# Pacira Pharmaceuticals, Inc.

# Notes to Consolidated Financial Statements—(continued)

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.

# 6. INVENTORIES

The components of inventories were as follows:

	Decemb	oer 31,
	2009	2008
	(in thou	sands)
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	\$1,729	\$2,028

# 7. FIXED ASSETS

Fixed assets, at cost, summarized by major category, consist of the following:

	Dece	mber 31,
	2009	2008
	(in th	ousands)
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	\$19,560	\$ 18,037

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:

	Decemb		Estimated
	(In thou	2008	Useful Life
Core Technology	(In thou	sailus)	
Gross Amount	\$ 2,900	\$ 2,900	9 years
Accumulated amortization	(886)	(564)	
Net	2,014	2,336	
Developed Technology			
Gross Amount	11,700	11,700	7 years
Accumulated amortization	(4,596)	(2,925)	
Net	7,104	8,775	
Trademarks and trade names			
Gross Amount	500	500	7 years
Accumulated amortization	(176)	(100)	
Net	324	400	
DepoDur Rights			
Gross Amount	2,058	1,736	Remaining patent life
Accumulated amortization	(322)	(163)	ending November 2018
Net	1,736	1,573	
Intangible assets, net	\$11,178	\$ 13,084	

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):

		Trademarks			
	Core	Developed	and	DepoDur	
	Technology	Technology	Tradenames	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
Total	\$ 2,014	\$ 7,104	\$ 324	\$1,736	\$11,178

# 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:

	Dece	December 31,	
	2009	2008	
	(in th	ousands)	
Prepaid expenses	\$ 761	\$ 868	
Other	311	308	
Total	\$1,072	\$1,176	

Accrued expenses consist of the following:

	Decem	December 31,	
	2009	2008	
	(in thou	ısands)	
Compensation and benefits	\$ 518	\$1,085	
Lease rent deferral - current portion	1,705	_	
Other	_1,255	648	
	\$ 3,478	\$ 1,733	

# 10. DEBT AND FINANCING ARRANGEMENTS

The composition of the Company's debt and financing obligations, including accrued interest, is as follows:

	Decem	December 31,	
	2009	2008	
	(in thou	isands)	
Related party debt, including accrued interest:			
Convertible notes payable	\$11,124	\$ —	
Secured notes payable	11,049	_	
	22,173		
Financing obligations:			
Royalty interest obligation, current portion	1,599	1,443	
Royalty interest obligation, long-term portion	3,647	3,618	
	5,246	5,061	
Total debt and financing obligations	\$27,419	\$5,061	

# 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 158,061 shares of the Company's common stock at an exercise price of \$2.69 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 \$2.69 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 464,900 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 6,322,640 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 \$13.44 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 158,061 of shares of the Company's common stock at an exercise price of \$2.69 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 23,244 shares of Series A convertible preferred stock at a price of \$13.44 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			20	007	
				(in th	ousands)			
Selling, general and administrative	\$	349		\$	126		\$	25
Research and development		175			116			5 5
	\$	524		\$	242		\$	80

# 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 650,860 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 650,860 shares to 1,066,946 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:

	GL	Weighted Average	Weighted Average Remaining
Outstanding at January 1, 2007	Shares	Exercise Price	Term (years)
Granted	560,290	\$ 1.61	
Exercised		— I.o.	
Forfeited	(2,070)	1.61	
Expired	(79)	1.61	
Outstanding at December 31, 2007	558,141	1.61	9.7
Granted	454,110	1.96	
Exercised	(107,264)	1.61	
Forfeited	(114,064)	1.63	
Expired	(1,546)	1.61	
Outstanding at December 31, 2008	789,377	1.81	9.1
Granted	741	2.69	
Exercised	(1,756)	1.61	
Forfeited	(655,350)	1.84	
Expired	(80,582)	1.61	
Outstanding at December 31, 2009	52,430	\$ 1.79	8.2
Exercisable at December 31, 2009	34,078	\$ 1.83	7.6
Vested and expected to vest at December 31, 2009	50,961	\$ 1.83	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 \$1.94, \$1.40 and \$1.08 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, 905,484 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 477,820 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:

	Y	ears 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		
		(in thousands)			
Cost of supply revenue	\$ 9,828	\$ 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	\$ 12,301	\$ 17,463	\$ 9,492		

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 23,244 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 \$13.44 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	$\frac{3,072}{\$30,038}$
	\$30,038

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):

	Y	81,	
	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>

Significant components of the Company's deferred tax assets are as follows:

	Year ended I	vecember 31,
	2009	2008
	(in thou	(sands)
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	54,455	41,539
Less valuation allowance for deferred tax assets	_(54,455)	(41,539)
Net deferred tax assets	\$	\$ —

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 477,805 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 DepoCyte 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 DepoCyte 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 was entitled to receive non-refundable license fees of \$5.0 million paid upon execution of the agreement in August 2007, \$5.0 million paid at the end of 2008, and \$5.0 million paid at the end of 2009. As noted above, the Company recognizes revenue from up-front license fees ratably over the performance period as determined under the agreement. The Company capitalized the up-front license fees into a deferred revenue liability, and amortizes the deferred revenue over a period of 15 years, which represents the contract period. Further, under the 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.

# Pacira Pharmaceuticals, Inc.

## Notes to Consolidated Financial Statements—(continued)

### 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 achievement of certain worldwide sales and a tiered royalty based upon sales. In April 2008, the Company received a non-refundable up-front license fee of \$8.0 million from Amylin. As noted above, the Company recognizes revenue from up-front license fees ratably over the performance period as determined under the agreement. The Company capitalized the up front license fee into a deferred revenue liability, and amortizes the deferred revenue over a period of approximately nine years. 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.

### Pacira Pharmaceuticals, Inc.

## Notes to Consolidated Financial Statements—(continued)

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.

#### 18. SUBSEQUENT EVENTS

The Company has evaluated subsequent events through November 1, 2010, except for the effects of the matters discussed in Note 1 ("Correction of Immaterial Errors") and ("Reverse Stock Split") which are as of December 3, 2010 and January 12, 2011, respectively, 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 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.

#### **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

# Pacira Pharmaceuticals, Inc.

## Notes to Consolidated Financial Statements—(continued)

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 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 ceases to own or control, directly or indirectly, all of the economic or voting rights of each of its subsidiaries.

# Pacira Pharmaceuticals, Inc.

#### Notes to Consolidated Financial Statements—(continued)

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 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 from 1,066,946 to 1,729,498 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 1,448,301 shares of common stock. The stock options have an exercise price of \$1.61 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 \$1.61 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

	September 30,  2010  (In thousands	December 31, 2009 s, except share
	and per sha	
ASSETS		
Current assets:	ф. 10 051	Φ 5.055
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	\$ 52,756	\$ 43,954
LIABILITIES AND STOCKHOLDERS' DEFICIT		
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, 6,322,640 issued and outstanding at		
September 30, 2010 and December 31, 2009 (liquidation preference \$85,000,000)	6	6
Common stock, par value \$0.001, 120,000,000 shares authorized, 574,903 shares issued and 573,838		
shares outstanding at September 30, 2010; 573,920, shares issued and outstanding at December 31, 2009	1	1
Additional paid-in capital	86,824	86,806
Accumulated deficit	(129,867)	(109,762)
	(43,036)	(22,949)
Less: treasury stock, 1,065 shares at cost	(43,030)	(22,549)
Total stockholders' deficit	(43,038)	(22,949)
Total liabilities and stockholders' deficit	\$ 52,756	\$ 43,954

# Pacira Pharmaceuticals, Inc.

# Condensed Consolidated Statements of Operations (Unaudited) Nine Months Ended September 30, 2010 and 2009

	Nine Mon Septem	
	2010	2009
	(in thousai share and da	per share
Revenues:		,
Supply revenue	\$ 7,127	\$ 4,273
Royalties	2,693	2,906
Collaborative licensing and development revenue	2,551	3,543
Total revenues	12,371	10,722
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	29,063	31,460
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	\$ (20,105)	\$ (22,736)
Net loss per common share:		
Basic and diluted net loss per share	\$ (35.02)	\$ (39.69)
Weighted average shares outstanding—basic and diluted	574,112	572,860

# Pacira Pharmaceuticals, Inc.

# Condensed Consolidated Statement of Stockholders' Deficit (Unaudited) Nine Months Ended September 30, 2010

	Preferr	ed Stock	<u> </u>	Comm	on Stoc	k	Additional			
	Shares	Am	<u>iount</u>	Shares	Am	<u>ount</u>	Paid-In <u>Capital</u> (in thousands)	Accumulated Deficit	asury ock_	Total
Balances, January 1, 2010	6,323	\$	6	574	\$	1	\$86,806	\$(109,762)	\$ _	\$(22,949)
Exercise of stock options				1			1			1
Share-based compensation							17			17
Purchase of treasury stock									(2)	(2)
Net loss								(20,105)	 	(20,105)
Balances, September 30, 2010	6,323	\$	6	575	\$	1	\$86,824	\$(129,867)	\$ (2)	\$ (43,038)

# Pacira Pharmaceuticals, Inc.

# Condensed Consolidated Statement of Cash Flows (Unaudited) Nine Months Ended September 30, 2010 and 2009

	Nine Months Ende	d September 30,
	2010	2009
Operating activities:	(in thous	ands)
Net loss	\$ (20,105)	\$ (22,736)
Adjustments to reconcile net loss to net cash used in operating activities:	\$ (20,103)	Ψ (22,750)
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	(19,040)	(21,677)
Investing activities—Purchase of fixed assets	(3,822)	(5,109)
Financing activities:		
Proceeds from exercise of stock options	1	2
Purchase of treasury stock	(2)	_
Proceeds from convertible notes	<del>-</del>	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	29,636	18,812
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	\$ 13,851	\$ 4,412
Supplemental cash flow information:		
Cash paid for interest	\$ 1,787	\$ 1,291
Non-cash investing and financing activities:		
Accrued fixed asset purchases	\$ —	\$ 2,254

#### 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 Consolidated Financial Statements—(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.

# Reverse Stock Split

On January 12, 2011, the board of directors of the Company approved, and on January 12, 2011 the stockholders of the Company approved, a one-for-10.755 reverse stock split of the Company's outstanding common stock, which was effected on January 12, 2011. Stockholders entitled to fractional shares as a result of the reverse stock split will receive a cash payment for such fractional shares within 180 days following the effective date of the reverse stock split in lieu of receiving fractional shares. The reverse stock split affected all holders of the Company's preferred stock and common stock uniformly. Shares of common stock underlying outstanding stock options were proportionately reduced and the respective exercise prices were proportionately increased in accordance with the terms of the agreements governing such securities. Shares of common stock reserved for issuance upon the conversion of the Company's series A preferred stock and convertible notes were proportionately reduced and the respective conversion prices were proportionately increased. All references to preferred and common stock and per share information, except par value and authorized shares, in these consolidated financial statements and notes have been adjusted to reflect the effects of the reverse stock split.

# 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%,

# Pacira Pharmaceuticals, Inc.

#### Notes to Condensed Consolidated Financial Statements (Unaudited)—(continued)

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.

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 7.2 million at September 30, 2010 and 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.

# Pacira Pharmaceuticals, Inc.

#### Notes to Condensed Consolidated Financial Statements (Unaudited)—(continued)

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. 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 the Company's 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).

# Pacira Pharmaceuticals, Inc.

# Notes to Condensed Consolidated Financial Statements (Unaudited)—(continued)

#### 5. INVENTORIES

The components of inventories were as follows:

	tember 30, 2010	D	December 31, 2009
	(i	n thousands)	
Raw materials	\$ 758	\$	811
Work-in-process	85		48
Finished goods	 302	_	965
	 1,145	_	1,824
Less provision for excess and obsolete inventories	(95)		(95)
Inventories, net	\$ 1,050	\$	1,729

# 6. DEBT AND FINANCING ARRANGEMENTS

The composition of the Company's debt and financing obligations, including accrued interest, is as follows:

	September 30, 2010	December 31, 2009	
		(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	_	
	42,652	22,173	
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	
	5,055	5,246	
Total debt and financing obligations	\$ 58,957	\$ 27,419	

# 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

### Pacira Pharmaceuticals, Inc.

#### Notes to Condensed Consolidated Financial Statements (Unaudited)—(continued)

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 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.

# Pacira Pharmaceuticals, Inc.

#### Notes to Condensed Consolidated Financial Statements (Unaudited)—(continued)

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.

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 the Company's 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 1,066,946 to 1,729,498 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 1,448,301 shares of the Company's common stock. The stock options have an exercise price of \$1.61 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 \$1.61 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;
- (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:

		weighteu	
		Average Exercise Price	
	Shares		
Outstanding at January 1, 2010	52,430	\$ 1.79	
Granted	1,456,757	1.61	
Exercised	(982)	1.83	
Forfeited	(2,071)	1.94	
Expired	(2,050)	1.83	
Outstanding at September 30, 2010	1,504,084	1.61	

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Notes to Condensed Consolidated Financial Statements (Unaudited)—(continued)

# Pacira Pharmaceuticals, Inc.

#### Notes to Condensed Consolidated Financial Statements (Unaudited)—(continued)

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 \$1.10 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 en	Nine months ended		
	September 30, 	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 the Company's 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 from the balance sheet date, the date at which the interim unaudited condensed consolidated financial statements were available to be issued, through January 12, 2011.

#### 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 December 31, 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 December 31, 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 178,986 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 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 \$13.44 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.

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Pacira Pharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (Unaudited)—(continued)

# Pacira Pharmaceuticals, Inc.

#### Notes to Condensed Consolidated Financial Statements (Unaudited)—(continued)

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).

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

# Pacira Pharmaceuticals, Inc.

#### Notes to Condensed Consolidated Financial Statements (Unaudited)—(continued)

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.

#### December 2010 Convertible Notes

On December 29, 2010, the Company sold \$15.0 million in aggregate principal amount of convertible promissory notes, or the December 2010 Convertible Notes, in a private placement to certain of its existing investors. 50% of the principal amount was funded on December 29, 2010. The remaining 50% of the principal amount will be funded in a second closing to occur upon written request of holders of at least 75% of the outstanding principal amount of the December 2010 Convertible Notes on or before the earlier of the completion of the Company's proposed initial public offering or March 31, 2011. In connection with the issuance and sale of the December 2010 Convertible Notes, the Company issued warrants to the holders of the December 2010 Convertible Notes to purchase an aggregate of 167,361 shares of its common stock with an exercise price of \$13.44 per share. Pursuant to the terms of the agreement for the issuance and sale of the December 2010 Convertible Notes, in the event a second closing of the issuance and sale of the December 2010 Convertible Notes occurs, the Company will issue warrants to the holders of the December 2010 Convertible Notes to purchase an additional 167,361 shares of its common stock with an exercise price of \$13.44 per share. The December 2010 Convertible Notes will have an interest rate of 5% per year from and after March 31, 2011 and all principal and accrued and unpaid interest on the December 2010 Convertible Notes is due and payable upon 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 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.

Upon completion of the Company's proposed initial public offering, all principal and interest due under the December 2010 Convertible Notes will be converted into shares of the Company's common stock at a conversion price equal to the price per share of common stock sold in the Company's proposed initial public offering. Purchasers of the December 2010 Convertible Notes included certain holders of more than 5% of the Company's capital stock, or entities affiliated with them.

The fair value of the warrants granted on December 29, 2010 is \$0.5 million and the fair value of the beneficial conversion feature is a corresponding \$0.5 million. The value of the warrants and the beneficial conversion feature will be recorded as a discount to the December 2010 Convertible Notes and amortized as a component of interest expense over the original term of the December 2010 Convertible Notes. Upon the completion of the Company's initial public offering, when the December 2010 Convertible Notes are converted into common stock, any unamortized balance will be recognized in full on the date of such event.

#### 2007 Plan Amendment

In December 2010, the Company amended the 2007 Plan to increase the number of shares of common stock authorized for issuance under the 2007 Plan from 1,729,498 shares to 2,546,657 shares.

# December 2010 Stock Option Grant

In December 2010, the Company's board of directors granted options to all of its employees, including its named executive officers, and its non-employee directors, for an aggregate of 571,300 shares of common stock.

# Pacira Pharmaceuticals, Inc.

# Notes to Condensed Consolidated Financial Statements (Unaudited)—(continued)

# 2011 Plan

The Company's 2011 stock incentive plan, or the 2011 plan, which will become effective immediately prior to the completion of the Company's proposed initial public offering, was adopted by its board of directors and approved by its stockholders in December 2010. The 2011 plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards and other stock-based awards. Upon effectiveness, the sum of (up to 2,546,657 shares) (x) the number of shares of its common stock reserved for issuance under the 2007 plan at such time, and (y) the number of shares of its common stock subject to awards granted under the 2007 plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by the Company pursuant to a contractual repurchase right, will be reserved for issuance under the 2011 plan. In addition, the 2011 plan contains an "evergreen" provision, which allows for an increase in the number of shares available for issuance under the 2011 plan on the first day of each calendar year from 2012 through 2015.

# 4,250,000 Shares



# **Common Stock**

Prospectus , 2011

# **Barclays Capital**

**Piper Jaffray** 

**Wedbush PacGrow Life Sciences** 

Brean Murray, Carret & Co.

Until , 2011 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.

	A	mount
Securities and Exchange Commission registration fee	\$	6,150
FINRA filing fee		9,125
The NASDAQ Global Market listing fee		125,000
Accountants' fees and expenses		300,000
Legal fees and expenses	1,	200,000
Blue Sky fees and expenses		10,000
Transfer Agent's fees and expenses		10,000
Printing and engraving expenses		325,000
Miscellaneous	:	314,725
Total Expenses	\$ 2.	,300,000

# 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

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 have entered 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 464,900 shares of common stock at a price per share of \$0.11 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 6,322,640 shares of Series A convertible preferred stock at a price per share of \$13.44 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 \$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.

In December 2010, we entered into an agreement for the issuance of convertible promissory notes to HBM BioVentures (Cayman) Ltd., entities affiliated with MPM Capital, entities affiliated with Orbimed Advisors and entities affiliated with Sanderling Ventures. On December 29, 2010, we issued notes for an aggregate principal amount \$7,500,000. Pursuant to the terms of the agreement, the remaining \$7,500,000 of principal amount of notes will be funded in a second closing to occur upon written request of holders of at least 75% of the outstanding principal amount of the notes issued on December 29, 2010. The notes have an annual interest rate of 5%.

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 3,043,198 shares of common stock as of December 31, 2010. As of December 31, 2010, options to purchase 110,196 shares of common stock had been exercised and options to purchase 2,073,864 shares of common stock remained outstanding at a weighted average exercise price of \$2.69 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.

#### (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 158,061 shares of common stock in connection with the 2009 Convertible Note Financing. The common stock warrants have an exercise price of \$2.69 per share.

In June 2009, we issued warrants for an aggregate of 23,244 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 178,986 shares of preferred stock in connection with the Hercules Credit Facility. The preferred stock warrant has an exercise price of \$13.44 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.

In December 2010, 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 an aggregate of 167,361 shares of common stock in connection with the issuance of certain convertible promissory notes. Pursuant to the terms of the agreement for the issuance of the notes, if a second closing of the issuance and sale of the notes occurs, we will issue warrants to purchase an additional 167,361 shares of common stock. The common stock warrants have an exercise price of \$13.44 per share.

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 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.

capacities and on the dates indicated.

# **SIGNATURES**

Pursuant to the requirements of the Securities Act, this Amendment No. 3 to Registration Statement has been signed by the following persons in the

Pursuant to the requirements of the Securities Act, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Parsippany, State of New Jersey, on the 13 th day of January, 2011.

PACIRA PHARMAC	EUTI	CALS, INC.	
By:	/s/	DAVID STACK	

David Stack President and Chief Executive Officer

Signature	<u>Title</u>	<u>Date</u>
/s/ DAVID STACK	Director, President and Chief Executive Officer	January 13, 2011
David Stack	(Principal Executive Officer)	
/s/ JAMES SCIBETTA  James Scibetta	Chief Financial Officer (Principal Financial and Accounting Officer)	January 13, 2011
James Sciocta		
*	Chairman	January 13, 2011
Fred Middleton		
*	Director	January 13, 2011
Luke Evnin		
*	Director	January 13, 2011
Carl Gordon		
*	Director	January 13, 2011
John Longenecker		
*	Director	January 13, 2011
Gary Pace		
*	Director	January 13, 2011
Andreas Wicki		
PACIRA PHARMACEUTICAI	LS, INC.	
Da	DAVID STACK  vid Stack  rney-in-fact	

# EXHIBIT INDEX

Exhibit number	Description
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
3.5	Certificate of Amendment to Amended and Restated Certificate of Incorporation
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

Exhibit number	Description
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
10.30†	Form of Warrant to purchase common stock of the Registrant, dated December 29, 2010
10.31†	2011 Stock Incentive Plan
10.32	Form of Indemnification Agreement between the Registrant and its directors and officers
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.

## [•] Shares

### Pacira Pharmaceuticals, Inc.

### **Common Stock**

#### UNDERWRITING AGREEMENT

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BARCLAYS CAPITAL INC.
PIPER JAFFRAY & Co.
As Representatives of the several
Underwriters named in Schedule I attached hereto,
745 Seventh Avenue
New York, New York 10019

Ladies and Gentlemen:

Pacira Pharmaceuticals, Inc., a Delaware corporation (the "Company"), proposes to sell [•] shares (the "Firm Stock") of the Company's common stock, par value \$0.001 per share (the "Common Stock"). In addition, the Company proposes to grant to the underwriters (the "Underwriters") named in Schedule I attached to this agreement (this "Agreement") an option to purchase up to [•] additional shares of the Common Stock on the terms set forth in Section 2 (the "Option Stock"). The Firm Stock and the Option Stock, if purchased, are hereinafter collectively called the "Stock". This Agreement is to confirm the agreement concerning the purchase of the Stock from the Company by the Underwriters.

- 1. Representations, Warranties and Agreements of the Company. The Company represents, warrants and agrees that:
- (a) A registration statement on Form S-1 (File No. 333-170245) relating to the Stock has (i) been prepared by the Company in conformity with the requirements of the Securities Act of 1933, as amended (the "Securities Act"), and the rules and regulations of the Securities and Exchange Commission (the "Commission") thereunder; (ii) been filed with the Commission under the Securities Act; and (iii) become effective under the Securities Act. Copies of such registration statement and any amendment thereto have been delivered by the Company to you as the representatives (the "Representatives") of the Underwriters. As used in this Agreement:
  - (i) "Applicable Time" means [•] [a.m.][p.m.] (New York City time) [•], 2011;
  - (ii) "Effective Date" means the date and time as of which the Registration Statement, or the most recent post-effective amendment thereto, was declared effective by the Commission;

- (iii) "Issuer Free Writing Prospectus" means each "free writing prospectus" (as defined in Rule 405 under the Securities Act) prepared by or on behalf of the Company or used or referred to by the Company in connection with the offering of the Stock;
- (iv) "Preliminary Prospectus" means any preliminary prospectus relating to the Stock included in such registration statement or filed with the Commission pursuant to Rule 424(b) under the Securities Act;
- (v) "Pricing Disclosure Package" means, as of the Applicable Time, the most recent Preliminary Prospectus, together with the information included in Schedule III hereto and each Issuer Free Writing Prospectus filed or used by the Company on or before the Applicable Time, other than a road show that is an Issuer Free Writing Prospectus but is not required to be filed under Rule 433 under the Securities Act, if any;
- (vi) "Prospectus" means the final prospectus relating to the Stock, as filed with the Commission pursuant to Rule 424(b) under the Securities Act; and
- (vii) "*Registration Statement*" means such registration statement, as amended as of the Effective Date, including any Preliminary Prospectus or the Prospectus, all exhibits to such registration statement and including the information deemed by virtue of Rule 430A under the Securities Act to be part of such registration statement as of the Effective Date.

Any reference to the "most recent Preliminary Prospectus" refers to the latest Preliminary Prospectus included in the Registration Statement or filed pursuant to Rule 424(b) under the Securities Act prior to or on the date hereof. The Commission has not issued any order preventing or suspending the use of any Preliminary Prospectus or the Prospectus or suspending the effectiveness of the Registration Statement, and no proceeding or examination for such purpose has been instituted or, to the Company's knowledge, threatened by the Commission.

- (b) The Company was not at the time of initial filing of the Registration Statement, is not on the date hereof and will not be on the applicable Delivery Date (as defined below) an "ineligible issuer" (as defined in Rule 405 under the Securities Act).
- (c) The Registration Statement conformed and will conform in all material respects on the Effective Date and on the applicable Delivery Date, and any amendment to the Registration Statement filed after the date hereof will conform in all material respects when filed, to the requirements of the Securities Act and the rules and regulations thereunder. The most recent Preliminary Prospectus conformed, and the Prospectus will conform, in all material respects when filed with the Commission pursuant to Rule 424(b) under the Securities Act and on the applicable Delivery Date to the requirements of the Securities Act and the rules and regulations thereunder.

- (d) The Registration Statement did not, as of the Effective Date, contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading; *provided* that no representation or warranty is made as to information contained in or omitted from the Registration Statement in reliance upon and in conformity with written information furnished to the Company through the Representatives by or on behalf of any Underwriter specifically for inclusion therein, which information is specified in Section 8(e).
- (e) The Prospectus will not, as of its date or as of the applicable Delivery Date, contain an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading; *provided* that no representation or warranty is made as to information contained in or omitted from the Prospectus in reliance upon and in conformity with written information furnished to the Company through the Representatives by or on behalf of any Underwriter specifically for inclusion therein, which information is specified in Section 8(e).
- (f) The Pricing Disclosure Package did not, as of the Applicable Time, contain an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading; *provided* that no representation or warranty is made as to information contained in or omitted from the Pricing Disclosure Package in reliance upon and in conformity with written information furnished to the Company through the Representatives by or on behalf of any Underwriter specifically for inclusion therein, which information is specified in Section 8(e).
- (g) The Pricing Disclosure Package, when taken together with each Issuer Free Writing Prospectus listed in Schedule IV hereto, did not, as of the Applicable Time, contain an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading; *provided* that no representation or warranty is made as to information contained in or omitted from the Pricing Disclosure Package (or any Issuer Free Writing Prospectus listed in Schedule IV hereto) in reliance upon and in conformity with written information furnished to the Company through the Representatives by or on behalf of any Underwriter specifically for inclusion therein, which information is specified in Section 8(e).
- (h) Each Issuer Free Writing Prospectus conformed or will conform in all material respects to the requirements of the Securities Act and the rules and regulations thereunder on the date of first use, and the Company has complied with all prospectus delivery and any filing requirements applicable to such Issuer Free Writing Prospectus pursuant to the Securities Act and rules and regulations thereunder. The Company has not made any offer relating to the Stock that would constitute an Issuer Free Writing Prospectus without the prior written consent of the Representatives, except as set forth on Schedule V hereto. The Company has retained in accordance with the Securities Act and the rules and regulations thereunder all Issuer Free Writing Prospectuses that were not required to be filed pursuant to the Securities Act and the rules and regulations thereunder. The Company has taken all actions necessary so that any "road show" (as defined in Rule 433 under the Securities Act) in connection with the offering of the Stock will not be required to be filed pursuant to the Securities Act and the rules and regulations thereunder.

- (i) The Company and each of its subsidiaries have been duly organized, is validly existing and in good standing as a corporation or other business entity under the laws of its jurisdiction of organization and is duly qualified to do business and in good standing as a foreign corporation or other business entity in each jurisdiction in which its ownership or lease of property or the conduct of its businesses requires such qualification, except where the failure to be so qualified or in good standing would not, in the aggregate, reasonably be expected to have a material adverse effect on the condition (financial or otherwise), results of operations, stockholders' equity, properties or business of the Company and its subsidiaries taken as a whole (a "Material Adverse Effect"). The Company and each of its subsidiaries have all requisite power and authority necessary to own or hold its properties and to conduct the businesses in which it is engaged. The Company does not own or control, directly or indirectly, any corporation, association or other entity other than the subsidiaries listed in Exhibit 21 to the Registration Statement. None of the subsidiaries of the Company (other than Pacira Pharmaceuticals, Inc., a California corporation ("Pacira")) is a "significant subsidiary" (as defined in Rule 405 under the Securities Act).
- (j) The Company has an authorized capitalization as set forth in each of the most recent Preliminary Prospectus and the Prospectus, and all of the issued shares of capital stock of the Company have been duly authorized and validly issued, are fully paid and non-assessable, conform to the description thereof contained in the most recent Preliminary Prospectus and were issued in compliance with federal and state securities laws and not in violation of any preemptive right, resale right, right of first refusal or similar right. All of the Company's options, warrants and other rights to purchase or exchange any securities for shares of the Company's capital stock have been duly authorized and validly issued, conform in all material respects to the description thereof contained in the most recent Preliminary Prospectus and were issued in compliance in all material respects with federal and state securities laws. All of the issued shares of capital stock of each subsidiary of the Company have been duly authorized and validly issued, are fully paid and non-assessable and are owned directly or indirectly by the Company, free and clear of all liens, encumbrances, equities or claims, except for such liens, encumbrances, equities or claims (i) disclosed in the Pricing Disclosure Package and the Prospectus or (ii) as would not, in the aggregate, reasonably be expected to have a Material Adverse Effect.
- (k) The shares of the Stock to be issued and sold by the Company to the Underwriters hereunder have been duly authorized and, upon payment and delivery in accordance with this Agreement, will be validly issued, fully paid and non-assessable, will conform in all material respects to the description thereof contained in the most recent Preliminary Prospectus, will be issued in compliance in all material respects with federal and state securities laws and will be free of statutory and contractual preemptive rights, rights of first refusal and similar rights.

- (l) The Company has all requisite corporate power and authority to execute, deliver and perform its obligations under this Agreement. This Agreement has been duly and validly authorized, executed and delivered by the Company.
- (m) The issue and sale of the Stock, the execution, delivery and performance of this Agreement by the Company, the consummation of the transactions contemplated hereby and the application of the proceeds from the sale of the Stock as described under "Use of Proceeds" in the most recent Preliminary Prospectus will not (i) conflict with or result in a breach or violation of any of the terms or provisions of, impose any lien, charge or encumbrance upon any property or assets of the Company and its subsidiaries, or constitute a default under, any indenture, mortgage, deed of trust, loan agreement, license, lease or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which the Company or any of its subsidiaries is bound or to which any of the property or assets of the Company or any of its subsidiaries; or (iii) result in any violation of the provisions of the charter or by-laws (or similar organizational documents) of the Company or any of its subsidiaries; or (iii) result in any violation of any statute or any judgment, order, decree, rule or regulation of any court or governmental agency or body having jurisdiction over the Company or any of its subsidiaries or any of their properties or assets, except, with respect to clauses (i) and (iii), conflicts or violations that would not reasonably be expected to have a Material Adverse Effect.
- (n) No consent, approval, authorization or order of, or filing, registration or qualification with, any court or governmental agency or body having jurisdiction over the Company or any of its subsidiaries or any of their properties or assets is required for the issue and sale of the Stock, the execution, delivery and performance of this Agreement by the Company, the consummation of the transactions contemplated hereby, the application of the proceeds from the sale of the Stock as described under "Use of Proceeds" in the most recent Preliminary Prospectus, except for the registration of the Stock under the Securities Act and such consents, approvals, authorizations, orders, filings, registrations or qualifications as may be required under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), applicable state or foreign securities laws and/or the bylaws and rules of the Financial Industry Regulatory Authority ("FINRA") in connection with the purchase and sale of the Stock by the Underwriters.
- (o) The historical financial statements (including the related notes and supporting schedules) included in the most recent Preliminary Prospectus comply as to form in all material respects with the requirements of Regulation S-X under the Securities Act and present fairly, in all material respects, the financial condition, results of operations and cash flows of the entities purported to be shown thereby at the dates and for the periods indicated (subject to year-end audit adjustments in the case of unaudited interim financial statements) and have been prepared in conformity with accounting principles generally accepted in the United States applied on a consistent basis throughout the periods indicated.

- (p) J.H. Cohn LLP, who have certified certain financial statements of the Company and its consolidated subsidiaries, whose report appears in the most recent Preliminary Prospectus and who have delivered the initial letter referred to in Section 7(g) hereof, are independent public accountants as required by the Securities Act and the rules and regulations thereunder.
- (q) The Company and each of its subsidiaries maintain internal accounting controls designed to provide reasonable assurances regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States, including, but not limited to, internal accounting controls designed to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorization, (ii) transactions are recorded as necessary to permit preparation of the Company's financial statements in conformity with accounting principles generally accepted in the United States and to maintain accountability for its assets, (iii) access to the Company's assets is permitted only in accordance with management's general or specific authorization, and (iv) the recorded accountability for the Company's assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences. As of the date of the most recent balance sheet of the Company and its consolidated subsidiaries reviewed or audited by J.H. Cohn LLP and the audit committee of the board of directors of the Company and included in the most recent Preliminary Prospectus, there were no material weaknesses in the Company's internal controls.
- (r) (i) The Company and each of its subsidiaries maintain disclosure controls and procedures (as such term is defined in Rule 13a-15(e) under the Exchange Act), (ii) such disclosure controls and procedures are designed to ensure that is accumulated and communicated to management of the Company and its subsidiaries, including their respective principal executive officers and principal financial officers, as appropriate, and (iii) such disclosure controls and procedures are effective in all material respects to perform the functions for which they were established.
- (s) Since the date of the most recent balance sheet of the Company and its consolidated subsidiaries reviewed or audited by J.H. Cohn LLP and the audit committee of the board of directors of the Company, (i) the Company has not been advised of or become aware of (A) any significant deficiencies in the design or operation of internal controls that would adversely affect the ability of the Company or any of its subsidiaries to record, process, summarize and report financial data, or any material weaknesses in internal controls, and (B) any fraud, whether or not material, that involves management or other employees who have a significant role in the internal controls of the Company and each of its subsidiaries; and (ii) there have been no significant changes in internal controls or in other factors that could significantly affect internal controls, including any corrective actions with regard to significant deficiencies and material weaknesses.
- (t) The section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Use of Estimates" set forth in the most recent Preliminary Prospectus accurately and fully describes in all material respects (i) the accounting policies that the Company believes are the most important in the portrayal of the Company's financial condition and results

of operations and that require management's most difficult, subjective or complex judgments (" *Critical Accounting Policies*") and (ii) the judgments and uncertainties affecting the application of Critical Accounting Policies.

- (u) Except as disclosed in the Pricing Disclosure Package and the Prospectus, since the date of the latest audited financial statements included in the most recent Preliminary Prospectus, neither the Company nor any of its subsidiaries has (i) sustained any loss or interference with its business from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor dispute or court or governmental action, order or decree, (ii) issued or granted any securities, (iii) incurred any material liability or obligation, direct or contingent, other than liabilities and obligations that were incurred in the ordinary course of business, (iv) entered into any material transaction not in the ordinary course of business, or (v) declared or paid any dividend on its capital stock, and, except as disclosed in the Pricing Disclosure Package and the Prospectus, since such date, there has not been any change in the capital stock or long-term debt of the Company or any of its subsidiaries or any adverse change, or any development involving a prospective adverse change, in or affecting the condition (financial or otherwise), results of operations, stockholders' equity, properties, management or business of the Company and its subsidiaries taken as a whole, in each case except as would not, in the aggregate, reasonably be expected to have a Material Adverse Effect.
- (v) The Company and each of its subsidiaries do not own any real property. The Company and each of its subsidiaries have good and marketable title to all personal property owned by them free and clear of all liens, encumbrances and defects, except such liens, encumbrances and defects as are described in the most recent Preliminary Prospectus or such as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and its subsidiaries. All assets held under lease by the Company and its subsidiaries are held by them under valid, subsisting and enforceable leases, with such exceptions as do not materially interfere with the use made and proposed to be made of such assets by the Company and its subsidiaries.
- (w) The Company and, to the Company's knowledge, its directors, officers, employees, and agents (while acting in such capacity) are, and at all times since January 1, 2007 have been, in material compliance with, all health care laws applicable to the Company or any of its products or activities, including, but not limited to, the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)), the Anti-Inducement Law (42 U.S.C. § 1320a-7a(a)(5)), the civil False Claims Act (31 U.S.C. §§ 3729 et seq.), the administrative False Claims Law (42 U.S.C. § 1320a-7b(a)), the Stark law (42 U.S.C. § 1395nn), the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. §§ 1320d et seq.) as amended by the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. §§ 17921 et seq.), the exclusion laws (42 U.S.C. § 1320a-7), the Federal Food Drug and Cosmetic Act (21 U.S.C. §§ 301 et seq.), the Controlled Substances Act (21 U.S.C. §§ 801 et seq.), Medicare (Title XVIII of the Social Security Act), Medicaid (Title XIX of the Social Security Act), the regulations promulgated pursuant to such laws, and any other state or federal law, accreditation standards, regulation, memorandum, opinion letter, or other issuance which imposes requirements

on the manufacturing, development, testing, labeling, marketing or distribution of pharmaceutical products, kickbacks, patient or program charges, recordkeeping, claims process, documentation requirements, medical necessity, referrals, the hiring of employees or acquisition of services or supplies from those who have been excluded from government health care programs, quality, safety, privacy, security, licensure, accreditation or any other aspect of providing health care or pharmaceutical services (collectively, "Health Care Laws"). The Company has not received any notification, correspondence or any other written or oral communication, including notification of any pending or threatened claim, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any governmental authority, including, without limitation, the United States Food and Drug Administration ("FDA"), the Drug Enforcement Agency ("DEA"), the Centers for Medicare & Medicaid Services, and the U.S. Department of Health and Human Services Office of Inspector General, of potential or actual non-compliance by, or liability of, the Company under any Health Care Laws. To the Company's knowledge, there are no facts or circumstances that would reasonably be expected to give rise to liability of the Company under any Health Care Laws.

- (x) The Company and, as applicable, each of its subsidiaries holds all material, and is operating in material compliance with, such permits, licenses, franchises, registrations, exemptions, approvals, authorizations and clearances of the FDA and other governmental authorities required for the conduct of its business as currently conducted (collectively, the "*Permits*"), and all such Permits are in full force and effect. The Company and each of its subsidiaries have fulfilled and performed all of its material obligations with respect to the Permits, and, to the Company's knowledge, no event has occurred which allows, or after notice or lapse of time would allow, revocation or termination thereof or results in any other material impairment of the rights of the holder of any Permit. To the Company's knowledge, all applications, notifications, submissions, information, claims, reports and statistics, and other data and conclusions derived therefrom, utilized as the basis for any and all requests for a Permit from the FDA or other governmental authority relating to the Company and its subsidiaries, their business and the products of the Company and its subsidiaries, when submitted to the FDA or other governmental authority, were true, complete and correct in all material respects as of the date of submission and any necessary or required updates, changes, corrections or modification to such applications, submissions, information and data have been submitted to the FDA or other governmental authority. To the Company's knowledge, the claims approved or allowed by the FDA and other governmental authorities for the products of the Company and its subsidiaries are valid and supported by adequate research, design, testing, analysis and disclosure.
- (y) The manufacture of Company products by or on behalf of the Company is being conducted in compliance in all material respects with all applicable Health Care Laws, including, without limitation, the FDA's current good manufacturing practice regulations at 21 C.F.R. Parts 210-211 for products sold in the United States, and the respective counterparts thereof promulgated by governmental authorities in countries outside the United States.

- (z) Except as disclosed in the Pricing Disclosure Package and the Prospectus or as would not reasonably be expected to have a Material Adverse Effect, during the three (3) year period ending on December 31, 2010, the Company has not had any product or manufacturing site (whether Company-owned or that of a contract manufacturer for Company products) subject to a governmental authority (including FDA) shutdown or import or export prohibition, nor received any FDA Form 483 or other governmental authority notice of inspectional observations, "warning letters," "untitled letters," requests to make changes to the Company products, processes or operations, or similar correspondence or notice from the FDA or other governmental authority alleging or asserting material noncompliance with any applicable Health Care Laws. To the Company's knowledge, neither the FDA nor any other governmental authority is considering such action.
- (aa) Except as would not reasonably be expected to have a Material Adverse Effect, (i) there are no recalls, field notifications, field corrections, market withdrawals or replacements, warnings, "dear doctor" letters, investigator notices, safety alerts or other notice of action relating to an alleged lack of safety, efficacy, or regulatory compliance of the Company products ("Safety Notices") during the three (3) year period ending on December 31, 2010, (ii) such Safety Notices, if any, were resolved or closed, and (iii) to the Company's knowledge, there are no material complaints with respect to the Company products that are currently unresolved. There are no Safety Notices, or, to the Company's knowledge, material product complaints with respect to the Company products, and to the Company's knowledge, there are no facts that would be reasonably likely to result in (i) a material Safety Notice with respect to the Company products, (ii) a material change in labeling of any the Company products, or (iii) a termination or suspension of marketing or testing of any the Company products.
- (bb) The clinical and pre-clinical studies and tests conducted by or on behalf of or sponsored by the Company, were, and if still pending, are, being conducted in all material respects in accordance with all applicable Health Care Laws, including, but not limited to, the Federal Food, Drug and Cosmetic Act and its applicable implementing regulations at 21 C.F.R. Parts 50, 54, 56, 58 and 312. Any descriptions of clinical, pre-clinical and other studies and tests, including any related results and regulatory status, contained in the Registration Statement, the Pricing Disclosure Package or the Prospectus are, and will be, accurate in all material respects. Except as disclosed in the Pricing Disclosure Package and the Prospectus and to the Company's knowledge, there are no studies, tests or trials the result of which reasonably call into question in any material respect the clinical trial results described or referred to in the Registration Statement, the Pricing Disclosure Package or the Prospectus. No investigational new drug application filed by or on behalf of the Company with the FDA has been terminated or suspended by the FDA, and neither the FDA nor any applicable foreign regulatory agency has commenced, or, to the Company's knowledge, threatened to initiate, any action to place a clinical hold order on, or otherwise terminate, delay or suspend, any proposed or ongoing clinical investigation conducted or proposed to be conducted by or on behalf of the Company.

- (cc) The Company is not a party to any corporate integrity agreements, monitoring agreements, consent decrees, settlement orders, or similar agreements with or imposed by any governmental authority.
- (dd) Neither the Company, nor, to the Company's knowledge, any of its directors, officers, employees and agents, is debarred or excluded, or has been convicted of any crime or engaged in any conduct that could result in a debarment or exclusion, from any federal or state government health care program under 21 U.S.C. § 335a or any similar state law, rule or regulation. As of the Effective Date, no claims, actions, proceedings or investigations that would reasonably be expected to result in such a debarment or exclusion are pending or, to the Company's knowledge, threatened against the Company, or the directors, officers, employees or agents of the Company.
- (ee) The Company and each of its subsidiaries own or possess adequate rights to use all material patents, patent applications, trademarks, service marks, trade names, trademark registrations, service mark registrations, copyrights, licenses, know-how, software, systems and technology (including trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures) necessary for the conduct of their respective businesses and have no reason to believe that the conduct of their respective businesses will conflict with, and have not received any notice of any claim of conflict with, any such rights of others.
- (ff) There are no legal or governmental proceedings pending to which the Company or any of its subsidiaries is a party or of which any property or assets of the Company or any of its subsidiaries is the subject that would, in the aggregate, reasonably be expected to have a Material Adverse Effect or would, in the aggregate, reasonably be expected to have a material adverse effect on the performance of this Agreement or the consummation of the transactions contemplated hereby; and to the Company's knowledge, no such proceedings are threatened or contemplated by governmental authorities or others.
- (gg) There are no contracts or other documents required under the Securities Act to be described in the Registration Statement or the most recent Preliminary Prospectus or filed as exhibits to the Registration Statement, that are not described or filed as required. The statements made in the most recent Preliminary Prospectus, insofar as they purport to constitute summaries of the terms of the contracts and other documents described and filed, constitute accurate summaries of the terms of such contracts and documents in all material respects. Neither the Company nor any of its subsidiaries has knowledge that any other party to any such contract or other document has any intention not to render performance in all material respects as contemplated by the terms thereof.
- (hh) The Company and each of its subsidiaries carry, or are covered by, insurance from insurers of recognized financial responsibility in such amounts and covering such risks as is adequate for the conduct of their respective businesses and the value of their respective properties and as is customary for companies engaged in similar businesses in similar industries. All policies of insurance of the Company and its subsidiaries are in full force and effect; the Company and each of its subsidiaries are in

compliance with the terms of such policies in all material respects; and neither the Company nor any of its subsidiaries has received notice from any insurer or agent of such insurer that capital improvements or other expenditures are required or necessary to be made in order to continue such insurance; there are no claims by the Company or any of its subsidiaries under any such policy or instrument as to which any insurance company is denying liability or defending under a reservation of rights clause; and neither the Company nor any such subsidiary has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not reasonably be expected to have a Material Adverse Effect.

- (ii) Except as described in the most recent Preliminary Prospectus, no relationship, direct or indirect, exists between or among the Company, on the one hand, and the directors, officers, stockholders, customers or suppliers of the Company, on the other hand, that is required to be described in the most recent Preliminary Prospectus which is not so described.
- (jj) No labor disturbance by or dispute with the employees of the Company or any of its subsidiaries exists or, to the knowledge of the Company, is imminent that would reasonably be expected to have a Material Adverse Effect.
- (kk) Neither the Company nor any of its subsidiaries (i) is in violation of its charter or by-laws (or similar organizational documents), (ii) is in default, and no event has occurred that, with notice or lapse of time or both, would constitute such a default, in the due performance or observance of any term, covenant, condition or other obligation contained in any indenture, mortgage, deed of trust, loan agreement, license or other agreement or instrument to which it is a party or by which it is bound or to which any of its properties or assets is subject, or (iii) is in violation of any statute or any order, rule or regulation of any court or governmental agency or body having jurisdiction over it or its property or assets or has failed to obtain any license, permit, certificate, franchise or other governmental authorization or permit necessary to the ownership of its property or to the conduct of its business, except in the case of clauses (ii) and (iii), to the extent any such conflict, breach, violation or default could not, in the aggregate, reasonably be expected to have a Material Adverse Effect.
- (II) The Company and each of its subsidiaries (i) are, and at all times prior hereto were, in compliance with all laws, regulations, ordinances, rules, orders, judgments, decrees, permits or other legal requirements of any governmental authority, including without limitation any international, foreign, national, state, provincial, regional, or local authority, relating to pollution, the protection of human health or safety, the environment, or natural resources, or to use, handling, storage, manufacturing, transportation, treatment, discharge, disposal or release of hazardous or toxic substances or wastes, pollutants or contaminants ("*Environmental Laws*") applicable to such entity, which compliance includes, without limitation, obtaining, maintaining and complying with all permits and authorizations and approvals required by Environmental Laws to conduct their respective businesses, and (ii) have not received notice or otherwise have knowledge of any actual or alleged violation of Environmental Laws, or of any actual or

potential liability for or other obligation concerning the presence, disposal or release of hazardous or toxic substances or wastes, pollutants or contaminants, except in the case of clause (i) or (ii) where such non-compliance, violation, liability, or other obligation would not, in the aggregate, reasonably be expected to have a Material Adverse Effect. Except as described in the most recent Preliminary Prospectus, (x) there are no proceedings that are pending, or known to be contemplated, against the Company or any of its subsidiaries under Environmental Laws in which a governmental authority is also a party, other than such proceedings regarding which it is reasonably believed no monetary sanctions of \$100,000 or more will be imposed, (y) the Company and its subsidiaries are not aware of any issues regarding compliance with Environmental Laws, including any pending or proposed Environmental Laws, or liabilities or other obligations under Environmental Laws or concerning hazardous or toxic substances or wastes, pollutants or contaminants, that would reasonably be expected to have a material effect on the capital expenditures, earnings or competitive position of the Company and its subsidiaries, and (z) none of the Company and its subsidiaries material capital expenditures relating to Environmental Laws.

(mm) The Company and each of its subsidiaries have filed all federal, state, local and foreign tax returns required to be filed through the date hereof, subject to permitted extensions, and have paid all taxes due, and no tax deficiency has been determined adversely to the Company or any of its subsidiaries, nor does the Company have any knowledge of any tax deficiencies that have been, or would reasonably be expected to be asserted against the Company, that would, in the aggregate, reasonably be expected to have a Material Adverse Effect.

(nn) (i) Each "employee benefit plan" (within the meaning of Section 3(3) of the Employee Retirement Security Act of 1974, as amended ("ERISA")) for which the Company or any member of its "Controlled Group" (defined as any organization which is a member of a controlled group of corporations within the meaning of Section 414 of the Internal Revenue Code of 1986, as amended (the "Code")) would have any material liability (each a "Plan") has been maintained in compliance in all material respects with its terms and with the requirements of all applicable statutes, rules and regulations including ERISA and the Code; (ii) no prohibited transaction, within the meaning of Section 406 of ERISA or Section 4975 of the Code, has occurred with respect to any Plan excluding transactions effected pursuant to a statutory or administrative exemption; (iii) with respect to each Plan subject to Title IV of ERISA (A) no "reportable event" (within the meaning of Section 4043(c) of ERISA) has occurred or is reasonably expected to occur, (B) no Plan subject to Title IV of ERISA is in "at risk" status (within the meaning of Section 430(i) of the Code), (C) no "multiemployer plan" (within the meaning of Section 4001(c)(3) of ERISA) is in "endangered status" or "critical status" (within the meaning of Section 432(b) of the Code), (D) the fair market value of the assets under each Plan exceeds the present value of all benefits accrued under such Plan (determined based on those assumptions used to fund such Plan), and (E) neither the Company or any member of its Controlled Group has incurred, or reasonably expects to incur, any liability under Title IV of ERISA (other than contributions to the Plan or premiums to the Pension Benefit Guaranty Corporation in the ordinary course and without default) in respect of a Plan (including a "multiemployer plan", within the meaning of Section 4001(c)(3) of

ERISA); and (iv) each Plan that is intended to be qualified under Section 401(a) of the Code is so qualified and nothing has occurred, whether by action or by failure to act, which would cause the loss of such qualification.

- (oo) The statistical and market-related data included in the most recent Preliminary Prospectus are based on or derived from sources that the Company believes to be reliable in all material respects.
- (pp) Neither the Company nor any of its subsidiaries is, and as of the applicable Delivery Date and, after giving effect to the offer and sale of the Stock and the application of the proceeds therefrom as described under "Use of Proceeds" in the most recent Preliminary Prospectus and the Prospectus, none of them will be, (i) an "investment company" or a company "controlled" by an "investment company" within the meaning of the Investment Company Act of 1940, as amended (the "Investment Company Act"), and the rules and regulations of the Commission thereunder, or (ii) a "business development company" (as defined in Section 2(a)(48) of the Investment Company Act).
- (qq) Except as described in the most recent Preliminary Prospectus, there are no contracts, agreements or understandings between the Company and any person granting such person the right (other than rights that have been waived in writing or otherwise satisfied) to require the Company to file a registration statement under the Securities Act with respect to any securities of the Company owned or to be owned by such person or to require the Company to include such securities in the securities registered pursuant to the Registration Statement or in any securities being registered pursuant to any other registration statement filed by the Company under the Securities Act.
- (rr) Neither the Company nor any of its subsidiaries is a party to any contract, agreement or understanding with any person (other than this Agreement) that would give rise to a valid claim against any of them or the Underwriters for a brokerage commission, finder's fee or like payment in connection with the offering and sale of the Stock.
- (ss) The Company has not sold or issued any securities that would be integrated with the offering of the Stock contemplated by this Agreement pursuant to the Securities Act, the rules and regulations thereunder or the interpretations thereof by the Commission.
- (tt) The Company and its affiliates have not taken, directly or indirectly, any action designed to or that has constituted or that would reasonably be expected to cause or result in the stabilization or manipulation of the price of any security of the Company in connection with the offering of the shares of the Stock.
- (uu) The Stock has been approved for listing, subject to official notice of issuance and evidence of satisfactory distribution on The NASDAQ Global Market.

- (vv) The Company has not distributed and, prior to the later to occur of any Delivery Date and completion of the distribution of the Stock, will not distribute any offering material in connection with the offering and sale of the Stock other than any Preliminary Prospectus, the Prospectus, any Issuer Free Writing Prospectus to which the Representatives have consented in accordance with Section 1(i) or 6(a)(vi) and any Issuer Free Writing Prospectus set forth on Schedule V hereto.
- (ww) Neither the Company nor any subsidiary is in violation of or has received notice of any violation with respect to any federal or state law relating to discrimination in the hiring, promotion or pay of employees, nor any applicable federal or state wage and hour laws, nor any state law precluding the denial of credit due to the neighborhood in which a property is situated, in each case the violation of any of which would reasonably be expected to have a Material Adverse Affect.
- (xx) Neither the Company nor any of its subsidiaries, nor, to the knowledge of the Company, any director, officer, agent, employee or other person associated with or acting on behalf of the Company or any of its subsidiaries, has (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; (ii) made any direct or indirect unlawful payment to any foreign or domestic government official or employee from corporate funds; (iii) violated or is in violation of any provision of the U.S. Foreign Corrupt Practices Act of 1977; or (iv) made any bribe, rebate, payoff, influence payment, kickback or other unlawful payment.
- (yy) The operations of the Company and its subsidiaries are and have been conducted since March 24, 2007 in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all jurisdictions, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "*Money Laundering Laws*") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.
- (zz) Neither the Company nor any of its subsidiaries nor, to the knowledge of the Company, any director, officer, agent, employee or affiliate of the Company or any of its subsidiaries is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("OFAC"); and the Company will not directly or indirectly use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity, for the purpose of financing the activities of any person currently subject to any U.S. sanctions administered by OFAC.

Any certificate signed by any officer of the Company and delivered to the Representatives or counsel for the Underwriters in connection with the offering of the Stock shall be deemed a representation and warranty by the Company, as to matters covered thereby, to each Underwriter.

2. Purchase of the Stock by the Underwriters. On the basis of the representations, warranties and covenants contained in, and subject to the terms and conditions of, this Agreement, the Company agrees to sell [•] shares of the Firm Stock to the several Underwriters, and each of the Underwriters, severally and not jointly, agrees to purchase the number of shares of the Firm Stock set forth opposite that Underwriter's name in Schedule I hereto. The respective purchase obligations of the Underwriters with respect to the shares of Firm Stock shall be rounded among the Underwriters to avoid fractional shares, as the Representative may determine.

In addition, the Company grants to the Underwriters an option to purchase up to [•] additional shares of Option Stock. Such option is exercisable in the event that the Underwriters sell more shares of Common Stock than the number of shares of Firm Stock in the offering and as set forth in Section 5 hereof. Each Underwriter agrees, severally and not jointly, to purchase the number of shares of Option Stock (subject to such adjustments to eliminate fractional shares as the Representatives may determine) that bears the same proportion to the total number of shares of Option Stock to be sold on such Delivery Date as the number of shares of Firm Stock set forth in Schedule I hereto opposite the name of such Underwriter bears to the total number of shares of Firm Stock.

The purchase price payable by the Underwriters for both the Firm Stock and any Option Stock is \$[•] per share.

The Company is not obligated to deliver any of the Firm Stock or Option Stock to be delivered on the applicable Delivery Date, except upon payment for all such Stock to be purchased on such Delivery Date as provided herein.

- 3. Offering of Stock by the Underwriters. Upon authorization by the Representatives of the release of the Firm Stock, the several Underwriters propose to offer the Firm Stock for sale upon the terms and conditions to be set forth in the Prospectus.
- 4. Delivery of and Payment for the Stock. Delivery of and payment for the Firm Stock shall be made at [10:00] A.M., New York City time, on the third (3<sup>rd</sup>) full business day following the date of this Agreement or at such other date or place as shall be determined by agreement between the Representatives and the Company. This date and time are sometimes referred to herein as the "Initial Delivery Date". Delivery of the Firm Stock shall be made to the Representatives for the account of each Underwriter against payment by the several Underwriters through the Representatives and of the respective aggregate purchase prices of the Firm Stock being sold by the Company to or upon the order of the Company of the purchase price by wire transfer in immediately available funds to the accounts specified by the Company. Time shall be of the essence, and delivery at the time and place specified pursuant to this Agreement is a further condition of the obligation of each Underwriter hereunder. The Company shall deliver the Firm Stock through the facilities of The Depository Trust Company ("DTC") unless the Representatives shall otherwise instruct.

The option for the Option Stock granted in Section 2 will expire thirty (30) days after the date of this Agreement and may be exercised in whole or from time to time in part by written notice being given to the Company by the Representatives; *provided* that if such date

falls on a day that is not a business day, the option granted in Section 2 will expire on the next succeeding business day. Such notice shall set forth the aggregate number of shares of Option Stock as to which the option is being exercised, the names in which the shares of Option Stock are to be registered, the denominations in which the shares of Option Stock are to be issued and the date and time, as determined by the Representatives, when the shares of Option Stock are to be delivered; *provided, however*, that this date and time shall not be earlier than the Initial Delivery Date nor earlier than the second (2 nd) business day after the date on which the options shall have been exercised. Each date and time the shares of Option Stock are delivered is sometimes referred to as an " *Option Stock Delivery Date*", and the Initial Delivery Date and any Option Stock Delivery Date are sometimes each referred to as a " *Delivery Date*".

Delivery of the Option Stock by the Company and payment for the Option Stock by the several Underwriters through the Representatives shall be made at [10:00] A.M., New York City time, on the date specified in the corresponding notice described in the preceding paragraph or at such other date or place as shall be determined by agreement between the Representatives and the Company. On the applicable Option Stock Delivery Date, the Company shall deliver or cause to be delivered the Option Stock to the Representatives for the account of each Underwriter against payment by the several Underwriters through the Representatives of the aggregate purchase price of the Option Stock being sold by the Company to or upon the order of the Company of the purchase price by wire transfer in immediately available funds to the accounts specified by the Company. Time shall be of the essence, and delivery at the time and place specified pursuant to this Agreement is a further condition of the obligation of each Underwriter hereunder. The Company shall deliver the Option Stock through the facilities of DTC unless the Representatives shall otherwise instruct.

- 5. Further Agreements of the Company and the Underwriters. (a) The Company agrees:
- (i) To prepare the Prospectus in a form approved by the Representatives and to file such Prospectus pursuant to Rule 424(b) under the Securities Act not later than the Commission's close of business on the second (2 nd) business day following the execution and delivery of this Agreement; to make no further amendment or any supplement to the Registration Statement or the Prospectus prior to the last Delivery Date except as provided herein; to advise the Representatives, promptly after it receives notice thereof, of the time when any amendment or supplement to the Registration Statement or the Prospectus has been filed and to furnish the Representatives with copies thereof; to advise the Representatives, promptly after it receives notice thereof, of the issuance by the Commission of any stop order or of any order preventing or suspending the use of the Prospectus or any Issuer Free Writing Prospectus, of the suspension of the qualification of the Stock for offering or sale in any jurisdiction, of the initiation or threatening of any proceeding or examination for any such purpose or of any request by the Commission for the amending or supplementing of the Registration Statement, the Prospectus or any Issuer Free Writing Prospectus or for additional information; and, in the event of the issuance of any stop order or of any order preventing or suspending the use of the Prospectus or any Issuer Free Writing Prospectus or suspending any such qualification, to use promptly its reasonable best efforts to obtain its withdrawal.

- (ii) To furnish promptly to the Representatives and to counsel for the Underwriters a signed copy of the Registration Statement as originally filed with the Commission, and each amendment thereto filed with the Commission, including all consents and exhibits filed therewith.
- (iii) To deliver promptly to the Representatives such number of the following documents as the Representatives shall reasonably request:

  (A) conformed copies of the Registration Statement as originally filed with the Commission and each amendment thereto (in each case excluding exhibits other than this Agreement and the computation of per share earnings), (B) each Preliminary Prospectus, the Prospectus and any amended or supplemented Prospectus, and (C) each Issuer Free Writing Prospectus; and, if the delivery of a prospectus is required at any time after the date hereof in connection with the offering or sale of the Stock or any other securities relating thereto and if at such time any events shall have occurred as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made when such Prospectus is delivered, not misleading, or, if for any other reason in the opinion of counsel for the Company it shall be necessary to amend or supplement the Prospectus in order to comply with the Securities Act, to notify the Representatives and, upon their request, to file such document and to prepare and furnish without charge to each Underwriter and to any dealer in securities as many copies as the Representatives may from time to time reasonably request of an amended or supplemented Prospectus that will correct such statement or omission or effect such compliance.
- (iv) To file promptly with the Commission any amendment or supplement to the Registration Statement or the Prospectus that may, in the judgment of the Company or the Representatives, be required by the Securities Act or requested by the Commission.
- (v) Prior to filing with the Commission any amendment or supplement to the Registration Statement, or the Prospectus, to furnish a copy thereof to the Representatives and counsel for the Underwriters and obtain the consent of the Representatives to the filing.
- (vi) Not to make any offer relating to the Stock that would constitute an Issuer Free Writing Prospectus without the prior written consent of the Representatives.
- (vii) To comply with all applicable requirements of Rule 433 under the Securities Act with respect to any Issuer Free Writing Prospectus. If at any time after the date hereof any events shall have occurred as a result of which any Issuer Free Writing Prospectus, as then amended or supplemented, would conflict with the information in the Registration Statement, the most recent Preliminary Prospectus or the Prospectus or would include an untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading, or, if for any other reason it shall be necessary in the opinion of counsel for the Company to amend or supplement any Issuer Free Writing Prospectus, to notify the Representatives and, upon their request, to file such document

and to prepare and furnish without charge to each Underwriter as many copies as the Representatives may from time to time reasonably request of an amended or supplemented Issuer Free Writing Prospectus that will correct such conflict, statement or omission or effect such compliance.

- (viii) As soon as practicable after the Effective Date (it being understood that the Company shall have until at least 410 days or, if the fourth quarter following the fiscal quarter that includes the Effective Date is the last fiscal quarter of the Company's fiscal year, 455 days after the end of the Company's current fiscal quarter), to make generally available to the Company's security holders and to deliver to the Representatives an earnings statement of the Company and its subsidiaries (which need not be audited) complying with Section 11(a) of the Securities Act and the rules and regulations thereunder (including, at the option of the Company, Rule 158).
- (ix) Promptly from time to time to take such action as the Representatives may reasonably request to qualify the Stock for offering and sale under the securities or Blue Sky laws of Canada and such other jurisdictions as the Representatives may reasonably request and to comply with such laws so as to permit the continuance of sales and dealings therein in such jurisdictions for as long as may be necessary to complete the distribution of the Stock; provided that in connection therewith the Company shall not be required to (i) qualify as a foreign corporation in any jurisdiction in which it would not otherwise be required to so qualify, (ii) file a general consent to service of process in any such jurisdiction, or (iii) subject itself to taxation in any jurisdiction in which it would not otherwise be subject.
- (x) For a period commencing on the date hereof and ending on the 180th day after the date of the Prospectus (the " *Lock-Up Period*"), not to, directly or indirectly, (A) offer for sale, sell, pledge, or otherwise dispose of (or enter into any transaction or device that is designed to, or would be expected to, result in the disposition by any person at any time in the future of) any shares of Common Stock or securities convertible into or exercisable or exchangeable for Common Stock (other than (i) the Stock, (ii) shares of Common Stock or other securities issued pursuant to employee benefit plans, stock option plans or other employee compensation plans or arrangements existing on the date hereof or pursuant to currently outstanding options, warrants or rights whether or not issued under one of those plans and (iii) shares of Common Stock or other securities issued in connection with acquisitions, strategic partnerships or lending, leasing or other commercial transactions; provided that, in each case, that the recipient of such shares of Common Stock or other securities are subject to substantially the same restrictions as those contained in this Section 5(x)), or sell or grant options, rights or warrants with respect to any shares of Common Stock or securities convertible into or exchangeable for Common Stock (other than the grant of options pursuant to option plans existing on the date hereof), (B) 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 such shares of Common Stock, whether any such transaction described in clause (A) or (B) above is to be settled by delivery of Common Stock or other securities, in cash or otherwise, (C) file or cause to be filed a registration statement, including any amendments thereto, with respect to the registration of any shares of Common Stock or

securities convertible, exercisable or exchangeable into Common Stock or any other securities of the Company (other than (x) any registration statement on Form S-8 or any successor form thereto or (y) any registration statement, including amendments thereto, that the Company is contractually obligated to file under the agreement described under "Description of Capital Stock—Registration Rights" in the most recent Preliminary Prospectus), or (D) publicly disclose the intention to do any of the foregoing, in each case without the prior written consent of the Representatives, on behalf of the Underwriters, and to cause each officer, director and stockholder of the Company set forth on Schedule II hereto to furnish to the Representatives, prior to the Initial Delivery Date, a letter or letters, substantially in the form of Exhibit A hereto (the "Lock-Up Agreements"); notwithstanding the foregoing, if (x) during the last seventeen (17) days of the Lock-Up Period, the Company issues an earnings release or material news or a material event relating to the Company occurs, or (y) prior to the expiration of the Lock-Up Period, then the restrictions imposed in this paragraph shall 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 the occurrence of the material event, unless the Representatives, on behalf of the Underwriters, waive such extension in writing. The Company will provide the Representatives, all other Underwriters, and each officer, director and stockholder listed on Schedule II hereto, with prior notice of any announcement that gives rise to the extension of the Lock-Up Period.

- (xi) To apply the net proceeds from the sale of the Stock being sold by the Company substantially in accordance with the description as set forth in the Prospectus under the caption "Use of Proceeds."
  - (xii) To file with the Commission such information on Form 10-Q or Form 10-K as may be required by Rule 463 under the Securities Act.
- (xiii) If the Company elects to rely upon Rule 462(b) under the Securities Act, the Company shall file a Rule 462(b) Registration Statement with the Commission in compliance with Rule 462(b) under the Securities Act by 10:00 P.M., Washington, D.C. time, on the date of this Agreement, and the Company shall at the time of filing pay the Commission the filing fee for the Rule 462(b) Registration Statement.
- (xiv) The Company and its affiliates will not take, directly or indirectly, any action designed to or that has constituted or that reasonably would be expected to cause or result in the stabilization or manipulation of the price of any security of the Company in connection with the offering of the Stock.
- (xv) The Company will do and perform all things required or necessary to be done and performed under this Agreement by it prior to each Delivery Date, and to satisfy all conditions precedent to the Underwriters' obligations hereunder to purchase the Stock.

- (b) Each Underwriter severally agrees that such Underwriter shall not include any "issuer information" (as defined in Rule 433 under the Securities Act) in any "free writing prospectus" (as defined in Rule 405 under the Securities Act) used or referred to by such Underwriter without the prior written consent of the Company (any such issuer information with respect to whose use the Company has given its consent, " *Permitted Issuer Information*"); provided that (i) no such consent shall be required with respect to any such issuer information contained in any document filed by the Company with the Commission prior to the use of such free writing prospectus, and (ii) "issuer information", as used in this Section 5(b), shall not be deemed to include information prepared by or on behalf of such Underwriter on the basis of or derived from issuer information.
- 6. Expenses. The Company agrees, whether or not the transactions contemplated by this Agreement are consummated or this Agreement is terminated, to pay all expenses, costs, fees and taxes incident to and in connection with (a) the authorization, issuance, sale and delivery of the Stock and any stamp duties or other taxes payable in that connection, and the preparation and printing of certificates for the Stock; (b) the preparation, printing and filing under the Securities Act of the Registration Statement (including any exhibits thereto), any Preliminary Prospectus, the Prospectus, any Issuer Free Writing Prospectus and any amendment or supplement thereto; (c) the distribution of the Registration Statement (including any exhibits thereto), any Preliminary Prospectus, the Prospectus, any Issuer Free Writing Prospectus and any amendment or supplement thereto, all as provided in this Agreement; (d) the production and distribution of this Agreement, any supplemental agreement among Underwriters, and any other related documents in connection with the offering, purchase, sale and delivery of the Stock; (e) any required review by FINRA of the terms of sale of the Stock (including related reasonable and documented fees and expenses of counsel to the Underwriters in an amount that is not greater than \$[•]); (f) the listing of the Stock on The NASDAQ Global Market and/or any other exchange; (g) the qualification of the Stock under the securities laws of the several jurisdictions as provided in Section 5(a)(ix) and the preparation, printing and distribution of a Blue Sky Memorandum (including related reasonable and documented fees and expenses of counsel to the Underwriters); (h) the preparation, printing and distribution of one or more versions of the Preliminary Prospectus and the Prospectus for distribution in Canada, often in the form of a Canadian "wrapper" (including related reasonable and documented fees and expenses of Canadian counsel to the Underwriters); (i) the investor presentations on any "road show" undertaken in connection with the marketing of the Stock, including, without limitation, expenses associated with any electronic road show, travel and lodging expenses of the representatives and officers of the Company (but specifically excluding the travel and lodging expenses of the representatives of the Underwriters) and fifty percent (50%) of the cost of any aircraft chartered in connection with the road show; and (j) all other costs and expenses incident to the performance of the obligations of the Company; provided, that except as expressly provided in this Section 6 and Section 11, the Underwriters shall pay their own costs and expenses, including, without limitation, the costs and expenses of its counsel, any transfer taxes on the Stock which they may sell and expenses of advertising any offering of the Stock made by the Underwriters.
- 7. Conditions of Underwriters' Obligations. The respective obligations of the Underwriters hereunder are subject to the accuracy in all material respects (except to the extent already qualified by materiality, in which case such obligations shall be subject to the

accuracy in all respects), when made and on each Delivery Date, of the representations and warranties of the Company contained herein, to the performance by the Company of its obligations hereunder, and to each of the following additional terms and conditions:

- (a) The Prospectus shall have been timely filed with the Commission in accordance with Section 5(a)(i). The Company shall have complied with all filing requirements applicable to any Issuer Free Writing Prospectus used or referred to after the date hereof; no stop order suspending the effectiveness of the Registration Statement or preventing or suspending the use of the Prospectus or any Issuer Free Writing Prospectus shall have been issued and no proceeding or examination for such purpose shall have been initiated or threatened in writing by the Commission; and any request of the Commission for inclusion of additional information in the Registration Statement or the Prospectus or otherwise shall have been complied with. If the Company has elected to rely upon Rule 462(b) under the Securities Act, the Rule 462(b) Registration Statement shall have become effective by 10:00 P.M., Washington, D.C. time, on the date of this Agreement.
- (b) No Underwriter shall have discovered and disclosed to the Company on or prior to such Delivery Date that the Registration Statement, the Prospectus or the Pricing Disclosure Package, or any amendment or supplement thereto, contains an untrue statement of a fact which, in the opinion of Latham & Watkins LLP, counsel for the Underwriters, is material or omits to state a fact which, in the opinion of such counsel, is material and is required to be stated therein or is necessary to make the statements therein not misleading.
- (c) All corporate proceedings and other legal matters incident to the authorization, form and validity of this Agreement, the Stock, the Registration Statement, the Prospectus and any Issuer Free Writing Prospectus, and all other legal matters relating to this Agreement and the transactions contemplated hereby shall be reasonably satisfactory in all material respects to counsel for the Underwriters, and the Company shall have furnished to such counsel all documents and information that they may reasonably request to enable them to pass upon such matters.
- (d) Wilmer Cutler Pickering Hale and Dorr LLP shall have furnished to the Representatives its written opinion, as counsel to the Company, addressed to the Underwriters and dated such Delivery Date, substantially in the form attached hereto as Exhibit B-1.
- (e) Kleinfeld, Kaplan and Becker, LLP shall have furnished to the Representatives its written opinion, as regulatory counsel to the Company, addressed to the Underwriters and dated such Delivery Date, substantially in the form attached hereto as Exhibit B-2.
- (f) The Representatives shall have received from Latham & Watkins LLP, counsel for the Underwriters, such opinion or opinions, dated such Delivery Date, with respect to the issuance and sale of the Stock, the Registration Statement, the Prospectus and the Pricing Disclosure Package and other related matters as the Representatives may reasonably require, and the Company shall have furnished to such counsel such documents as they reasonably request for the purpose of enabling them to pass upon such matters.

- (g) At the time of execution of this Agreement, the Representatives shall have received from J.H. Cohn LLP a letter, substantially in the form attached hereto as Exhibit C, addressed to the Underwriters and dated the date hereof (i) confirming that they are independent public accountants within the meaning of the Securities Act and are in compliance with the applicable requirements relating to the qualification of accountants under Rule 2-01 of Regulation S-X of the Commission, and (ii) stating, as of the date hereof (or, with respect to matters involving changes or developments since the respective dates as of which specified financial information is given in the most recent Preliminary Prospectus, as of a date not more than three (3) days prior to the date hereof), the conclusions and findings of such firm with respect to the financial information and other matters ordinarily covered by accountants' "comfort letters" to underwriters in connection with registered public offerings.
- (h) With respect to the letter of J.H. Cohn LLP referred to in the preceding paragraph and delivered to the Representatives concurrently with the execution of this Agreement (the "initial letter"), J.H. Cohn LLP shall have furnished to the Representatives a letter (the "bring-down letter") of such accountants, addressed to the Underwriters and dated such Delivery Date (i) confirming that they are independent public accountants within the meaning of the Securities Act and are in compliance with the applicable requirements relating to the qualification of accountants under Rule 2-01 of Regulation S-X of the Commission, (ii) stating, as of the date of the bring-down letter (or, with respect to matters involving changes or developments since the respective dates as of which specified financial information is given in the Prospectus, as of a date not more than three days prior to the date of the bring-down letter), the conclusions and findings of such firm with respect to the financial information and other matters covered by the initial letter, and (iii) confirming in all material respects the conclusions and findings set forth in the initial letter.
- (i) The Company shall have furnished to the Representatives a certificate, dated such Delivery Date, of its Chief Executive Officer and its Chief Financial Officer as to such matters as the Representatives may reasonably request, including, without limitation, a statement that:
  - (i) The representations, warranties and agreements of the Company in Section 1 are true and correct in all material respects (except to the extent already qualified by materiality, in which case such representations, warranties and agreements shall be subject to the accuracy in all respects) on and as of such Delivery Date, and the Company has complied with all its agreements contained herein and satisfied all the conditions on its part to be performed or satisfied hereunder at or prior to such Delivery Date;

- (ii) No stop order suspending the effectiveness of the Registration Statement has been issued; and no proceedings or examination for that purpose have been instituted or, to the knowledge of such officers, threatened; and
- (iii) They have examined the Registration Statement, the Prospectus and the Pricing Disclosure Package, and, in their opinion, (A) (1) the Registration Statement, as of the Effective Date, (2) the Prospectus, as of its date and on the applicable Delivery Date, and (3) the Pricing Disclosure Package, as of the Applicable Time, did not and do not contain any untrue statement of a material fact and did not and do not omit to state a material fact required to be stated therein or necessary to make the statements therein (except in the case of the Registration Statement, in the light of the circumstances under which they were made) not misleading, and (B) since the Effective Date, no event has occurred that should have been set forth in a supplement or amendment to the Registration Statement, the Prospectus or any Issuer Free Writing Prospectus that has not been so set forth
- (j) Except as described in the most recent Preliminary Prospectus, (i) neither the Company nor any of its subsidiaries shall have sustained, since the date of the latest audited financial statements included in the most recent Preliminary Prospectus, any loss or interference with its business from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor dispute or court or governmental action, order or decree, or (ii) since such date there shall not have been any change in the capital stock or long-term debt of the Company or any of its subsidiaries or any change, or any development involving a prospective change, in or affecting the condition (financial or otherwise), results of operations, stockholders' equity, properties, management, business or prospects of the Company and its subsidiaries taken as a whole, the effect of which, in any such case described in clause (i) or (ii), is, individually or in the aggregate, in the judgment of the Representatives, so material and adverse as to make it impracticable or inadvisable to proceed with the public offering or the delivery of the Stock being delivered on such Delivery Date on the terms and in the manner contemplated in the Prospectus.
- (k) Subsequent to the execution and delivery of this Agreement (i) no downgrading shall have occurred in the rating accorded the Company's debt securities or preferred stock by any "nationally recognized statistical rating organization" (as that term is defined by the Commission for purposes of Rule 436(g)(2) under the Securities Act), and (ii) no such organization shall have publicly announced that it has under surveillance or review, with possible negative implications, its rating of any of the Company's debt securities or preferred stock.
- (l) Subsequent to the execution and delivery of this Agreement there shall not have occurred any of the following: (i) trading in securities generally on The New York Stock Exchange, The NASDAQ Global Select Market, The NASDAQ Global Market, or The NASDAQ Capital Market, or trading in any securities of the Company on any exchange, shall have been suspended or materially limited or the settlement of such trading generally shall have been materially disrupted or minimum prices shall have been

established on any such exchange or such market by the Commission, by such exchange or by any other regulatory body or governmental authority having jurisdiction, (ii) a general moratorium on commercial banking activities shall have been declared by federal or state authorities, (iii) the United States shall have become engaged in hostilities, there shall have been an escalation in hostilities involving the United States or there shall have been a declaration of a national emergency or war by the United States, or (iv) there shall have occurred such a material adverse change in general economic, political or financial conditions, including, without limitation, as a result of terrorist activities after the date hereof (or the effect of international conditions on the financial markets in the United States shall be such), in any such case described in clause (i), (ii), (iii) or (iv), as to make it, in the judgment of the Representatives, impracticable or inadvisable to proceed with the public offering or delivery of the Stock being delivered on such Delivery Date on the terms and in the manner contemplated in the Prospectus.

- (m) The NASDAQ Global Market shall have approved the Stock for listing, subject only to official notice of issuance and evidence of satisfactory distribution.
- (n) The Lock-Up Agreements between the Representatives and the officers, directors and stockholders of the Company set forth on Schedule II, delivered to the Representatives on or before the date of this Agreement, shall be in full force and effect on such Delivery Date.
- (o) On or prior to each Delivery Date, the Company shall have furnished to the Underwriters such further certificates and documents as the Representatives may reasonably request.

All opinions, letters, evidence and certificates mentioned above or elsewhere in this Agreement shall be deemed to be in compliance with the provisions hereof only if they are in form and substance reasonably satisfactory to counsel for the Underwriters.

- 8. Indemnification and Contribution.
- (a) The Company and Pacira, jointly and severally, hereby agree to indemnify and hold harmless each Underwriter, its affiliates, directors, officers and employees and each person, if any, who controls any Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, from and against any loss, claim, damage or liability, joint or several, or any action in respect thereof (including, but not limited to, any loss, claim, damage, liability or action relating to purchases and sales of Stock), to which that Underwriter, affiliate, director, officer, employee or controlling person may become subject, under the Securities Act or otherwise, insofar as such loss, claim, damage, liability or action arises out of, or is based upon, (i) any untrue statement or alleged untrue statement of a material fact contained in (A) any Preliminary Prospectus, the Registration Statement, the Prospectus or in any amendment or supplement thereto, (B) any Issuer Free Writing Prospectus or in any amendment or supplement thereto, (C) any Permitted Issuer Information used or referred to in any "free writing prospectus" (as defined in Rule 405 under the Securities Act) used or referred to by any Underwriter, (D) any materials or information provided to investors by, or with

the approval of, the Company in connection with the marketing of the offering of the Stock, including any "road show" (as defined in Rule 433 under the Securities Act) not constituting an Issuer Free Writing Prospectus ("Marketing Materials"), or (E) any Blue Sky application or other document prepared or executed by the Company (or based upon any written information furnished by the Company specifically for use therein) specifically for the purpose of qualifying any or all of the Stock under the securities laws of any state or other jurisdiction (any such application, document or information being hereinafter called a "Blue Sky Application"), or (ii) the omission or alleged omission to state in any Preliminary Prospectus, the Registration Statement, the Prospectus, any Issuer Free Writing Prospectus or in any amendment or supplement thereto or in any Permitted Issuer Information, any Marketing Materials or any Blue Sky Application, any material fact required to be stated therein or necessary to make the statements therein (except in the case of the Registration Statement, in light of the circumstances under which they were made) not misleading, and shall reimburse each Underwriter and each such affiliate, director, officer, employee or controlling person promptly upon demand for any legal or other expenses reasonably incurred by that Underwriter, affiliate, director, officer, employee or controlling person in connection with investigating or defending or preparing to defend against any such loss, claim, damage, liability or action as such expenses are incurred; provided, however, that neither the Company nor Pacira shall be liable in any such case to the extent that any such loss, claim, damage, liability or action arises out of, or is based upon, any untrue statement or alleged untrue statement or omission or alleged omission made in any Preliminary Prospectus, the Registration Statement, the Prospectus, any Issuer Free Writing Prospectus or in any such amendment or supplement thereto or in any Permitted Issuer Information, any Marketing Materials or any Blue Sky Application, in reliance upon and in conformity with written information concerning such Underwriter furnished to the Company through the Representatives by or on behalf of any Underwriter specifically for inclusion therein, which information consists solely of the information specified in Section 8(e). The foregoing indemnity agreement is in addition to any liability which the Company or Pacira may otherwise have to any Underwriter or to any affiliate, director, officer, employee or controlling person of that Underwriter.

(b) Each Underwriter, severally and not jointly, shall indemnify and hold harmless the Company and Pacira, their respective directors, officers and employees, and each person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, from and against any loss, claim, damage or liability, joint or several, or any action in respect thereof, to which the Company or any such director, officer, employee or controlling person may become subject, under the Securities Act or otherwise, insofar as such loss, claim, damage, liability or action arises out of, or is based upon, (i) any untrue statement or alleged untrue statement of a material fact contained in any Preliminary Prospectus, the Registration Statement, the Prospectus, any Issuer Free Writing Prospectus or in any amendment or supplement thereto or in any Marketing Materials or Blue Sky Application, or (ii) the omission or alleged omission to state in any Preliminary Prospectus, the Registration Statement, the Prospectus, any Issuer Free Writing Prospectus or in any amendment or supplement thereto or in any Marketing Materials or Blue Sky Application, any material fact required to be stated therein or necessary to make

the statements therein (except in the case of the Registration Statement, in light of the circumstances under which they were made) not misleading, but in each case only to the extent that the untrue statement or alleged untrue statement or omission or alleged omission was made in reliance upon and in conformity with written information concerning such Underwriter furnished to the Company through the Representatives by or on behalf of that Underwriter specifically for inclusion therein, which information is limited to the information set forth in Section 8(e). The foregoing indemnity agreement is in addition to any liability that any Underwriter may otherwise have to the Company, Pacira or any such director, officer, employee or controlling person.

(c) Promptly after receipt by an indemnified party under this Section 8 of notice of any claim or the commencement of any action, the indemnified party shall, if a claim in respect thereof is to be made against the indemnifying party under this Section 8, notify the indemnifying party in writing of the claim or the commencement of that action; provided, however, that the failure to notify the indemnifying party shall not relieve it from any liability which it may have under this Section 8 except to the extent it has been materially prejudiced (through the forfeiture of substantive rights and defenses) by such failure and, provided, further, that the failure to notify the indemnifying party shall not relieve it from any liability which it may have to an indemnified party otherwise than under this Section 8. If any such claim or action shall be brought against an indemnified party, and it shall notify the indemnifying party thereof, the indemnifying party shall be entitled to participate therein and, to the extent that it wishes, jointly with any other similarly notified indemnifying party, to assume the defense thereof with counsel reasonably satisfactory to the indemnified party. After notice from the indemnifying party to the indemnified party of its election to assume the defense of such claim or action, the indemnifying party shall not be liable to the indemnified party under this Section 10 for any legal or other expenses subsequently incurred by the indemnified party in connection with the defense thereof other than reasonable costs of investigation; provided, however, that the indemnified party shall have the right to employ counsel to represent jointly the indemnified party and those other indemnified parties and their respective directors, officers, employees and controlling persons who may be subject to liability arising out of any claim in respect of which indemnity may be sought under this Section 8 if (i) the indemnified party and the indemnifying party shall have so mutually agreed; (ii) the indemnifying party has failed within a reasonable time to retain counsel reasonably satisfactory to the indemnified party; (iii) the indemnified party and its directors, officers, employees and controlling persons shall have reasonably concluded that there may be legal defenses available to them that are different from or in addition to those available to the indemnifying party; or (iv) the named parties in any such proceeding (including any impleaded parties) include both the indemnified parties or their respective directors, officers, employees or controlling persons, on the one hand, and the indemnifying party, on the other hand, and representation of both sets of parties by the same counsel would be inappropriate due to actual or potential differing interests between them, and in any such event the fees and expenses of such separate counsel shall be paid by the indemnifying party. No indemnifying party shall (x) without the prior written consent of the indemnified parties (which consent shall not be unreasonably withheld, conditioned or delayed), settle or compromise or consent to the entry of any judgment with respect to any pending or threatened claim, action, suit or proceeding in

respect of which indemnification or contribution may be sought hereunder (whether or not the indemnified parties are actual or potential parties to such claim or action) unless such settlement, compromise or consent includes an unconditional release of each indemnified party from all liability arising out of such claim, action, suit or proceeding and does not include a statement as to, or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party, or (y) be liable for any settlement of any such action effected without its written consent (which consent shall not be unreasonably withheld, conditioned or delayed), but if settled with the consent of the indemnifying party or if there be a final judgment for the plaintiff in any such action, the indemnifying party agrees to indemnify and hold harmless any indemnified party from and against any loss or liability by reason of such settlement or judgment.

(d) If the indemnification provided for in this Section 8 shall for any reason be unavailable to or insufficient to hold harmless an indemnified party under Section 8(a) or 8(b) in respect of any loss, claim, damage or liability, or any action in respect thereof or referred to therein, then each indemnifying party shall, in lieu of indemnifying such indemnified party, contribute to the amount paid or payable by such indemnified party as a result of such loss, claim, damage or liability, or action in respect thereof, (i) in such proportion as shall be appropriate to reflect the relative benefits received by the Company, on the one hand, and the Underwriters, on the other, from the offering of the Stock, or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and the Underwriters, on the other, with respect to the statements or omissions that resulted in such loss, claim, damage or liability, or action in respect thereof, as well as any other relevant equitable considerations. The relative benefits received by the Company, on the one hand, and the Underwriters, on the other, with respect to such offering shall be deemed to be in the same proportion as the total net proceeds from the offering of the Stock purchased under this Agreement (before deducting expenses) received by the Company, as set forth in the table on the cover page of the Prospectus, on the one hand, and the total underwriting discounts and commissions received by the Underwriters with respect to the shares of the Stock purchased under this Agreement, as set forth in the table on the cover page of the Prospectus, on the other hand. The relative fault shall be determined by reference to whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or the Underwriters, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and the Underwriters agree that it would not be just and equitable if contributions pursuant to this Section 8(d) were to be determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation that does not take into account the equitable considerations referred to herein. The amount paid or payable by an indemnified party as a result of the loss, claim, damage or liability, or action in respect thereof, referred to above in this Section 8(d) shall be deemed to include, for purposes of this Section 8(d), any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim. Notwithstanding the provisions of this Section 8(d), in no event shall an Underwriter be required to contribute any

amount in excess of the amount by which the total underwriting discounts and commissions received by such Underwriter with respect to the offering of the Stock exceeds the amount of any damages that such Underwriter has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The Underwriters' obligations to contribute as provided in this Section 8(d) are several in proportion to their respective underwriting obligations and not joint.

(e) The Underwriters severally confirm and the Company acknowledges and agrees that the statements regarding delivery of shares by the Underwriters set forth on the cover page of, and the concession and reallowance figures and the paragraph relating to stabilization by the Underwriters appearing under the caption "Underwriting" in, the most recent Preliminary Prospectus and the Prospectus are correct and constitute the only information concerning such Underwriters furnished in writing to the Company by or on behalf of the Underwriters specifically for inclusion in any Preliminary Prospectus, the Registration Statement, the Prospectus, any Issuer Free Writing Prospectus or in any amendment or supplement thereto or in any Marketing Materials.

## 9. Defaulting Underwriters.

(a) If, on any Delivery Date, any Underwriter defaults in its obligations to purchase the Stock that it has agreed to purchase under this Agreement, the remaining non-defaulting Underwriters may in their discretion arrange for the purchase of such Stock by the non-defaulting Underwriters or other persons satisfactory to the Company on the terms contained in this Agreement. If, within thirty-six (36) hours after any such default by any Underwriter, the non-defaulting Underwriters do not arrange for the purchase of such Stock, then the Company shall be entitled to a further period of thirty-six (36) hours within which to procure other persons reasonably satisfactory to the non-defaulting Underwriters to purchase such Stock on such terms. In the event that within the respective prescribed periods, the non-defaulting Underwriters notify the Company that they have so arranged for the purchase of such Stock, or the Company notifies the non-defaulting Underwriters that it has so arranged for the purchase of such Stock, either the non-defaulting Underwriters or the Company may postpone such Delivery Date for up to seven (7) full business days in order to effect any changes that in the opinion of counsel for the Company or counsel for the Underwriters may be necessary in the Registration Statement, the Prospectus or in any other document or arrangement, and the Company agrees to promptly prepare any amendment or supplement to the Registration Statement, the Prospectus or in any such other document or arrangement that effects any such changes. As used in this Agreement, the term "Underwriter" includes, for all purposes of this Agreement unless the context requires otherwise, any party not listed in Schedule I hereto that, pursuant to this Section 9, purchases Stock that a defaulting Underwriter agreed but failed to purchase.

- (b) If, after giving effect to any arrangements for the purchase of the Stock of a defaulting Underwriter or Underwriters by the non-defaulting Underwriters and the Company as provided in paragraph (a) above, the total number of shares of the Stock that remains unpurchased does not exceed one-eleventh of the total number of shares of all the Stock, then the Company shall have the right to require each non-defaulting Underwriter to purchase the total number of shares of Stock that such Underwriter agreed to purchase hereunder plus such Underwriter's <u>pro rata</u> share (based on the total number of shares of Stock that such Underwriter agreed to purchase hereunder) of the Stock of such defaulting Underwriter or Underwriters for which such arrangements have not been made; *provided* that the non-defaulting Underwriters shall not be obligated to purchase more than 110% of the total number of shares of Stock that it agreed to purchase on such Delivery Date pursuant to the terms of Section 2.
- (c) If, after giving effect to any arrangements for the purchase of the Stock of a defaulting Underwriter or Underwriters by the non-defaulting Underwriters and the Company as provided in paragraph (a) above, the total number of shares of Stock that remains unpurchased exceeds one-eleventh of the total number of shares of all the Stock, or if the Company shall not exercise the right described in paragraph (b) above, then this Agreement shall terminate without liability on the part of the non-defaulting Underwriters. Any termination of this Agreement pursuant to this Section 9 shall be without liability on the part of the Company, except that the Company will continue to be liable for the payment of expenses as set forth in Sections 6 and 11 and except that the provisions of Section 8 shall not terminate and shall remain in effect.
- (d) Nothing contained herein shall relieve a defaulting Underwriter of any liability it may have to the Company or any non-defaulting Underwriter for damages caused by its default.
- 10. *Termination*. The obligations of the Underwriters hereunder may be terminated by the Representatives by notice given to and received by the Company prior to delivery of and payment for the Firm Stock if, prior to that time, any of the events described in Sections 7(i), 7(j) and 7(k) shall have occurred or if the Underwriters shall decline to purchase the Stock for any reason expressly permitted under this Agreement.
- 11. Reimbursement of Underwriters' Expenses. If (a) the Company shall fail to tender the Stock for delivery to the Underwriters for any reason, or (b) the Underwriters shall decline to purchase the Stock for any reason expressly permitted under this Agreement, the Company will reimburse the Underwriters for all reasonable out-of-pocket expenses (including reasonable and documented fees and disbursements of counsel for the Underwriters) incurred by the Underwriters in connection with this Agreement and the proposed purchase of the Stock, and upon demand the Company shall pay the full amount thereof to the Representatives. If this Agreement is terminated pursuant to Section 9 by reason of the default of one or more Underwriters, the Company shall not be obligated to reimburse any defaulting Underwriter on account of those expenses.

- 12. Research Analyst Independence. The Company acknowledges that the Underwriters' research analysts and research departments are required to be independent from their respective investment banking divisions and are subject to certain regulations and internal policies, and that such Underwriters' research analysts may hold views and make statements or investment recommendations and/or publish research reports with respect to the Company and/or the offering that differ from the views of their respective investment banking divisions. The Company hereby waives and releases, to the fullest extent permitted by law, any claims that the Company may have against the Underwriters with respect to any conflict of interest that may arise from the fact that the views expressed by their independent research analysts and research departments may be different from or inconsistent with the views or advice communicated to the Company by such Underwriters' investment banking divisions. The Company acknowledges that each of the Underwriters is a full service securities firm and as such from time to time, subject to applicable securities laws, may effect transactions for its own account or the account of its customers and hold long or short positions in debt or equity securities of the companies that may be the subject of the transactions contemplated by this Agreement.
- 13. No Fiduciary Duty. The Company acknowledges and agrees that in connection with this offering, sale of the Stock or any other services the Underwriters may be deemed to be providing hereunder, notwithstanding any preexisting relationship, advisory or otherwise, between the parties or any oral representations or assurances previously or subsequently made by the Underwriters: (a) no fiduciary or agency relationship between the Company and any other person, on the one hand, and the Underwriters, on the other, exists; (b) the Underwriters are not acting as advisors, expert or otherwise, to the Company, including, without limitation, with respect to the determination of the public offering price of the Stock, and such relationship between the Company, on the one hand, and the Underwriters, on the other, is entirely and solely commercial, based on arms-length negotiations; (c) any duties and obligations that the Underwriters may have to the Company shall be limited to those duties and obligations specifically stated herein; and (d) the Underwriters and their respective affiliates may have interests that differ from those of the Company. The Company hereby waives any claims that the Company may have against the Underwriters with respect to any breach of fiduciary duty in connection with this offering.
  - 14. Notices, etc. All statements, requests, notices and agreements hereunder shall be in writing, and:
  - (a) if to the Underwriters, shall be delivered by mail to Barclays Capital Inc., 745 Seventh Avenue, New York, New York 10019, Attention: Syndicate Registration, with a copy, in the case of any notice pursuant to Section 8(c), to the Director of Litigation, Office of the General Counsel, Barclays Capital Inc., 745 Seventh Avenue, New York, New York 10019; and
  - (b) if to the Company, shall be delivered or sent by mail or facsimile transmission to the address of the Company set forth in the Registration Statement, Attention: James Scibetta (Fax: (973) 267-0060).

Any such statements, requests, notices or agreements shall take effect at the time of receipt thereof. The Company shall be entitled to act and rely upon any request, consent, notice or agreement given or made on behalf of the Representatives.

- 15. Persons Entitled to Benefit of Agreement. This Agreement shall inure to the benefit of and be binding upon the Underwriters, the Company and their respective successors. This Agreement and the terms and provisions hereof are for the sole benefit of only those persons, except that (a) the representations, warranties, indemnities and agreements of the Company contained in this Agreement shall also be deemed to be for the benefit of the directors, officers and employees of the Underwriters and each person or persons, if any, who control any Underwriter within the meaning of Section 13 of the Securities Act, and (b) the indemnity agreement of the Underwriters contained in Section 8(b) of this Agreement shall be deemed to be for the benefit of the directors of the Company, the officers of the Company who have signed the Registration Statement and any person controlling the Company within the meaning of Section 13 of the Securities Act. Nothing in this Agreement is intended or shall be construed to give any person, other than the persons referred to in this Section 15, any legal or equitable right, remedy or claim under or in respect of this Agreement or any provision contained herein.
- 16. Survival. The respective indemnities, representations, warranties and agreements of the Company and the Underwriters contained in this Agreement or made by or on behalf of them, respectively, pursuant to this Agreement, shall survive the delivery of and payment for the Stock and shall remain in full force and effect, regardless of any investigation made by or on behalf of any of them or any person controlling any of them.
- 17. Definition of the Terms "Business Day", "Affiliate" and "Subsidiary". For purposes of this Agreement, (a) "business day" means each Monday, Tuesday, Wednesday, Thursday or Friday that is not a day on which banking institutions in New York are generally authorized or obligated by law or executive order to close, and (b) "affiliate" and "subsidiary" have the meanings set forth in Rule 405 under the Securities Act.
  - 18. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York.
- 19. Waiver of Jury Trial. The Company and the Underwriters hereby irrevocably waive, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.
- 20. *Counterparts*. This Agreement may be executed in one or more counterparts and, if executed in more than one counterpart, the executed counterparts shall each be deemed to be an original but all such counterparts shall together constitute one and the same instrument.
- 21. *Headings*. The headings herein are inserted for convenience of reference only and are not intended to be part of, or to affect the meaning or interpretation of, this Agreement.

[signature page follows]

that purpose below.	
	Very truly yours,
	Pacira Pharmaceuticals, Inc., a Delaware corporation
	By: Name: Title:
	Pacira Pharmaceuticals, Inc., a California corporation
	By: Name:

If the foregoing correctly sets forth the agreement between the Company and the Underwriters, please indicate your acceptance in the space provided for

Title:

Accepted:
For themselves and as Representatives of the several Underwriters named in Schedule I hereto
By BARCLAYS CAPITAL INC.
By:
Authorized Representative
By Piper Jaffray & Co.
By:
Authorized Representative

# SCHEDULE I

	Number of Shares	Number of Shares
<u>Underwriters</u>	of Firm Stock	of Option Stock
Barclays Capital Inc.		
Piper Jaffray & Co.		
Wedbush Securities Inc.		
Brean Murray, Carret & Co.		
Total		

## **SCHEDULE II**

## PERSONS DELIVERING LOCK-UP AGREEMENTS

## **Executive Officers and Directors**

David M. Stack

James S. Scibetta Gary Patou

William Lambert

Mark Walters

Fred Middleton

Luke Evnin

Carl Gordon

John Longenecker

Gary W. Pace

Andreas Wicki

Lynette Bowman

Vladimir Kharitonov

Fred Ryan

## Stockholders

HBM BioVentures (Cayman) Ltd. Sanderling Venture Partners VI, L.P. Orbimed Private Investments III, LP MPM BioVentures IV LLC

# SCHEDULE III

# ORALLY CONVEYED PRICING INFORMATION

- 1. [Public offering price]
- 2. [Number of shares offered]

# SCHEDULE IV

# ISSUER FREE WRITING PROSPECTUSES – ROAD SHOW MATERIALS

Insert list of certain "road show" materials

# SCHEDULE V

# ISSUER FREE WRITING PROSPECTUS

Insert list of all "Issuer Free Writing Prospectuses"

## EXHIBIT A

# LOCK-UP LETTER AGREEMENT

[See Attached]

Exhibit A

#### **EXHIBIT B-1**

### FORM OF OPINION OF COMPANY'S COUNSEL

Wilmer Cutler Pickering Hale and Dorr LLP shall have furnished to the Underwriters its written opinion, as counsel to the Company, addressed to the Underwriters and dated the Delivery Date, in form and substance reasonably satisfactory to the Representative, to the effect that:

- (a) Each of the Company and Pacira has been duly incorporated and is validly existing as a corporation in good standing under the laws of its jurisdiction of organization and has the corporate power and authority to carry on its business and to own, lease and operate its properties, as such business and properties are described in the Pricing Disclosure Package and the Prospectus
- (b) Each of the Company and its subsidiaries is duly qualified to do business and in good standing as a foreign corporation or other business entity in each jurisdiction in which its ownership or lease of property or the conduct of its businesses requires such qualification, except where the failure to be so qualified or in good standing, in the aggregate, would not reasonably be expected to have a Material Adverse Effect.
- (b) The Company has an authorized capitalization as set forth in each of the most recent Preliminary Prospectus and the Prospectus, and all of the outstanding shares of capital stock of the Company have been duly authorized and validly issued, fully paid and non-assessable.
- (c) The Stock has been duly authorized and, when issued and delivered to the Underwriters against payment therefor as provided by the Underwriting Agreement, will be validly issued, fully paid and non-assessable, and the issuance of such Shares will not be subject to any preemptive rights under the statutes codified as 8 Del.C. §§101-398 and known as the General Corporation Law of the State of Delaware (the " *DGCL Statute*") or the Certificate of Incorporation or Bylaws of the Company (the " *Governing Documents*").
  - (d) The Agreement has been duly authorized, executed and delivered by the Company and Pacira.
- (e) The execution and delivery of the Agreement by the Company and Pacira and the consummation by the Company and Pacira of the transactions contemplated thereby will not (A) conflict with or constitute a breach of any of the terms or provisions of, or a default under, the Governing Documents or any indenture, loan agreement, mortgage, lease or other agreement or instrument to which the Company is a party and that is filed as an exhibit to the Registration Statement or (B) violate or conflict with any United States federal, New York or California law, rule or regulation that in our experience is normally applicable in transactions of the type contemplated by the Agreement, the DGCL Statute, or any judgment, order or decree specifically naming the Company of which we are aware.

Exhibit B-1-1

- (f) Except as may be required under the Securities Act and the rules and regulations thereunder and the Exchange Act and the rules and regulations thereunder, no filing with, or authorization, approval, consent, license, order, registration, qualification or decree of, any United States federal, New York or California governmental authority or agency is necessary for the issuance, sale and delivery of the Stock by the Company to the Underwriters pursuant to the Agreement.
- (g) The Registration Statement has become effective under the Act. To our knowledge, no stop order suspending the effectiveness of the Registration Statement has been issued and no proceeding for such purpose are pending or threatened by the Commission. The Preliminary Prospectus has been filed in accordance with Rule 424(b) under the Act, the Prospectus has been filed in accordance with Rule 424(b) and 430B under the Act, and the Issuer Free Writing Prospectus[es] [has] [have] been filed in accordance with Rule 433(d) under the Act.
- (h) The statements made in the Pricing Disclosure Package and the Prospectus under the caption "Description of Capital Stock", insofar as such statements constitute matters of law or legal conclusions or summarize the terms of agreements, are correct in all material respects.
- (i) The statements made in each of the most recent Preliminary Prospectus and the Prospectus under the caption "Underwriting" insofar as such statements constitute matters of law or legal conclusions are correct in all material respects.
- (j) The statements made in the Pricing Disclosure Package and the Prospectus under the caption "Certain United States Federal Income Tax Consequences", insofar such statements constitute matters of law or legal conclusions are correct in all material respects.
- (k) The Company is not, and immediately after giving effect to the sale of the Stock in accordance with the Underwriting Agreement and the application of the proceeds as described in the Prospectus under the caption "Use of Proceeds," will not be required to be, registered as an "investment company" within the meaning of the Investment Company Act of 1940, as amended.

In addition to the opinions provided above, we confirm to you as follows: in the course of acting as counsel for the Company in connection with the preparation of the Registration Statement, the Pricing Disclosure Package and the Prospectus, we have participated in conferences with officers and other representatives of the Company, representatives of and counsel for the Underwriters and representatives of the registered independent public accounting firm of the Company, during which the contents of the Registration Statement, the Pricing Disclosure Package and the Prospectus were discussed. While the limitations inherent in the independent verification of factual matters and the character of determinations involved in the registration process are such that we are not passing upon and do not assume any responsibility for the accuracy, completeness or fairness of the statements contained in the Registration Statement, the Pricing Disclosure Package or the Prospectus (except to the extent expressly set forth in paragraphs (h), (i) and (j) above), subject to the foregoing and based on such participation and discussions:

(a) the Registration Statement, as of the Effective Date, and the Prospectus, as of the date thereof (except for the financial statements, including the notes and schedules thereto, and other financial and accounting data included therein or omitted therefrom, as to which we express no view), appear on their face to be appropriately responsive in all material respects to the requirements of the Securities Act and the applicable rules and regulations thereunder;

- (b) no facts have come to our attention that have caused us to believe that (i) the Registration Statement, as of the Effective Date, contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading (except as set forth in the parenthetical in clause (a) above), (ii) the Pricing Disclosure Package, as of the Applicable Time, contained an untrue statement of a material fact or omitted to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading (except as set forth in the parenthetical in clause (a) above) or (iii) the Prospectus, as of its date or as of the date hereof, contained or contains an untrue statement of a material fact or omitted or omits to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading (except as set forth in the parenthetical in clause (a) above);
- (c) we are not aware of any contract or other document of a character required by the Securities Act and the applicable rules and regulations of the Commission thereunder to be filed as an exhibit to the Registration Statement that is not so filed; and
- (d) we are not aware of any action, proceeding or litigation pending, contemplated or threatened against the Company before any court or governmental or administrative agency or body that is required by the Securities Act or the rules and regulations thereunder to be described in the Registration Statement or the Prospectus that is not so described.

Exhibit B-1-3

## **EXHIBIT B-2**

# FORM OF OPINION OF COMPANY'S REGULATORY COUNSEL

Kleinfeld, Kaplan and Becker LLP shall have furnished to the Underwriters its written opinion, as regulatory counsel to the Company, addressed to the Underwriters and dated the Delivery Date, in form and substance reasonably satisfactory to the Representative, to the effect that:

## [TO BE SEPARATELY PROVIDED]

Exhibit B-2-1

# EXHIBIT C

Form of Comfort Letter
[See Attached]

Exhibit C-1

#### AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

OI

### PACIRA PHARMACEUTICALS, INC.

(originally incorporated on December 22, 2006 under the name Blue Acquisition Corp.)

FIRST: The name of the Corporation is Pacira Pharmaceuticals, Inc.

SECOND: The address of the Company's registered office in the State of Delaware is Corporation Trust Center, 1209 Orange Street, in the City of Wilmington, County of New Castle. The name of its registered agent at that address is The Corporation Trust Company.

THIRD: The nature of the business or purposes to be conducted or promoted by the Company is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware.

FOURTH: The total number of shares of all classes of stock that the Company shall have authority to issue is 255,000,000 shares, consisting of (i) 250,000,000 shares of Common Stock, \$0.001 par value per share ("Common Stock"), and (ii) 5,000,000 shares of Preferred Stock, \$0.001 par value per share ("Preferred Stock").

The following is a statement of the designations and the powers, privileges and rights, and the qualifications, limitations or restrictions thereof in respect of each class of capital stock of the Company.

### A. COMMON STOCK.

- 1. <u>General</u>. The voting, dividend and liquidation rights of the holders of the Common Stock are subject to and qualified by the rights of the holders of the Preferred Stock of any series as may be designated by the Board of Directors upon any issuance of the Preferred Stock of any series.
- 2. <u>Voting</u> The holders of the Common Stock shall have voting rights at all meetings of stockholders, each such holder being entitled to one vote for each share thereof held by such holder; <u>provided</u>, <u>however</u>, that, except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to this Certificate of Incorporation (which, as used herein, shall mean the certificate of incorporation of the Company, as amended from time to time, including the terms of any certificate of designations of any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon pursuant to this Certificate of Incorporation. There shall be no cumulative voting.

The number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the stock of the Company entitled to vote, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law of the State of Delaware.

- 3. <u>Dividends</u>. Subject to any preferential dividend or other rights of any then outstanding Preferred Stock, the holders of shares of Common Stock shall be entitled to receive dividends and other distributions (payable in cash, property or capital stock of the Company) when, as and if declared thereon by the Board of Directors from time to time out of any assets or funds of the Company legally available therefor and shall share equally on a per share basis in such dividends and distributions.
- 4. <u>Liquidation</u>. Upon any voluntary or involuntary liquidation, dissolution or winding-up of the Company, after payment or provision for payment of the debts and other liabilities of the Company and subject to any preferential or other rights of any then outstanding Preferred Stock, holders of Common Stock shall be entitled to receive all the remaining assets of the Company available for distribution to its stockholders, ratably in proportion to the number of shares of Common Stock held by them.

### B. PREFERRED STOCK.

Preferred Stock may be issued from time to time in one or more series, each of such series to have such terms as stated or expressed herein and in the resolution or resolutions providing for the issue of such series adopted by the Board of Directors of the Company as hereinafter provided. Any shares of Preferred Stock that may be redeemed, purchased or acquired by the Company may be reissued except as otherwise provided by law.

Authority is hereby expressly granted to the Board of Directors from time to time to issue the Preferred Stock in one or more series, and in connection with the creation of any such series, by adopting a resolution or resolutions providing for the issuance of the shares thereof and by filing a certificate of designations relating thereto in accordance with the General Corporation Law of the State of Delaware, to determine and fix the number of shares of such series and such voting powers, full or limited, or no voting powers, and such designations, preferences and relative participating, optional or other special rights, and qualifications, limitations or restrictions thereof, including dividend rights, conversion rights, redemption privileges and liquidation preferences, as shall be stated and expressed in such resolutions, all to the full extent now or hereafter permitted by the General Corporation Law of the State of Delaware. Without limiting the generality of the foregoing, the resolutions providing for issuance of any series of Preferred Stock may provide that such series shall be superior or rank equally or be junior to any other series of Preferred Stock to the extent permitted by law.

The number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares then outstanding) by the affirmative vote of the holders of a majority of the voting power of the capital stock of the Company entitled to vote thereon, voting as a single class, irrespective of the provisions of Section 242(b)(2) of the General Corporation Law of the State of Delaware.

FIFTH: Except as otherwise provided herein, the Company reserves the right to amend, alter, change or repeal any provision contained in this Certificate of Incorporation, in the manner now or hereafter prescribed by statute and this Certificate of Incorporation, and except as set forth in Article EIGHTH, all rights conferred upon stockholders, directors or any other persons by and pursuant to this Certificate of Incorporation are granted subject to this reservation.

SIXTH: In furtherance and not in limitation of the powers conferred upon it by the General Corporation Law of the State of Delaware, and subject to the terms of any series of Preferred Stock, the Board of Directors shall have the power to adopt, amend, alter or repeal the Bylaws of the Company by the affirmative vote of a majority of the directors present at any regular or special meeting of the Board of Directors at which a quorum is present. The stockholders may not adopt, amend, alter or repeal the Bylaws of the Company, or adopt any provision inconsistent therewith, unless such action is approved, in addition to any other vote required by this Certificate of Incorporation, by the affirmative vote of the holders of at least 75% of the votes that all the stockholders would be entitled to cast in an election of directors or class of directors. Notwithstanding any other provision of law, this Certificate of Incorporation or the Bylaws of the Company, and notwithstanding the fact that a lesser percentage may be specified by law, the affirmative vote of the holders of at least 75% of the votes that all the stockholders would be entitled to cast in an election of directors or class of directors shall be required to amend, alter or repeal, or to adopt any provision inconsistent with, this Article SIXTH.

SEVENTH: Except to the extent that the General Corporation Law of the State of Delaware, as the same exists or hereafter may be amended, prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty, no person who is or was a director of the Company shall be personally liable to the Company or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability. No amendment to or repeal of this provision by the stockholders of the Company or by changes in law, or the adoption of any other provision of this Certificate of Incorporation inconsistent with this Article Seventh, unless otherwise required by law, shall apply to or have any effect on the liability or alleged liability of any director of the Company for or with respect to any acts or omissions of such director occurring prior to such amendment, repeal or adoption of such inconsistent provision, provided, however, that if the General Corporation Law of the State of Delaware is amended to permit further elimination or limitation of the personal liability of directors, then the liability of a director of the Company shall be eliminated or limited to the fullest extent permitted by the General Corporation Law of the State of Delaware as so amended.

EIGHTH: The Company shall provide indemnification as follows:

1. Actions, Suits and Proceedings Other than by or in the Right of the Company. The Company shall indemnify each person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the Company) by reason of the fact that he or she is or was, or has agreed to become, a director or officer of the Company, or is or was serving, or has agreed to serve, at the request of the Company, as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan) (all such persons being referred to hereafter 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), liabilities,

losses, judgments, fines, excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974, and amounts paid in settlement actually and reasonably incurred by or on behalf of Indemnitee in connection with such action, suit or proceeding and any appeal therefrom, if Indemnitee acted in good faith and in a manner that Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Company, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that Indemnitee did not act in good faith and in a manner that Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Company, and, with respect to any criminal action or proceeding, had reasonable cause to believe that his or her conduct was unlawful.

- 2. Actions or Suits by or in the Right of the Company. The Company shall indemnify any Indemnitee who was or is a party to or threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the Company to procure a judgment in its favor by reason of the fact that Indemnitee is or was, or has agreed to become, a director or officer of the Company, or is or was serving, or has agreed to serve, at the request of the Company, as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan), 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 by or on behalf of Indemnitee in connection with such action, suit or proceeding and any appeal therefrom, if Indemnitee acted in good faith and in a manner that Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Company, except that no indemnification shall be made under this Section 2 in respect of any claim, issue or matter as to which Indemnitee shall have been adjudged to be liable to the Company, unless, and only to the extent, that the Court of Chancery of Delaware or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of such liability but in view of all the circumstances of the case, Indemnitee is fairly and reasonably entitled to indemnity for such expenses (including attorneys' fees) that the Court of Chancery of Delaware or such other court shall deem proper.
- 3. <u>Indemnification for Expenses of Successful Party.</u> Notwithstanding any other provisions of this Article EIGHTH, to the extent that an Indemnitee has been successful, on the merits or otherwise, in defense of any action, suit or proceeding referred to in Sections 1 and 2 of this Article EIGHTH, or in defense of any claim, issue or matter therein, or on appeal from any such action, suit or proceeding, Indemnitee shall be indemnified against all expenses (including attorneys' fees) actually and reasonably incurred by or on behalf of Indemnitee in connection therewith. Without limiting the foregoing, Indemnitee shall be considered for the purposes hereof to have been wholly successful with respect to any action, suit or proceeding, or in defense of any claim, issue or matter therein or any appeal therefrom, that is disposed of, on the merits or otherwise (including a disposition without prejudice), without (i) the disposition being adverse to Indemnitee, (ii) an adjudication that Indemnitee was liable to the Company, (iii) a plea of guilty or nolo contendere by Indemnitee, (iv) an adjudication that Indemnitee did not act in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the Company, and (v) with respect to any criminal proceeding, an adjudication that Indemnitee had reasonable cause to believe his or her conduct was unlawful.

- 4. Notification and Defense of Claim. As a condition precedent to an Indemnitee's right to be indemnified, such Indemnitee must notify the Company in writing as soon as practicable of any action, suit, proceeding or investigation involving such Indemnitee for which indemnity will or could be sought. With respect to any action, suit, proceeding or investigation of which the Company is so notified, the Company will be entitled to participate therein at its own expense and/or to assume the defense thereof at its own expense, with legal counsel reasonably acceptable to Indemnitee. After notice from the Company to Indemnitee of its election so to assume such defense, the Company shall not be liable to Indemnitee for any legal or other expenses subsequently incurred by Indemnitee in connection with such action, suit, proceeding or investigation, other than as provided below in this Section 4. Indemnitee shall have the right to employ his or her own counsel in connection with such action, suit, proceeding or investigation, but the fees and expenses of such counsel incurred after notice from the Company of its assumption of the defense thereof shall be at the expense of Indemnitee unless (i) the employment of counsel by Indemnitee has been authorized by the Company, (ii) counsel to Indemnitee shall have reasonably concluded that there may be a conflict of interest or position on any significant issue between the Company and Indemnitee in the conduct of the defense of such action, suit, proceeding or investigation or (iii) the Company shall not in fact have employed counsel to assume the defense of such action, suit, proceeding or investigation, in each of which cases the fees and expenses of counsel for Indemnitee shall be at the expense of the Company, except as otherwise expressly provided by this Article EIGHTH. The Company shall not be entitled, without the consent of Indemnitee, to assume the defense of any claim brought by or in the right of the Company or as to which counsel for Indemnitee shall have reasonably made the conclusion provided for in clause (ii) above. The Company shall not be required to indemnify Indemnitee under this Article EIGHTH for any amounts paid in settlement of any action, suit, proceeding or investigation effected without its written consent. The Company shall not settle any action, suit, proceeding or investigation in any manner that would impose any penalty or limitation on Indemnitee without Indemnitee's written consent. Neither the Company nor Indemnitee will unreasonably withhold or delay its consent to any proposed settlement.
- 5. Advancement of Expenses. Subject to the provisions of Section 6 of this Article EIGHTH, in the event of any threatened or pending action, suit, proceeding or investigation of which the Company receives notice under this Article EIGHTH, any expenses (including attorneys' fees) incurred by or on behalf of Indemnitee in defending an action, suit, proceeding or investigation or any appeal therefrom shall be paid by the Company in advance of the final disposition of such matter; provided, however, that the payment of such expenses incurred by or on behalf of Indemnitee in advance of the final disposition of such matter shall be made only upon receipt of an undertaking by or on behalf of Indemnitee to repay all amounts so advanced in the event that it shall ultimately be determined by final judicial decision from which there is no further right to appeal that Indemnitee is not entitled to be indemnified by the Company as authorized in this Article EIGHTH; and provided further that no such advancement of expenses shall be made under this Article EIGHTH if it is determined (in the manner described in Section 6) that (i) Indemnitee did not act in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the Company, or (ii) with respect to any criminal action or proceeding, Indemnitee had reasonable cause to believe his or her conduct was unlawful. Such undertaking shall be accepted without reference to the financial ability of Indemnitee to make such repayment.

- 6. Procedure for Indemnification and Advancement of Expenses. In order to obtain indemnification or advancement of expenses pursuant to Section 1, 2, 3 or 5 of this Article EIGHTH, an Indemnitee shall submit to the Company a written request. Any such indemnification and advancement of expenses shall be made promptly, and in any event within 60 days after receipt by the Company of the written request of Indemnitee, except in the case of a claim for an advancement of expenses, the applicable period shall be 30 days, unless (i) the Company has assumed the defense pursuant to Section 4 of this Article EIGHTH (and none of the circumstances described in Section 4 of this Article EIGHTH that would nonetheless entitle the Indemnitee to indemnification for the fees and expenses of separate counsel have occurred) or (ii) the Company determines within such applicable period that Indemnitee did not meet the applicable standard of conduct set forth in Section 1, 2 or 5 of this Article EIGHTH, as the case may be. Any such indemnification, unless ordered by a court, shall be made with respect to requests under Section 1 or 2 only as authorized in the specific case upon a determination by the Company that the indemnification of Indemnitee is proper because Indemnitee has met the applicable standard of conduct set forth in Section 1 or 2, as the case may be. Such determination shall be made in each instance (a) by a majority vote of the directors of the Company consisting of persons who are not at that time parties to the action, suit or proceeding in question ("disinterested directors"), whether or not a quorum, (b) by a committee of disinterested directors designated by majority vote of disinterested directors, whether or not a quorum, (c) if there are no disinterested directors, or if the disinterested directors so direct, by independent legal counsel (who may, to the extent permitted by law, be regular legal counsel to the Company) in a written opinion, or (d) by the stockholders of the Company.
- 7. Remedies. The right to indemnification or advancement of expenses as granted by this Article EIGHTH shall be enforceable by Indemnitee in any court of competent jurisdiction. Neither the failure of the Company to have made a determination prior to the commencement of such action that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Company pursuant to Section 6 of this Article EIGHTH that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct. In any suit brought by Indemnitee to enforce a right to indemnification, or brought by the Company to recover an advancement of expenses pursuant to the terms of an undertaking, the Company shall have the burden of proving that Indemnitee is not entitled to be indemnified, or to such advancement of expenses, under this Article EIGHTH. Indemnitee's expenses (including attorneys' fees) reasonably incurred in connection with successfully establishing Indemnitee's right to indemnification, in whole or in part, in any such proceeding shall also be indemnified by the Company. Notwithstanding the foregoing, in any suit brought by Indemnitee to enforce a right to indemnification hereunder it shall be a defense that the Indemnitee has not met any applicable standard for indemnification set forth in the General Corporation Law of the State of Delaware.
- 8. <u>Limitations</u>. Notwithstanding anything to the contrary in this Article EIGHTH, except as set forth in Section 7 of this Article EIGHTH, the Company shall not indemnify an Indemnitee pursuant to this Article EIGHTH in connection with a proceeding (or part thereof) initiated by such Indemnitee unless the initiation thereof was approved by the Board of Directors of the Company. Notwithstanding anything to the contrary in this Article EIGHTH, the Company shall not indemnify an Indemnitee to the extent such Indemnitee is reimbursed from

the proceeds of insurance, and in the event the Company makes any indemnification payments to an Indemnitee and such Indemnitee is subsequently reimbursed from the proceeds of insurance, such Indemnitee shall promptly refund indemnification payments to the Company to the extent of such insurance reimbursement.

- 9. <u>Subsequent Amendment</u>. No amendment, termination or repeal of this Article EIGHTH or of the relevant provisions of the General Corporation Law of the State of Delaware or any other applicable laws, or the adoption of any other provision of this Certificate of Incorporation inconsistent with this Article EIGHTH, shall adversely affect or diminish in any way the rights of any Indemnitee to indemnification under the provisions hereof with respect to any action, suit, proceeding or investigation arising out of or relating to any actions, transactions or facts occurring prior to the final adoption of such amendment, termination or repeal (except to the extent such amendment, termination or repeal permits the Company to provide broader indemnification rights on a retroactive basis than permitted prior thereto).
- 10. Other Rights. The indemnification and advancement of expenses provided by this Article EIGHTH shall not be deemed exclusive of any other rights to which an Indemnitee seeking indemnification or advancement of expenses may be entitled under any law (common or statutory), this Certificate of Incorporation, the Bylaws of the Company, an agreement or vote of stockholders or disinterested directors or otherwise, both as to action in Indemnitee's official capacity and as to action in any other capacity while holding office for the Company, and shall continue as to an Indemnitee who has ceased to be a director or officer, and shall inure to the benefit of the estate, heirs, executors and administrators of Indemnitee. Nothing contained in this Article EIGHTH shall be deemed to prohibit, and the Company is specifically authorized to enter into, agreements with officers and directors providing indemnification rights and procedures different from those set forth in this Article EIGHTH. In addition, the Company may, to the extent authorized from time to time by its Board of Directors, grant indemnification rights to other employees or agents of the Company or other persons serving the Company and such rights may be equivalent to, or greater or less than, those set forth in this Article EIGHTH.
- 11. <u>Partial Indemnification</u>. If an Indemnitee is entitled under any provision of this Article EIGHTH to indemnification by the Company for some or a portion of the expenses (including attorneys' fees), liabilities, losses, judgments, fines (including excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974) or amounts paid in settlement actually and reasonably incurred by or on behalf of Indemnitee in connection with any action, suit, proceeding or investigation and any appeal therefrom but not, however, for the total amount thereof, the Company shall nevertheless indemnify Indemnitee for the portion of such expenses (including attorneys' fees), liabilities, losses, judgments, fines (including excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974) or amounts paid in settlement to which Indemnitee is entitled.
- 12. <u>Insurance</u>. The Company may purchase and maintain insurance, at its expense, to protect itself and any director, officer, employee or agent of the Company or another corporation, partnership, joint venture, trust or other enterprise (including any employee benefit plan) against any expense, liability or loss incurred by him or her in any such capacity, or arising out of his or her status as such, whether or not the Company would have the power to indemnify such person against such expense, liability or loss under the General Corporation Law of the State of Delaware.

- 13. Savings Clause. If this Article EIGHTH or any portion hereof shall be held invalid, illegal or unenforceable on any ground whatsoever by any court of competent jurisdiction, (a) the validity, legality and enforceability of the remaining provisions of this Article EIGHTH shall not in any way be effected or impaired thereby; and (b) the Company shall nevertheless indemnify each Indemnitee as to any expenses (including attorneys' fees), liabilities, losses, judgments, fines (including excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974) and amounts paid in settlement in connection with any action, suit, proceeding or investigation, whether civil, criminal or administrative, including an action by or in the right of the Company, to the fullest extent permitted by any applicable portion of this Article EIGHTH that shall not have been invalidated and to the fullest extent permitted by applicable law, provided further, that to the fullest extent possible, the provisions of this Article EIGHTH (including, without limitation, each such portion of this Article EIGHTH containing any such provisions held to be invalid, illegal or unenforceable) shall be construed so as to give effect to the intent manifested by the provision held invalid, illegal or unenforceable.
- 14. <u>Definitions</u>. Terms used herein and defined in Section 145(h) and Section 145(i) of the General Corporation Law of the State of Delaware shall have the respective meanings assigned to such terms in such Section 145(h) and Section 145(i).

NINTH: This Article NINTH is inserted for the management of the business and for the conduct of the affairs of the Company.

- 1. General Powers. The business and affairs of the Company shall be managed by or under the direction of the Board of Directors.
- 2. <u>Number of Directors</u>; <u>Election of Directors</u>. Subject to the rights of holders of any series of Preferred Stock to elect directors, the number of directors of the Company shall be established by the Board of Directors. Election of directors need not be by written ballot, except as and to the extent provided in the Bylaws of the Company.
- 3. <u>Classes of Directors</u>. Subject to the rights of holders of any series of Preferred Stock to elect directors, the Board of Directors shall be and is divided into three classes, designated Class I, Class II and Class III. Each class shall consist, as nearly as may be possible, of one-third of the total number of directors constituting the entire Board of Directors. The Board of Directors is authorized to assign members of the Board of Directors already in office to Class I, Class III at the time such classification becomes effective.
- 4. <u>Terms of Office</u>. Subject to the rights of holders of any series of Preferred Stock to elect directors, each director shall serve for a term ending on the date of the third annual meeting of stockholders following the annual meeting of stockholders at which such director was elected; <u>provided</u> that each director initially assigned to Class I shall serve for a term expiring at the Company's first annual meeting of stockholders held after the effectiveness of this Restated Certificate of Incorporation; each director initially assigned to Class II shall serve for a term

expiring at the Company's second annual meeting of stockholders held after the effectiveness of this Restated Certificate of Incorporation; and each director initially assigned to Class III shall serve for a term expiring at the Company's third annual meeting of stockholders held after the effectiveness of this Restated Certificate of Incorporation; <u>provided further</u>, that the term of each director shall continue until the election and qualification of his or her successor and be subject to his or her earlier death, resignation or removal.

- 5. Quorum. The greater of (a) a majority of the directors at any time in office and (b) one-third of the number of directors fixed pursuant to Section 2 of this Article NINTH shall constitute a quorum of the Board of Directors. If at any meeting of the Board of Directors there shall be less than such a quorum, a majority of the directors present may adjourn the meeting from time to time without further notice other than announcement at the meeting, until a quorum shall be present.
- 6. <u>Action at Meeting</u>. Every act or decision done or made by a majority of the directors present at a meeting duly held at which a quorum is present shall be regarded as the act of the Board of Directors unless a greater number is required by law or by this Certificate of Incorporation.
- 7. <u>Removal</u>. Subject to the rights of holders of any series of Preferred Stock, directors of the Company may be removed only for cause and only by the affirmative vote of the holders of at least 75% of the votes that all the stockholders would be entitled to cast in an election of directors or class of directors.
- 8. <u>Vacancies</u>. Subject to the rights of holders of any series of Preferred Stock, any vacancies or newly-created directorships in the Board of Directors, however occurring, shall be filled only by vote of a majority of the directors then in office, although less than a quorum, or by a sole remaining director and shall not be filled by the stockholders. A director elected to fill a vacancy or to fill a position resulting from a newly-created directorship shall hold office until the next election of the class for which such director shall have been chosen, subject to the election and qualification of a successor and to such director's earlier death, resignation or removal.
- 9. <u>Stockholder Nominations and Introduction of Business, Etc.</u> Advance notice of stockholder nominations for election of directors and other business to be brought by stockholders before a meeting of stockholders shall be given in the manner provided by the Bylaws of the Company.
- 10. Amendments to Article. Notwithstanding any other provision of law, this Certificate of Incorporation or the Bylaws of the Company, and notwithstanding the fact that a lesser percentage may be specified by law, the affirmative vote of the holders of at least 75% of the votes that all the stockholders would be entitled to cast in an election of directors or class of directors shall be required to amend or repeal, or to adopt any provision inconsistent with, this Article NINTH.

TENTH: Stockholders of the Company may not take any action by written consent in lieu of a meeting. Notwithstanding any other provision of law, this Certificate of Incorporation or the Bylaws of the Company, and notwithstanding the fact that a lesser percentage may be specified by law, the affirmative vote of the holders of at least 75% of the votes that all the stockholders would be entitled to cast in an election of directors or class of directors shall be required to amend or repeal, or to adopt any provision inconsistent with, this Article TENTH.

ELEVENTH: Special meetings of stockholders for any purpose or purposes may be called at any time by the Board of Directors, the Chairman of the Board or the Chief Executive Officer, but such special meetings may not be called by any other person or persons. Business transacted at any special meeting of stockholders shall be limited to matters relating to the purpose or purposes stated in the notice of meeting. Notwithstanding any other provision of law, this Certificate of Incorporation or the Bylaws of the Company, and notwithstanding the fact that a lesser percentage may be specified by law, the affirmative vote of the holders of at least 75% of the votes that all the stockholders would be entitled to cast in an election of directors or class of directors shall be required to amend or repeal, or to adopt any provision inconsistent with, this Article ELEVENTH.

IN WITNESS WHEREOF, this Restated Certificate of Incorporation, which restates, integrates and amends the certificate of incorporation of the Company, and which has been duly adopted in accordance with Sections 228, 242 and 245 of the General Corporation Law of the State of Delaware, has been executed by its duly authorized officer this [\_\_] day of [\_\_\_\_\_\_], 2011.

PACIRA PHARMACEUTICALS, INC.

Bv:

David M. Stack Chief Executive Officer

## AMENDED AND RESTATED BYLAWS

OF

# PACIRA PHARMACEUTICALS, INC.

Adopted January 11, 2011,

to be effective upon the closing of the Company's initial public offering

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### ARTICLE I STOCKHOLDERS

- 1.1 <u>Place of Meetings</u>. All meetings of stockholders shall be held at such place as may be designated from time to time by the Board of Directors, the Chairman of the Board, the Chief Executive Officer or the President or, if not so designated, at the principal office of the corporation.
- 1.2 <u>Annual Meeting</u>. The annual meeting of stockholders for the election of directors to succeed those whose terms expire and for the transaction of such other business as may properly be brought before the meeting shall be held on a date and at a time designated by the Board of Directors, the Chairman of the Board, the Chief Executive Officer or the President (which date shall not be a legal holiday in the place where the meeting is to be held).
- 1.3 <u>Special Meetings</u>. Special meetings of stockholders for any purpose or purposes may be called at any time only by the Board of Directors, the Chairman of the Board or the Chief Executive Officer, and may not be called by any other person or persons. The Board of Directors may postpone or reschedule any previously scheduled special meeting of stockholders. Business transacted at any special meeting of stockholders shall be limited to matters relating to the purpose or purposes stated in the notice of meeting.
- 1.4 Notice of Meetings. Except as otherwise provided by law, notice of each meeting of stockholders, whether annual or special, shall be given not less than 10 nor more than 60 days before the date of the meeting to each stockholder entitled to vote at such meeting. Without limiting the manner by which notice otherwise may be given to stockholders, any notice shall be effective if given by a form of electronic transmission consented to (in a manner consistent with the General Corporation Law of the State of Delaware) by the stockholder to whom the notice is given. The notices of all meetings shall state the place, date and time of the meeting and the means of remote communications, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such meeting. The notice of a special meeting shall state, in addition, the purpose or purposes for which the meeting is called. If notice is given by mail, such notice shall be deemed given when deposited in the United States mail, postage prepaid, directed to the stockholder at such stockholder's address as it appears on the records of the corporation. If notice is given by electronic transmission, such notice shall be deemed given at the time specified in Section 232 of the General Corporation Law of the State of Delaware.
- 1.5 <u>Voting List</u>. The Secretary shall prepare, at least 10 days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting, arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting, for a period of at least 10 days prior to the meeting: (a) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (b) during ordinary business hours, at the principal place of business of the corporation. The list shall also be produced and kept at the time and place of the meeting during the whole time thereof, and may be inspected by any stockholder who is present. The list shall presumptively determine the identity of the stockholders entitled to vote at the meeting and the number of shares held by each of them.

- 1.6 Quorum. Except as otherwise provided by law, the Certificate of Incorporation or these Bylaws, the holders of a majority in voting power of the shares of the capital stock of the corporation issued and outstanding and entitled to vote at the meeting, present in person, present by means of remote communication in a manner, if any, authorized by the Board of Directors in its sole discretion, or represented by proxy, shall constitute a quorum for the transaction of business; provided, however, that where a separate vote by a class or classes or series of capital stock is required by law or the Certificate of Incorporation, the holders of a majority in voting power of the shares of such class or classes or series of the capital stock of the corporation issued and outstanding and entitled to vote on such matter, present in person, present by means of remote communication in a manner, if any, authorized by the Board of Directors in its sole discretion, or represented by proxy, shall constitute a quorum entitled to take action with respect to the vote on such matter. A quorum, once established at a meeting, shall not be broken by the withdrawal of enough votes to leave less than a quorum.
- 1.7 <u>Adjournments</u>. Any meeting of stockholders may be adjourned from time to time to any other time and to any other place at which a meeting of stockholders may be held under these Bylaws by the chairman of the meeting or by the stockholders present or represented at the meeting and entitled to vote, although less than a quorum. It shall not be necessary to notify any stockholder of any adjournment of less than 30 days if the time and place of the adjourned meeting, and the means of remote communication, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such adjourned meeting, are announced at the meeting at which adjournment is taken, unless after the adjournment a new record date is fixed for the adjourned meeting. At the adjourned meeting, the corporation may transact any business that might have been transacted at the original meeting.
- 1.8 Voting and Proxies. Each stockholder shall have one vote for each share of stock entitled to vote held of record by such stockholder and a proportionate vote for each fractional share so held, unless otherwise provided by law or the Certificate of Incorporation. Each stockholder of record entitled to vote at a meeting of stockholders may vote in person (including by means of remote communications, if any, by which stockholders may be deemed to be present in person and vote at such meeting) or may authorize another person or persons to vote for such stockholder by a proxy executed or transmitted in a manner permitted by the General Corporation Law of the State of Delaware by the stockholder or such stockholder's authorized agent and delivered (including by electronic transmission) to the Secretary of the corporation. No such proxy shall be voted upon after three years from the date of its execution, unless the proxy expressly provides for a longer period.
- 1.9 Action at Meeting. When a quorum is present at any meeting, any matter other than the election of directors to be voted upon by the stockholders at such meeting shall be decided by the vote of the holders of shares of stock having a majority in voting power of the votes cast by the holders of all of the shares of stock present or represented at the meeting and voting affirmatively or negatively on such matter (or if there are two or more classes or series of stock entitled to vote as separate classes, then in the case of each such class or series, the holders of a majority in voting power of the shares of stock of that class or series present or represented

at the meeting and voting affirmatively or negatively on such matter), except when a different vote is required by law, the Certificate of Incorporation or these Bylaws. When a quorum is present at any meeting, any election by stockholders of directors shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election.

### 1.10 Nomination of Directors.

(a) Except for (1) any directors entitled to be elected by the holders of preferred stock, (2) any directors elected in accordance with Section 2.9 hereof by the Board of Directors to fill vacancies or newly-created directorships or (3) as otherwise required by applicable law or stock exchange regulation, at any meeting of stockholders, only persons who are nominated in accordance with the procedures in this Section 1.10 shall be eligible for election as directors. Nomination for election to the Board of Directors at a meeting of stockholders may be made (i) by or at the direction of the Board of Directors or (ii) by any stockholder of the corporation who (x) timely complies with the notice procedures in Section 1.10(b), (y) is a stockholder of record on the date of the giving of such notice and on the record date for the determination of stockholders entitled to vote at such meeting and (z) is entitled to vote at such meeting.

(b) To be timely, a stockholder's notice must be received in writing by the Secretary at the principal executive offices of the corporation as follows: (1) in the case of an election of directors at an annual meeting of stockholders, not less than 90 days nor more than 120 days prior to the first anniversary of the preceding year's annual meeting; provided, however, that (x) in the case of the annual meeting of stockholders of the corporation to be held in 2012 or (y) in the event that the date of the annual meeting in any other year is advanced by more than 20 days, or delayed by more than 60 days, from the first anniversary of the preceding year's annual meeting, a stockholder's notice must be so received not earlier than the 120th day prior to such annual meeting and not later than the close of business on the later of (A) the 90th day prior to such annual meeting and (B) the tenth day following the day on which notice of the date of such annual meeting was made, whichever first occurs; or (2) in the case of an election of directors at a special meeting of stockholders, provided that the Board of Directors, the Chairman of the Board or the Chief Executive Officer has determined, in accordance with Section 1.3, that directors shall be elected at such special meeting and provided further that the nomination made by the stockholder is for one of the director positions that the Board of Directors, the Chairman of the Board or the Chief Executive Officer, as the case may be, has determined will be filled at such special meeting, not earlier than the 120th day prior to such special meeting and not later than the close of business on the later of (x) the 90th day prior to such special meeting was mailed or public disclosure of the date of such special meeting was made, whichever first occurs. In no event shall the adjournment or postponement of a meeting (or the public disclosure thereof) commence a new time period (or extend any time period) for the giving of a stockholder's notice.

The stockholder's notice to the Secretary shall set forth: (A) as to each proposed nominee (1) such person's name, age, business address and, if known, residence address, (2) such person's principal occupation or employment, (3) the class and series and number of shares of

stock of the corporation that are, directly or indirectly, owned, beneficially or of record, by such person, (4) a description of all direct and indirect compensation and other material monetary agreements, arrangements and understandings during the past three years, and any other material relationships, between or among (x) the stockholder, the beneficial owner, if any, on whose behalf the nomination is being made and the respective affiliates and associates of, or others acting in concert with, such stockholder and such beneficial owner, on the one hand, and (v) each proposed nominee, and his or her respective affiliates and associates, or others acting in concert with such nominee(s), on the other hand, including all information that would be required to be disclosed pursuant to Item 404 of Regulation S-K if the stockholder making the nomination and any beneficial owner on whose behalf the nomination is made or any affiliate or associate thereof or person acting in concert therewith were the "registrant" for purposes of such Item and the proposed nominee were a director or executive officer of such registrant, and (5) any other information concerning such person that must be disclosed as to nominees in proxy solicitations pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended (the "Exchange Act"); and (B) as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination is being made (1) the name and address of such stockholder, as they appear on the corporation's books, and of such beneficial owner, (2) the class and series and number of shares of stock of the corporation that are, directly or indirectly, owned, beneficially or of record, by such stockholder and such beneficial owner, (3) a description of any agreement, arrangement or understanding between or among such stockholder and/or such beneficial owner and each proposed nominee and any other person or persons (including their names) pursuant to which the nomination(s) are being made or who may participate in the solicitation of proxies in favor of electing such nominee(s), (4) a description of any agreement, arrangement or understanding (including any derivative or short positions, swaps, profit interests, options, warrants, convertible securities, stock appreciation or similar rights, hedging transactions, and borrowed or loaned shares) that has been entered into by, or on behalf of, such stockholder or such beneficial owner, the effect or intent of which is to mitigate loss to, manage risk or benefit of share price changes for, or increase or decrease the voting power of, such stockholder or such beneficial owner with respect to shares of stock of the corporation, (5) any other information relating to such stockholder and such beneficial owner that would be required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for the election of directors in a contested election pursuant to Section 14 of the Exchange Act and the rules and regulations promulgated thereunder, (6) a representation that such stockholder intends to appear in person or by proxy at the meeting to nominate the person(s) named in its notice and (7) a representation whether such stockholder and/or such beneficial owner intends or is part of a group that intends (x) to deliver a proxy statement and/or form of proxy to holders of at least the percentage of the corporation's outstanding capital stock reasonably believed by such stockholder or such beneficial owner to be sufficient to elect the nominee (and such representation shall be included in any such proxy statement and form of proxy) and/or (y) otherwise to solicit proxies from stockholders in support of such nomination (and such representation shall be included in any such solicitation materials). Not later than 10 days after the record date for the meeting, the information required by items (A)(1)-(5) and (B)(1)-(5) of the prior sentence shall be supplemented by the stockholder giving the notice to provide updated information as of the record date. In addition, to be effective, the stockholder's notice must be accompanied by the written consent of the proposed nominee to serve as a director if elected. The corporation may require any proposed nominee to

furnish such other information as the corporation may reasonably require to determine the eligibility of such proposed nominee to serve as a director of the corporation or whether such nominee would be independent under applicable Securities and Exchange Commission and stock exchange rules and the corporation's publicly disclosed corporate governance guidelines. A stockholder shall not have complied with this Section 1.10(b) if the stockholder (or beneficial owner, if any, on whose behalf the nomination is made) solicits or does not solicit, as the case may be, proxies in support of such stockholder's nominee in contravention of the representations with respect thereto required by this Section 1.10.

- (c) The chairman of any meeting shall have the power and duty to determine whether a nomination was made in accordance with the provisions of this Section 1.10 (including whether the stockholder or beneficial owner, if any, on whose behalf the nomination is made solicited (or is part of a group that solicited) or did not so solicit, as the case may be, proxies in support of such stockholder's nominee in compliance with the representations with respect thereto required by this Section 1.10), and if the chairman should determine that a nomination was not made in accordance with the provisions of this Section 1.10, the chairman shall so declare to the meeting and such nomination shall not be brought before the meeting.
- (d) Except as otherwise required by applicable law, nothing in this Section 1.10 shall obligate the corporation or the Board of Directors to include in any proxy statement or other stockholder communication distributed on behalf of the corporation or the Board of Directors information with respect to any nominee for director submitted by a stockholder.
- (e) Notwithstanding the foregoing provisions of this Section 1.10, unless otherwise required by law, if the stockholder (or a qualified representative of the stockholder) does not appear at the meeting to present a nomination, such nomination shall not be brought before the meeting, notwithstanding that proxies in respect of such nominee may have been received by the corporation. For purposes of this Section 1.10, to be considered a "qualified representative of the stockholder", a person must be authorized by a written instrument executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the meeting of stockholders and such person must produce such written instrument or electronic transmission, or a reliable reproduction of the written instrument or electronic transmission, at the meeting of stockholders.
- (f) For purposes of this Section 1.10, "public disclosure" shall include disclosure in a press release reported by the Dow Jones News Service, Associated Press or comparable national news service or in a document publicly filed by the corporation with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the Exchange Act.

### 1.11 Notice of Business at Annual Meetings.

(a) At any annual meeting of the stockholders, only such business shall be conducted as shall have been properly brought before the meeting. To be properly brought before an annual meeting, business must be (1) specified in the notice of meeting (or any supplement thereto) given by or at the direction of the Board of Directors, (2) otherwise properly brought before the meeting by or at the direction of the Board of Directors, or (3) properly brought before the meeting by a stockholder. For business to be properly brought

before an annual meeting by a stockholder, (i) if such business relates to the nomination of a person for election as a director of the corporation, the procedures in Section 1.10 must be complied with and (ii) if such business relates to any other matter, the business must constitute a proper matter under Delaware law for stockholder action and the stockholder must (x) have given timely notice thereof in writing to the Secretary in accordance with the procedures in Section 1.11(b), (y) be a stockholder of record on the date of the giving of such notice and on the record date for the determination of stockholders entitled to vote at such annual meeting and (z) be entitled to vote at such annual meeting.

(b) To be timely, a stockholder's notice must be received in writing by the Secretary at the principal executive offices of the corporation not less than 90 days nor more than 120 days prior to the first anniversary of the preceding year's annual meeting; provided, however, that (1) in the case of the annual meeting of stockholders of the corporation to be held in 2011 or (2) in the event that the date of the annual meeting in any other year is advanced by more than 20 days, or delayed by more than 60 days, from the first anniversary of the preceding year's annual meeting, a stockholder's notice must be so received not earlier than the 120th day prior to such annual meeting and not later than the close of business on the later of (x) the 90th day prior to such annual meeting and (y) the tenth day following the day on which notice of the date of such annual meeting was mailed or public disclosure of the date of such annual meeting was made, whichever first occurs. In no event shall the adjournment or postponement of an annual meeting (or the public disclosure thereof) commence a new time period (or extend any time period) for the giving of a stockholder's notice.

The stockholder's notice to the Secretary shall set forth: (A) as to each matter the stockholder proposes to bring before the annual meeting (1) a brief description of the business desired to be brought before the annual meeting, (2) the text of the proposal (including the exact text of any resolutions proposed for consideration and, in the event that such business includes a proposal to amend the Bylaws, the exact text of the proposed amendment), and (3) the reasons for conducting such business at the annual meeting, and (B) as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the proposal is being made (1) the name and address of such stockholder, as they appear on the corporation's books, and of such beneficial owner, (2) the class and series and number of shares of stock of the corporation that are, directly or indirectly, owned, beneficially or of record, by such stockholder and such beneficial owner, (3) a description of any material interest of such stockholder or such beneficial owner and the respective affiliates and associates of, or others acting in concert with, such stockholder or such beneficial owner in such business, (4) a description of any agreement, arrangement or understanding between or among such stockholder and/or such beneficial owner and any other person or persons (including their names) in connection with the proposal of such business or who may participate in the solicitation of proxies in favor of such proposal, (5) a description of any agreement, arrangement or understanding (including any derivative or short positions, swaps, profit interests, options, warrants, convertible securities, stock appreciation or similar rights, hedging transactions, and borrowed or loaned shares) that has been entered into by, or on behalf of, such stockholder or such beneficial owner, the effect or intent of which is to mitigate loss to, manage risk or benefit of share price changes for, or increase or decrease the voting power of, such stockholder or such benefici

in connection with solicitations of proxies for the business proposed pursuant to Section 14 of the Exchange Act and the rules and regulations promulgated thereunder, (7) a representation that such stockholder intends to appear in person or by proxy at the annual meeting to bring such business before the meeting and (8) a representation whether such stockholder and/or such beneficial owner intends or is part of a group that intends (x) to deliver a proxy statement and/or form of proxy to holders of at least the percentage of the corporation's outstanding capital stock required to approve or adopt the proposal (and such representation shall be included in any such proxy statement and form of proxy) and/or (y) otherwise to solicit proxies from stockholders in support of such proposal (and such representation shall be included in any such solicitation materials). Not later than 10 days after the record date for the meeting, the information required by Items (A)(3) and (B)(1)-(6) of the prior sentence shall be supplemented by the stockholder giving the notice to provide updated information as of the record date. Notwithstanding anything in these Bylaws to the contrary, no business shall be conducted at any annual meeting of stockholders except in accordance with the procedures in this Section 1.11; provided that any stockholder proposal that complies with Rule 14a-8 of the proxy rules (or any successor provision) promulgated under the Exchange Act and is to be included in the corporation's proxy statement for an annual meeting of stockholders shall be deemed to comply with the notice requirements of this Section 1.11. A stockholder shall not have complied with this Section 1.11(b) if the stockholder (or beneficial owner, if any, on whose behalf the proposal is made) solicits or does not solicit, as the case may be, proxies in support of such stockholder's proposal in contravention of the representations with respect thereto required by this Section 1.11.

- (c) The chairman of any annual meeting shall have the power and duty to determine whether business was properly brought before the annual meeting in accordance with the provisions of this Section 1.11 (including whether the stockholder or beneficial owner, if any, on whose behalf the proposal is made solicited (or is part of a group that solicited) or did not so solicit, as the case may be, proxies in support of such stockholder's proposal in compliance with the representation with respect thereto required by this Section 1.11), and if the chairman should determine that business was not properly brought before the annual meeting in accordance with the provisions of this Section 1.11, the chairman shall so declare to the meeting and such business shall not be brought before the annual meeting.
- (d) Except as otherwise required by law, nothing in this Section 1.11 shall obligate the corporation or the Board of Directors to include in any proxy statement or other stockholder communication distributed on behalf of the corporation or the Board of Directors information with respect to any proposal submitted by a stockholder.
- (e) Notwithstanding the foregoing provisions of this Section 1.11, unless otherwise required by applicable law, if the stockholder (or a qualified representative of the stockholder) does not appear at the annual meeting to present business, such business shall not be considered, notwithstanding that proxies in respect of such business may have been received by the corporation.
- (f) For purposes of this Section 1.11, the terms "qualified representative of the stockholder" and "public disclosure" shall have the same meaning as in Section 1.10.

### 1.12 Conduct of Meetings.

- (a) Unless otherwise provided by the Board of Directors, meetings of stockholders shall be presided over by the Chairman of the Board, if any, or in the Chairman's absence by the Vice Chairman of the Board, if any, or in the Vice Chairman's absence by the Chief Executive Officer, or in the Chief Executive Officer's absence by the President, or in the President's absence by a Vice President, or in the absence of all of the foregoing persons by a chairman designated by the Board of Directors. The Secretary shall act as secretary of the meeting, but in the Secretary's absence the chairman of the meeting may appoint any person to act as secretary of the meeting.
- (b) The Board of Directors may adopt by resolution such rules, regulations and procedures for the conduct of any meeting of stockholders of the corporation as it shall deem appropriate including, without limitation, such guidelines and procedures as it may deem appropriate regarding the participation by means of remote communication of stockholders and proxyholders not physically present at a meeting. Except to the extent inconsistent with such rules, regulations and procedures as adopted by the Board of Directors, the chairman of any meeting of stockholders shall have the right and authority to prescribe such rules, regulations and procedures and to do all such acts as, in the judgment of such chairman, are appropriate for the proper conduct of the meeting. Such rules, regulations or procedures, whether adopted by the Board of Directors or prescribed by the chairman of the meeting, may include, without limitation, the following: (i) the establishment of an agenda or order of business for the meeting; (ii) rules and procedures for maintaining order at the meeting and the safety of those present; (iii) limitations on attendance at or participation in the meeting to stockholders of record of the corporation, their duly authorized and constituted proxies or such other persons as shall be determined; (iv) restrictions on entry to the meeting after the time fixed for the commencement thereof; and (v) limitations on the time allotted to questions or comments by participants. Unless and to the extent determined by the Board of Directors or the chairman of the meeting, meetings of stockholders shall not be required to be held in accordance with the rules of parliamentary procedure.
- (c) The chairman of the meeting shall announce at the meeting when the polls for each matter to be voted upon at the meeting will be opened and closed. After the polls close, no ballots, proxies or votes or any revocations or changes thereto may be accepted.
- (d) In advance of any meeting of stockholders, the Board of Directors, the Chairman of the Board, the Chief Executive Officer or the President shall appoint one or more inspectors of election to act at the meeting and make a written report thereof. One or more other persons may be designated as alternate inspectors to replace any inspector who fails to act. If no inspector or alternate is present, ready and willing to act at a meeting of stockholders, the chairman of the meeting shall appoint one or more inspectors to act at the meeting. Unless otherwise required by law, inspectors may be officers, employees or agents of the corporation. Each inspector, before entering upon the discharge of such inspector's duties, shall take and sign an oath faithfully to execute the duties of inspector with strict impartiality and according to the best of such inspector's ability. The inspector shall have the duties prescribed by law and shall take charge of the polls and, when the vote is completed, shall make a certificate of the result of the vote taken and of such other facts as may be required by law. Every vote taken by ballots shall be counted by a duly appointed inspector or duly appointed inspectors.

1.13 No Action by Consent in Lieu of a Meeting. Stockholders of the corporation may not take any action by written consent in lieu of a meeting.

### ARTICLE II DIRECTORS

- 2.1 <u>General Powers</u>. The business and affairs of the corporation shall be managed by or under the direction of a Board of Directors, who may exercise all of the powers of the corporation except as otherwise provided by applicable law or the Certificate of Incorporation.
- 2.2 <u>Number, Election and Qualification</u>. Subject to the rights of holders of any series of Preferred Stock to elect directors, the number of directors of the corporation shall be established by the Board of Directors. Election of directors need not be by written ballot. Directors need not be stockholders of the corporation.
- 2.3 Chairman of the Board; Vice Chairman of the Board. The Board of Directors may appoint from its members a Chairman of the Board and a Vice Chairman of the Board, neither of whom need be an employee or officer of the corporation. If the Board of Directors appoints a Chairman of the Board, such Chairman shall perform such duties and possess such powers as are assigned by the Board of Directors and, if the Chairman of the Board is also designated as the corporation's Chief Executive Officer, shall have the powers and duties of the Chief Executive Officer prescribed in Section 3.7 of these Bylaws. If the Board of Directors appoints a Vice Chairman of the Board, such Vice Chairman shall perform such duties and possess such powers as are assigned by the Board of Directors or the Chairman of the Board. Unless otherwise provided by the Board of Directors, the Chairman of the Board or, in the Chairman's absence, the Vice Chairman of the Board, if any, shall preside at all meetings of the Board of Directors and stockholders.
- 2.4 <u>Classes of Directors</u>. Subject to the rights of holders of any series of Preferred Stock to elect directors, the Board of Directors shall be and is divided into three classes: Class I, Class II and Class III. Each class shall consist, as nearly as may be possible, of one-third of the total number of directors constituting the entire Board of Directors. The allocation of directors among classes shall be determined by resolution of the Board of Directors.
- 2.5 Terms of Office. Subject to the rights of holders of any series of Preferred Stock to elect directors, each director shall serve for a term ending on the date of the third annual meeting of stockholders following the annual meeting of stockholders at which such director was elected; provided that each director initially assigned to Class I shall serve for a term expiring at the corporation's first annual meeting of stockholders held after the effectiveness of these Bylaws; each director initially assigned to Class II shall serve for a term expiring at the corporation's second annual meeting of stockholders held after the effectiveness of these Bylaws; and each director initially assigned to Class III shall serve for a term expiring at the corporation's third annual meeting of stockholders held after the effectiveness of these Bylaws; provided further, that the term of each director shall continue until the election and qualification of his or her successor and be subject to his or her earlier death, resignation or removal.

- 2.6 Quorum. The greater of (a) a majority of the directors at any time in office and (b) one-third of the number of directors established by the Board of Directors pursuant to Section 2.2 of these Bylaws shall constitute a quorum of the Board of Directors. If at any meeting of the Board of Directors there shall be less than such a quorum, a majority of the directors present may adjourn the meeting from time to time without further notice other than announcement at the meeting, until a quorum shall be present.
- 2.7 <u>Action at Meeting</u>. Every act or decision done or made by a majority of the directors present at a meeting duly held at which a quorum is present shall be regarded as the act of the Board of Directors, unless a greater number is required by law or by the Certificate of Incorporation.
- 2.8 <u>Removal</u>. Subject to the rights of holders of any series of Preferred Stock, directors of the corporation may be removed only for cause and only by the affirmative vote of the holders of at least 75% of the votes that all the stockholders would be entitled to cast in an election of directors or class of directors.
- 2.9 <u>Vacancies</u>. Subject to the rights of holders of any series of Preferred Stock, vacancies or newly-created directorships on the Board of Directors, however occurring, shall be filled only by vote of a majority of the directors then in office, although less than a quorum, or by a sole remaining director and shall not be filled by the stockholders. A director elected to fill a vacancy or to fill a position resulting from a newly-created directorship shall hold office until the next election of the class for which such director shall have been chosen, subject to the election and qualification of a successor or until such director's earlier death, resignation or removal.
- 2.10 <u>Resignation</u>. Any director may resign by delivering a resignation in writing or by electronic transmission to the corporation at its principal office or to the Chairman of the Board, the Chief Executive Officer, the President or the Secretary. Such resignation shall be effective upon delivery unless it is specified to be effective at some later time or upon the happening of some later event.
- 2.11 Regular Meetings. Regular meetings of the Board of Directors may be held without notice at such time and place as shall be determined from time to time by the Board of Directors; provided that any director who is absent when such a determination is made shall be given notice of the determination. A regular meeting of the Board of Directors may be held without notice immediately after and at the same place as the annual meeting of stockholders.
- 2.12 Special Meetings. Special meetings of the Board of Directors may be held at any time and place designated in a call by the Chairman of the Board, the Chief Executive Officer, the President, two or more directors, or by one director in the event that there is only a single director in office.
- 2.13 Notice of Special Meetings. Notice of the date, place and time of any special meeting of directors shall be given to each director by the Secretary or by the officer or one of

the directors calling the meeting. Notice shall be duly given to each director (a) in person or by telephone at least 24 hours in advance of the meeting, (b) by sending written notice by reputable overnight courier, telecopy, facsimile or electronic transmission, or delivering written notice by hand, to such director's last known business, home or electronic transmission address at least 48 hours in advance of the meeting, or (c) by sending written notice by first-class mail to such director's last known business or home address at least 72 hours in advance of the meeting. A notice or waiver of notice of a meeting of the Board of Directors need not specify the purposes of the meeting.

- 2.14 <u>Meetings by Conference Communications Equipment</u>. Directors may participate in meetings of the Board of Directors or any committee thereof by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and participation by such means shall constitute presence in person at such meeting.
- 2.15 Action by Consent. Any action required or permitted to be taken at any meeting of the Board of Directors or of any committee thereof may be taken without a meeting, if all members of the Board of Directors or committee, as the case may be, consent to the action in writing or by electronic transmission, and the written consents or electronic transmissions are filed with the minutes of proceedings of the Board of Directors or committee. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.
- 2.16 Committees. The Board of Directors may designate one or more committees, each committee to consist of one or more of the directors of the corporation with such lawfully delegable powers and duties as the Board of Directors thereby confers, to serve at the pleasure of the Board of Directors. The Board of Directors may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members of the committee present at any meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the Board of Directors to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent provided in the resolution of the Board of Directors and subject to the provisions of law, shall have and may exercise all the powers and authority of the Board of Directors in the management of the business and affairs of the corporation and may authorize the seal of the corporation to be affixed to all papers that may require it. Each such committee shall keep minutes and make such reports as the Board of Directors may from time to time request. Except as the Board of Directors may otherwise determine, any committee may make rules for the conduct of its business, but unless otherwise provided by the directors or in such rules, its business shall be conducted as nearly as possible in the same manner as is provided in these Bylaws for the Board of Directors. Except as otherwise provided in the Certificate of Incorporation, these Bylaws, or the resolution of the Board of Directors designating the committee, a committee may create one or more subcommittees, each subcommittee to consist of one or more members of the committee, and delegate to a subcommittee any or all of the powers and authority of the committee.

2.17 <u>Compensation of Directors</u>. Directors may be paid such compensation for their services and such reimbursement for expenses of attendance at meetings as the Board of Directors may from time to time determine. No such payment shall preclude any director from serving the corporation or any of its parent or subsidiary entities in any other capacity and receiving compensation for such service.

#### ARTICLE III OFFICERS

- 3.1 <u>Titles</u>. The officers of the corporation shall consist of a Chief Executive Officer, a President, a Secretary, a Treasurer and such other officers with such other titles as the Board of Directors shall determine, which may include one or more Vice Presidents, Assistant Treasurers and Assistant Secretaries. The Board of Directors may appoint such other officers as it may deem appropriate.
- 3.2 <u>Election</u>. The Chief Executive Officer, President, Treasurer and Secretary shall be elected annually by the Board of Directors at its first meeting following the annual meeting of stockholders. Other officers may be appointed by the Board of Directors at such meeting or at any other meeting.
  - 3.3 Qualification. No officer need be a stockholder. Any two or more offices may be held by the same person.
- 3.4 <u>Tenure</u>. Except as otherwise provided by law, by the Certificate of Incorporation or by these Bylaws, each officer shall hold office until such officer's successor is elected and qualified, unless a different term is specified in the resolution electing or appointing such officer, or until such officer's earlier death, resignation or removal.
- 3.5 <u>Resignation and Removal</u>. Any officer may resign by delivering a written resignation to the corporation at its principal office or to the Chief Executive Officer, the President or the Secretary. Such resignation shall be effective upon receipt unless it is specified to be effective at some later time or upon the happening of some later event. Any officer may be removed at any time, with or without cause, by vote of a majority of the directors then in office. Except as the Board of Directors may otherwise determine, no officer who resigns or is removed shall have any right to any compensation as an officer for any period following such officer's resignation or removal, or any right to damages on account of such removal, whether such officer's compensation be by the month or by the year or otherwise, unless such compensation is expressly provided for in a duly authorized written agreement with the corporation.
- 3.6 <u>Vacancies</u>. The Board of Directors may fill any vacancy occurring in any office for any reason and may, in its discretion, leave unfilled for such period as it may determine any offices other than those of Chief Executive Officer, President, Treasurer and Secretary. Each such successor shall hold office for the unexpired term of such officer's predecessor and until a successor is elected and qualified, or until such officer's earlier death, resignation or removal.
- 3.7 <u>President; Chief Executive Officer</u>. Unless the Board of Directors has designated another person as the corporation's Chief Executive Officer, the President shall be the Chief Executive Officer of the corporation. The Chief Executive Officer shall have general charge and

supervision of the business of the corporation subject to the direction of the Board of Directors, and shall perform all duties and have all powers that are commonly incident to the office of the chief executive or that are delegated to such officer by the Board of Directors. The President shall perform such other duties and shall have such other powers as the Board of Directors or the Chief Executive Officer (if the President is not the Chief Executive Officer) may from time to time prescribe. In the event of the absence, inability or refusal to act of the Chief Executive Officer or the President (if the President is not the Chief Executive Officer), the Vice President (or if there shall be more than one, the Vice Presidents in the order determined by the Board of Directors) shall perform the duties of the Chief Executive Officer and when so performing such duties shall have all the powers of and be subject to all the restrictions upon the Chief Executive Officer.

- 3.8 <u>Vice Presidents</u>. Each Vice President shall perform such duties and possess such powers as the Board of Directors or the Chief Executive Officer may from time to time prescribe. The Board of Directors may assign to any Vice President the title of Executive Vice President, Senior Vice President or any other title selected by the Board of Directors.
- 3.9 <u>Secretary and Assistant Secretaries</u>. The Secretary shall perform such duties and shall have such powers as the Board of Directors or the Chief Executive Officer may from time to time prescribe. In addition, the Secretary shall perform such duties and have such powers as are incident to the office of the secretary, including without limitation the duty and power to give notices of all meetings of stockholders and special meetings of the Board of Directors, to attend all meetings of stockholders and the Board of Directors and keep a record of the proceedings, to maintain a stock ledger and prepare lists of stockholders and their addresses as required, to be custodian of corporate records and the corporate seal and to affix and attest to the same on documents.

Any Assistant Secretary shall perform such duties and possess such powers as the Board of Directors, the Chief Executive Officer or the Secretary may from time to time prescribe. In the event of the absence, inability or refusal to act of the Secretary, the Assistant Secretary (or if there shall be more than one, the Assistant Secretaries in the order determined by the Board of Directors) shall perform the duties and exercise the powers of the Secretary.

In the absence of the Secretary or any Assistant Secretary at any meeting of stockholders or directors, the chairman of the meeting shall designate a temporary secretary to keep a record of the meeting.

3.10 <u>Treasurer and Assistant Treasurers</u>. The Treasurer shall perform such duties and shall have such powers as may from time to time be assigned by the Board of Directors or the Chief Executive Officer. In addition, the Treasurer shall perform such duties and have such powers as are incident to the office of treasurer, including without limitation the duty and power to keep and be responsible for all funds and securities of the corporation, to deposit funds of the corporation in depositories selected in accordance with these Bylaws, to disburse such funds as ordered by the Board of Directors, to make proper accounts of such funds, and to render as required by the Board of Directors statements of all such transactions and of the financial condition of the corporation.

The Assistant Treasurers shall perform such duties and possess such powers as the Board of Directors, the Chief Executive Officer or the Treasurer may from time to time prescribe. In the event of the absence, inability or refusal to act of the Treasurer, the Assistant Treasurer (or if there shall be more than one, the Assistant Treasurers in the order determined by the Board of Directors) shall perform the duties and exercise the powers of the Treasurer.

- 3.11 <u>Salaries</u>. Officers of the corporation shall be entitled to such salaries, compensation or reimbursement as shall be fixed or allowed from time to time by the Board of Directors.
- 3.12 <u>Delegation of Authority</u>. The Board of Directors may from time to time delegate the powers or duties of any officer to any other officer or agent, notwithstanding any provision hereof.

#### ARTICLE IV CAPITAL STOCK

- 4.1 <u>Issuance of Stock</u>. Subject to the provisions of the Certificate of Incorporation, the whole or any part of any unissued balance of the authorized capital stock of the corporation or the whole or any part of any shares of the authorized capital stock of the corporation held in the corporation's treasury may be issued, sold, transferred or otherwise disposed of by vote of the Board of Directors in such manner, for such lawful consideration and on such terms as the Board of Directors may determine.
- 4.2 <u>Stock Certificates; Uncertificated Shares</u>. The shares of the corporation may be held in certificated or uncertificated form. Every holder of stock of the corporation represented by certificates shall be entitled to have a certificate, in such form as may be prescribed by law and by the Board of Directors, representing the number and class of shares held by such holder in registered in certificate form. Each such certificate shall be signed in a manner that complies with Section 158 of the General Corporation Law of the State of Delaware.

Each certificate for shares of stock that are subject to any restriction on transfer pursuant to the Certificate of Incorporation, these Bylaws, applicable securities laws or any agreement among any number of stockholders or among such holders and the corporation shall have conspicuously noted on the face or back of the certificate either the full text of the restriction or a statement of the existence of such restriction.

If the corporation shall be authorized to issue more than one class of stock or more than one series of any class, the powers, designations, preferences and relative participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of each certificate representing shares of such class or series of stock, provided that in lieu of the foregoing requirements there may be set forth on the face or back of each certificate representing shares of such class or series of stock a statement that the corporation will furnish without charge to each stockholder who so requests a copy of the full text of the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

Within a reasonable time after the issuance or transfer of uncertificated shares, the corporation shall send to the registered owner thereof a written notice containing the information required to be set forth or stated on certificates pursuant to Sections 151, 202(a) or 218(a) of the General Corporation Law of the State of Delaware or, with respect to Section 151 of the General Corporation Law of the State of Delaware, a statement that the corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

- 4.3 <u>Transfers</u>. Shares of stock of the corporation shall be transferable in the manner prescribed by law and in these Bylaws. Transfers of shares of stock of the corporation shall be made only on the books of the corporation or by transfer agents designated to transfer shares of stock of the corporation. Subject to applicable law, shares of stock represented by certificates shall be transferred only on the books of the corporation by the surrender to the corporation or its transfer agent of the certificate representing such shares properly endorsed or accompanied by a written assignment or power of attorney properly executed, and with such proof of authority or the authenticity of signature as the corporation or its transfer agent may reasonably require. Except as may be otherwise required by law, by the Certificate of Incorporation or by these Bylaws, the corporation shall be entitled to treat the record holder of stock as shown on its books as the owner of such stock for all purposes, including the payment of dividends and the right to vote with respect to such stock, regardless of any transfer, pledge or other disposition of such stock until the shares have been transferred on the books of the corporation in accordance with the requirements of these Bylaws.
- 4.4 <u>Lost, Stolen or Destroyed Certificates</u>. The corporation shall issue a new certificate of stock in place of any previously issued certificate alleged to have been lost, stolen or destroyed, upon such terms and conditions as the Board of Directors may prescribe, including the presentation of reasonable evidence of such loss, theft or destruction and the giving of such indemnity and posting of such bond as the Board of Directors may require for the protection of the corporation or any transfer agent or registrar.
- 4.5 Record Date. The Board of Directors may fix in advance a date as a record date for the determination of the stockholders entitled to notice of or to vote at any meeting of stockholders, or entitled to receive payment of any dividend or other distribution or allotment of any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action. Such record date shall not precede the date on which the resolution fixing the record date is adopted, and such record date shall not be more than 60 nor less than 10 days before the date of such meeting, nor more than 60 days prior to any other action to which such record date relates.

If no record date is fixed, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day before the day on which notice is given, or, if notice is waived, at the close of business on the day before the day on which the meeting is held. If no record date is fixed, the record date for determining stockholders for any other purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating to such purpose.

A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board of Directors may fix a new record date for the adjourned meeting.

4.6 <u>Regulations</u>. The issue, transfer, conversion and registration of shares of stock of the corporation shall be governed by such other regulations as the Board of Directors may establish.

#### ARTICLE V GENERAL PROVISIONS

- 5.1 Fiscal Year. Except as from time to time otherwise designated by the Board of Directors, the fiscal year of the corporation shall begin on the first day of January of each year and end on the last day of December in each year.
  - 5.2 Corporate Seal. The corporate seal shall be in such form as shall be approved by the Board of Directors.
- 5.3 Waiver of Notice. Whenever notice is required to be given by law, by the Certificate of Incorporation or by these Bylaws, a written waiver signed by the person entitled to notice, or a waiver by electronic transmission by the person entitled to notice, whether given before, at or after the time of the event for which notice is to be given, shall be deemed equivalent to notice required to be given to such person. Neither the business nor the purpose of any meeting need be specified in any such waiver. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened.
- 5.4 <u>Voting of Securities</u>. Except as the Board of Directors may otherwise designate, the Chief Executive Officer, the President or the Treasurer may waive notice of, vote, or appoint any person or persons to vote, on behalf of the corporation at, and act as, or appoint any person or persons to act as, proxy or attorney-in-fact for this corporation (with or without power of substitution) at, any meeting of stockholders or securityholders of any other entity, the securities of which may be held by this corporation.
- 5.5 Evidence of Authority. A certificate by the Secretary, or an Assistant Secretary, or a temporary Secretary, as to any action taken by the stockholders, directors, a committee or any officer or representative of the corporation shall as to all persons who rely on the certificate in good faith be conclusive evidence of such action.
- 5.6 <u>Certificate of Incorporation</u>. All references in these Bylaws to the Certificate of Incorporation shall be deemed to refer to the Certificate of Incorporation of the corporation, as it may be amended and in effect from time to time.

- 5.7 <u>Severability</u>. Any determination that any provision of these Bylaws is for any reason inapplicable, illegal or ineffective shall not affect or invalidate any other provision of these Bylaws.
- 5.8 <u>Pronouns</u>. All pronouns used in these Bylaws shall be deemed to refer to the masculine, feminine or neuter, singular or plural, as the identity of the person or persons may require.

#### ARTICLE VI AMENDMENTS

These Bylaws may be altered, amended or repealed, in whole or in part, or new Bylaws may be adopted by the Board of Directors or by the stockholders as provided in the Certificate of Incorporation.

# CERTIFICATE OF AMENDMENT OF AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF PACIRA PHARMACEUTICALS, INC.

PACIRA PHARMACEUTICALS, INC. (hereinafter called the "Corporation"), a corporation organized and existing under the laws of the State of Delaware, HEREBY CERTIFIES AS FOLLOWS:

- 1. This amendment to the Amended and Restated Certificate of Incorporation as set forth herein has been duly approved by the Board of Directors of the Corporation pursuant to Sections 141 and 242 of the Delaware General Corporation Law.
- 2. This amendment to the Amended and Restated Certificate of Incorporation as set forth herein has been duly approved by the required vote of stockholders of the Corporation in accordance with Sections 228 and 242 of the Delaware General Corporation Law.
- 3. The Amended and Restated Certificate of Incorporation is hereby amended by deleting the first two paragraphs of Article Fourth thereof and by substituting in lieu of said first two paragraphs of Article Fourth the following:

FOURTH: That, effective upon the filing of this Certificate of Amendment of the Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware (the "Effective Time"), a one-for-10.755 reverse stock split of each of the Corporation's Common Stock (as defined below) and Preferred Stock (as defined below) shall become effective, pursuant to which 10.755 shares of each of the Common Stock and Preferred Stock outstanding and held of record by each stockholder of the Corporation (including treasury shares) immediately prior to the Effective Time shall be reclassified and combined into one (1) share of Common Stock and one (1) share of Preferred Stock, respectively, automatically and without any action by the holder thereof upon the Effective Time and shall represent one (1) share of Common Stock and one (1) share of Preferred Stock, respectively, from and after the Effective Time (such reclassification and combination of shares designated as the "Reverse Stock Split"). Within 180 days following the Effective Time, the Corporation shall pay cash for any and all fractional shares issued as a result of the Reverse Stock Split in an amount equal to such fraction multiplied by the then fair market value of the Common Stock or Preferred Stock, as applicable, as determined by the Board of Directors of the Corporation.

Each stock certificate that, immediately prior to the Effective Time, represented shares of Common Stock or Preferred Stock, as applicable, that were issued and outstanding immediately prior to the Effective Time shall, from and after the Effective Time, automatically and without the necessity of presenting the same for exchange, represent that number of whole shares of Common Stock or Preferred Stock, as

applicable, after the Effective Time into which the shares formerly represented by such certificate have been reclassified pursuant to the Reverse Stock Split (as well as the right to receive cash in lieu of fractional shares of Common Stock or Preferred Stock, as applicable, after the Effective Time); provided, however, that each person of record holding a certificate that represented shares of Common Stock or Preferred Stock, as applicable, that were issued and outstanding immediately prior to the Effective Time shall receive, upon surrender of such certificate, a new certificate evidencing and representing the number of whole shares of Common Stock or Preferred Stock, as applicable, after the Effective Time into which the shares of Common Stock or Preferred Stock, as applicable, formerly represented by such certificate shall have been reclassified pursuant to the Reverse Stock Split.

The total number of shares of all classes of stock which the Corporation shall have authority to issue is (i) 120,000,000 shares of Common Stock, \$0.001 par value per share ("Common Stock"), and (ii) 88,000,000 shares of Preferred Stock, \$0.001 par value per share ("Preferred Stock").

The following is a statement of the designations and the powers, privileges and rights, and the qualifications, limitations or restrictions thereof in respect of each class of capital stock of the Corporation.

4. The Amended and Restated Certificate of Incorporation is hereby amended by deleting the last sentence of Article Fourth, Part C, Section 1 thereof and by substituting in lieu of said last sentence of Article Fourth, Part C, Section 1 the following:

The "Series A Original Issue Price" shall mean \$13.44375 per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Series A Preferred Stock.

5. The Amended and Restated Certificate of Incorporation is hereby amended by deleting the second sentence of Article Fourth, Part C, Section 4.1.1 thereof and by substituting in lieu of said second sentence of Article Fourth, Part C, Section 4.1.1 the following:

The "Series A Conversion Price" shall initially be equal to \$13.44375.

\*\*\*\*

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Amendment to be executed by its duly authorized officer this  $12\,^{th}$  day of January, 2011.

/s/ James Scibetta

Name: James Scibetta

Title: Chief Financial Officer and Secretary

016570| 003590|127C|RESTRICTED||4|057-423 COMMON STOCK COMMON STOCK PAR VALUE \$0.001 C PACIRA THIS CERTIFICATE IS TRANSFERABLE IN CANTON, MA AND NEW YORK, NY Certificate Shares \*\*600620\*\*\*\*\* Number \*\*\*600620\*\*\*\* \*\*\*\*600620\*\*\* \*\*\*\*\*600620\*\* ZQ 000000 PACIRA PHARMACEUTICALS, INC. INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE THIS CERTIFIES THAT MR. SAMPLE & MRS. SAMPLE & CUSIP 695127 10 0 MR. SAMPLE & MRS. SAMPLE SEE REVERSE FOR CERTAIN DEFINITIONS is the owner of \* \* \* SIX HUNDRED THOUSAND SIX HUNDRED AND TWENTY\* \* \* FULLY-PAID AND NON-ASSESSABLE SHARES OF THE COMMON STOCK OF Pacira Pharmaceuticals, Inc. (hereinafter called the "Company"), transferable on the books of the Company in person or by duly authorized attorney, upon surrender of this Certificate properly endorsed. This Certificate and the shares represented hereby, are issued and shall be held subject to all of the provisions of the Articles of Incorporation, as amended, and the Bylaws, as amended, of the Company (copies of which are on file with the Company and with the Transfer Agent), to all of which each holder, by acceptance hereof, assents. This Certificate is not valid unless countersigned and registered by the Transfer Agent and Registrar. Witness the facsimile seal of the Company and the facsimile signatures of its duly authorized officers. DATED <<Month Day, Year>> COUNTERSIGNED AND REGISTERED: COMPUTERSHARE TRUST COMPANY, N.A. TRANSFER AGENT AND REGISTRAR,

1234567

PACIRA PHARMACEUTICALS, INC.
THE COMPANY WILL FURNISH WITHOUT CHARGE TO EACH SHAREHOLDER WHO SO REQUESTS, A SUMMARY OF THE POWERS, DESIGNATIONS, PREFERENCES AND RELATIVE, PARTICIPATING, OPTIONAL OR OTHER SPECIAL RIGHTS OF EACH CLASS OF STOCK OF THE COMPANY AND THE QUALIFICATIONS, LIMITATIONS OR RESTRICTIONS OF SUCH PREFERENCES AND RIGHTS, AND THE VARIATIONS IN RIGHTS, PREFERENCES AND LIMITATIONS DETERMINED FOR EACH SERIES, WHICH ARE FIXED BY THE ARTICLES OF INCORPORATION OF THE COMPANY, AS AMENDED, AND THE RESOLUTIONS OF THE BOARD OF DIRECTORS OF THE COMPANY, AND THE RESOLUTIONS OF THE BOARD OF DIRECTORS OF THE COMPANY TO THE BOARD OF DIRECTORS TO DETERMINE VARIATIONS FOR FUTURE SERIES. SUCH REQUEST MAY BE MADE TO THE OFFICE OF THE SECRETARY OF THE COMPANY OR TO THE TRANSFER AGENT. THE BOARD OF DIRECTORS MAY REQUIRE THE COMPANY FOR DIRECTORS MAY REQUIRE THE OWNERS OF A LOST OR DESTROYED STOCK CIRTIFICATE, OR HIS LEGAL REPRESENTATIVES, TO GIVE THE COMPANY A BOND TO INDEMNIFY IT AND ITS TRANSFER AGENTS AND REGISTRARS AGAINST ANY CLAIM THAT MAY BE MADE AGAINST THEM ON ACCOUNT OF THE ALLEGED LOSS OR DESTRUCTION OF ANY SUCH CERTIFICATE.

according to applicable laws or regulations:		
TEN COM - as tenants in common	UNIF GIFT MIN ACT	- Custodian (Miner)
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January 13, 2011

Pacira Pharmaceuticals 5 Sylvan Way, Suite 125 Parsippany, NJ 07054



+1 650 858 6016(t) +1 650 858 6100(f) joe.wyatt@wilmerhale.com

Re: Registration Statement on Form S-1

Ladies and Gentlemen:

This opinion is furnished to you in connection with a Registration Statement on Form S-1 (File No. 333-170245) (the "Registration Statement") filed with the Securities and Exchange Commission (the "Commission") under the Securities Act of 1933, as amended (the "Securities Act"), for the registration of 4,887,500 shares of Common Stock, \$0.001 par value per share (the "Shares"), of Pacira Pharmaceuticals, Inc., a Delaware corporation (the "Company"), including 637,500 shares issuable upon exercise of an over-allotment option granted by the Company.

The Shares are to be sold by the Company pursuant to an underwriting agreement (the "Underwriting Agreement") to be entered into by and among the Company and Barclays Capital Inc. and Piper Jaffray & Co., as representatives of the several underwriters named in the Underwriting Agreement, the form of which has been filed as Exhibit 1.1 to the Registration Statement.

We are acting as counsel for the Company in connection with the issue and sale by the Company of the Shares. We have examined signed copies of the Registration Statement as filed with the Commission. We have also examined and relied upon the Underwriting Agreement, minutes of meetings of the stockholders and the Board of Directors of the Company as provided to us by the Company, stock record books of the Company as provided to us by the Company, the Certificate of Incorporation and Bylaws of the Company, each as restated and/or amended to date, and such other documents as we have deemed necessary for purposes of rendering the opinions hereinafter set forth.

In our examination of the foregoing documents, we have assumed the genuineness of all signatures, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted to us as copies, the authenticity of the originals of such latter documents and the legal competence of all signatories to such documents.

We express no opinion herein as to the laws of any state or jurisdiction other than the General Corporation Law of the State of Delaware and the federal laws of the United States of America.

Based upon and subject to the foregoing, we are of the opinion that the Shares have been duly authorized for issuance and, when the Shares are issued and paid for in accordance with the terms and conditions of the Underwriting Agreement, the Shares will be validly issued, fully paid and nonassessable.

Wilmer Cutler Pickering Hale and Dorr LLP, 950 Page Mill Road, Palo Alto, CA 94304

Beijing Berlin Boston Brussels Frankfurt London Los Angeles New York Oxford Palo Alto Waltham Washington

## WILMERHALE

January 13, 2011 Page 2

Please note that we are opining only as to the matters expressly set forth herein, and no opinion should be inferred as to any other matters. This opinion is based upon currently existing statutes, rules, regulations and judicial decisions, and we disclaim any obligation to advise you of any change in any of these sources of law or subsequent legal or factual developments which might affect any matters or opinions set forth herein.

We hereby consent to the filing of this opinion with the Commission as an exhibit to the Registration Statement in accordance with the requirements of Item 601(b)(5) of Regulation S-K under the Securities Act and to the use of our name therein and in the related Prospectus under the caption "Legal Matters." In giving such consent, we do not hereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission.

Very truly yours,

WILMER CUTLER PICKERING HALE AND DORR LLP

By: /s/ Joseph K. Wyatt

Joseph K. Wyatt, a Partner

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

DATED 30th JUNE 2003

SKYEPHARMA INC

and

MUNDIPHARMA MEDICAL COMPANY

SUPPLY AGREEMENT

#### THIS AGREEMENT is made on 30th 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

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 ox 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

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;

means Skye making available at the Packaging Facility the Product for collection by Mundipharma or its nominated carrier,

means that date upon which the Product is available for collection from the Packaging Facility;

means the distribution agreement in relation to the Product between Skye and Mundipharma International Holdings Limited;

means the European Medicines Evaluation Agency or any successors thereto;

"Delivery"

"Delivery Date"

"Distribution Agreement"

"EMEA"

**"Equipment"** means the equipment used in the Manufacture, assembly, Packaging, analysis and testing of the Product;

"Finished Product" means Product presented in Vials, packaged and labelled for sale to end users;

"Intellectual Property" 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;

"Manufacture" 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;

"Manufacturing Approval" means all necessary or appropriate approvals, licences, permits, registrations and authorisations in respect of the

Manufacture and Quality Control of the Product;

"Manufacturing Licence" means any licence as granted by the Regulatory Authority to Skye or the Third Party Manufacturer in the

applicable territory to Manufacture the Product;

"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

"Net Sales"

"Packaging"

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, sublicensees 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;

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;

"Product"

means the Depofoam formulation of cytarabine (a sustained release formulation of cytarabine (ara-C) a pyrimidine

analogue (L01BC01)) made to the Specification;

"Product Price"

means [\*\*] Euros per Vial of Finished Product;

"Qualified Person"

means a Qualified Person as defined in European Directive 2001/83/EC;

"Quality Control"

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;

means any three month period ending on the last day of March, June, September or December in any calendar

year;

"Raw Materials"

means all raw materials required to produce the Product;

"Regulatory Authority"

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;

"Release"

"Quarter"

means release of the Finished Product from the Packaging Facility to Mundipharma for sale;

"Specification"

means the specification of the Product as set out in the Appendix;

"Technical Agreement" means the technical agreement between the parties relating to the Manufacture of the Product to be agreed in good

faith;

"Term" means the term of this Agreement as set out in Clause 9;

"Third Party Manufacturer" means a third party appointed by Skye to Manufacture the Product on its behalf; and

"Vial" 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.

#### 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.

#### 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 IA 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

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.

- 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

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.

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;

- 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

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.

### 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.

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.

#### 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.

#### 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:

<u>To Mundipharma</u> <u>To Skye</u>

Address: Mundipharma House, Address: 10450 Sciences Center

14 Par-la-Ville Road, Drive, San Diego, P.O. Box HM 2332, California 92121 USA

Hamilton, HM JX,

Bermuda

Attention: General Manager Attention: President

Copy To: Christopher B. Mitchell Solicitors, Copy To: Skye Legal Department,

15 North Audley Street, 105 Piccadilly, London

London W1V9FN W1K 6WZ

Fax: +44 20 7408 0714 Fax: +44 20 74913338

#### 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;

- 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.

- 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	) /s/ Michael R. D Ashton
SKYEPHARMA INC	
	)
	MICHAEL R. D ASHTON
	Print Name
SIGNED for and by behalf of	) /s/ James M. Keyes
MUNDIPHARMA MEDICAL	
COMPANY	)
	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	[**]		[**]
рН	[**]	[**]	[**]
Particle Size	[**]		[**]
	[**]		
Uracil Arabinoside	[**]	[**]	[**]
Cytosine	[**]		
Cytidine	[**]		
Uridine	[**]		
Uracil	[**]		
Total Cytarabine Related Impurities			
(Excluding Uracil Arabinoside)	[**]	[**]	[**]
Cholesterol	[**]	[**]	[**]
Trioleln	[**]	[**]	[**]
DPPG*	[**]	[**]	[**]
DOPC**	[**]	[**]	[**]
Lyso DOPC**	[**]	[**]	[**]
Sodium		[**]	[**]
Chlorides		[**]	[**]

<sup>\*</sup> DPPG -1,2-Dipalmitoyl-*sn*-glycero-3-phosprio-*rac*-(1 -glycerol)

<sup>\*\*</sup> DOPC - 1,2-Dieleoyl-*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)	[**]	[**]	[**]
	[**]	[**]	
In Vitro Release Assay:			[**]
day-0			
day-1	[**]	[**]	
day-2	[**]	[**]	
day-3	[**]	[**]	
day-4	[**]	[**]	
Sterility	[**]		[**]
Bacterial Endotoxins	[**]		[**]

<sup>\*</sup> DPPG -1,2-Dipalmitoyl-*sn*-glycero-3-phosprio-*rac*-(1 -glycerol)

LT Less than MT More than NMT Not more than

<sup>\*\*</sup> DOPC - 1,2-Dieleoyl-*sn*-glycero-3-phosphocholine

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

# DATED 30th JUNE 2003

## SKYEPHARMA INC

and

# MUNDIPHARMA INTERNATIONAL HOLDINGS LIMITED

DISTRIBUTION AGREEMENT

1

#### THIS AGREEMENT is made on 30th 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**

#### **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"

"Applicable Laws"

"Commercial Delivery"

"Competing Product"

"Confidential Information"

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;

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;

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;

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;

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;

- (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;
- 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;

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;

means the date of this Agreement;

means the European Medicines Evaluation Agency or any successors thereto;

means The Food and Drug Administration of the United States of America or any successor thereto;

means the intrathecal treatment of malignant disease (including without limitation lymphomatous meningitis and, if an approved indication, the treatment of neoplastic meningitis);

1

"EEA"

"Effective Date"

"EMEA"

"FDA"

"Field"

"Finished Product"

"Force Majeure"

"Improvements"

"Intellectual Property"

"Know-How"

means Product presented in Vials, packaged and labelled for sale to end users;

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;

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);

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;

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;

"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 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;

"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;

"Milestone Event"

means the event identified in Schedule III which triggers a one-off Milestone Payment;

"Milestone Payment"

means each one-off payment by Mundipharma to Skye identified in Schedule III which is triggered by a

Milestone Event;

"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
- (f) amounts repaid or credited (other than in respect of outdated goods) for rejected, returned or recalled goods;

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;

"Patents"

"Phase IV Trial" means the phase IV clinical trial entitled Skye 0101-010;

"Regulatory Approval"

"Skye IP"

"Pricing Approval" means grant of all necessary pricing and reimbursement approvals by a regulatory, governmental or non-

governmental authority in any country of the Territory;

"Product" means the Depofoam formulation of cytarabine (a sustained release formulation of cytarabine (ara-C) a

pyrimidine analogue (L01BC01));

"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 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 Year;

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;

"Regulatory Authority" 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;

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);

"Skye Patents" 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);

"Skye Technology" means the Skye Patents and Skye IP;

"Supply Agreement" means the agreement between Skye and Mundipharma Medical Company for the manufacture and supply of the

Finished Product by Skye;

"Term" means the term of this Agreement as set out in Clause 15;

"Territory" means each of the countries and territories listed or referred to in Schedule VII;

"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; and

"Year" 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.

#### 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.

- 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

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

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.

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.

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;

- 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;

- 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.".

- 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

- 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

Supply Agreement shall be [\*\*] Euros ( $\varepsilon$ [\*\*]) 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

- 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

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

EMEA 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 EMEA.
- 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

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.

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

- 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.

- 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.
- 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

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;

- 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 preclinical 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

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

- 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.
- 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

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

- 10.7.2 a reasonable level of self-insurance.
- 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 ( $\mathbb{C}[**]$ ).
- 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.
- 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.

## 11 Confidentiality, Press Releases and Publications

- 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.
- 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.
- 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.
- 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

- 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.
- 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.

## 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 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 fifteen (15) years and shall continue thereafter from year to year unless terminated by either party giving to the other no less than twelve (12) months prior written notice expiring on or after the fifteenth anniversary of the Effective Date.

## 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

- 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
- 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,.
- 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.
- 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;
  - 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

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

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:

<u>To Mundipharma</u> <u>To Skye</u>

Address: Mundipharma House, Address: 10450 Sciences Center

14 Par-la-Ville Road, Drive, San Diego, P.O. Box HM 2332, California 92121

Hamilton, HM JX, USA

Bermuda

London

W1K 6W

**Attention:** General Manager **Attention:** President 2

Copy To: Christopher B. Mitchell Solicitors, Copy To: Skye Legal Department,

15 North Audley Street, 105 Piccadilly, London

W1V 9FN

Fax: +44 20 7408 0714 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.

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

- 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.

- 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.
- 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.
- 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.

- 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.
- 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.
- 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/ Michael R.D. Ashton
SKYEPHARMA INC )	
)	
	Michael R.D. Ashton
	Print Name
SIGNED for and by behalf of )	/s/ James M. Keyes
MUNDIPHARMA INTERNATIONAL )	
HOLDINGS LIMITED )	
	James M. Keyes
	Print name

# SCHEDULE I

# **PATENTS**

Patent entitled "[\*\*]"

Country	Filing date	Application no.	Grant date	Publication no.	Status
Norway	[**]	[**]	[**]	[**]	[**]
Sweden	[**]	[**]	[**]	[**]	[**]
Italy	[**]	[**]	[**]	[**]	[**]
Luxembourg	[**]	[**]	[**]	[**]	[**]
Netherlands	[**]	[**]	[**]	[**]	[**]
Portugal	[**]	[**]	[**]	[**]	[**]
United Kingdom	[**]	[**]	[**]	[**]	[**]
Denmark	[**]	[**]	[**]	[**]	[**]
Belgium	[**]	[**]	[**]	[**]	[**]
Ireland	[**]	[**]	[**]	[**]	[**]
Germany	[**]	[**]	[**]	[**]	[**]
EPO	[**]	[**]	[**]	[**]	[**]
Spain	[**]	[**]	[**]	[**]	[**]
Finland	[**]	[**]	[**]	[**]	[**]
France	[**]	[**]	[**]	[**]	[**]
Austria	[**]	[**]	[**]	[**]	[**]
Greece	[**]	[**]	[**]	[**]	[**]
Switzerland	[**]	[**]	[**]	[**]	[**]
Liechtenstein	[**]	[**]	[**]	[**]	[**]

# SCHEDULE II

# TRADE MARKS

No.	Owner	Trade Mark	Country	Class(s)	Reg/App No.	Status
1.	[**]	[**]	[**]	[**]	[**]	[**]
2.	[**]	[**]	[**]	[**]	[**]	[**]
3.	[**]	[**]	[**]	[**]	[**]	[**]
4.	[**]	[**]	[**]	[**]	[**]	[**]

# SCHEDULE III

# MILESTONE PAYMENTS

Mundipharma shall pay Skye the following one-off milestone payments.

No.	Milestone Event	Milestone Payment
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 $\mathfrak{E}[**]$ 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 $\{\ell\}^*$ per Vial.	€[**]

## **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 reported 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

- · 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.

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.

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)

# 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

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

	Minimum Aggregate Net Sales
Marketing Year	in Territory (millions)
[**]	€[**]
[**]	$\epsilon$ [**]
[**]	€[**]
[**]	€[**]

# B. Neoplastic Indication granted by EMEA by the end of Year 2

	Minimum Aggregate Net Sales
Marketing Year	in Territory (millions)
[**]	$\epsilon$ [**]
[**]	€[**]
[**]	$\epsilon$ [**]
[**]	€[**]

# C. Neoplastic Indication granted by EMEA by the end of Year 3

	Minimum Aggregate Net Sales
Marketing Year	in Territory (millions)
[**]	€[**]
[**]	€[**]
[**]	€[**]
[**]	€[**]

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.

Not For release - <u>DRAFT 4</u> \*\* June, 2003

# European marketing rights for DepoCyte®

## 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 DepoCyte®, 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 €4.25 million on signature plus additional milestone payments that may amount in total to €10.75 million. 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 DepoCyte \*. Mundipharma shares our view that lymphomatous meningitis is both under-diagnosed and under-treated and that DepoCyte \* offers great potential to bring relief of suffering from this devastating complication of cancer. We look forward to working together."

DepoCyte® (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 \*/DepoCyte\* 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 \*/DepoCyte\* 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

Nippon-Sbinyaku in 2001 although the product is not yet on the market. DepoCyte \* was approved by the European Medicines Evaluation Authority in August 2001. European marketing and distribution rights for DepoCyte \* 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<sup>TM</sup>

DepoFoam<sup>TM</sup> 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<sup>TM</sup> 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®/DepoCyte® 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.

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 17777

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

# 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

### 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.

- 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.

# **DATED** July 27, 2005

# SKYEPHARMA INC

and

# MUNDIPHARMA INTERNATIONAL HOLDINGS LIMITED

**DISTRIBUTION AGREEMENT** (Depocyte - Additional Territories)

# THIS AGREEMENT is made on July 27, 2005

## **BETWEEN**

- 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;

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 th 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

"Applicable Laws"

"Commercial Delivery"

"Competing Product"

"Confidential Information"

maximum percentage permitted, provided such percentage is no less than 30%) of such company, corporation, firm, individual, trust or other entity;

means all laws, rules, regulations and codes of practice regarding the representation, promotion and marketing of the Product in any jurisdiction in the Territory;

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;

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;

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;
- (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;

- 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;
- (e) received from Third Parties who were lawfully entitled to disclose such information;

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;

means the date of this Agreement;

means the European Medicines Evaluation Agency or any successors thereto;

means the intrathecal treatment of malignant disease (including without limitation lymphomatous meningitis and, if an approved indication, the treatment of neoplastic meningitis);

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

"EEA"

"Effective Date"

"EMEA"

"Field"

"Finished Product"

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);

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;

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);

means Patents, Trade Marks, service marks, logos, trade names, rights in designs, copyright, utility models, rights in Know-How and other intellectual

"Force Majeure"

"Improvements"

"Intellectual Property"

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;

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"

"Know-How"

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

"Marketing Plan"

"Neoplastic Indication"

"Net Sales"

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;

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;

means the use of the Product for the treatment of neoplastic meningitis;

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

"Patents"

"Pricing Approval"

"Product"

"Product Data"

"Quarter"

(f) amounts repaid or credited (other than in respect of outdated goods) for rejected, returned or recalled goods;

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;

means grant of all necessary pricing and reimbursement approvals by a regulatory, governmental or non-governmental authority in any country of the Territory;

means the DepoFoam formulation of cytarabine (a sustained release formulation of cytarabine (ara-C) a pyrimidine analogue (L01BC01));

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;

means a three month period ending on the last day of March, June, September or December in any Year;

"Regulatory Approval" 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:

"Regulatory Authority" means any competent regulatory authority or other governmental body responsible for granting Regulatory

Approval in the Territory;

"Skye IP" 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);

"Skye Patents" 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);

"Skye Technology" means the Skye Patents and Skye IP;

"Supply Agreement" means the agreement between Skye and Mundipharma Medical Company dated 30 th June 2003 for the

manufacture and supply of the Finished Product by Skye;

"Term" means the term of this Agreement as set out in Clause 15;

"Territory" means each of the countries and territories listed or referred to in Schedule IV;

"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; and

"Year" 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.

# 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.

- 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.

# 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

- 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;

- 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;

- 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 \* is distributed by Mundipharma under an exclusive licence from SkyePharma Inc.".

- 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.

- 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,

packaging and supply of the Finished Product, Mundipharma agrees that the supply price under the Supply Agreement shall be [\*\*] Euros  $(\epsilon[**])$  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

- 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.

- 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

- 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.

- 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

- 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

- 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 preclinical 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.

# 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.

- 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.

- 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 ( $\epsilon$ [\*\*]).

- 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 ( $\epsilon$ [\*\*]).
- 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.

- 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

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.

# 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

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

- 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.

- 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;

- 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.

# 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 To Skye

Mundipharma House,Address:10450 Sciences14 Par-la-Ville Road,Center Drive,P.O. Box HM 2332,San Diego,Hamilton, HM JX,California 92121

Bermuda USA

**Attention:** General Manager **Attention:** President

Copy To: Christopher B. Mitchell Copy To: Skye Legal Department,

Solicitors, 15 North 105 Piccadilly,
Audley Street, London
London, W1J7NJ
W1K6WZ

Fax: +44 20 7408 0714 Fax: +44 20 7491 3338

# 20. Assignment and Change of Control

Address:

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.

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.

- 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.

- 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**

	~			Application		Grant	
SkyePharma reference	Country	Status	Filing Date	number	Grant Date	number	
[**]	[**]	[**]	[**]	[**]	[**]	[**]	
. ,		. ,		. ,	. ,		

# SCHEDULE II

# TRADE MARKS

				Registration	Registration
Country	Status	Filing Date	Application No.	Date	No.
[**]	[**]	·	[**]	[**]	[**]
[**]	[**]		[**]	[**]	[**]
[**]	[**]	[**]	[**]		
[**]	[**]		[**]	[**]	[**]
	[**]		[**]	[**]	[**]
	[**]		[**]	[**]	[**]

#### 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.

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.

# 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

## 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.

# DATED: OCTOBER 15, 2009

# PACIRA PHARMACEUTICALS, INC.

and

# EKR THERAPEUTICS, INC.

# AMENDED AND RESTATED STRATEGIC LICENSING, DISTRIBUTION AND MARKETING AGREEMENT

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

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**

## l. <u>Definitions</u>

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 with the food of the Products including but not limited to the Federal Food with the food of the Products including but not limited to the Federal Food with the food wit
"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 Article 5;

A

"Competing Product"

"Confidential Information"

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;

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 knowhow, (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:

- (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 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 Schedule III, (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 "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 "Distribution Rights" Shall have the meaning set forth in <u>Section 2.1</u> hereof;

Shall mean Depodur.com and any other domain names owned or licensed by PPI related to the Product set forth on

Schedule IV hereto;

"Domain Name"

"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 Injectible Liposomal Epidural 10 mg/ml NDC # [\*\*]; and (ii) DepoDur Injectible 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;

"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;

"Marketing Authorization"	Means the new drug application ("NDA") 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> ;

"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;

"PPI IP"

"PPI Know-How"

"PPI Patents"

Means the Copyrights, PPI Know-How, PPI Patents and PPI Improvements; and PPI's interest in Joint Improvements;

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;

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;

"Product(s)" Means: (i) DepoDur Injectible Liposomal Epidural [\*\*] mg/ml [\*\*]; (ii) DepoDur Injectible 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);

"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 Schedule II;

"Transition Services and

Means that certain Transition Services and Inventory Agreement entered into between the Parties on the Effective Date;

Inventory Agreement"
"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

- (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 <u>Grant of License and Distribution Rights</u>. 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 <u>Grant of Trademark Rights.</u> 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

purposes of <u>Sections 2.1, 2.2</u> and <u>2.3</u> 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 <u>Condition of Appointment</u>. 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. <u>Undertakings of PPI</u>

- 3.1 <u>Manufacturing Activities</u>. Subject to <u>Section 17.5</u>, 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 <u>Transfer of Transferred NDA</u>. 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 <u>Schedule XI(A)</u> or <u>Schedule XI(B)</u> (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

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.
- 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 subcontractors 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

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 <u>Delivery of Materials</u>. 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.

- 3.8 <u>Customer Orders.</u> 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 <u>Payment of Third Party Royalties</u>. 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 <u>Customer Returns.</u> 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.

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 – Graham May, *MD - CMO*PPI – Gary Patou, *MD - CMO* 

- 3.15 Reserved.
- 3.16 <u>Recalls and PostMarket Notifications</u>. 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 <u>Assignment of ICS Agreement</u>. The Parties acknowledge that effective upon the termination or expiration of the Transition Services and Inventory Agreement, PPI has

- 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.
- 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 <a href="Schedule XII">Schedule XII</a> (the "Transferred Equipment"). The

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

- 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 <u>Section 17.5</u> 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

- 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

- 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.
- (I) 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.

## 4. <u>Undertakings of EKR.</u>

- 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 <u>Liaison with Regulatory Authorities</u>. Pursuant to <u>Section 4.1</u> 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;

- 4.3 <u>Submission of Promotional Materials</u>. Pursuant to <u>Section 4.1</u> 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 <u>Pre-Launch and Post Launch Activities</u>. Pursuant to <u>Section 4.1</u> 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 <u>Launch of Products</u>. Pursuant to <u>Section 4.1</u> 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 <u>Marketing Activities</u>. 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 <u>SubDistributors</u>. EKR shall at its own cost and expense maintain, or use reasonable commercial efforts to ensure that sub-distributors maintain, adequate sales and, where

- 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 <u>Inventory and Promotional Materials</u>. 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 <u>Section 17.5</u>, 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 <u>Promotional Materials</u>. 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

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 <u>Compliance</u>. 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;

- (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 <u>Prohibition on Sales Outside the Territory.</u> 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 <u>PPI as Exclusive Provider</u>. 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 <u>Section 17.5</u> below) or as provided in the Supply Agreement, EKR shall purchase all of its requirements for the Product from PPI
- 4.18 <u>Packaging.</u> 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

- 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 <u>Section 4.10</u>, 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 <u>Customer Orders.</u> 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 <u>Governmental Rebates</u>. 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. <u>Commercialization Committee</u>.

5.1 <u>Establishment of Committee</u>. 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.

- 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.
- 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 to 2009 and October 15 to 6 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 <u>Decision Making</u>. 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

- 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 <u>Up-Front Payment</u>. 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 <u>Deferred Milestone Payments</u>. 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:

Deferred Milestone	Due Date
\$[**] (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:
  - 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;

- (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 <u>Section 20.4</u>) 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.

- (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 it 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.

- (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.
- Royalty: 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.

- 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 <u>Section 6.4</u>, and any deductions taken pursuant to <u>Section 6.3</u>.
- 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 <u>Reconciliation</u>. Within forty-five (45) days of the end of each Contract Year, there shall be a reconciliation between the sums paid under <u>Section 6.6</u> and the Royalties payable under <u>Section 6.4</u>, 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.

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 <u>Currency</u>. 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 <u>Maintenance of Records</u>. 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 <u>Inspection</u>. 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

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 <u>Confidentiality.</u> PPI shall procure that any independent auditor appointed under <u>Section 7.4</u> 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. <u>Intellectual Property and Trademarks</u>.

8.1 <u>Limitation of License</u>. 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.

- 8.2 <u>Trademark Standards</u>. 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 <u>Maintenance of Trademarks</u>. 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 <u>Domain Names</u>. 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 <u>Improvements</u>. 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.

### 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) <u>Organization</u>. 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) <u>Authorization</u>. 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) <u>Valid Obligation</u>. 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) <u>Execution and Delivery</u>. 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) <u>Debarment.</u> 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.

- 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) <u>Third Party Interests</u>. 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) <u>Distribution Rights and other Rights.</u> 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

- 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) <u>Trademarks</u>. 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) <u>Right to License</u>. 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) <u>Litigation</u>. 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

- 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. <u>Liability, Insurance and Indemnities</u>

- 10.1 <u>Indemnification of EKR</u>. 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);

- (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(1) 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.

- 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 <u>Section 10.1</u> above.

- 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 <u>Assumption of Defense</u>. 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).

- 10.5 <u>Settlement of Claims</u>. 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.
- 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

- 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 <u>Limitation of Damages</u>. 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 <u>Section 7.2.12</u> of the Supply Agreement.
- 10.11 <u>Definition of Claims</u>. In this <u>Section 10</u>, "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 <u>Confidential Information</u>. 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.

- 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 <u>Duration</u>. 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 <u>Public Announcements</u>. 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 <u>Schedule VI</u> 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 <u>Maintenance</u>. 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

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. <u>Infringement of Third Party Rights</u>

- 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 <u>Infringement of Third Party IP</u>. 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 <u>Infringement Indemnification.</u> Notwithstanding any other provisions of this Agreement, PPI will defend, indemnify and hold harmless the EKR Infringement

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. <u>Infringement of PPI IP</u>

- 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.

- 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 <u>Cooperation</u>. Each Party shall keep the other Party reasonably informed and consult with the other Party with regard to any infringement action under this <u>Article 14</u>.

### 15. <u>Term</u>

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.

### 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

- (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 <u>Section 18.2</u> 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)

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 <u>Effect of Termination</u>. 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 <u>Section 17.4</u> 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 <u>Sections 2.1</u>, <u>2.2</u> and <u>2.3</u> 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 <u>Sections 17.2</u> and <u>17.3</u>;

- (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 <u>Sale of Remaining Inventory.</u> Where this Agreement has expired or has been terminated for any reason other than by PPI in accordance with <u>Section 16.1</u> or EKR in accordance with <u>Section 16.3(b)</u>, 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

- 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.
- 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.

#### 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

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.

18.2 <u>Duration</u>. 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 <u>Delivery</u>. 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.

19.3 <u>Notice of Parties</u>. The address for services of notices and other documents on the Parties shall be:

To EKR To PPI

Address: 1545 Route 206 South Address: 10450 Science Center

Third Floor

Fax:

Bedminster, NJ 07921 California 92121 USA

Fax: 858 623 0376

Attention: Chairman & CEO Attention: President

With a copy to: With a copy to:

Lowenstein Sandler Wilmer Cutler Pickering Hale & Dorr LLP 65 Livingston Avenue 1117 S California Avenue

 Fax:
 973-597-6395
 Fax:
 650-858-6100

 Attention:
 Michael J. Lerner
 Attention:
 Joseph K. Wyatt

# 20. Assignment and Change of Control

Roseland, New Jersey 07068

20.1 <u>Assignment.</u> Subject to <u>Section 20.2</u>, 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; <u>provided, however</u>, that except as provided in <u>Section 20.4</u> 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 <u>Sub-Distribution</u>. 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;

Drive, San Diego,

Palo Alto, CA 94304 USA

- (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 <a href="Article 11">Article 11</a> 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 <u>Responsibility of EKR</u>. 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 <u>Relationship of the Parties.</u> 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 <u>Dispute Resolution</u>. 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 <u>Schedule VIII</u>.
- 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 <u>Expenses</u>. Each Party shall pay its own costs, charges and expenses incurred in connection with the negotiation, preparation and completion of this agreement.
- 21.5 <u>Entire Agreement</u>. 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 <u>Amendment</u>. 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 <u>Unenforceability</u>. 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.

- 21.10 <u>Cumulative Rights</u>. 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 <u>Counterparts</u>. 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 <u>Successors and Assigns</u>. Subject to <u>Section 20.1</u>, 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)

AS WITNESS the hands of the Pa	rties or their duly authorized representatives effective a	as of the Effective Date.
SIGNED for and by behalf of	)	By: /s/ David Stack
PACIRA PHARMACEUTICALS, INC.	)	
		David Stack Print Name
SIGNED for and by behalf of EKR THERAPEUTICS, INC.	)	By: /s/ Richard DeSimone
ERR THERAFEUTICS, INC.		Richard DeSimone, CFO Print Name

### SCHEDULE I

### **PATENTS**

				[**]			
Attorneys'		Application	Application	Patent/			
Ref:	Country	date	no.	Publication no.	Grant date	Expiry date	Status
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]							
Attorneys'		Application	Application	Patent/			
Ref:	Country	date	no.	Publication no.	Grant date	Expiry date	Status
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
				[**]			
				Patent/			
Attorneys'		Application	Application	Publication			
Ref:	Country	date	no.	no.	Grant date	Expiry date	Status
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]				[**]
[**]	[**]						[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
				[**]			
Attorneys'		Application	Application	Patent/			
Ref:	Country	date	no.	Publication no.	Grant date	Expiry date	Status
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]				[**]

[	*	*	]

Attorneys'		Application	Application	Patent/ Publication				
Ref:	Country	date	no.	no.	Grant date	Expiry date	Status	
[**]	[**]	[**]	[**]	[**]		[**]	[**]	
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	
* Publication	on date of Applicati	ion – 13 Apr 06.						

[\*\*]

				L J				
Attorneys'		Application	Application	Patent/				
Ref:	Country	date	no.	Publication no.	Grant date	Expiry date	Status	
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	
[**]	[**]	[**]	[**]	[**]	[**]	[**]	[**]	

#### 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.

#### SCHEDULE III

#### COPYRIGHTS

There are no recorded copyrights

### SCHEDULE IV

#### DOMAIN NAMES

DepoDur.com

#### 

#### MARKETING AUTHORIZATIONS

United States Food and Drug Administration New Drug Application: [\*\*]

# **EKR**THERAPEUTICS

#### 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<sup>TM</sup> and Biosphere<sup>TM</sup> 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."

"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 \$20 million.

#### **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 <a href="http://www.ekrtx.com">http://www.ekrtx.com</a>.

#### 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 <a href="http://www.pacira.com">http://www.pacira.com</a>

####

Contact for EKR Therapeutics Stuart Z. Levine, Ph.D. Corporate Communications 877-435-2524 s.levine@ekrtx.com

#### 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

#### 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.

- 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>	Unit Sales Forecast
August 1 – December 31, 2007	[**]
January 1 – December 31, 2008	[**]
January 1 – December 31, 2009	[**]

#### SCHEDULE X

#### PHASE IV STUDIES

A DepoDur study in pediatric patients. Pacira has requested a waiver and is awaiting a response from the FDA

#### SCHEDULE XI

#### NDA TRANSFER LETTERS

PACIRA PHARMACEUTICALS, INC.

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] DepoDur® NDA [\*\*] General Correspondence: Transfer of NDA Ownership \_\_\_\_\_, 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,

-80-

B. Fransier Letter to be Flied by EKK
[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]

#### 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. <u>Definitions</u>. 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. <u>Conveyance</u>. 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 <u>Schedule A</u> to this Bill of Sale.
- 3. <u>Further Assurances</u>. 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. <u>Successors and Assigns</u>. 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. <u>Counterparts</u>; <u>Facsimile Signature Pages</u>. 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]

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:				

#### 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. <u>Payments</u>. On the fifth anniversary of the date of this Note, all principal and interest (calculated according to <u>Paragraph 3</u> below) accrued on this Note and not sooner paid in accordance with the terms hereof shall be payable in full (the " **Payment**").
- 2. <u>Place of Payment</u>. 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. <u>Defaults</u>. 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;

- (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 _	<del>.</del>
_	
-	, 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 <u>Appendix 2</u>, as such specifications may be amended pursuant to <u>Section 2.4</u> 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 <u>Section 2.11</u> 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 <u>Section 2.3.6</u> 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 <a href="Schedule VIII">Schedule VIII</a> 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 <u>Section 2.11</u> 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 (<u>i.e.</u>, 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, Trycaprilyn 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, Trycaprilyn 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 of Backup Raw Material Suppliers for DOPC, Trycaprilyn 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 <u>Section 3.2.3</u>, 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 <u>Section 3.2.12</u> 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 <u>Appendix 1</u>. 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 <u>Section 4</u>.
- 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

- 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: Patricia Brady

Senior Manager, Supply Operations

For Company: Susan Bacso

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.
- **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 <u>Schedule VIII</u> 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.
- 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 <u>Section 10</u> 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.
- 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 <u>Section 17.4</u> 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 knowhow 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 <a href="Schedule VIII">Schedule VIII</a> 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)

			~ ~		
PACIR	$\Delta X_T$	HKR	CONE	DENTIAL	

IN WITNESS WHEREOF this Agreement has been signed on behalf of the Parties hereto effective as of the Effective Date.

# EKR THERAPEUTICS, INC.

# PACIRA PHARMACEUTICALS, INC. (F/K/A SKYEPHARMA, INC.)

By:	/s/ Richard DeSimone	By:	/s/ David Stack
Print Name:	Richard DeSimone	Print Name:	David Stack
Title:	CFO	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

# STRATEGIC MARKETING AGREEMENT

THIS AGREEMENT is made on this 25th 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.

"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; means the date of the first sale to a Third Party customer for commercial use of Product in a country within the Territory "Commercial Delivery" following the grant of Marketing Authorisation(s) in that country and any necessary Pricing Approval being given in that "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; means all confidential information, data and materials in whatever form disclosed by or on behalf of one party or its "Confidential Information"

Affiliates to the other party or its Affiliates including, without

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;

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.

means the date upon which this Agreement commences, namely the \_\_\_ of September, 2007;

means the European Medicines Evaluation Agency or any successors thereto;

"Control"

"Effective Date"

"EMEA"

"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;

"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;

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:

"Net Sales"

- following amounts actually deducted or allowed:

  (i) transport, freight and insurance costs (including for cross border movement of bulk shipments and local distribution
- (ii) sales and excise taxes and duties;

within any country of the Territory);

(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;

"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<sup>TM</sup> 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;

"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.

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.

#### 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.

- 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

- (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;

- 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;

- 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;

- 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.

- 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.

- 4.4 Flynn Pharma shall within 45 days of the Effective Date, and on or before October 15 th 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.

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

- 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

- 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

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.
- 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.

	Minimum Total		[**]% payable		[**]% payable on	
Market	Fee for each country		on signing for each country		MA approval for each country	
France	€	[**]	€	[**]	€	[**]
Germany	€	[**]	€	[**]	€	[**]
Italy	€	[**]	€	[**]	$\epsilon$	[**]
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

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.

## 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.

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.

- 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.

#### 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.

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
  - 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);
  - 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);

- 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
- 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

- 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.
- 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

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 ( $\mathcal{E}$ [\*\*]).

- 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.

- 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

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.

- 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

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

- 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;

- 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.

## 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 To Pacira

2nd Floor10450 Sciences Center Drive,The MakingsSan Diego, California 92121Bridge StreetUSAHitchin

 Fax: +44 146 245 0755
 Fax: +858 623 0376

 Attention: President
 Attention: President

with a copy to:with a copy to:Roiter Zucker SolicitorsCohen Tauber Spievack & Wagner LLPRegent House420 Lexington Ave., Suite 24005-7 Broadhurst GardensNew York, NY 10170Swiss Cottage, London NW6 3RZUSA

**Fax:** +44 20 7328 9111 **Fax:** + 212 586 5095

Attention: Alia Hares Attention: Y. Jerry Cohen, Esq.

## 20 Assignment and Change of Control

Hertfordshire SG5 2DE

**ENGLAND** 

- 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

- 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.

- 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.

- 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

AS WITNESS the hands of the parties or their duly authorised representate	tives the	day and the year first above written.
SIGNED for and by behalf of <b>PACIRA PHARMACEUTICALS, INC.</b>	) )	/s/ Mark A. Walters
		Mark A. Walters V.P. Business & Commercial Development Print Name and Title
SIGNED for and by behalf of FLYNN PHARMA LIMITED	) )	
		Print Name and Title

$\boldsymbol{AS\ WITNESS}\ the\ hands\ of\ the\ parties\ or\ their\ duly\ authorised\ representation of\ the\ parties\ or\ their\ duly\ authorised\ representation\ of\ the\ parties\ or\ the$	ives the	day and the year first above written.
SIGNED for and by behalf of <b>PACIRA PHARMACEUTICALS, INC.</b>	) )	
SIGNED for and by behalf of FLYNN PHARMA LIMITED	)	/s/ David Fakes
	,	D W Fakes, Director Print Name and Title

# SCHEDULE I

# PACIRA PATENTS

## **Granted Patents**

Patent Applications

Number	Country	Matter
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
[**]	[**]	[**]
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# SCHEDULE II

# TRADE MARKS

				Trademark	Registration
Trademark	Country	Class	Status	No.	Date
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
L J	[ ]	L J	[ ]	[ ]	L J
[**]	[**]	[**]	[**]	[**]	[**]
				Trademark	Registration
Trademark	Country	Class	Status	No.	Date
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L J	L J	L J	L J	L J	L J
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- [**]	[**]	[**]	[**]	[**]	[**]
L J	[ ]	L J	[ ]	[ ]	L J
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
LJ	L J	L J	r 1	r 1	r j
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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)

<u>Detailed Forecast</u>. 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.

<u>Firm Purchase Requirement</u>. 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.

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.

## 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

#### 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.

- 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.

## PACIRA PHARMACEUTICALS, INC.

### INDEMNIFICATION AGREEMENT

This Indemnification Agreement made and entered into this _	day of	, (the "Agreement"), by	y and between Pacira Pharmaceutica	ıls,
Inc., a Delaware corporation (the "Company," which term shall inclu	ude, where appropriate, a	any Entity (as hereinafter of	defined) controlled directly or indirect	ctly
by the Company) and (the "Indemnitee"):				

WHEREAS, it is essential to the Company that it be able to retain and attract as directors and officers the most capable persons available;

WHEREAS, increased corporate litigation has subjected directors and officers to litigation risks and expenses, and the limitations on the availability of directors and officers liability insurance have made it increasingly difficult for the Company to attract and retain such persons;

WHEREAS, the Certificate of Incorporation of the Company (the "Certificate of Incorporation") requires it to indemnify its directors and officers to the fullest extent permitted by law and permit it to make other indemnification arrangements and agreements;

WHEREAS, the Company desires to provide Indemnitee with specific contractual assurance of Indemnitee's rights to full indemnification against litigation risks and expenses (regardless, among other things, of any amendment to or revocation of the Certificate of Incorporation or the Bylaws of the Company (the "Bylaws") or any change in the ownership of the Company or the composition of its Board of Directors);

WHEREAS, the Company intends that this Agreement provide Indemnitee with greater protection than that which is provided by the Certificate of Incorporation and the Bylaws; and

WHEREAS, Indemnitee is relying upon the rights afforded under this Agreement in continuing as a [director /officer] of the Company.

NOW, THEREFORE, in consideration of the promises and the covenants contained herein, the Company and Indemnitee do hereby covenant and agree as follows:

# 1. Definitions.

- (a) "Corporate Status" describes the status of a person who is serving or has served (i) as a director or officer of the Company, (ii) in any capacity with respect to any employee benefit plan of the Company, or (iii) as a director, partner, trustee, officer, employee, or agent of any other Entity at the request of the Company. For purposes of subsection (iii) of this Section I(a), if Indemnitee is serving or has served as a director, partner, trustee, officer, employee or agent of a Subsidiary, Indemnitee shall be deemed to be serving at the request of the Company.
- (b) "Entity" shall mean any corporation, partnership, limited liability company, joint venture, trust, foundation, association, organization or other legal entity.

- (c) "Expenses" shall mean all reasonable fees, costs and expenses incurred by Indemnitee in connection with any Proceeding (as defined in Section 1(f) below) (including in connection with investigating, defending, being a witness in or defending any Proceeding, or any preparation for any of the foregoing), including, without limitation, attorneys' fees, disbursements and retainers (including, without limitation, any such fees, disbursements and retainers incurred by Indemnitee pursuant to Section 11 or 12(c) below), fees and disbursements of expert witnesses, private investigators and professional advisors (including, without limitation, accountants and investment bankers), court costs, transcript costs, fees of experts, travel expenses, duplicating, printing and binding costs, telephone and fax transmission charges, postage, delivery services, secretarial services, and other disbursements and expenses.
- (d) "Indemnifiable Expenses," "Indemnifiable Liabilities" and "Indemnifiable Amounts" shall have the meanings ascribed to those terms in Section 3(a) below.
- (e) "Liabilities" shall mean judgments, damages, liabilities, losses, penalties, excise taxes, fines and amounts paid in settlement.
- (f) "Proceeding" shall mean any threatened, pending or completed claim, action, suit, arbitration, alternate dispute resolution process, investigation, administrative hearing, appeal, or any other proceeding, whether civil, criminal, administrative, arbitrative or investigative, whether formal or informal, including any inquiry which the Indemnitee reasonably believes might lead to the institution of any of the foregoing and further including any proceeding initiated by Indemnitee pursuant to Section 11 below to enforce Indemnitee's rights hereunder.
- (g) "Subsidiary" shall mean any corporation, partnership, limited liability company, joint venture, trust or other Entity of which the Company owns (either directly or through or together with another Subsidiary of the Company) either (i) a general partner, managing member or other similar interest or (ii) (A) 50% or more of the voting power of the voting capital equity interests of such corporation, partnership, limited liability company, joint venture or other Entity, or (B) 50% or more of the outstanding capital stock or other equity interests of such corporation, partnership, limited liability company, joint venture or other Entity.
- 2. <u>Services of Indemnitee</u>. In consideration of the Company's covenants and commitments hereunder, Indemnitee agrees to serve and continue to serve as a [director/officer] of the Company. However, this Agreement shall not impose any obligation on Indemnitee or the Company to continue Indemnitee's service to the Company beyond any period otherwise required by law or by other agreements or commitments of the parties, if any.
  - 3. Agreement to Indemnify. The Company agrees to indemnify Indemnitee as follows:
  - (a) <u>Proceedings Other Than By or In the Right of the Company</u>. Subject to the exceptions contained in Section 4(a) below, if Indemnitee was or is a party or is

- threatened to be made a party to any Proceeding (other than an action by or in the right of the Company) by reason of Indemnitee's Corporate Status, Indemnitee shall be indemnified by the Company against all Expenses and Liabilities incurred or paid by Indemnitee (referred to herein as "Indemnifiable Expenses" and "Indemnifiable Liabilities," respectively, and collectively as "Indemnifiable Amounts") in connection therewith.
- (b) <u>Proceedings By or In the Right of the Company</u>. Subject to the exceptions contained in Section 4(b) below, if Indemnitee was or is a party or is threatened to be made a party to any Proceeding by or in the right of the Company by reason of Indemnitee's Corporate Status, Indemnitee shall be indemnified by the Company against all Indemnifiable Expenses incurred or paid by Indemnitee in connection therewith.
- (c) Conclusive Presumption Regarding Rights to Indemnification. In making any determination required to be made under Delaware law with respect to entitlement to indemnification hereunder, the person, persons or entity making such determination shall presume that Indemnitee is entitled to indemnification under this Agreement if Indemnitee submitted a request therefor in accordance with Section 7 below, and the Company shall have the burden of proof to overcome that presumption in connection with the making by any person, persons or entity of any determination contrary to that presumption.
- 4. Exceptions to Indemnification. Indemnitee shall be entitled to indemnification under Sections 3(a) and 3(b) above in all circumstances other than with respect to any specific claim, issue or matter involved in the Proceeding out of which Indemnitee's claim for indemnification has arisen (each such specific claim, issue or matter, a "Specific Claim") as follows:
  - (a) Proceedings Other Than By or In the Right of the Company. If indemnification is requested under Section 3(a) above and it has been finally adjudicated by a court of competent jurisdiction that, in connection with a Specific Claim, Indemnitee failed to act (i) in good faith and (ii) in a manner Indemnitee reasonably believed to be in or not opposed to the best interests of the Company, or, with respect to any criminal Proceeding, Indemnitee had reasonable cause to believe that Indemnitee's conduct was unlawful, Indemnitee shall not be entitled to payment hereunder of any Indemnifiable Amounts incurred or paid by Indemnitee by reason of such Specific Claim.
  - (b) Proceedings By or In the Right of the Company. If indemnification is requested under Section 3(b) above and
    - (i) subject to the provisions of Section 8, it has been finally adjudicated by a court of competent jurisdiction that, in connection with a Specific Claim, Indemnitee failed to act (A) in good faith and (B) in a manner Indemnitee reasonably believed to be in or not opposed to the best interests of the Company, Indemnitee shall not be entitled to payment hereunder of any Indemnifiable Expenses incurred or paid by Indemnitee by reason of such Specific Claim;

- (ii) it has been finally adjudicated by a court of competent jurisdiction that Indemnitee is liable to the Company with respect to such Specific Claim, Indemnitee shall not be entitled to payment hereunder of any Indemnifiable Expenses incurred or paid by Indemnitee by reason of such Specific Claim unless the Court of Chancery or another court in which such Proceeding was brought shall determine upon application that, despite the adjudication of liability, but in view of all the circumstances of the case, Indemnitee is fairly and reasonably entitled to indemnification for such Indemnifiable Expenses which such court shall deem proper; or
- (iii) it has been finally adjudicated by a court of competent jurisdiction that Indemnitee is liable to the Company for an accounting of profits made from the purchase or sale by the Indemnitee of securities of the Company pursuant to the provisions of Section 16(b) of the Securities Exchange Act of 1934, the rules and regulations promulgated thereunder and amendments thereto or similar provisions of any federal, state or local statutory law, Indemnitee shall not be entitled to payment of Indemnifiable Expenses hereunder.
- (c) <u>Insurance Proceeds</u>. To the extent payment of Indemnifiable Amounts in connection with a Specific Claim is actually made to the Indemnitee under a valid and collectible insurance policy the premiums for which have been paid by the Company, Indemnitee shall not be entitled to payment hereunder of Indemnifiable Amounts with respect to such Specific Claim except to the extent that the amount of payment under such insurance policy is less than such Indemnifiable Amounts. Any fees, costs and expenses incurred or paid by Indemnitee in enforcing Indemnitee's rights under any liability insurance policy paid for by the Company and insuring Indemnitee shall be considered an Indemnifiable Expense hereunder.
- 5. Additional Indemnity. In addition to, and without regard to any limitations on, the indemnification provided for in Section 3 above, the Company shall and hereby does indemnity and hold harmless Indemnitee against all Expenses and Liabilities incurred by Indemnitee or on Indemnitee's behalf if, by reason of Indemnitee's Corporate Status, Indemnitee is, or is threatened to be made, a party to or participant in any Proceeding (including a Proceeding by or in the right of the Company), including, without limitation, all liability arising out of the negligence or active or passive wrongdoing of Indemnitee. The only limitation that shall exist upon the Company's obligations pursuant to this Agreement shall be that the Company shall not be obligated to make any payment to Indemnitee that is finally determined (under the procedures, and subject to the presumptions, set forth in Sections 3 and 9 hereof) to be unlawful.

# 6. Contribution.

- (a) Whether or not the indemnification provided in Sections 3 and 5 hereof is available, in respect of any Proceeding in which the Company is jointly liable with Indemnitee (or would be if joined in such Proceeding), the Company shall pay, in the first instance, the entire amount of any judgment or settlement of such Proceeding without requiring Indemnitee to contribute to such payment and the Company hereby waives and relinquishes any right of contribution it may have against Indemnitee. The Company shall not enter into any settlement of any Proceeding in which the Company is jointly liable with Indemnitee (or would be if joined in such Proceeding) unless such settlement provides for a full and final release of all claims asserted against Indemnitee.
- (b) Without diminishing or impairing the obligations of the Company set forth in Section 6(a) above, if, for any reason, Indemnitee shall elect or be required to pay all or any portion of any judgment or settlement in any Proceeding in which the Company is jointly liable with Indemnitee (or would be if joined in such Proceeding), the Company shall contribute to the amount of Indemnifiable Amounts paid or payable by Indemnitee in proportion to the relative benefits received by the Company and all officers, directors or employees of the Company, other than Indemnitee, who are jointly liable with Indemnitee (or would be if joined in such Proceeding), on the one hand, and Indemnitee, on the other hand, from the transaction or events from which such Proceeding arose; provided, however, that the proportion determined on the basis of relative benefit may, to the extent necessary to conform to law, be further adjusted by reference to the relative fault of the Company and all officers, directors or employees of the Company other than Indemnitee who are jointly liable with Indemnitee (or would be if joined in such Proceeding), on the one hand, and Indemnitee, on the other hand, in connection with the transaction or events that resulted in such expenses, judgments, fines or settlement amounts, as well as any other equitable considerations which applicable law may require to be considered. The relative fault of the Company and all officers, directors or employees of the Company, other than Indemnitee, who are jointly liable with Indemnitee (or would be if joined in such Proceeding), on the one hand, and Indemnitee, on the other hand, shall be determined by reference to, among other things, the degree to which their actions were motivated by intent to gain personal profit or advantage, the degree to which their liability is primary or secondary and the degree to which their conduct is active or passive.
- (c) The Company hereby agrees to fully indemnify and hold Indemnitee harmless from any claims of contribution which may be brought by officers, directors or employees of the Company, other than Indemnitee, who may be jointly liable with Indemnitee.
- (d) To the fullest extent permissible under applicable law, if the indemnification provided for in this Agreement is unavailable to Indemnitee for any reason whatsoever, the Company, in lieu of indemnifying Indemnitee, shall contribute to the Indemnifiable Amounts incurred by Indemnitee in such proportion as is deemed fair and reasonable in light of all of the circumstances of such Proceeding

in order to reflect (i) the relative benefits received by the Company and Indemnitee as a result of the event(s) and/or transaction(s) giving cause to such Proceeding; and/or (ii) the relative fault of the Company (and its directors, officers, employees and agents) and Indemnitee in connection with such event(s) and/or transaction(s).

- 7. <u>Procedure for Payment of Indemnifiable Amounts</u>. Indemnitee shall submit to the Company a written request specifying the Indemnifiable Amounts for which Indemnitee seeks payment under Section 3 above and the basis for the claim. The Company shall pay such Indemnifiable Amounts to Indemnitee within sixty (60) calendar days of receipt of the request and receipt of the documentation referred to in the next sentence, as applicable. At the request of the Company, Indemnitee shall furnish such documentation and information as are reasonably available to Indemnitee and necessary to establish that Indemnitee is entitled to indemnification hereunder.
- 8. Indemnification for Expenses of a Party Who is Wholly or Partly Successful. Notwithstanding any other provision of this Agreement, to the extent that Indemnitee is, by reason of Indemnitee's Corporate Status, a party to or otherwise the subject of, and is successful, on the merits or otherwise, in, any Proceeding, Indemnitee shall be indemnified against all Expenses reasonably incurred by Indemnitee or on Indemnitee's behalf in connection therewith. If Indemnitee is not wholly successful in such Proceeding but is successful, on the merits or otherwise, as to one or more but less than all claims, issues or matters in such Proceeding, the Company shall indemnity Indemnitee against all Expenses reasonably incurred by Indemnitee or on Indemnitee's behalf in connection with each successfully resolved claim, issue or matter. For purposes of this Agreement, the termination of any claim, issue or matter in such a Proceeding by dismissal, with or without prejudice, by reason of settlement, judgment, order or otherwise, shall be deemed to be a successful result as to such claim, issue or matter.
- 9. Effect of Certain Resolutions. The termination of any Proceeding by judgment, order, settlement, conviction, or upon a plea of nolo contendere or its equivalent shall not create a presumption that Indemnitee did not act in good faith and in a manner which Indemnitee reasonably believed to be in or not opposed to the best interests of the Company or, with respect to any criminal Proceeding, had reasonable cause to believe that Indemnitee's action was unlawful
- 10. Agreement to Advance Expenses: Undertaking. The Company shall advance all Expenses incurred by or on behalf of Indemnitee in connection with any Proceeding, including a Proceeding by or in the right of the Company, in which Indemnitee is involved by reason of Indemnitee's Corporate Status within twenty (20) calendar days after the receipt by the Company of a written statement from Indemnitee requesting such advance or advances from time to time, whether prior to or after final disposition of such Proceeding. To the extent required by Delaware law, Indemnitee hereby undertakes to repay any and all of the amount of Indemnifiable Expenses paid to Indemnitee if it is finally determined by a court of competent jurisdiction that Indemnitee is not entitled under this Agreement to indemnification with respect to such Expenses. This undertaking is an unlimited general obligation of Indemnitee.

# 11. Remedies of Indemnitee.

- (a) Adjudication. In the event that the it should appear to Indemnitee that the Company has failed to comply with any of its obligations under this Agreement or in the event that the Company or any other person takes or threatens to take any action to declare this Agreement void or unenforceable, or institutes any action, suit or other proceeding designed to deny, or to recover from, Indemnitee the benefits provided or intended to be provided to Indemnitee hereunder, Indemnitee shall be entitled to an adjudication in an appropriate court of the State of Delaware, or in any other court of competent jurisdiction, of Indemnitee's entitlement to such indemnification. Indemnitee shall commence such proceeding seeking an adjudication within 180 days following the date on which Indemnitee first has the right to commence such proceeding pursuant to this Section 11(a). The Company shall not oppose Indemnitee's right to seek any such adjudication.
- (b) Legal Fees and Expenses. It is the intent of the Company that Indemnitee not be required to incur legal fees or other Expenses associated with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement by litigation or otherwise because the cost and expense thereof would substantially detract from the benefits intended to be extended to Indemnitee hereunder. Accordingly, if it should appear to Indemnitee that the Company has failed to comply with any of its obligations under this Agreement or in the event that the Company or any other person takes or threatens to take any action to declare this Agreement void or unenforceable, or institutes any action, suit or other proceeding designed to deny, or to recover from, Indemnitee the benefits provided or intended to be provided to Indemnitee hereunder, the Company irrevocably authorizes Indemnitee from time to time to retain counsel of Indemnitee's choice, at the expense of the Company as hereafter provided, to advise and represent Indemnitee in connection with any such interpretation, enforcement or defense, including without limitation the initiation or defense of any action, suit or other proceeding, whether by or against the Company or any director, officer, stockholder or other person affiliated with the Company, in any jurisdiction. Notwithstanding any existing or prior attorney-client relationship between the Company and any counsel, the Company irrevocably consents to Indemnitee's entering into an attorney-client relationship with such counsel, and in that connection the Company and Indemnitee agree that a confidential relationship shall exist between Indemnitee and such counsel. Without respect to whether Indemnitee prevails, in whole or in part, in connection with any of the foregoing, the Company will pay and be solely financially responsible for any and all Expenses incurred by the Indemnitee in connection with any of the foregoing.
- (c) <u>Burden of Proof.</u> In any action, suit or other proceeding brought under Section 11(a) above to obtain payment by the Company of any Indemnifiable Amounts, the Company shall have the burden of proving that Indemnitee is not entitled to such payment hereunder.

### (d) Prior Determinations Made Concerning Permissibility of Payment of Indemnifiable Amounts .

- (i) The failure of the Company (including its Board of Directors or any committee thereof, independent legal counsel, or stockholders) to make a determination concerning the permissibility of the payment of Indemnifiable Amounts or the advancement of Indemnifiable Expenses under this Agreement shall not be a defense in any action, suit or other proceeding brought under Section 11(a) above, and shall not create a presumption that such payment or advancement is not permissible.
- (ii) In the event that the Company has made a determination that the payment of Indemnifiable Amounts or the advancement of Indemnifiable Expenses under this Agreement is not permissible and/or that the Indemnitee is not entitled to indemnification, any action, suit or other proceeding brought under Section 11(a) above shall be conducted in all respects as a de novo trial on the merits, and Indemnitee shall not be prejudiced by reason of such adverse determination by the Company.
- (iii) In the event that the Company has made a determination that the payment of Indemnifiable Amounts or the advancement of Indemnifiable Expenses under this Agreement is permissible and/or that the Indemnitee is entitled to indemnification, the Company shall be bound by such determination in any action, suit or other proceeding brought under Section 11(a) above, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's misstatement not materially misleading in connection with the application for indemnification, or (ii) a prohibition of such indemnification under applicable law.
- (iv) Notwithstanding anything in this Agreement to the contrary, no determination as to the permissibility of the payment of Indemnifiable Amounts and/or the advancement of Indemnifiable Expenses or as to the entitlement to indemnification under this Agreement shall be required to be made prior to the final disposition of the Proceeding.
- (e) The Company shall be precluded from asserting in any action, suit or other proceeding brought under Section 11(a) above that the procedures and presumptions of this Agreement are not valid, binding and enforceable and shall stipulate in any such court that the Company is bound by all the provisions of this Agreement.

### 12. <u>Defense of the Underlying Proceeding</u>.

(a) Notice by Indemnitee. Indemnitee agrees to notify the Company promptly upon being served with any summons, citation, subpoena, complaint, indictment, information, or other document relating to any Proceeding which may result in the payment of Indemnifiable Amounts or the advancement of Indemnifiable Expenses hereunder; provided, however, that the failure to give any such notice shall not disqualify Indemnitee from the right, or otherwise affect in any manner any right of Indemnitee, to receive payments of Indemnifiable Amounts or advancements of Indemnifiable Expenses unless the Company's ability to defend in such Proceeding is materially and adversely prejudiced thereby.

- (b) <u>Defense by Company</u>. Subject to the provisions of the last sentence of this Section 12(b) and Section 12(c) below, the Company shall have the right to defend Indemnitee in any Proceeding which may give rise to the payment of Indemnifiable Amounts hereunder with counsel reasonably satisfactory to the Indemnitee; provided, however, that the Company shall notify Indemnitee of any such decision to defend within ten (10) calendar days of receipt of notice of any such Proceeding under Section 12(a) above. The Company shall not, without the prior written consent of Indemnitee, consent to the entry of any judgment against Indemnitee or enter into any settlement or compromise which (i) includes an admission of fault of Indemnitee or (ii) does not include, as an unconditional term thereof, the full release of Indemnitee from all liability in respect of such Proceeding, which release shall be in form and substance reasonably satisfactory to Indemnitee. This Section 12(b) shall not apply to a Proceeding brought by Indemnitee under Section 11(a) above or to any counterclaims or defenses of Indemnitee referred to in Section 20 below.
- (c) <u>Indemnitee's Right to Counsel</u>. Notwithstanding the provisions of Section 12(b) above, if in a Proceeding to which Indemnitee is a party by reason of Indemnitee's Corporate Status, (i) Indemnitee reasonably concludes that he or she may have separate defenses or counterclaims to assert with respect to any issue which may be different from or in addition to those of the Company or other defendants in such Proceeding, (ii) a conflict of interest or potential conflict of interest exists between Indemnitee and the Company or the representation of the Indemnitee by the Company would be precluded under the applicable standards of professional conduct then prevailing, or (iii) the Company fails to assume the defense of such Proceeding in a timely manner, Indemnitee shall be entitled to be represented by separate legal counsel of Indemnitee's choice (but not more than one law firm plus, if applicable, local counsel in respect of any one Proceeding) at the expense of the Company.
- 13. Representations and Warranties of the Company. The Company hereby represents and warrants to Indemnitee as follows:
- (a) <u>Authority</u>. The Company has all necessary power and authority to enter into, and be bound by the terms of, this Agreement, and the execution, delivery and performance of the undertakings contemplated by this Agreement have been duly authorized by the Company.
- (b) Enforceability. This Agreement, when executed and delivered by the Company in accordance with the provisions hereof, shall be a legal, valid and binding obligation of the Company, enforceable against the Company in accordance with its terms, except as such enforceability may be limited by applicable bankruptcy, insolvency, moratorium, reorganization or similar laws affecting the enforcement of creditors' rights generally.

14. <u>Insurance</u>. The Company shall, from time to time, make the good faith determination whether or not it is practicable for the Company to obtain and maintain a policy or policies of insurance with a reputable insurance company providing the Indemnitee with coverage for losses from wrongful acts or omissions. For so long as Indemnitee shall remain a [director/officer] of the Company and with respect to any such prior service, in all policies of director and officer liability insurance, Indemnitee shall be named as an insured in such a manner as to provide Indemnitee the same rights and benefits as are accorded to the most favorably insured of the Company's officers and directors. Notwithstanding the foregoing, the Company shall have no obligation to obtain or maintain such insurance if the Company determines in good faith that such insurance is not reasonably available, if the premium costs for such insurance are disproportionate to the amount of coverage provided, or if the coverage provided by such insurance is limited by exclusions so as to provide an insufficient benefit. The Company shall promptly notify Indemnitee of any good faith determination not to provide such coverage.

# 15. Contract Rights Not Exclusive[; Third Party Indemnitors] 1

- (a) Except as otherwise provided in Section 4(c) above, the rights to payment of Indemnifiable Amounts and advancement of Indemnifiable Expenses provided by this Agreement shall be in addition to, but not exclusive of, any other rights which Indemnitee may have at any time under applicable law, the Certificate of Incorporation or Bylaws, or any other agreement, vote of stockholders or directors (or a committee of directors), or otherwise, both as to action in Indemnitee's official capacity and as to action in any other capacity as a result of Indemnitee's serving as a [director/officer] of the Company.
  - (b) [The Company hereby acknowledges that Indemnitee may have certain rights to indemnification, advancement of expenses and/or insurance provided by third parties, including stockholders of the Company (the "Third Party Indemnitors"). The Company hereby agrees:
    - (i) that it is the indemnitor of first resort (i.e., its obligations to Indemnitee are primary and any obligation of the Third Party Indemnitors to advance expenses or to provide indemnification for the same expenses or liabilities incurred by Indemnitee are secondary);
    - (ii) that it shall be required to advance the full amount of Expenses incurred by Indemnitee and shall be liable for the full amount of all Expenses and Liabilities to the extent legally permitted and as required by the terms of the Certificate of Incorporation, the Bylaws and/or this Agreement, without regard to any rights Indemnitee may have against the Third Party Indemnitors; and
- Include only for directors associated with a venture capital or private equity fund.

- (iii) that it irrevocably waives, relinquishes and releases the Third Party Indemnitors from any and all claims against the Third Party Indemnitors for contribution, subrogation or any other recovery of any kind in respect thereof.
- (iv) The Company further agrees that no advancement or payment by the Third Party Indemnitors on behalf of Indemnitee with respect to any claim for which Indemnitee has sought indemnification from the Company shall affect the foregoing and the Third Party Indemnitors shall have a right of contribution and/or be subrogated to the extent of such advancement or payment to all of the rights of recovery of Indemnitee against the Company. The Company agrees that the Third Party Indemnitors are express third party beneficiaries of the terms of this Section 15(b).]
- (c) [Except as provided in Section 15(b) above, t]/[T]he Company shall not be liable under this Agreement to make any payment of amounts otherwise indemnifiable hereunder if and to the extent that Indemnitee has otherwise actually received such payment under any insurance policy, contract, agreement or otherwise.
- (d) [Except as provided in Section 15(b) above, t]/[T]he Company's obligation to indemnify or advance Expenses hereunder to Indemnitee who is or was serving at the request of the Company as a director, officer, employee or agent of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise shall be reduced by any amount Indemnitee has actually received as indemnification or advancement of expenses from such other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise.
- 16. <u>Successors</u>. This Agreement shall be (a) binding upon all successors and assigns of the Company (including any transferee of all or a substantial portion of the business, stock and/or assets of the Company and any direct or indirect successor by merger or consolidation or otherwise by operation of law) and (b) binding on and shall inure to the benefit of the heirs, personal representatives, executors and administrators of Indemnitee. This Agreement shall continue for the benefit of Indemnitee and such heirs, personal representatives, executors and administrators after Indemnitee has ceased to have Corporate Status with respect to acts and omissions by Indemnitee that shall have occurred while Indemnitee had Corporate Status.
- 17. <u>Subrogation</u>. In the event of any payment of Indemnifiable Amounts under this Agreement, the Company shall be subrogated to the extent of such payment to all of the rights of contribution or recovery of Indemnitee against other persons, and Indemnitee shall take, at the request of the Company, all reasonable action necessary to secure such rights, including the execution of such documents as are necessary to enable the Company to bring suit to enforce such rights.

- 18. Change in Law; Amendments. To the extent that a change in Delaware law (whether by statute or judicial decision) shall permit broader indemnification or advancement of expenses than is provided under the terms of the Certificate of Incorporation, the Bylaws and/or this Agreement, Indemnitee shall be entitled to such broader indemnification and advancements, and this Agreement shall be deemed to be amended to such extent. The Company will not adopt any amendments to its Certificate of Incorporation or Bylaws the effect of which would be to deny or diminish or encumber Indemnitee's right to indemnification under this Agreement.
- 19. <u>Severability</u>. Whenever possible, each provision of this Agreement shall be interpreted in such a manner as to be effective and valid under applicable law, but if any provision of this Agreement, or any clause thereof, shall be determined by a court of competent jurisdiction to be illegal, invalid or unenforceable, in whole or in part, such provision or clause shall be limited or modified in its application to the minimum extent necessary to make such provision or clause valid, legal and enforceable, and the remaining provisions and clauses of this Agreement shall remain fully enforceable and binding on the parties.
- 20. <u>Indemnitee as Plaintiff</u>. Except as provided in Section 11 above, in the last sentence of Section 4(c) above and in the next sentence, Indemnitee shall not be entitled to payment of Indemnifiable Amounts or advancement of Indemnifiable Expenses with respect to any Proceeding brought by Indemnitee against the Company, any Entity which it controls, any director or officer thereof, or any third party, unless the Board of Directors of the Company has consented to the initiation of such Proceeding. This Section shall not apply to counterclaims or affirmative defenses asserted by Indemnitee in any Proceeding brought against Indemnitee.
- 21. <u>Modifications and Waiver</u>. Except as provided in Section 18 above with respect to changes in Delaware law which broaden the right of Indemnitee to be indemnified by the Company, no supplement, modification or amendment of this Agreement shall be binding unless executed in writing by each of the parties hereto. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provisions of this Agreement (whether or not similar), nor shall such waiver constitute a continuing waiver.
- 22. <u>General Notices</u>. All notices, requests, demands and other communications hereunder shall be in writing and shall be deemed to have been duly given (a) when delivered by hand, (b) when transmitted by facsimile and receipt is acknowledged, (c) if sent for next-day delivery by means of a nationally recognized overnight courier service, on the next day after it is so sent, or (d) if mailed by certified or registered mail with postage prepaid, on the third business day after the date on which it is so mailed:
  - (i) If to Indemnitee, to:
  - (ii) If to the Company, to:

Pacira Pharmaceuticals, Inc. 5 Sylvan Way

# Parsippany, NJ 07054 Attention: Chief Financial Officer

or to such other address as may have been furnished in the same manner by any party to the others.

23. Governing Law: Consent to Jurisdiction; Service of Process. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware without regard to its rules of conflict of laws. Each of the Company and the Indemnitee hereby irrevocably and unconditionally consents to submit to the exclusive jurisdiction of the Court of Chancery of the State of Delaware and the courts of the United States of America located in the State of Delaware (the "Delaware Courts") for any litigation arising out of or relating to this Agreement and the transactions contemplated hereby (and agrees not to commence any litigation relating thereto except in such courts), waives any objection to the laying of venue of any such litigation in the Delaware Courts and agrees not to plead or claim in any Delaware Court that such litigation brought therein has been brought in an inconvenient forum. Each of the parties hereto agrees that service of process may also be made on such party by prepaid certified mail with a proof of mailing receipt validated by the United States Postal Service constituting evidence of valid service. Service made pursuant to the preceding sentence shall have the same legal force and effect as if served upon such party personally within the State of Delaware.

[signature page follows]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

# By: \_\_\_\_\_\_ Name: \_\_\_\_\_ Title: \_\_\_\_ INDEMNITEE

PACIRA PHARMACEUTICALS, INC.

# Consent of Independent Registered Public Accounting Firm

We consent to the inclusion in Amendment No. 3 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 matters discussed in Note 1 ("Correction of Immaterial Errors") which are as of December 3, 2010 and ("Reverse Stock Split") which are as of January 12, 2011, 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 January 12, 2011