

Use these links to rapidly review the document

[TABLE OF CONTENTS](#)

[Index to Consolidated Financial Statements](#)

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549  
**FORM 10-K**

(Mark One)

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Fiscal Year Ended: December 31, 2015

Or

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 001-35060

**PACIRA PHARMACEUTICALS, INC.**

(Exact Name of Registrant as Specified in its Charter)

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

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

**5 Sylvan Way, Suite 300**  
**Parsippany, New Jersey 07054**  
(Address and Zip Code of Principal Executive Offices)

**(973) 254-3560**  
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, \$0.001 par value	The NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of “large accelerated filer,” “accelerated filer,” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The aggregate market value of the Registrant’s voting stock held by non-affiliates of the registrant, based upon the closing sale price of the common stock as reported on the NASDAQ on June 30, 2015, the last business day of the registrant’s most recently completed second fiscal quarter, of \$70.72 per share was \$1.3 billion. Shares of common stock held by each director and executive officer (and their respective affiliates) and by each person who owns 10 percent or more of the outstanding common stock or who is otherwise believed by the registrant to be in a control position have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 18, 2016, 37,053,372 shares of the registrant’s common stock, \$0.001 par value per share, were outstanding.

#### DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates certain information by reference from the registrant’s proxy statement for the 2016 annual meeting of stockholders to be filed no later than 120 days after the end of the registrant’s fiscal year ended December 31, 2015.

**Table of Contents**

	<u>Page No.</u>
<a href="#">PART I</a>	<a href="#">2</a>
<a href="#">Item 1. Business</a>	<a href="#">2</a>
<a href="#">Item 1A. Risk Factors</a>	<a href="#">22</a>
<a href="#">Item 1B. Unresolved Staff Comments</a>	<a href="#">46</a>
<a href="#">Item 2. Properties</a>	<a href="#">46</a>
<a href="#">Item 3. Legal Proceedings</a>	<a href="#">46</a>
<a href="#">Item 4. Mine Safety Disclosures</a>	<a href="#">47</a>
<a href="#">PART II</a>	<a href="#">48</a>
<a href="#">Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</a>	<a href="#">48</a>
<a href="#">Item 6. Selected Financial Data</a>	<a href="#">49</a>
<a href="#">Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations</a>	<a href="#">51</a>
<a href="#">Item 7A. Quantitative and Qualitative Disclosures about Market Risk</a>	<a href="#">64</a>
<a href="#">Item 8. Financial Statements and Supplementary Data</a>	<a href="#">65</a>
<a href="#">Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</a>	<a href="#">65</a>
<a href="#">Item 9A. Controls and Procedures</a>	<a href="#">65</a>
<a href="#">Item 9B. Other Information</a>	<a href="#">67</a>
<a href="#">PART III</a>	<a href="#">67</a>
<a href="#">Item 10. Directors, Executive Officers and Corporate Governance</a>	<a href="#">67</a>
<a href="#">Item 11. Executive Compensation</a>	<a href="#">67</a>
<a href="#">Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</a>	<a href="#">67</a>
<a href="#">Item 13. Certain Relationships and Related Transactions, and Director Independence</a>	<a href="#">67</a>
<a href="#">Item 14. Principal Accounting Fees and Services</a>	<a href="#">67</a>
<a href="#">PART IV</a>	<a href="#">67</a>
<a href="#">Item 15. Exhibits, Financial Statement Schedules</a>	<a href="#">67</a>

**Forward-Looking Statements**

This Annual Report on Form 10-K and certain other communications made by us contain forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934 (the “Exchange Act”), including statements about our growth and future operating results, discovery and development of products, strategic alliances and intellectual property. For this purpose, any statement that is not a statement of historical fact should be considered a forward-looking statement. We often use the words “believe,” “anticipate,” “plan,” “expect,” “intend,” “may” and similar expressions to help identify forward-looking statements. We cannot assure you that our estimates, assumptions and expectations will prove to have been correct. These forward-looking statements include, among others, statements about: the success of our sales and manufacturing efforts in support of the commercialization of EXPAREL® (bupivacaine liposome injectable suspension); 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; the Company’s plans to expand the indications of EXPAREL to additional indications and opportunities, and the timing and success of any related clinical trials; the related timing and success of United States Food and Drug Administration supplemental New Drug Applications; the outcome of the U.S. Department of Justice inquiry; the Company’s plans to evaluate, develop and pursue additional DepoFoam®-based product candidates; clinical studies in support of an existing or potential DepoFoam-based product; the Company’s plans to continue to manufacture and provide support services for its commercial partners who have licensed DepoCyt(e); our commercialization and marketing capabilities and the Company’s and Patheon UK Limited’s ability to successfully and timely construct EXPAREL manufacturing suites. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements, including those discussed below in Part I-Item 1A. *Risk Factors*. We undertake no intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, and readers should not rely on the forward-looking statements as representing our views as of any date subsequent to the date of the filing of this Annual Report on Form 10-K.

These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the Company’s actual results, levels of activity, performance or achievements to differ materially from those expressed or implied by these statements. These factors include the matters discussed and referenced in Part I-Item 1A. *Risk Factors*.

## PART I

### Item 1. Business

#### References

Pacira Pharmaceuticals, Inc., a Delaware corporation, is the holding company for our California operating subsidiary of the same name, or Pacira California. In March 2007, we acquired Pacira California from SkyePharma Holdings, Inc., or Skyepharma (referred to in this Annual Report on Form 10-K as the “Acquisition”). Unless the context requires otherwise, references to “Pacira,” “we,” the “Company,” “us” and “our” in this Annual Report on Form 10-K refers to Pacira Pharmaceuticals, Inc., a Delaware corporation, and its subsidiaries.

#### Corporate 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. Our principal executive offices are located at 5 Sylvan Way, Suite 300, Parsippany, New Jersey 07054, and our telephone number is (973) 254-3560.

Pacira®, EXPAREL®, DepoFoam®, DepoCyt® (U.S. registration), DepoCyt® (E.U. registration), the Pacira logo and other trademarks or service marks of Pacira appearing in this Annual Report on Form 10-K are the property of Pacira. In addition, references in this Annual Report on Form 10-K to DepoCyt(e) mean DepoCyt when discussed in the context of the United States and Canada and DepoCyt when discussed in the context of Europe.

This Annual Report on Form 10-K contains additional trade names, trademarks and service marks of other companies.

#### Overview

We are a specialty pharmaceutical company focused on the development, commercialization and manufacture of proprietary pharmaceutical products, based on our proprietary DepoFoam® extended release drug delivery technology, for use primarily in hospitals and ambulatory surgery centers. We operate in one reportable segment. On October 28, 2011, the United States Food and Drug Administration, or FDA, approved our New Drug Application, or NDA, for our lead product candidate, EXPAREL® (bupivacaine liposome injectable suspension), which consists of bupivacaine encapsulated in DepoFoam, and is an amide-type local anesthetic indicated for single-dose infiltration into the surgical site to produce postsurgical analgesia. We believe EXPAREL addresses 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 have developed an internal sales force entirely dedicated to commercializing EXPAREL, which we commercially launched in the United States in April 2012. Our net sales for EXPAREL in 2015 were \$239.9 million, and our net sales for EXPAREL in the quarter ended December 31, 2015, which was the fifteenth quarter of our launch, were \$67.2 million. We believe EXPAREL will ultimately become a major hospital pharmaceutical brand.

In addition to EXPAREL, DepoFoam is also the basis for our other FDA-approved commercial product, DepoCyt(e), which we manufacture for our commercial partners, as well as our other product candidates. For the years ended December 31, 2015, 2014 and 2013 sales of EXPAREL accounted for 96%, 95% and 89% of total revenues and DepoCyt(e) 3%, 4% and 10%, respectively.

[Table of Contents](#)

Our current product portfolio and product candidate pipeline, along with expected timelines, is summarized in the table below\*:

	2016	2017	2018	2019	2020
<b>EXPAREL®</b>					
Infiltration	Approved (as of October 2011)				
Nerve Block	Phase 3	sNDA	Expected Approval		
Pediatric <sup>1</sup>	Phase 3				
Chronic Pain <sup>2</sup>		Phase 2	Phase 3	sNDA	Expected Approval
RCTs (incl. Academic Collaborations)	Initiated				
Nocita® Animal Health (Aratana Therapeutics, Inc.) <sup>3</sup>	Expected Approval (Dogs)				
<b>DepoFoam®-Based Products</b>					
DepoCyt(e) (Sigma-Tau – U.S.) (Mundipharma – Europe)	Approved (accelerated as of April 1999; full approval as of April 2007)				
DepoMeloxicam		Phase 1	Phase 2	Phase 3	NDA Expected Approval
DepoTranexamic Acid		Phase 2	Phase 3	NDA	Expected Approval

\* These timelines represent our current estimates, but we can make no assurances that we will meet these clinical development or commercialization timelines.

1. Expected initiation of Phase 3 pediatric study in 2016. FDA meeting planned in Q1 2016.
2. Timeline may be updated at an appropriate time following further progress and development of the nerve block indication.
3. Expected approval (dogs) in late 2016. Source: Aratana Therapeutics, Inc.

**Our Strategy**

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

- fully commercializing EXPAREL in the United States for postsurgical analgesia by infiltration;
- continuing to build and expand a streamlined commercial organization concentrating on major hospitals and ambulatory surgery centers in the United States and targeting surgeons, anesthesiologists, pharmacists and nurses; further, we plan to launch EXPAREL into the oral surgery market by targeting oral surgeons late in the third quarter of 2016;
- demonstrating the economic benefits of EXPAREL, working directly with managed care payers, quality improvement organizations, Key Opinion Leaders, or KOLs, in the field of postsurgical pain management and leading influential hospitals in conducting Phase 4 retrospective and prospective trials and drug utilization evaluations;
- servicing and educating strategic commercial audiences for local infiltration procedures, including soft tissue, orthopedic, spine, anesthesia (such as infiltration into the transversus abdominis plane, or TAP block) and oral and maxillofacial surgeries, to ensure appropriate use of the product;
- obtaining FDA approval for additional indications for EXPAREL including nerve block;
- leveraging the development success of EXPAREL in the animal health market through our commercial partner Aratana Therapeutics, Inc., which intends to market the product as Nocita® (bupivacaine liposome injectable suspension) to serve animal health indications;

## [Table of Contents](#)

- manufacturing all our DepoFoam-based products, including EXPAREL, in facilities compliant with current Good Manufacturing Practices, or cGMP, and expanding such manufacturing capacity to meet demand;
- continuing to expand our marketed product portfolio through development of additional DepoFoam-based hospital products utilizing a Section 505(b)(2) strategy, which permits us to rely upon the FDA’s previous findings of safety and effectiveness for an approved product. A Section 505(b)(2) strategy may not succeed if there are successful challenges to the FDA’s interpretation of Section 505(b)(2) under the Federal Food, Drug and Cosmetic Act; and
- continuing research and development partnerships to provide DepoFoam-based products to enhance the duration of action and patient compliance for partner products.

### **EXPAREL—Our Lead Product**

Based on our clinical data, EXPAREL provides continuous and extended postsurgical analgesia and reduces the consumption of opioid medications. We believe EXPAREL simplifies postsurgical pain management, minimizes breakthrough episodes of pain and has the potential to result in improved patient outcomes and enhanced hospital economics.

Our EXPAREL strategy has several principal elements:

*Replace the use of bupivacaine via elastomeric pumps as the foundation of a multimodal regimen for long-acting postsurgical pain management.* Based on our clinical data, EXPAREL:

- extends postsurgical analgesia;
- leverages 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 sites.

*Become the foundation of a long-acting postsurgical pain management regimen in order to reduce and delay opioid usage.* Based on the clinical data from our Phase 3 hemorrhoidectomy trial as well as our retrospective health outcomes studies data, EXPAREL significantly delays and reduces opioid usage while improving postsurgical pain management.

In our Phase 3 hemorrhoidectomy trial, EXPAREL:

- delayed median time to rescue analgesic use (opioids) to 15 hours for patients treated with EXPAREL and one hour for patients treated with placebo;
- significantly increased the percentage of patients requiring no opioid rescue medication through 72 hours post-surgery to 28%, compared to 10% for placebo;
- resulted in 45% less opioid usage through 72 hours post-surgery compared to placebo; and
- increased the percentage of patients who are pain free at 24 hours post-surgery compared to placebo.

*Improve patient satisfaction and outcomes.* We believe EXPAREL:

- provides effective pain control without the need for expensive and difficult-to-use delivery technologies that extend the duration of action for bupivacaine, such as elastomeric bags, or opioids administered through patient-controlled analgesia, or PCA, when used as part of a multimodal postsurgical pain regimen;
- 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; and

## [Table of Contents](#)

- promotes maintenance of early postsurgical pain management, which may reduce the time spent in the intensive care unit.

*Develop and seek approval of additional indications for EXPAREL, including for nerve block administration.* We believe the nerve block indication for EXPAREL:

- presents a relatively low-cost opportunity for a new indication; and
- enables us to fully leverage our manufacturing and sales infrastructure.

### **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 that these health economic benefits are an often overlooked 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 successful launch of commercial products. Our strategy is to work directly with our hospital C-suite customers, group purchasing organizations, integrated health networks, quality improvement organizations, KOLs in the field of postsurgical pain management and leading influence hospitals and to provide them with retrospective and prospective studies to demonstrate the economic benefits of EXPAREL.

Our national, regional and local analyses assessing retrospective health outcomes, conducted in conjunction with hospital customer groups utilizing their own hospital databases, revealed that the use of opioids for postsurgical pain control is a significant driver of hospital resource consumption, including higher hospitalization costs, longer length of stay and the potential for opioid-related adverse events.

### **EXPAREL Regulatory Plan**

EXPAREL consists of bupivacaine encapsulated in DepoFoam:

- 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.

The NDA for EXPAREL was approved on October 28, 2011, using a 505(b)(2) application. The FDA approved EXPAREL for administration into the surgical site to produce postsurgical analgesia.

### **FDA Litigation**

On December 15, 2015, we announced that we achieved an amicable resolution with the United States in our lawsuit filed on September 8, 2015, *Pacira Pharmaceuticals, Inc. et al v. United States Food & Drug Administration et al*, 15-cv-07055 (SDNY Sept. 8, 2015)(LAK). The resolution confirms that EXPAREL is, and has been since 2011, broadly indicated for administration into the surgical site to provide postsurgical analgesia.

The key features of the resolution are as follows:

- The U.S. Food and Drug Administration, or FDA, confirms that EXPAREL has, since its approval on October 28, 2011, been approved for “administration into the surgical site to produce postsurgical analgesia” in a variety of surgeries not limited to those studied in its pivotal trials.
- The FDA approved a labeling supplement which amends the EXPAREL Package Insert to clarify and reinforce that:
  - The use, efficacy and safety of EXPAREL is not limited to any specific surgery type or site;
  - The proper dosage and administration of EXPAREL is based on various patient and procedure-specific factors, with the two surgical models utilized in the pivotal trials provided as examples for the purpose of providing general guidance;



## [Table of Contents](#)

- There was a significant treatment effect for EXPAREL compared to placebo over the first 72 hours in the pivotal hemorrhoidectomy study;
  - The description of that duration of effect now includes a graphical representation of the mean pain intensity scores over time for the EXPAREL and placebo groups for the full 72-hour efficacy period, as well as information about median time to first opioid use and percentage of opioid-free patients in each treatment group.
- EXPAREL may be admixed with bupivacaine—including co-administered in the same syringe—provided certain medication ratios are observed.
- The September 2014 FDA Warning Letter was formally withdrawn via a “Rescission Letter” from the Director of the FDA Center for Drug Evaluation and Research (CDER).
  - At the request of Pacira, the Rescission Letter included FDA guidance related to two key procedures:
    - TAP block, which is a field block technique covered by the approved indication for EXPAREL.
    - Infiltration to produce postsurgical analgesia at the site of oral surgery procedures, including tooth extractions, which is also covered by the approved indication for EXPAREL.
- The United States acknowledged that the rescission of the Warning Letter and approval of the labeling supplement reflect the scope of the indication in the NDA that FDA approved on October 28, 2011.
- Pacira and the FDA agreed that in future interactions, they will deal with each other in an open, forthright and fair manner.

### ***Clinical Studies***

#### ***Nerve Block***

We are pursuing several additional indications for EXPAREL and submitted a United States Food and Drug Administration supplemental New Drug Application, or sNDA, for nerve block administration in May 2014 and received a Complete Response Letter, or CRL, in March 2015. We collaborated with the FDA to address the CRL and intend on resubmitting the nerve block supplement in the first quarter of 2017 for a six-month Prescription Drug User Fee Act, or PDUFA, review. We believe that this additional indication for EXPAREL is a low-cost opportunity and will allow us to fully leverage our manufacturing and commercial infrastructure.

Nerve block is a general term used to refer to the injection of local anesthetic onto or near nerves for pain control. Nerve blocks can be single injections, but currently 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.

In the first quarter of 2016, we initiated two pivotal nerve block trials comparing the effect of EXPAREL versus placebo through a femoral nerve block study for total knee arthroplasty and a brachial plexus block study for total shoulder arthroplasty or rotator cuff repair procedures. We believe that this new indication will present an alternative long-term method of pain control with a single injection, replacing the costly and cumbersome standard of care requiring a perineural catheter, drug reservoir and pump needed to continuously deliver bupivacaine.

#### ***Chronic Pain***

A large population of Americans suffer from chronic pain, a complex condition with multiple sources, including, but not limited to, inflammation, demyelination, viral injury, progressive loss of nerve fiber function, spinal cord injury, inadequate control of acute pain and nerve root damage, such as facet joint dysfunction. Approximately 80 percent of Americans suffer from lower back pain in their lifetime. A leading source of chronic back pain is facet joint dysfunction for which local anesthetics are often administered as a monotherapy and for which surgery is not a viable option except in complex cases. We intend to initiate a Phase 2 trial in 2016 with patients suffering from chronic lower back pain caused by facet joint dysfunction

## [Table of Contents](#)

with EXPAREL as a single dose administration to define the duration of efficacy and determine the optimal dose, which will better inform a Phase 3 study design.

### ***Pediatrics***

The FDA, as a condition of EXPAREL approval, has required us to study EXPAREL in pediatric patients. We were granted a deferral for the required pediatric studies in all age groups for EXPAREL in the setting of wound infiltration and plan to conduct these pediatric studies as a postmarketing requirement, which was stated in the NDA 22-496 approval letter for EXPAREL. We will meet with the FDA in the first quarter of 2016 for a discussion and agreement on a path forward for these required pediatric studies. The primary goal of this meeting is to discuss and gain agreement on the pediatric study design in all age groups. We plan on initiating the first pediatric study in the second half of 2016.

### ***Randomized Control Trials***

In addition, we are initiating a multicenter randomized double-blind placebo controlled study in patients undergoing a primary unilateral Total Knee Arthroplasty, or TKA. Patients will receive either EXPAREL plus short-acting bupivacaine or a sham (normal saline) with short-acting bupivacaine as part of a multimodal pain management regimen. The primary objective of this study is to compare pain control and total opioid consumption following local infiltration analgesia, or LIA, with EXPAREL to LIA without EXPAREL in adult subjects undergoing TKA. The secondary objectives of this study are to compare additional efficacy, safety and health economic outcomes following LIA with EXPAREL to LIA without EXPAREL. We also plan to initiate a randomized control trial in patients undergoing spine surgery.

### ***Oral Surgery***

In February 2016, we announced topline results of a randomized controlled trial in third molar (“wisdom teeth”) procedures, with a per-protocol analysis demonstrating statistical significance and an intention-to-treat analysis strongly trending towards significance in spite of the underpowered study size resulting from one of three clinical sites being eliminated for protocol violations. We plan to generate Phase 4 studies in additional oral and maxillofacial surgeries to provide clinical guidance to the oral and maxillofacial community. We anticipate a late third quarter 2016 launch for oral surgery.

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

In the years ended December 31, 2015, 2014 and 2013, we spent \$28.7 million, \$18.7 million and \$21.6 million, respectively, on research and development activities. For additional information, see Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Research and Development Expenses.”

### ***Sales and Marketing***

We have built our marketing and sales organization to commercialize EXPAREL and our product candidates in the United States. We intend to out-license 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 products that we bring to the market. The primary target audience for EXPAREL is healthcare practitioners who influence pain management decisions, including surgeons, anesthesiologists, pharmacists and nurses.

In October 2015, we announced the promotion of James Scibetta to President. He will be responsible for the day-to-day operations and tactical execution of our newly formed Customer and Patient Solutions group, comprised of customer-facing resources. Mr. Scibetta will continue to serve as Chief Financial Officer while we conduct a search for his successor.

Our field team, consisting of both sales representatives and scientific and medical affairs professionals, executes on a full range of activities for EXPAREL, including:

- providing publications and abstracts showing the EXPAREL clinical program efficacy and safety, health outcomes program and review articles on pain management;
- working in tandem with hospital staff, such as registered nurses, surgeons, heads of quality, pharmacists and C-level executives, to provide access and resources for drug utilization or medication use evaluations and health outcomes studies, which provide retrospective and prospective analyses for our hospital customers using their own hospital data to demonstrate the true cost of opioid-based postsurgical pain control;

## [Table of Contents](#)

- working with KOLs and advisory boards to address topics of best practice techniques as well as guidelines and protocols for the use of EXPAREL, meeting the educational and training needs of our physician, surgeon, anesthesiologist, pharmacist and registered nurse customers; and
- undertaking education initiatives such as center of excellence programs; preceptorship programs; pain protocols and predictive models for enhanced patient care; interactive discussion forums; patient education platforms leveraging public relations, advocacy partnerships and public affairs efforts where appropriate; web-based training and virtual launch programs.

Our internal sales force is supported by our current marketing team as well as teams of healthcare professionals, including medical affairs, scientific affairs and nursing teams, who support our formulary approval and customer education initiatives. Additionally, effective October 1, 2013, we entered into an agreement with CrossLink BioScience, LLC, or CrossLink, to act as a local agent and lead partner in collaboration with additional distributors to promote and sell EXPAREL in select territories in the United States for postsurgical pain management following orthopedic procedures.

In order to increase the speed with which we address market segments, or to increase our access to market segments that we are currently not addressing, we may expand our sales resources in the future directly or by developing additional relationships with third parties that agree to sell our product.

### **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.

We believe the DepoFoam formulation provides several technical, regulatory and commercial advantages over competitive technologies, including:

- *Convenience.* Our DepoFoam products are ready to use, do not require reconstitution or mixing with another solution, and can be used with patient-friendly narrow gauge needles and pen systems;
- *Multiple regulatory precedents.* Our current and past DepoFoam products, including 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 fifteen years of safety data as DepoCyt(e) has been sold in the United States since 1999;
- *Proven manufacturing capabilities.* We make the DepoFoam-based products, EXPAREL and DepoCyt(e), in our cGMP facilities;
- *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 recognized revenue from DepoCyt(e) of \$8.1 million from our commercial partners in 2015.

## **Product Candidates**

In January 2015, we announced two product candidates to our DepoFoam based pipeline: DepoMeloxicam, or DepoMLX, and DepoTranexamic Acid, or DepoTXA.

### ***DepoMeloxicam***

Our preclinical product candidate, DepoMLX, is a long-acting non-steroidal anti-inflammatory drug, or NSAID, designed to treat moderate to severe acute postsurgical pain as part of a non-opioid multimodal regimen. A product designed for single dose local administration such as DepoMLX could provide a longer duration of pain relief at a significantly lower concentration of systemic NSAIDs, which are known to cause dose dependent gastrointestinal side effects. Meloxicam, which is currently available as an oral formulation, is a commonly used NSAID on the market today. We expect our customer audience for this drug to be similar to the target for EXPAREL infiltration.

DepoMLX is currently in pre-clinical development, and we expect the initiation of a Phase 1 clinical study under an investigational new drug application, or IND, in the second half of 2016.

### ***DepoTranexamic Acid***

Tranexamic Acid, or TXA, is currently used off-label as a systemic injection or as a topical application, and is used to treat or prevent excessive blood loss during surgery by promoting hemostasis. The current formulation of tranexamic acid, however, has a short-lived effect consisting of only a few hours, while the risk of bleeding continues for two to three days after surgery. We believe DepoTXA, a long acting local antifibrinolytic agent combining immediate and extended release TXA, could address the unmet, increasing need for rapid ambulation and discharge in the ambulatory surgery environment for joint surgery (primarily orthopedic surgery, including spine and trauma procedures and cardiothoracic surgery). Designed for single dose local administration into the surgical site, DepoTXA could provide enhanced hemostabilization and improved safety and tolerability for patients over the systemic use of TXA by reducing bleeding, the need for blood transfusions, swelling, soft-tissue hematomas and the need for post-operative drains, thereby increasing not only vigor in patients, but also by decreasing overall costs to the hospital system.

DepoTXA is currently in pre-clinical development, and we expect an IND approval to be followed by the initiation of a Phase 2 clinical study in the second half of 2016.

## **Commercial Partners and Agreements**

### ***SkyePharma Holdings, Inc.***

In connection with the stock purchase agreement related to the Acquisition, we agreed to certain earn-out payments based on a percentage of net sales of EXPAREL collected and certain other yet-to-be-developed products as well as milestone payments for EXPAREL as follows:

- (i) \$10.0 million upon first commercial sale in the United States;
- (ii) \$4.0 million upon first commercial sale in a major E.U. country (United Kingdom, France, Germany, Italy and Spain);
- (iii) \$8.0 million when annual net sales collected reach \$100.0 million;
- (iv) \$8.0 million when annual net sales collected reach \$250.0 million; and
- (v) \$32.0 million when annual net sales collected reach \$500.0 million.

## [Table of Contents](#)

The first milestone was met in April 2012, resulting in a \$10.0 million payment to Skyepharma. In September 2014, we made an \$8.0 million milestone payment to Skyepharma in connection with achieving \$100.0 million of annual EXPAREL net sales collected. For purposes of meeting future milestone payments, with certain exceptions, annual net sales are measured on a rolling quarterly basis.

Additionally, we agreed to pay to Skyepharma a certain percentage of net sales of EXPAREL collected in the United States, Japan, the United Kingdom, France, Germany, Italy and Spain. Such obligations to make percentage payments 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. The expiration date of the last valid claim will occur in 2018. Cumulatively through December 31, 2015, Skyepharma has earned \$14.9 million of percentage payments on net sales of EXPAREL collected. We have the right to cease paying the percentage payments in the event that Skyepharma breaches certain covenants not to compete contained in the stock purchase agreement.

See Note 6, *Goodwill and Intangible Assets*, to our consolidated financial statements included herein for further information related to the Skyepharma agreement.

### ***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 the collection of revenues 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, Inc.***

In December 2002, we entered into a supply and distribution agreement with Enzon Pharmaceuticals Inc., or Enzon, 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 for the United States and Canada, which has been renewed through 2016. Under the supply and distribution agreement, we supply unlabeled DepoCyt vials to Sigma-Tau. Under these agreements, we receive a fixed payment for the sale of DepoCyt vials, as well as a royalty on their sales in the thirty percent range.

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. In April 2014, we amended the agreements to extend the term of the agreements by an additional 15 years to June 2033 and we expanded Mundipharma's exclusive territory to include all countries other than the United States, Canada and Japan. In connection with the amendments, in May 2014, we received a non-refundable upfront payment of \$8.0 million. Under the agreement, as amended, and a separate supply agreement, we receive a fixed payment for the sale of DepoCyte vials, as well as a royalty in the thirty percent range. If annual sales exceed a certain amount, we receive an additional mid single-digit royalty. We are also entitled to receive up to €10.0 million in milestone payments from Mundipharma upon the achievement by Mundipharma of certain milestone events, of which we have already received €2.5 million and do not expect to receive the remaining €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.

***Paul Capital Advisors LLC***

In March 2007, we entered into an amended and restated royalty interests assignment agreement with Paul Capital Advisors LLC, or 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 Skyepharma 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 Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Royalty Interests Assignment Agreement.” Our related financing arrangement with Paul Capital Advisors terminated on December 31, 2014, and the final payment to Paul Capital occurred in March 2015.

***Aratana Therapeutics, Inc.***

In December 2012, we entered into an Exclusive License, Development and Commercialization Agreement and related Supply Agreement with Aratana Therapeutics, Inc., or Aratana. Under the agreements, we granted Aratana an exclusive royalty-bearing license, including the limited right to grant sublicenses, for the development and commercialization of our bupivacaine liposome injectable suspension product for animal health indications. Under the agreement, Aratana will develop and seek approval for the use of the product in veterinary surgery to manage postsurgical pain, focusing initially on developing it for cats and dogs. Aratana announced in December 2014 that they have initiated a pivotal field effectiveness study of our bupivacaine liposome injectable suspension in dogs undergoing knee surgery, and announced in July 2015 positive results from its pivotal field effectiveness study. Aratana intends to market the product as Nocita®.

In connection with our entry into the agreement, we received a one-time payment of \$1.0 million and are eligible to receive up to an additional aggregate \$42.5 million upon the achievement of development and commercial milestones, of which we received \$0.5 million in 2013. If the product is approved by the FDA for sale in the United States, Aratana will pay us a tiered double digit royalty on net sales made in the United States. If the product is approved by foreign regulatory agencies for sale outside of the United States, Aratana will pay us a tiered double digit royalty on such net sales. Royalty rates will be reduced by a certain percentage upon the entry of a generic competitor for animal health indications into a jurisdiction or if Aratana must pay royalties to third parties under certain circumstances.

Either party has the right to terminate the license agreement in connection with (i) an insolvency event involving the other party that is not discharged in a specified period of time; (ii) a material breach of the agreement by the other party that remains uncured for a specified cure period or (iii) the failure to achieve a minimum annual revenue as set forth in the agreement, all on specified notice. We may terminate the agreement in connection with (i) Aratana’s failure to pay any amounts due under the agreement; (ii) Aratana’s failure to achieve regulatory approval in a particular jurisdiction with respect to such jurisdiction or (iii) Aratana’s failure to achieve its first commercial sale within a certain amount of time on a country by country basis after receiving regulatory approval, all on specified notice. Aratana may terminate the license agreement (i) upon the entry of a generic competitor for animal health indications on a country by country basis or (ii) at any time on a country by country basis except with respect to the United States and any country in the European Union, all on specified notice. The parties may also terminate the license agreement by mutual consent. The license agreement will terminate automatically if we terminate the supply agreement. In the event that the license agreement is terminated, all rights to the product (on a jurisdiction by jurisdiction basis) will be terminated and returned to us.

Unless terminated earlier pursuant to its terms, the license agreement is effective until December 5, 2027, after which Aratana has the option to extend the agreement for an additional five (5) year term, subject to certain requirements.

***CrossLink BioScience, LLC***

Effective October 1, 2013, we and CrossLink commenced a five-year arrangement for the promotion and sale of EXPAREL, pursuant to the terms of a Master Distributor Agreement (as amended, the “Agreement”). We entered into the Agreement on March 11, 2013, which provided for an initial small-scale pilot period commencing on April 1, 2013 and ending on September 30, 2013 (the “Pilot Period”), during which CrossLink was appointed as the exclusive distributor of EXPAREL for certain specified accounts. The Agreement permitted either party to terminate the Agreement within 15 days prior to the expiration of the Pilot Period, and unless such termination was effected, the Agreement would automatically renew for a term of five years, commencing on October 1, 2013 and ending on September 30, 2018 (the “Term”). Neither party provided notice of termination, and upon the commencement of the Term, certain performance metrics and payment terms became effective and CrossLink’s distribution territory expanded.

## [Table of Contents](#)

Under the Agreement, we appointed CrossLink as the exclusive third-party distributor during the Term to promote and sell EXPAREL to orthopedic surgeons in the United States, with the exception of certain geographical areas and accounts (the “Territory”). The prices and purchasing terms related to sales of EXPAREL are determined by us, and all orders are subject to acceptance or rejection by us. CrossLink is entitled to receive commissions on its sales of EXPAREL in the Territory, subject to certain conditions and adjustments. CrossLink may receive additional performance-based payments if it achieves certain sales goals, and we may terminate the Agreement if CrossLink fails to meet certain minimum performance metrics.

CrossLink and any sub-distributors engaged by CrossLink pursuant to the terms of the Agreement are subject to certain obligations and restrictions, including required compliance with certain laws and regulations, confidentiality obligations and our policies. The Agreement contains customary representations and warranties and mutual indemnification obligations. In addition, CrossLink and its sub-distributors are prohibited from promoting, selling or distributing any competitive products during the Term.

Pacira and CrossLink have mutual termination rights under the Agreement, and we have additional unilateral termination rights under certain circumstances. The Agreement also permits us to terminate the Agreement without cause effective September 30, 2016, subject to certain terms and conditions set forth in the Agreement.

Effective March 1, 2015, the Agreement was amended to, among other things, amend certain payment terms and specify certain sub-distributors that may promote and sell EXPAREL under the Agreement.

### **Significant Customers**

We had three customers each comprising 10% or more of our total revenue for the year ended December 31, 2015: AmerisourceBergen Health Corporation, Cardinal Health, Inc. and McKesson Drug Company, which accounted for 33%, 29% and 28% of our revenues. These customers are wholesalers that process orders for EXPAREL under a drop-ship program.

### **Manufacturing and Research Facilities**

#### *Internal Facilities*

We manufacture EXPAREL and DepoCyt(e) in two manufacturing facilities in San Diego, California. 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. We also have a research and development facility, Building 2, which sits adjacent to Building 1, and a warehouse, Building 7, located within five miles of our manufacturing facilities. We refer to these four buildings as the Science Center Campus, and together these four buildings consist of approximately 172,000 square feet. Our manufacturing facilities are inspected regularly and approved for pharmaceutical manufacturing by the FDA, the European Medicines Agency, or EMA, the Medicines and Healthcare Products Regulatory Agency, or MHRA, and the Environmental Protection Agency.

We purchase raw materials and components from third party suppliers in order to manufacture EXPAREL. In most instances, alternative sources of supply are available, although switching to an alternative source would, in some instances, take time and could lead to delays in manufacturing our drug candidates. We also purchase raw materials and equipment from third party suppliers for the manufacture of DepoCyt(e). While we have not experienced shortages of our raw materials in the past, such suppliers may not sell these raw materials to us at the times that we need them or on commercially reasonable terms and we do not have direct control over the availability of these raw materials from our suppliers.

All manufacturing of products, initial product release and stability testing are conducted by us in accordance with cGMP.

Building 1 is an approximately 84,000 square foot concrete structure located on a five acre site. It was custom built as a pharmaceutical R&D and manufacturing facility in 1995. Activities in this facility include the manufacture of EXPAREL bulk product on dedicated production lines and its fill/finish into vials, microbiological and quality control testing, product storage, development of analytical methods and manufacturing of development products. Prior to 2014, the bulk manufacturing of all EXPAREL product sold to the marketplace had occurred in a manufacturing line housed in what we refer to as Suite A. In 2014, the FDA approved our recently installed manufacturing lines, referred to as Suite C. Suite C significantly increased our manufacturing capacity and ability to meet the growing demand for EXPAREL. In 2015, we transitioned Suite A into a clinical suite, which could also be used for the commercial production of development products. We are expanding our manufacturing capacity directly and through agreements with a third party, Patheon, as demand for EXPAREL increases.

## [Table of Contents](#)

Building 2 is a recently renovated approximately 45,000 square foot steel and concrete structure located adjacent to Building 1, originally built as a pharmaceutical R&D lab and office building in 2003. We moved most of our Science Center related general and administrative functions to this building in 2015, as roughly half of the building is office space. The other half of the building is being used for research and development activities as it includes both laboratories and the building infrastructure necessary to support the formulation, analytical testing, clinical and process development activities for additional commercial product indications and new pipeline products.

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) 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.

Building 7 is an approximately 21,000 square foot concrete panel structure built in 1988 which serves as the main cGMP warehouse for all of our San Diego operations. It was recently renovated in early 2014 to support the expansion of EXPAREL. The warehouse is primarily used for the storage of materials used in the production of our products. It contains ambient as well as cold temperature cGMP warehouse storage for materials used in our manufacturing operations. It also features a quality control clean room for sampling incoming materials.

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 utilize similar cold-chain processes for DepoCyt(e).

### ***Co-Production Facilities***

In April 2014, we and Patheon U.K. Limited, or Patheon, entered into a Strategic Co-Production Agreement, Technical Transfer and Service Agreement and Manufacturing Supply Agreement (the "Patheon Agreements") to collaborate in the manufacture of EXPAREL. Patheon has agreed to undertake certain technical transfer activities and construction services needed to prepare Patheon's Swindon, England facility for the manufacture of EXPAREL in two dedicated manufacturing suites. We will provide Patheon with the equipment necessary to manufacture EXPAREL and will pay fees to Patheon based on Patheon's achievement of certain technical transfer and construction milestones. We will also reimburse Patheon for certain nominal expenses and additional services. We also currently expect, subject to receipt of regulatory approvals, the first commercial manufacturing suite at Patheon's facility to commence commercial production in early 2017.

The Technical Transfer and Service Agreement expires upon receipt of FDA approval of the manufacturing suites. We may terminate the Technical Transfer and Service Agreement if Patheon does not meet certain construction and manufacturing milestones, or at any time for convenience upon 30 days' notice. Either party may terminate the Technical Transfer and Service Agreement in the event of a breach by or bankruptcy of the other party. If the Technical Transfer and Service Agreement is terminated before the completion of the first manufacturing suite, the Manufacturing and Supply Agreement and Strategic Co-Production Agreement will concurrently and automatically terminate.

The initial term of the Manufacturing Supply Agreement is 10 years from the date of FDA approval of the initial manufacturing suite. We will pay fees to Patheon for their operation of the manufacturing suites and the amount of EXPAREL produced by Patheon. We will also reimburse Patheon for purchases made on our behalf, certain nominal expenses and additional services. We may terminate this agreement upon one month's notice if a regulatory authority causes the withdrawal of EXPAREL from the United States or any other market that represents 80% of our overall sales, or at any time for convenience by providing between 18 and 36 months' notice (depending on the number of years after the FDA approval date). Either party may terminate the Manufacturing Supply Agreement in the event of the breach or bankruptcy of the other party.

Upon termination of these agreements (other than termination by us for a breach by Patheon), we will pay for the make good costs occasioned by the removal of our manufacturing equipment and for Patheon's termination costs up to a maximum amount of \$2.4 million.

### **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 December 31, 2015, there are over 14 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, as discussed below, with the last currently issued patent expiring in 2018.

In regards to patents providing protection for EXPAREL, issued patents in the United States relating to methods for modifying the rate of drug release of the product candidate and the composition of the product candidate expire in January 2017 and September 2018, respectively. A patent relating to compositions including EXPAREL, but not EXPAREL specifically, expired in November 2013. A patent relating to the composition of the product issued in September 2014 and will expire in September 2018. A patent relating to the method of treatment using EXPAREL issued in December 2015 and will expire in September 2018. Two pending U.S. applications relating to the process for making the product candidate, if granted, would expire in November 2018. In Europe, granted patent(s) related to the composition of the product candidate expire in September 2018 and certain European patent(s) expired in November 2014. 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. In April 2010, 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. In April 2011, we filed a non-provisional patent application which, if granted, could prevent others from using this process until 2031. In 2015, this patent application was granted as a patent in the Peoples Republic of China. 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.

We have also taken steps to protect our two pipeline candidates, DepoMLX and DepoTXA. Pending patent applications for compositions and methods of treatment of DepoMLX, if granted, would expire in October 2031. In addition, a provisional patent application for DepoTXA has been filed and, if granted, would expire in January 2036.

### ***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 third parties 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 developing, 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.

## [Table of Contents](#)

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.

EXPAREL competes 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 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. EXPAREL also competes with currently-marketed non-opioid products such as bupivacaine, marcaine, ropivacaine and other anesthetics/analgesics such as morphine, 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. Currently EXPAREL also competes with elastomeric pump/catheter devices intended to provide bupivacaine over several days. I-FLOW Corporation (acquired by Kimberly-Clark Corporation in 2009 and spun off into Halyard Health, Inc. in 2014) 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 research, development, testing, manufacturing, distribution, safety, efficacy, approval, labeling, storage, record keeping, reporting, advertising and promotion of such products under the Federal Food, Drug and Cosmetic Act, or 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, refusal to approve pending applications, withdrawal of an approval, 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. Any agency or judicial enforcement action could have a material adverse effect on us.

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

Generally, the FDA must approve any new drug, including a new use of a previously approved 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 regulations;
- submission to the FDA of an investigational new drug, or 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 adequate and well-controlled human clinical trials in accordance with the FDA's good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each intended use;
- completion of process validation, quality product release and stability;
- submission of a new drug application, or 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 current Good Manufacturing Practice, or cGMP, requirement 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

## [Table of Contents](#)

- review 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 Pacira to amend an existing IND for each successive clinical trial conducted during product development. Further, an IRB covering each site 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. We may also suspend or terminate a clinical study based on evolving business objectives and/or competitive climate.

Clinical trials involve the administration of the product candidate to healthy volunteers or patients having the disease being studied 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. Sponsors of clinical trials generally must register and report, at the NIH-maintained website [www.clinicaltrials.gov](http://www.clinicaltrials.gov), key parameters of certain clinical trials. 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 or be combined:

- *Phase 1:* Sponsors initially conduct clinical trials in a limited population, either patients or healthy volunteers, to test the product candidate for safety, dose tolerance, absorption, metabolism, distribution, excretion and clinical pharmacology, and, if possible, to gain early evidence of effectiveness. In the cases of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing often is conducted only on patients having the specific disease.
- *Phase 2:* Sponsors conduct clinical trials generally in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted indications and to determine dose tolerance, optimal dosage and dosing schedule. 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.

Some clinical studies may be overseen by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study. The process of completing clinical testing and obtaining FDA approval for a new drug is likely to take a number of years and require the expenditure of substantial resources. If an application is submitted, there can be no assurance that the FDA will review and approve the NDA. In addition, sponsors may elect to conduct, or be required by the FDA to conduct, post-approval 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.

### ***U.S. Review and Approval Process***

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, sponsors submit the results of product development, preclinical studies and clinical trials to the FDA as part of an NDA requesting approval to market the product for one or more indications. 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

## [Table of Contents](#)

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. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission has been accepted for filing, the FDA begins an in-depth substantive review. If the FDA accepts the submission for substantive review, the FDA typically reviews the NDA in accordance with established timeframes. Under the PDUFA, the FDA establishes 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 within six months. Standard Review applies to all applications that are not eligible for Priority Review. The FDA aims to complete Standard Review NDAs within ten months. 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 the 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 will 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.

Applications under Section 505(b)(2) 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 FDA's 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 brings 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

[Table of Contents](#)

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.

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 FDA-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 September 2014, we received a warning letter from the FDA's Office of Prescription Drug Promotion, or OPDP, pertaining to certain promotional aspects of EXPAREL. We took actions to immediately address FDA's concerns and minimize further disruption to our business. Ultimately, however, we filed a lawsuit on September 8, 2015 seeking a court order to defend

## [Table of Contents](#)

against any retroactive attempt to limit the broad indication for EXPAREL and restrict communications supported by the approved label. On December 15, 2015, we announced that the FDA had formally withdrawn the September 2014 Warning Letter via a “Rescission Letter,” and that the FDA and Pacira had reached an amicable resolution of the lawsuit. As part of the resolution of this matter, the FDA confirmed that EXPAREL was broadly approved for “administration into the surgical site to product postsurgical analgesia” in a variety of surgeries not limited to those studied in its pivotal trials. The FDA also approved a labeling supplement for EXPAREL that further clarified that EXPAREL was not limited to any specific surgery type or site, that the proper dosage and administration of EXPAREL is based on various patient and procedure-specific factors, that there was a significant treatment effect for EXPAREL compared to placebo over the first 72 hours in the pivotal hemorrhoidectomy study and that EXPAREL may be admixed with bupivacaine, provided certain medication ratios are observed. Pacira and the FDA have agreed that, in future interactions, they will deal with each other in an open, forthright and fair manner.

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.

### ***International Regulation***

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

For example, in Europe, there are several tracks for marketing approval, for product approval and post-approval regulatory processes, depending on the type of product for which approval is sought. Under the centralized procedure, a company submits a single application to the EMA. The marketing application is similar to the NDA in the U.S. and is evaluated by the Committee for Medicinal Products for Human Use, or CHMP, the expert scientific committee of the EMA. If the CHMP determines that the marketing application fulfills the requirements for quality, safety and efficacy, it will submit a favorable opinion to the European Commission, or EC. The CHMP opinion is not binding, but is typically adopted by the EC. A marketing application approved by the EC is valid in all member states. The centralized procedure is required for all biological products, orphan medicinal products and new treatments for neurodegenerative disorders, and it is available for certain other products, including those which constitute a significant therapeutic, scientific or technical innovation.

In addition to the centralized procedure, Europe also has (i) a nationalized procedure, which requires a separate application to and approval determination by each country; (ii) a decentralized procedure whereby applicants submit identical applications to several countries and receive simultaneous approval and (iii) a mutual recognition procedure, where applicants submit an application to one country for review and the other countries may accept or reject the initial decision. Regardless of the approval process employed, various parties share responsibilities for the monitoring, detection and evaluation of adverse events post-approval, including national authorities, the EMA, the EC and the marketing authorization holder.

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.

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 products and 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

## [Table of Contents](#)

aimed at cost containment that could impact our ability to sell our products at a price level high enough to realize an appropriate return on our investment, which would materially impact our results of operations.

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 Affordable Care Act, 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. The Affordable Care Act revised the definition of “average manufacturer price” for reporting purposes, which could increase the amount of Medicaid drug rebates owed to states by pharmaceutical manufacturers for covered outpatient drugs. The Affordable Care Act also established a new Medicare Part D coverage gap discount program, in which drug manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand name 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. Further, the new law imposed 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. There have been proposed in Congress a number of legislative initiatives regarding healthcare, including possible repeal of the Affordable Care Act. At this time, it remains unclear whether there will be any changes made to the Affordable Care Act. The full impact that the Affordable Care and other new laws will have on our business is uncertain. However, such laws appear 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 marketability of our products may suffer if the government and third-party payers fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased, and we expect will continue to increase, the pressure on pharmaceutical pricing. Some third-party payers require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers that use such therapies, or place limits on the amount of reimbursement. Coverage policies and third-party payer reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for our products, less favorable coverage policies and reimbursement rates may be implemented in the future.

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 or that an adequate level of reimbursement will be available so that the third-party payers’ reimbursement policies will not adversely affect our ability to sell our products profitably.

### ***Marketing/Data Exclusivity***

The FDA may grant three or five years of marketing exclusivity in the United States for the approval of new or supplemental NDAs, including Section 505(b)(2) NDAs, for, among other things, new indications, dosages or dosage forms of an existing drug, if new clinical investigations that were conducted or sponsored by the applicant are essential to the approval of the application. Additionally, six months of marketing exclusivity in the United States is available under Section 505A of the FDCA if, in response to a written request from the FDA, a sponsor submits and the agency accepts requested information relating to the use of the approved drug in the pediatric population. This six month pediatric exclusivity period is not a standalone exclusivity period, but rather is added to any existing patent or non-patent exclusivity period for which the drug product is eligible. Based on our clinical trial program for EXPAREL, the FDA granted three years of marketing exclusivity to EXPAREL, which expired on October 28, 2014.

### ***Manufacturing Requirements***

We must comply with the FDA’s cGMP requirements and comparable regulations in other countries. The cGMP provisions 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 and other authorities pursuant to a pre-approval inspection before we can use them to manufacture our products. We and any third-party manufacturers we engage or with which we partner 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

## [Table of Contents](#)

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 or product complaints must be reported 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.

### ***Regulations Pertaining to Sales and Marketing***

We are subject to various federal and state laws pertaining to health care “fraud and abuse,” including anti-kickback laws and false claims laws. Anti-kickback laws generally prohibit a prescription drug manufacturer from soliciting, offering, receiving, or paying any remuneration to generate business, including the purchase or prescription of a particular drug. Although the specific provisions of these laws vary, their scope is generally broad and there may be no regulations, guidance or court decisions that clarify how the laws apply to particular industry practices. There is therefore a possibility that our practices might be challenged under the anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third party payers (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal or civil sanctions, including fines and civil monetary penalties and exclusion from federal health care programs (including Medicare and Medicaid). In the U.S., federal and state authorities are paying increased attention to enforcement of these laws within the pharmaceutical industry and private individuals have been active in alleging violations of the laws and bringing suits on behalf of the government under the federal civil False Claims Act. If we were subject to allegations concerning, or were convicted of violating, these laws, our business could be harmed.

Laws and regulations have been enacted by the federal government and various states to regulate the sales and marketing practices of pharmaceutical manufacturers. The laws and regulations generally limit financial interactions between manufacturers and health care providers or require disclosure to the government and public of such interactions. The laws include the federal Physician Payment Sunshine Act, or “sunshine” provisions, enacted in 2010 as part of the Affordable Care Act. The sunshine provisions apply to pharmaceutical manufacturers with products reimbursed under certain government programs and require those manufacturers to disclose annually to the federal government (for re-disclosure to the public) certain payments made to physicians and certain other healthcare practitioners or to teaching hospitals. State laws may also require disclosure of pharmaceutical pricing information and marketing expenditures. Many of these laws and regulations contain ambiguous requirements. Given the lack of clarity in laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent federal and state laws and regulations. Outside the U.S., other countries have implemented requirements for disclosure of financial interactions with healthcare providers and additional countries may consider or implement such laws.

### ***Healthcare Privacy and Security Laws***

We may be subject to, or our marketing activities may be limited by the Health Insurance Portability and Accountability Act, or 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.

### ***Environmental Matters***

Our research and development processes and our manufacturing processes involve the controlled use of hazardous materials and chemicals and produce waste products. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. We do not expect the cost of complying with these laws and regulations to be material. While we believe we are in compliance with applicable



environmental regulations, the failure to fully comply with any such regulations could result in the imposition of penalties, fines and/or sanctions which could have a material adverse effect on our business.

## Employees

As of December 31, 2015, we had 487 employees. All of our employees are located in the United States except for two located in England. None of our employees are represented by a labor union, and we consider our current employee relations to be good.

## Available Information

We file reports and other information with the SEC as required by the Exchange Act. We make available free of charge through our website (<http://www.pacira.com>) our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Exchange Act. We make these reports available through our website as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the SEC. In addition, we regularly use our website to post information regarding our business, product development programs and governance, and we encourage investors to use our website, particularly the information in the section entitled "Investors & Media," as a source of information about us. The foregoing references to our website are not intended to, nor shall they be deemed to, incorporate information on our website into this Annual Report on Form 10-K by reference.

## Item 1A. Risk Factors

In addition to the other information in this Annual Report on Form 10-K, any of the factors set forth below could significantly and negatively affect our business, financial condition, results of operations or prospects. The trading price of our common stock may decline due to these risks. This section contains forward-looking statements. You should refer to the explanation of the qualifications and limitations on forward-looking statements beginning on page 1.

### Risks Related to the Development and Commercialization of Our Product Candidates

#### *Our success depends on our ability to successfully commercialize EXPAREL.*

We have invested a significant portion of our efforts and financial resources in the development and commercialization of our lead product, EXPAREL, which was approved by the FDA on October 28, 2011 and commercially launched in April 2012. During 2015, sales of EXPAREL constituted the vast majority of our total revenue, and our success depends on our ability to continue to effectively commercialize EXPAREL. Our ability to effectively generate revenues from EXPAREL will depend on our ability to, among other things:

- create market demand for EXPAREL through our marketing and sales activities and other arrangements established for the promotion of EXPAREL;
- train, deploy and support a qualified sales force;
- secure formulary approvals for EXPAREL at a substantial number of targeted hospitals;
- manufacture EXPAREL in sufficient quantities in compliance with requirements of the FDA and similar foreign regulatory agencies and at acceptable quality and pricing levels in order to meet commercial demand;
- implement and maintain agreements with wholesalers, distributors and group purchasing organizations on commercially reasonable terms;
- receive adequate levels of coverage and reimbursement for EXPAREL from commercial health plans and governmental health programs;
- maintain compliance with regulatory requirements;
- obtain regulatory approvals for additional indications for the use of EXPAREL;
- ensure that our entire supply chain efficiently and consistently delivers EXPAREL to our customers; and
- maintain and defend our patent protection and regulatory exclusivity for EXPAREL.

## [Table of Contents](#)

Any disruption in our ability to generate revenues from the sale of EXPAREL will have a material and adverse impact on our results of operations.

***Our efforts to successfully commercialize EXPAREL are subject to many internal and external challenges and if we cannot overcome these challenges in a timely manner, our future revenues and profits could be materially and adversely impacted.***

EXPAREL has been a commercialized drug for less than four years. As a result, we continue to expend significant time and resources to train our sales force to be credible and persuasive in convincing physicians and hospitals to use EXPAREL. In addition, we also must train our sales force to ensure that a consistent and appropriate message about EXPAREL is delivered to our potential customers. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits and risks of EXPAREL and its proper administration, our efforts to successfully commercialize EXPAREL could be put in jeopardy, which could have a material adverse effect on our future revenues and profits.

In addition to our extensive internal efforts, the successful commercialization of EXPAREL will require many third parties, over whom we have no control, to choose to utilize EXPAREL. These third parties include physicians and hospital pharmacy and therapeutics committees, which we refer to as P&T committees. Generally, before we can attempt to sell EXPAREL in a hospital, EXPAREL must be approved for addition to that hospital's list of approved drugs, or formulary list, by the hospital's P&T committee. A hospital's P&T committee typically governs all matters pertaining to the use of medications within the institution, including the review of medication formulary data and recommendations for the appropriate use of drugs within the institution to the medical staff. The frequency of P&T committee meetings at hospitals varies considerably, and P&T committees often require additional information to aid in their decision-making process. Therefore, we may experience substantial delays in obtaining formulary approvals. Additionally, hospital pharmacists may be concerned that the cost of acquiring EXPAREL for use in their institutions will adversely impact their overall pharmacy budgets, which could cause pharmacists to resist efforts to add EXPAREL to the formulary, or to implement restrictions on the usage of EXPAREL in order to control costs. We cannot guarantee that we will be successful in obtaining the approvals we need from enough P&T committees quickly enough to optimize hospital sales of EXPAREL.

Even if we obtain hospital formulary approval for EXPAREL, physicians must still prescribe EXPAREL for its commercialization to be successful. Because EXPAREL is a relatively new drug with a limited track record of sales in the United States, any inability to timely supply EXPAREL to our customers, or any unexpected side effects that develop from use of the drug, particularly early in product launch, may lead physicians to not accept EXPAREL as a viable treatment alternative.

If EXPAREL does not achieve broad market acceptance, the revenues that we generate from its sales will be limited. The degree of market acceptance of EXPAREL also depends on a number of other factors, including:

- changes in the standard of care for the targeted indications for EXPAREL, which could reduce the marketing impact of any claims that we can make;
- the relative efficacy, 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, both in absolute terms and 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 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 therefore 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

## [Table of Contents](#)

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.

In addition, the labeling approved by the FDA does not contain claims that EXPAREL is safer or more effective than competitive products and does not 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 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 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 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 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 or our product candidates.

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

EXPAREL competes 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 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 competes 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.

EXPAREL also competes with elastomeric bag/catheter devices intended to provide bupivacaine over several days. I-FLOW Corporation (acquired by Kimberly-Clark Corporation in 2009 and spun off into Halyard Health, Inc. in 2014) has marketed these medical devices in the United States since 2004.

***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, and allegations of our failure to comply with such approved indications could limit our sales efforts and have a material adverse effect on our business.***

The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs. 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. Any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA. For example, the FDA-approved label for EXPAREL does not include an indication in obstetrical paracervical block anesthesia. 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 in the United States may choose, and are generally permitted 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 narrowly 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. Although recent court decisions suggest that certain off-label promotional activities may be protected under the First Amendment, the scope of any such protection is unclear. If our promotional activities fail to comply with the FDA's 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, bring an enforcement action against us, 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 reputation and our business.

In September 2014, we received a warning letter from the OPDP pertaining to certain promotional aspects of EXPAREL, and in February 2015, agreement was reached with the OPDP on the content and mechanisms for distribution of corrective action, which consisted of a Dear Healthcare Provider Letter and a corrective journal advertisement. Although the warning letter was subsequently withdrawn we expect that it had a negative impact on our customers' perception of us. We can make no assurances that we will not receive FDA warning letters in the future or be subject to other regulatory action. As noted above, any regulatory violation or allegations of a violation may have a material adverse effect on our reputation and business.

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

We are continuing to build our commercial infrastructure for the marketing, sale and distribution of pharmaceutical products. In order to continue commercializing EXPAREL effectively, we must continue to build our marketing, sales and distribution capabilities. We entered into an agreement with Quintiles for the outsourcing of our specialty sales force, which we then hired as direct employees in January 2013. The establishment, development and training of our sales force and related compliance plans to market EXPAREL is expensive and time consuming. In the event we are not successful in developing our marketing and sales infrastructure, we may not be able to successfully commercialize EXPAREL, which would limit our ability to generate product revenues.

In addition to our internal marketing and sales efforts, we have entered into agreements with third party distributors to promote and sell EXPAREL in certain territories. For example, following a pilot program, effective October 1, 2013, we appointed CrossLink as our exclusive third-party distributor to promote and sell EXPAREL to orthopedic surgeons in the United States, with the exception of certain geographical areas and accounts, for a five year term. We may seek additional distribution arrangements in the future, including arrangements with third party distributors to commercialize and sell EXPAREL in certain foreign countries. The use of distributors involves certain risks, including risks that such distributors will:

- not effectively distribute or support our products;
- not provide us with accurate or timely information regarding their inventories, the number of accounts using our products or complaints about our products;
- fail to comply with their obligations to us;
- fail to comply with laws and regulations to which they are subject, whether in the U.S. or in foreign jurisdictions;
- reduce or discontinue their efforts to sell or promote our products; or
- cease operations.

Any such failure may result in decreased sales, which would have an adverse effect on our business.

***We rely on third parties to perform many essential services for EXPAREL and any other products that we commercialize, including services related to customer service support, warehousing and inventory program services, distribution services, contract administration and chargeback processing services, accounts receivable management and cash application services, and financial management and information technology services. 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 have entered into agreements with third-party service providers to perform a variety of functions related to the sale and distribution of EXPAREL, key aspects of which are out of our direct control. These service providers provide key services related to customer service support, warehousing and inventory program services, distribution services, contract administration and chargeback processing services, accounts receivable management and cash application services, financial management and information technology services. In addition, our inventory is stored at two warehouses maintained by two service providers.

## [Table of Contents](#)

We substantially rely on these providers 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, including EXPAREL, requires cold-chain distribution provided by third parties, whereby the product must be maintained between specified temperatures. We and our partners have utilized similar cold-chain processes for DepoCyt(e) and, when it was produced, 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. We have obtained limited inventory and cargo insurance coverage for our products. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. 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 effectively manage our sales force, and we may experience difficulties in managing growth.***

As of December 31, 2015, we had 487 employees. We may need to expand our personnel resources in order to manage our operations and sales of EXPAREL. 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 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 for the commercialization of EXPAREL, and establish appropriate systems, policies and infrastructure to support that organization;
- continue to establish and maintain effective relationships with distributors and commercial partners for the promotion and sale of our products;
- ensure that our distributors, partners, suppliers, consultants and other service providers successfully carry out their contractual obligations, provide high quality results and meet expected deadlines;
- manage our development efforts and clinical trials effectively;
- expand our manufacturing capabilities and effectively manage our co-production arrangement with Patheon;
- 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. Additionally, these tasks may impose a strain on our administrative and operational infrastructure. If we are unable to effectively manage our growth, our product sales and resulting revenues will be negatively impacted.

***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, as well as universities, non-profit research organizations and government entities, 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

## [Table of Contents](#)

management team, including David Stack, our Chief Executive Officer and Chairman and James Scibetta, our President and Chief Financial 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.

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

The use of DepoCyt(e), EXPAREL and any 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. We have been a party of these suits in the past and may be again in the future. 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, including our indemnification obligations to other parties. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage on acceptable terms, 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 upon 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.

***If we fail to manufacture EXPAREL 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 or be unable to meet market demand, and may lose potential revenues.***

The manufacture of EXPAREL requires significant expertise and capital investment, including the development of advanced manufacturing techniques, process controls and the use of specialized processing equipment. We must comply with federal, state and foreign regulations, including the FDA's regulations governing cGMP, enforced by the FDA through its facilities inspection program and by similar regulatory authorities in other jurisdictions where we do business. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The FDA or similar foreign regulatory authorities at any time may implement new standards, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of our products. Any failure by us or our manufacturing partner to comply with applicable regulations may result in fines and civil penalties, suspension of production, product seizure or recall, operating restrictions, imposition of a consent decree, modification or withdrawal of product approval or criminal prosecution and would limit the availability of our product. Any manufacturing defect or error discovered after products have been produced and distributed also could result in 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.

***We will need to expand our manufacturing operations or outsource such operations to third parties.***

To successfully meet future customer demand for EXPAREL, we will need to expand our existing commercial manufacturing facilities or establish large-scale commercial manufacturing capabilities. In addition, as our drug development pipeline increases and matures, we will have a greater need for clinical trial and commercial manufacturing capacity. As a result, we must continue to improve our manufacturing processes to allow us to reduce our production costs. We may not be able to manufacture our drugs at a cost or in quantities necessary to be commercially successful.

The build-up or other expansion of our internal manufacturing capabilities for EXPAREL production in San Diego, California exposes us to significant up-front fixed costs. If market demand for EXPAREL does not align with our expanded manufacturing capacity, we may be unable to offset these costs and to achieve economies of scale, and our operating results may be adversely affected as a result of high operating expenses. Alternatively, if we experience demand for EXPAREL in excess of our estimates, our facilities may be insufficient to support higher production volumes, which could harm our customer relationships and overall reputation. Our ability to meet such excess demand could also depend on our ability to raise additional capital and effectively scale our manufacturing operations.

In addition, the procurement time for the equipment that we use to manufacture EXPAREL requires long lead times. Therefore, we may experience delays, additional or unexpected costs and other adverse events in connection with our capacity expansion projects, including those associated with potential delays in the procurement of manufacturing equipment required to manufacture EXPAREL, including the equipment for the construction of manufacturing suites at Patheon.

In addition to expanding our internal manufacturing facilities, we may enter into arrangements with third parties to supply, manufacture, package, test and/or store EXPAREL or our other products, such as our manufacturing arrangement with Patheon. Entering into such arrangements requires testing and compliance inspections, FDA approvals and development of the processes and facilities necessary for the production of our products. Such arrangements also involve additional risks, many of which would be outside of our control. Such risks include disruptions or delays in production, manufactured products that do not meet our required specifications, the failure of such third party manufacturers to comply with cGMP regulations or other regulatory requirements, protection of our intellectual property and manufacturing process, loss of control of our complex manufacturing process, inability to fulfill our commercial needs and financial risks in connection with our investment in setting up a third party manufacturing process, such as substantial capital outlays required by us to assist in setting up our manufacturing process at Patheon's facilities.

If we are unable to achieve and maintain satisfactory production yields and quality, whether through our internal manufacturing capabilities or arrangements with contract manufacturers, our relationships with potential customers and overall reputation may be harmed and our revenues could decrease.

***We are currently the sole manufacturer of EXPAREL and DepoCyt(e). Our inability to continue manufacturing adequate supplies of these products could result in a disruption in the supply to our customers and partners, which could have a material adverse impact on our business and results of operations.***

We are currently the sole manufacturer of EXPAREL and DepoCyt(e), and we expect to be the sole manufacturer until, if and when manufacturing operations commence at Patheon's facility, which we currently expect, subject to receipt of regulatory approvals, to commence in one to two years' time. We develop and manufacture EXPAREL and DepoCyt(e) at our facilities in San Diego, California, which are the only FDA approved sites for manufacturing EXPAREL and DepoCyt(e) in the world. We may experience temporary or prolonged suspensions in production of our products due to issues in our manufacturing process that must be remediated or in response to inspections conducted by the FDA or similar foreign regulatory authorities, which could have a material adverse effect on our business, financial position and results of operations.

For example, in 2012 we temporarily ceased the manufacturing of DepoCyt(e) for sales in the European Union to implement a remediation plan to address certain issues noted in an inspection report issued by the MHRA, in July 2012 regarding our DepoCyt(e) manufacturing facility, which is located in a separate building from our EXPAREL manufacturing facility. The assessment report also recommended a selective recall of DepoCyt(e) in European Union member states where DepoCyt(e) is not considered to be an "essential medicinal product," which contributed to a reduction in product sales of DepoCyt(e) during fiscal year 2012. Although we received notice from the MHRA in January 2013 that our remediation efforts were successful and that we could resume production of DepoCyt(e) for sale in Europe, we may be required in the future to cease manufacturing operations at our facilities in response to inspection reports or other regulatory actions, and such temporary cessations could result in additional costs or delays in the production and sale of our products.

Our San Diego facilities are also subject to the risks of a natural or man-made disaster, including earthquakes and fires, or other business disruption. In addition, we have obtained limited property and business interruption insurance coverage for our

## [Table of Contents](#)

facilities in San Diego. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. There can be no assurance that we would be able to meet our requirements for EXPAREL and DepoCyt(e) 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 EXPAREL and DepoCyt(e) at our facilities in San Diego, California could result in a disruption in the supply of EXPAREL and DepoCyt(e), respectively, to our customers and partners and a breach of our contractual obligations to such counterparties.

***Our co-production and other agreements with Patheon may involve unanticipated expenses and delays, including the need for the Patheon facilities to receive regulatory approvals required for manufacturing to commence at the Patheon suites.***

We and Patheon have entered into a Co-Production Agreement, Technical Transfer and Service Agreement and Manufacturing Supply Agreement. Under these agreements, Patheon will undertake certain technical transfer activities and construction services to prepare Patheon's Swindon, England facility for the manufacture of EXPAREL in two dedicated manufacturing suites. We have agreed with Patheon, among other things, to provide them with the process equipment necessary to manufacture EXPAREL in these suites. We have anticipated and budgeted for capital expenditures associated with the two Patheon suites, including the equipment purchase and construction of the suites as well as payments to be made to Patheon.

The Patheon facilities must be approved by the FDA prior to any production and manufacturing of EXPAREL. We currently expect, subject to receipt of regulatory approvals, that the first commercial manufacturing suite at Patheon's facility will commence commercial production in 2016 or 2017. If the construction of the Patheon suites is delayed, if Patheon experiences unanticipated cost overruns, or if the Patheon suites do not receive regulatory approvals in the timeframe anticipated (if at all), this could have a material adverse effect on our business, financial position and results of operations.

Further, if and when the Patheon facilities are constructed and have received the required FDA approvals, the production under these agreements involve additional risks, many of which would be outside of our control, such as disruptions or delays in production, manufactured products that do not meet our required specifications, the failure of Patheon to comply with cGMP regulations or other regulatory requirements, protection of our intellectual property and manufacturing process, loss of control of our complex manufacturing process and inability to fulfill our commercial needs.

***We rely on third parties for the timely supply of specified raw materials and equipment for the manufacture of DepoCyt(e) and EXPAREL. 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.***

We purchase certain raw materials and equipment from various suppliers in order to manufacture our products. The acquisition of certain of these materials may require considerable lead times, and our ability to source such materials is also dependent on logistics providers. If we are unable to source the required raw materials and equipment from our suppliers on a timely basis and in accordance with our specifications, we may experience delays in manufacturing and may not be able to meet our customers' or partners' demands for our products. In addition, we and our third-party suppliers must comply with federal, state and foreign regulations, including cGMP regulations, and any failure to comply with applicable regulations, or failure of government agencies to provide necessary authorizations, may harm our ability to manufacture and commercialize our products on a timely and competitive basis, which could result in decreased product sales and lower revenues.

***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:

- significant capital expenditures;
- 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;



## [Table of Contents](#)

- 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 entering markets in which we have limited or no direct experience;
- 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, including public and private research organizations, academic institutions and government agencies, in our efforts to establish new collaborations and in-licensing opportunities. These competitors may have access to greater financial resources, research and development staffs and facilities than us and may have greater expertise in identifying and evaluating new opportunities. We may not be successful in locating and acquiring or in-licensing additional desirable product candidates on acceptable terms or at all. 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 or unintended failure to comply with these laws and regulations. In the event of an accident or failure to comply with these laws and regulations, 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, human error, unauthorized access, natural disasters, intentional acts of vandalism, 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, reputation damage and harm to our business operations.

***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.

***Clinical trials may fail to demonstrate the safety and efficacy of our drug products, which could prevent or significantly delay obtaining regulatory approval.***

Prior to receiving approval to commercialize any of our drug products, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA, other regulatory authorities in the United States, and other countries, that each of the products is both safe and effective. For each drug product, we will need to demonstrate its efficacy and monitor its safety throughout the process. If such development is unsuccessful, our business and reputation would be harmed and our stock price would be adversely affected.

All of our drug products are prone to the risks of failure inherent in drug development. Clinical trials of new drug products sufficient to obtain regulatory marketing approval are expensive and take years to complete. We may not be able to successfully complete clinical testing within the time frame we have planned, or at all. We may experience numerous unforeseen events during, or as a result of, the clinical trial process which could delay or prevent us from receiving regulatory approval or commercializing our drug products. In addition, the results of pre-clinical studies and early-stage clinical trials of our drug products do not necessarily predict the results of later-stage clinical trials. Later-stage clinical trials may fail to demonstrate that a drug product is safe and effective despite having progressed through initial clinical testing. Even if we believe the data collected from clinical trials of our drug products is promising, such data may not be sufficient to support approval by the FDA or any other U.S. or foreign regulatory approval authority. Pre-clinical and clinical data can be interpreted in different ways.

Accordingly, FDA officials could interpret such data in different ways than we or our partners do which could delay, limit or prevent regulatory approval. The FDA, other regulatory authorities, our institutional review boards, our contract research organizations or we ourselves may suspend or terminate our clinical trials for our drug products. Any failure or significant delay in completing clinical trials for our drug products, or in receiving regulatory approval for the sale of any drugs resulting from our drug products, may severely harm our business and reputation. Even if we receive FDA and other regulatory approvals, our drug products may later exhibit adverse effects that may limit or prevent their widespread use, may cause the FDA to revoke, suspend or limit their approval, or may force us to withdraw products derived from those drug products from the market.

***Our dependence on contract research organizations could result in delays in and additional costs for our drug development efforts.***

We may rely on contract research organizations, or CROs, to perform preclinical testing and clinical trials for drug candidates that we choose to develop without a collaborator. If the CROs that we hire to perform our preclinical testing and clinical trials or our collaborators or licensees do not meet deadlines, do not follow proper procedures or a conflict arises between us and our CROs, our preclinical testing and clinical trials may take longer than expected, may be delayed or may be terminated. If we were forced to find a replacement CRO to perform any of our preclinical testing or clinical trials, we may not be able to find a suitable replacement on favorable terms, if at all. Even if we were able to find another CRO to perform a preclinical test or clinical trial, any material delay in a test or clinical trial may result in significant additional expenditures that could adversely affect our operating results. Events such as these may also delay regulatory approval for our drug candidates or our ability to commercialize our products.

***We depend on clinical investigators and clinical sites to enroll patients in our clinical trials and sometimes other third parties to manage the trials and to perform related data collection and analysis, and, as a result, we may face costs and delays outside of our control.***

We rely on clinical investigators and clinical sites to enroll patients and sometimes third parties to manage our trials and to perform related data collection and analysis. However, we may be unable to control the amount and timing of resources that the clinical sites which conduct the clinical testing may devote to our clinical trials.

Our clinical trials may be delayed or terminated due to the inability of our clinical investigators to enroll enough patients. Patient enrollment depends on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites and the eligibility criteria for the study. If our clinical investigators and clinical sites fail to enroll a sufficient number of patients in our clinical trials or fail to enroll them on our planned schedule, we may face increased costs, delays or termination of the trials, which could delay or prevent us from obtaining regulatory approvals for our product candidates.

## [Table of Contents](#)

Our agreements with clinical investigators and clinical sites for clinical testing and for trial management services place substantial responsibilities on these parties, which could result in delays in, or termination of, our clinical trials if these parties fail to perform as expected. For example, if any of our clinical trial sites fail to comply with FDA-approved GCPs, we may be unable to use the data gathered at those sites. If these clinical investigators, clinical sites or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, our clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for, or successfully commercialize, our product candidates.

***We are subject to periodic litigation, which could result in losses or unexpected expense of time and resources.***

From time to time, we are called upon to defend ourselves against lawsuits relating to our business. Due to the inherent uncertainties of litigation, we cannot accurately predict the ultimate outcome of any such proceedings. See Item 3 *Legal Proceedings* in Part I of this Form 10-K for a detailed description of a pending purported stockholder class action lawsuit filed against us and a government investigation. An unfavorable outcome in either of these or other proceedings could have an adverse impact on our business, financial condition and results of operations. In addition, any significant litigation in the future, regardless of its merits, could divert management's attention from our operations and result in substantial legal fees. In addition, if our stock price is volatile, we may become involved in additional securities class action lawsuits in the future. Any litigation could result in substantial costs and a diversion of management's attention and resources that are needed to successfully run our business.

### **Regulatory Risks**

***We are involved in an ongoing inquiry by the United States Department of Justice, the results of which could result in significant liability and have a material adverse effect on our sales, financial condition, results of operations and cash flows.***

In April 2015, we received a subpoena from the U.S. Department of Justice, U.S. Attorney's Office for the District of New Jersey, requiring the production of a broad range of documents pertaining to marketing and promotional practices related to EXPAREL. We are cooperating with the government's inquiry. We cannot estimate what impact this inquiry and any results from this inquiry or any proceedings could have on our business, financial condition, results of operations or cash flows. Cooperation with this inquiry may divert the attention of management and require the devotion of a substantial amount of time and resources. The existence of the inquiry could also adversely impact our sales activity or our customers' perception of us or EXPAREL. Any of these impacts could have a material adverse effect on our business, financial condition, results of operations and cash flows.

If, as a result of this inquiry, proceedings are initiated and we are found to have violated one or more applicable laws, we may be subject to significant liability, including without limitation, civil fines, criminal fines and penalties, civil damages and exclusion from federal funded healthcare programs such as Medicare and Medicaid, as well as potential liability under the federal False Claims Act and state false claims acts, and/or be required to enter into a corporate integrity or other settlement with the government, any of which could materially affect our reputation, business, financial condition, results of operations and cash flows. Conduct giving rise to such liability could also form the basis for private civil litigation by third-party payors or other persons allegedly harmed by such conduct. In addition, if some of our existing business practices are challenged as unlawful, we may have to change those practices, including changes and impacts on the practices of our sales force, which could also have a material adverse effect on our business, financial condition, results of operations and cash flows.

***Our business could be materially adversely affected if the FDA determines that we are promoting or have in the past promoted the "Off-label" use of drugs.***

The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs. 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. According to these regulations, companies may not promote drugs for "Off-label" uses—that is, uses that are not described in the product's labeling and that differ from those that were approved by the FDA. For example, the FDA-approved label for EXPAREL does not include an indication in obstetrical paracervical block anesthesia. 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 in the United States may choose, and are generally permitted 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, under the FDA's regulations our ability to promote the products is narrowly limited to those indications that are approved by the FDA. "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. Although recent court decisions suggest that certain off-label promotional activities may be protected under the First Amendment, the scope of such protection is unclear. Moreover, while we promote our products consistent with what we believe to be the approved indication for our drugs, the FDA may disagree. If the FDA determines that our promotional activities fail to comply with the FDA's 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, bring an enforcement action against us, 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 reputation and our business.

In September 2014, we received a warning letter from the OPDP pertaining to certain promotional aspects of EXPAREL. We took actions to immediately address the FDA's concerns and minimize further disruption to our business. Ultimately, however, in September 2015, we, along with two independent physicians, filed a lawsuit in federal court against the FDA and other governmental defendants seeking to exercise our lawful rights to communicate truthful and non-misleading information about EXPAREL. The complaint outlined our belief that the FDA's warning letter received in September 2014 and regulations restricting our truthful and non-misleading speech about EXPAREL violate the Administrative Procedure Act and the First and Fifth Amendments of the U.S. Constitution. The lawsuit sought a declaration and injunctive relief to permit us to promote EXPAREL consistent with its approved indication and pivotal studies that supported FDA approval. On December 15, 2015, we announced that the FDA had formally withdrawn the September 2014 Warning Letter via a "Rescission Letter," and that the FDA and Pacira had reached an amicable resolution of the lawsuit. As part of the resolution of this matter, the FDA confirmed that EXPAREL was broadly approved for "administration into the surgical site to produce postsurgical analgesia" in a variety of surgeries not limited to those studied in its pivotal trials. The FDA also approved a labeling supplement for EXPAREL that further clarified that EXPAREL was not limited to any specific surgery type or site, that the proper dosage and administration of EXPAREL is based on various patient and procedure-specific factors, that there was a significant treatment effect for EXPAREL compared to placebo over the first 72 hours in the pivotal hemorrhoidectomy study and that EXPAREL may be admixed with bupivacaine, provided certain medication ratios are observed. Pacira and the FDA have agreed that, in future interactions, they will deal with each other in an open, forthright and fair manner.

We are unable to predict whether such regulatory actions will have an effect on EXPAREL sales, and even if such actions are ultimately resolved favorably, our sales may suffer due to reputational or other concerns. We can make no assurances that we will not receive FDA warning letters in the future or be subject to other regulatory action. As noted above, any regulatory violation or allegations of a violation may have a material adverse effect on our reputation and business.

***We may not receive regulatory approval for any of our 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 any of our 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. Although the FDA's longstanding position has been that the Agency may rely upon prior findings of safety or effectiveness to support approval of a 505(b)(2) application, this policy has been controversial and subject to challenge in the past. If the FDA's policy is successfully challenged administratively or in court, we may be required to seek approval of our products via full NDAs that contain a complete data package demonstrating the safety and effectiveness of our product candidates, which would be time-consuming, expensive and would have a material adverse effect on our business and financial condition.

The FDA, as a condition of the EXPAREL approval on October 28, 2011, has required us to study EXPAREL in pediatric patients. We have agreed to a trial timeline where, over several years, we will study pediatric patient populations in descending order starting with 12-18 year olds and ending with children under two years of age. These trials will be expensive and time consuming and we are required to meet the timelines for submission of protocols and data and for completion as agreed with the FDA, and we may be delayed in meeting such timelines. We are required to conduct these trials even if we believe that the costs and potential benefits of conducting the trials are not warranted from a scientific or financial perspective. The failure to conduct these pediatric trials or to meet applicable deadlines could result in the imposition of sanctions, including, among other things, issuance of warnings letters or imposition of seizures or injunctions.

***The FDA may determine that EXPAREL or any of our product candidates have undesirable side effects.***

## [Table of Contents](#)

If concerns are raised regarding the safety of a new product candidate 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 product candidate could also result in the inclusion of unfavorable information in our product labeling, imposition of distribution or use restrictions, a requirement to conduct post-market studies or to implement a risk evaluation and mitigation strategy, denial, suspension or withdrawal 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 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.

Following approval of EXPAREL or any of our product candidates, if we or others later identify previously unknown undesirable side effects caused by such products, if known side effects are more frequent or severe than in the past, or if we or others detect unexpected safety signals for such products or any products perceived to be similar to such products:

- regulatory authorities may require the addition of unfavorable labeling statements, specific warnings or contraindications (including boxed warnings);
- 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, reformulate the product, change the labeling of the product or change or obtain re-approvals of manufacturing facilities;
- sales of the product may be significantly decreased from projected sales;
- we may be subject to government investigations, 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 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. For example, the FDA-approved label for EXPAREL does not include an indication in obstetrical paracervical block anesthesia. 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. Although recent court decisions suggest that certain off-label promotional activities may be protected under the First Amendment, the scope of any such protection is unclear. If our promotional activities fail to comply with the FDA's 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

## [Table of Contents](#)

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 do not comply with federal, state and foreign laws and regulations relating to the health care business, we could face substantial penalties.***

We and our customers are subject to extensive regulation by the federal government, and the governments of the states and foreign countries in which we may conduct our business. In the United States, the laws that directly or indirectly affect our ability to operate our business include the following:

- the Federal Anti-Kickback Law, which prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual or furnishing or arranging for a good or service for which payment may be made under federal health care programs such as Medicare and Medicaid;
- other Medicare laws and regulations that prescribe the requirements for coverage and payment for services performed by our customers, including the amount of such payment;
- the Federal False Claims Act, which imposes civil and criminal liability on individuals and entities who submit, or cause to be submitted, false or fraudulent claims for payment to the government;
- the Federal False Statements Act, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with delivery of or payment for health care benefits, items or services; and
- various state laws that impose similar requirements and liability with respect to state healthcare reimbursement and other programs.

If our operations are found to be in violation of any of the laws and regulations described above or any other law or governmental regulation to which we or our customers are or will be subject, we may be subject to civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment or restructuring of our operations. Similarly, if our customers are found to be non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on us. Any penalties, damages, fines, curtailment or restructuring of our operations would adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation.

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

The design, development, manufacture, supply and distribution of EXPAREL and DepoCyt(e) is highly regulated and technically complex. 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 and other FDA and MHRA regulations, including potentially prior regulatory approval. In addition, any expansion of our existing manufacturing facilities or the introduction of any new manufacturing facilities, including the manufacturing suites to be constructed at Patheon's facility, also require conformity with cGMP and other FDA and MHRA regulations. In complying with these requirements, we, along with our co-production partners and 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 co-production partners and suppliers, are subject to unannounced inspections by the FDA, MHRA 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 July 2012, the MHRA issued its inspection report in which the MHRA noted certain critical and major failures to comply with the Principles and Guidelines of Good Manufacturing Practices related to our DepoCyt(e) manufacturing facility. We responded to the MHRA regarding these inspectional observations, completed implementation of our proposed remediation plan and were reinspected by the MHRA in December 2012. In January 2013, we

## [Table of Contents](#)

received notice from the MHRA that our remediation efforts were successful and that we could recommence manufacturing DepoCyt(e) for Europe.

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

The testing, manufacturing, quality control, labeling, safety, effectiveness, advertising, promotion, storage, sales, distribution, import, export and marketing, among other things, of our products EXPAREL and DepoCyt(e) are subject to extensive regulation by governmental authorities in the United States and elsewhere throughout the world. Quality control and manufacturing procedures regarding EXPAREL and DepoCyt(e) must conform to cGMP. Regulatory authorities, including the FDA and the MHRA, periodically inspect manufacturing facilities to assess compliance with cGMP. Our failure, or the failure of any contract manufacturers with whom we may work in the future, to comply with the laws administered by the FDA, the MHRA 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;
- reputational concerns of our customers or the medical community;
- operating restrictions;
- warning letters;
- injunctions;
- refusal to permit import or export of an approved product;
- refusal to approve pending applications or supplements to approved applications that we submit;
- denial of permission to file an application or supplement in a jurisdiction;
- consent decrees;
- suspension or termination of ongoing clinical trials;
- 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 EXPAREL, DepoCyt(e) or any future products, 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. Although hospitals currently receive separate reimbursement for EXPAREL used in the hospital outpatient setting, EXPAREL, DepoCyt(e) or any 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, 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. For example, third-party payers may limit the indications for which our products will be reimbursed to a smaller set of indications than we believe is appropriate or limit the circumstances under which our products will be reimbursed to a smaller set of circumstances than we believe is appropriate. 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, as federal, state and foreign governments continue to propose and pass new legislation designed to reduce or contain the cost of healthcare. 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.

***Public concern regarding the safety of drug products such as EXPAREL could 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. The FDAAA 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 provide additional clinical or preclinical data for EXPAREL, the indications for which this product candidate was approved may be limited or there may be specific warnings or limitations on dosing, and our efforts to commercialize EXPAREL may be otherwise adversely impacted.

#### **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 and DepoCyt(e) are bupivacaine and cytarabine, respectively. Patent protection for the bupivacaine and cytarabine 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 and DepoCyt(e) 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 as 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.



## [Table of Contents](#)

Because EXPAREL has been 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: (i) there is no patent information listed in the FDA's Orange Book with respect to our NDA for EXPAREL; (ii) the patents listed in the Orange Book have expired; (iii) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third-party's generic drug product. A certification that the new product will not infringe the Orange Book-listed patents for EXPAREL, or that such patents are invalid, is called a paragraph IV certification. If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third-party's ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third-party's ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled or the court reaches a decision in the infringement lawsuit in favor of the third party. If we do not file a patent infringement lawsuit within the required 45-day period, the third-party's ANDA will not be subject to the 30-month stay. Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business and may result in unfavorable results that could adversely impact our ability to prevent third parties from competing with our products.

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

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for EXPAREL, DepoCyt(e), DepoFoam and for any 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. Patent positions and policies outside the United States are 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, may not have sufficient scope or strength to protect the technologies they were intended to protect or may be challenged by third parties;
- others may design around our patent claims to produce competitive products that fall outside the scope of our patents;
- we may not develop or in-license additional proprietary technologies that are patentable;
- patents of others may have an adverse effect on our business; or
- competitors may infringe our patents and we may not have adequate resources to enforce our patents.

## [Table of Contents](#)

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 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 United States 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 are issued, 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. Furthermore, while we generally apply for patents in those countries where we intend to make, have made, use or sell patented products, we may not accurately predict all of the countries where patent protection will ultimately be desirable. If we fail to timely file a patent application in any such country, we may be precluded from doing so at a later date. We also cannot assure you that the patents issuing as a result of our foreign patent applications will have the same scope of coverage as our United States patents.

Some of our older patents have already expired. In the case of DepoCyt(e), key patents providing protection in Europe have expired. In the case of EXPAREL, our European and U.S. patent applications have been granted and provide protection through November 2018 and September 2018, respectively. An existing formulation patent for EXPAREL expired in November 2013. An existing formulation patent for EXPAREL expired in the U.S. in 2013 and its equivalents in Canada, Germany, France, Spain, Italy and the United Kingdom expired in 2014. Once our patents covering EXPAREL have expired, we will be 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 through confidentiality and non-disclosure agreements, our licensors, employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Policing unauthorized use of our trade secrets or 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, trade secret laws in other countries may not be as protective as they are in the United States. Thus, 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.

In order to protect the goodwill associated with our company and product names, we rely on trademark protection for our marks. We have registered the “Pacira”, “EXPAREL”, “DepoCyt” and “DepoCyte” marks with the United States Patent and Trademark Office. A third party may assert a claim that one of our marks is confusingly similar to its mark, and such claims or the failure to timely register a mark or objections by the FDA could force us to select a new name for one of our product candidates, which could cause us to incur additional expense or delay the commercialization of such product.

If we fail to obtain or maintain patent protection or trade secret protection for EXPAREL, DepoCyt(e), DepoFoam or any 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 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 effect 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 or DepoCyt(e) may infringe. There could also be existing patents of which we are not aware that EXPAREL or DepoCyt(e) may inadvertently infringe.

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

## [Table of Contents](#)

- 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**

#### ***Cumulatively, we have incurred significant losses since our inception and may incur additional losses in the future.***

We are a specialty pharmaceutical company with a limited operating history. We have focused primarily on developing and commercializing EXPAREL. Up until 2015, we had incurred losses in each year since our inception in December 2006. While we had net income of \$1.9 million for the year ended December 31, 2015, we had net losses of \$13.7 million and \$63.9 million for the years ended December 31, 2014 and 2013, respectively. As of December 31, 2015, we had an accumulated deficit of \$308.3 million. These losses, among other things, have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. We incurred significant pre-commercialization expenses as we prepared for the commercial launch of EXPAREL, and we incur significant sales, marketing and manufacturing expenses, as well as continued development expenses related to the commercialization of EXPAREL. As a result, we had not been profitable prior to 2015. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or if we will continue to remain profitable.

#### ***We may not continue to be profitable.***

Our ability to remain profitable depends upon our ability to generate revenue from EXPAREL. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- manufacture commercial quantities of EXPAREL at acceptable cost levels; and
- continue to develop a commercial organization and the supporting infrastructure required to successfully market and sell EXPAREL.

We anticipate incurring significant additional costs associated with the commercialization of EXPAREL and are unsure as to whether we will be able to continue to be profitable. If we are unable to generate revenues, we will not remain profitable and may be unable to continue operations without continued funding.

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

We were incorporated in December 2006 and have been conducting operations with respect to EXPAREL since March 2007. Our operations to date include 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). Further, we worked to establish our commercial infrastructure for EXPAREL, which we launched in the second quarter of 2012. 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 may 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.***

## [Table of Contents](#)

Developing and commercializing 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 may need to raise additional capital to:

- continue to fund our operations;
- continue our efforts to hire additional personnel and build a commercial infrastructure to commercialize EXPAREL;
- qualify, outsource or build additional commercial-scale manufacturing of our products under cGMP; and
- in-license and develop additional product candidates.

We may not have sufficient financial resources to continue our operations or meet all of our objectives, which could require us to postpone, scale back or eliminate some, or all, of these objectives. Our future funding requirements will depend on many factors, including, but not limited to:

- the costs of maintaining a commercial organization to sell, market and distribute EXPAREL;
- the success of the commercialization of EXPAREL;
- the cost and timing of manufacturing sufficient supplies of EXPAREL to meet customer demand, including the cost of expanding our manufacturing facilities to produce 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 effect of competing technological and market developments;
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish; and
- 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.

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 or supplement future cash needs through public or private equity offerings, debt financings, product supply revenue and royalties, 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 operating results will be affected by numerous factors, including:

- the level of underlying hospital demand for EXPAREL and end-user buying patterns;
- maintaining our existing manufacturing facilities and expanding our manufacturing capacity and constructing facilities for the manufacture of EXPAREL with our co-production partner, Patheon, including installing specialized processing equipment for the manufacturing of EXPAREL;

## [Table of Contents](#)

- our execution of other collaborative, licensing, distribution, manufacturing 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; and
- regulatory developments, lawsuits and investigations affecting EXPAREL or the product candidates of our competitors;

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.

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

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on the effectiveness of our internal control over financial reporting. 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 and (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.

To achieve compliance with Section 404, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we have dedicated internal resources, hired additional employees for our finance function, and engaged outside consultants and adopted 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 will be limited.***

We have significant federal and state net operating loss carryforwards and federal and state research and development tax credit carryforwards. Our net operating loss carryforwards and research and development tax credits may expire and not be used. Our net operating loss carryforwards will begin expiring in 2025 for federal purposes and 2016 for state purposes if we have not used them prior to that time. Additionally, our ability to use certain 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 because we experienced cumulative changes in ownership of more than 50% within a three-year period. Such ownership changes were triggered by the cumulative ownership changes arising as a result of the initial acquisition of the Company's stock in 2007 and the completion of our initial public offering and our other financing transactions. Because of the ownership changes, we will be limited regarding the amount of net operating loss carryforwards and research tax credits that we can utilize annually in the future to offset taxable income or tax, respectively. Such an annual limitation will 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 downturns.***

Our results of operations could be materially negatively affected by general economic conditions, 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, low 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 Our Indebtedness and our Common Stock**

***Our common stock price may be subject to significant fluctuations and volatility.***

Our stock price is volatile, and from February 3, 2011, the first day of trading of our common stock, to February 18, 2016, the trading prices of our stock have ranged from \$6.16 to \$121.95 per share.

Our stock could be subject to wide fluctuations in price in response to various factors, including the following:

- the commercial success of EXPAREL;
- 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;
- regulatory concerns or government actions
- 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. Fluctuations in our stock price could, among other things, adversely impact the trading price of the Notes and our shares issuable upon conversion of the Notes.

***Servicing our indebtedness requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial indebtedness.***

Our ability to make payments of the principal of, to pay interest on or to refinance our indebtedness, including the notes issued in our private offering completed on January 23, 2013, or Notes, as described below, or to make cash payments in connection with any conversion of the Notes depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our indebtedness and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring indebtedness or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

On January 23, 2013, the Company completed a private offering of \$120.0 million in aggregate principal amount of 3.25% convertible senior notes due 2019 and entered into an indenture with Wells Fargo Bank, National Association, a national banking association, as trustee, governing the Notes. The Notes accrue interest at a rate of 3.25% per year, payable semiannually in arrears on February 1 and August 1 of each year, beginning on August 1, 2013. The Notes will mature on February 1, 2019.

As of December 31, 2015, our total consolidated gross indebtedness was \$118.5 million, all of which was unsecured indebtedness, and our subsidiaries had no indebtedness (in each case, excluding trade payables, intercompany liabilities and income tax-related liabilities).

***Despite our current indebtedness levels, we may still incur substantially more indebtedness or take other actions which would intensify the risks discussed above.***

Despite our current consolidated indebtedness levels, we and our subsidiaries may be able to incur substantial additional indebtedness in the future, subject to any restrictions contained in our then-existing debt instruments, some of which may be secured indebtedness. We are not restricted under the terms of the indenture governing the Notes from incurring additional indebtedness, securing existing or future indebtedness, recapitalizing our indebtedness or taking a number of other actions that could have the effect of diminishing our ability to make payments on the Notes or any future indebtedness.

***We may not have the ability to raise the funds necessary to settle conversions of the Notes in cash to the extent required or to repurchase the Notes upon a fundamental change, and our future indebtedness may contain limitations on our ability to pay cash upon conversion of the Notes or limitations on our ability to repurchase the Notes.***

Holders of the Notes will have the right to require us to repurchase their Notes upon the occurrence of a fundamental change at a repurchase price equal to 100% of their principal amount, plus accrued and unpaid interest, if any. In addition, upon conversion of the Notes, we will be required to make cash payments for each \$1,000 in principal amount of Notes converted of at least the lesser of \$1,000 and the sum of the daily conversion values. However, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of Notes surrendered therefor or Notes being converted. Any credit facility or other agreement that we may enter into may limit our ability to make cash payments at the time of a fundamental change or upon conversion of the Notes. Further, our ability to repurchase the Notes or to pay cash upon conversions of the Notes may be limited by law, by regulatory authority or by agreements governing our future indebtedness. Our failure to repurchase Notes at a time when the repurchase is required by the indenture or to pay any cash payable on future conversions of the Notes as required by the indenture would constitute a default under the indenture. A default under the indenture or the fundamental change itself could also lead to a default under agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Notes or make cash payments upon conversions thereof. In February 2015, we received notice of an election for conversion from one of the holders of the Notes. The principal amount of the conversion request was \$1.5 million was paid in cash pursuant to the terms of the Indenture. We elected to settle the conversion premium with shares of our common stock. There is no assurance that we will not receive more conversion requests.

***The conditional conversion feature of the Notes, if triggered and elected, may adversely affect our financial condition and operating results.***

Under certain circumstances, holders of the Notes are entitled to convert the Notes to common stock at any time during specified periods at their option. If one or more holders elect to convert their Notes, we would be required to settle any converted principal through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not

elect to convert their Notes, we have reclassified all of the outstanding principal of the Notes as a current rather than long-term liability, which has resulted in a material reduction of our net working capital.

***Conversion of the Notes may dilute the ownership interest of existing stockholders, including holders who had previously converted their Notes, or may otherwise depress the price of our common stock.***

The conversion of the Notes into shares of our common stock, to the extent that we choose not to deliver all cash for the conversion value in excess of the principal amount, will dilute the ownership interests of existing stockholders. Any sales in the public market of the common stock issuable upon conversion of the Notes could adversely affect prevailing market prices of our common stock. In addition, the existence of the Notes may encourage short selling by market participants due to this dilution or may facilitate trading strategies involving the Notes and our common stock.

***Future sales in the public market or issuances of our common stock could lower the market price for our common stock and adversely impact the trading price of the Notes.***

In the future, we may sell additional shares of our common stock to raise capital. Except under limited circumstances, we are not restricted from issuing additional common stock, including securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. The issuance of additional shares of our common stock or convertible securities, including upon exercise of our outstanding options or otherwise, will dilute the ownership interest of our common stockholders. In addition, our greater than 5% stockholders may sell a substantial number of their shares in the public market, which could also affect the market price for our common stock. We cannot predict the size of future sales or issuances of our common stock or the effect, if any, that they may have on the market price for our common stock. The liquidity and trading volume of our common stock is limited. For the three months ended December 31, 2015, the average per day trading volume of our common stock was 958,555 shares. The issuance and/or sale of substantial amounts of common stock, or the perception that such issuances and/or sales may occur, could adversely affect the market price of our common stock and the trading price of the Notes and impair our ability to raise capital through the sale of additional equity or debts securities.

***The accounting method for convertible debt securities that may be settled in cash, such as the Notes, could have a material effect on our reported financial results.***

In May 2008, the Financial Accounting Standards Board, or FASB, issued FASB Staff Position No. APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)*, which has subsequently been codified as Accounting Standards Codification 470-20, *Debt with Conversion and Other Options*, or ASC 470-20. Under ASC 470-20, an entity must separately account for the liability and equity components of the convertible debt instruments (such as the Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. The effect of ASC 470-20 on the accounting for the Notes is that the equity component is required to be included in the additional paid-in capital section of stockholders' equity on our consolidated balance sheet at the issuance date and the value of the equity component would be treated as debt discount for purposes of accounting for the debt component of the Notes. As a result, we are required to record a greater amount of non-cash interest expense in current periods presented as a result of the amortization of the discounted carrying value of the Notes to their face amount over the term of the Notes. We will report larger net losses in our financial results because ASC 470-20 will require interest to include both the current period's amortization of the debt discount and the instrument's coupon interest, which could adversely affect our reported or future financial results, the trading price of our common stock and the trading price of the Notes.

In addition, under certain circumstances, convertible debt instruments (such as the Notes) that may be settled entirely or partly in cash are currently accounted for utilizing the treasury stock method, the effect of which is that the shares issuable upon conversion of the Notes are not included in the calculation of diluted earnings per share except to the extent that the conversion value of the Notes exceeds their principal amount. Under the treasury stock method, for diluted earnings per share purposes, the transaction is accounted for as if the number of shares of common stock that would be necessary to settle such excess, if we elected to settle such excess in shares, are issued. We cannot be sure that the accounting standards in the future will continue to permit the use of the treasury stock method. If we are unable to use the treasury stock method in accounting for the shares issuable upon conversion of the Notes, then our net losses per share would be increased.

***Holders of the Notes will not be entitled to any rights with respect to our common stock, but will be subject to all changes made with respect to them to the extent our conversion obligation includes shares of our common stock.***

Holders of Notes will not be entitled to any rights with respect to our common stock (including, without limitation, voting rights and rights to receive any dividends or other distributions on our common stock) prior to the last trading day of the observation period, but, to the extent our conversion obligation includes shares of our common stock, holders of Notes will be subject to all changes affecting our common stock. For example, if an amendment is proposed to our certificate of incorporation or bylaws requiring stockholder approval and the record date for determining the stockholders of record entitled to vote on the amendment occurs prior to the last trading day of the relevant observation period, then to the extent our conversion obligation includes shares of our common stock, such holder will not be entitled to vote on the amendment, although such holder will nevertheless be subject to any changes affecting our common stock as a result of such amendment.



## [Table of Contents](#)

***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, 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.

***We do not intend to pay dividends on our common stock for the foreseeable future.***

We have never declared or paid cash dividends on our common stock. We currently intend to retain our future earnings, if any, to finance the further development and expansion of our business and do not intend to pay cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our Board of Directors and will depend upon our financial condition, results of operations, capital requirements, restrictions contained in future financing instruments and such other factors as our Board of Directors deems relevant.

### **Item 1B. Unresolved Staff Comments**

None.

### **Item 2. Properties**

We occupy four facilities totaling approximately 172,000 square feet at our Science Center Campus in San Diego, California. We use these facilities for research and development, manufacturing, general and administrative purposes and the storage of inventory and raw materials. All of our properties in San Diego are under leases which expire in August 2020. In addition, we maintain our executive offices and our commercial and business development facility in Parsippany, New Jersey, where we occupy approximately 42,000 square feet under a lease expiring in March 2028.

We believe that our research and development and manufacturing facilities at our Science Center Campus and yet to be completed Patheon facility (as discussed in Item 1-Business above) will be sufficient for our commercial and pipeline development needs. We also may add new facilities or expand existing facilities as we add employees, expand our geographic markets and if demand for EXPAREL increases and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

### **Item 3. 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. Except as described below, we are not presently a party to any litigation that we believe to be material and we are not aware of any pending or threatened litigation against us that we believe could have a material adverse effect on our business, operating results, financial condition or cash flows.

In September 2014, the FDA’s Office of Prescription Drug Promotion issued us a warning letter related to certain promotional materials. We took actions to address the immediate FDA concerns and minimize further disruption to our

## [Table of Contents](#)

business, but ultimately sought a court order to defend against any retroactive attempt to limit the broad indication for EXPAREL and restrict communications supported by the approved label. On September 8, 2015, we, along with two independent physicians, filed a lawsuit in the U.S. District Court for the Southern District of New York against the FDA and other governmental defendants seeking to exercise our lawful right to communicate truthful and non-misleading information about EXPAREL. The complaint outlined our belief that the FDA's warning letter and regulations restricting our truthful and non-misleading speech about EXPAREL violated the Administrative Procedure Act and the First and Fifth Amendments of the U.S. Constitution. The lawsuit sought a declaration and injunctive relief to permit us to promote EXPAREL consistent with its approved indication and pivotal studies that supported FDA approval. On December 15, 2015, our lawsuit against the FDA was amicably resolved. The FDA approved a revised label for EXPAREL confirming that EXPAREL has, since its approval on October 28, 2011, been approved for administration into the surgical site to produce postsurgical analgesia in a variety of surgeries not limited to those studied in its pivotal trials, and issued a rescission letter withdrawing its previously issued warning letter.

On October 3, 2014, a purported class action lawsuit was filed in the U.S. District Court for the District of New Jersey against us and several of our current officers, *Nicholas R. Lovallo v. Pacira Pharmaceuticals, Inc., et al.*, Case No. 2:14-cv-06172-WHW-CLW. The plaintiff amended the lawsuit on May 29, 2015. The lawsuit asserted claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and is premised on allegedly false and/or misleading statements, and non-disclosure of material facts, regarding our business, operations, prospects and performance during the proposed class period of February 24, 2014 to April 29, 2015. On November 19, 2015, the suit was dismissed with leave to re-plead by a New Jersey federal judge. On January 22, 2016, the parties agreed to and filed a Stipulation of Dismissal with Prejudice.

In April 2015, we received a subpoena from the U.S. Department of Justice, U.S. Attorney's Office for the District of New Jersey, requiring the production of a broad range of documents pertaining to marketing and promotional practices related to EXPAREL. We are cooperating with the government's inquiry. We can make no assurances as to the time or resources that will need to be devoted to this inquiry or its final outcome, or the impact, if any, of this inquiry or any proceedings on our business, financial condition, results of operations and cash flows.

#### **Item 4. Mine Safety Disclosures**

Not applicable.

**PART II****Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities**

Our common stock is listed under the ticker symbol "PCRX" on The NASDAQ Global Select Market. The following table sets forth, for the periods indicated, the high and low intraday sales prices of our common stock as reported by the NASDAQ:

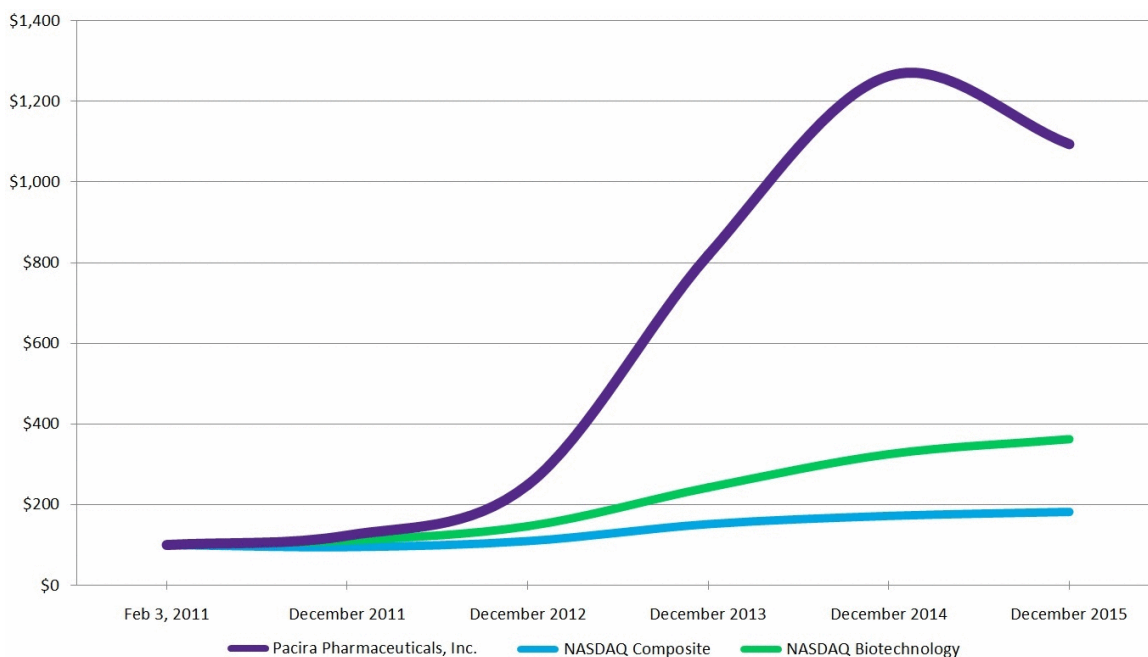
<b>Year Ended 2015</b>	<b>High</b>	<b>Low</b>
Fourth Quarter	\$ 80.25	\$ 35.78
Third Quarter	72.98	39.29
Second Quarter	93.22	65.00
First Quarter	121.95	82.00
<b>Year Ended 2014</b>	<b>High</b>	<b>Low</b>
Fourth Quarter	\$ 112.00	\$ 84.93
Third Quarter	109.94	81.51
Second Quarter	93.13	60.30
First Quarter	83.41	54.23

On February 18, 2016, the closing price of our common stock as reported on The NASDAQ Global Select Market was \$60.17 per share and we had approximately 15 holders of record of our common stock.

***Performance Graph***

The following graph shows the value of an investment of \$100 on February 3, 2011, the date of our initial public offering, or IPO, in each of Pacira common stock (PCRX), the NASDAQ Composite index (^IXIC) and the NASDAQ Biotechnology index (^NBI). The indices are included for comparative purposes only and do not necessarily reflect management's opinion that such indices are an appropriate measure of the relative performance of our common stock. All results assume the reinvestment of dividends, if any, and are calculated as of December 31 of each year. The historical stock price performance of our common stock shown in the performance graph is not necessarily indicative of future stock price performance.

**Comparison of Cumulative Total Returns Since Our IPO**



**Cumulative Total Return**

	February 3, 2011	December 31, 2011	December 31, 2012	December 31, 2013	December 31, 2014	December 31, 2015
Pacira Pharmaceuticals, Inc. (PCRX)	\$ 100.00	\$ 123.22	\$ 248.86	\$ 818.95	\$ 1,262.96	\$ 1,093.87
NASDAQ Composite (^IXIC)	100.00	94.60	109.65	151.66	171.98	181.83
NASDAQ Biotechnology (^NBI)	100.00	111.01	146.42	242.49	325.17	362.31

**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, and as such we do not expect to pay any cash dividends on our common stock in the foreseeable future. The 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 future financing instruments, provisions of applicable law and any other factors the board deems relevant.

**Item 6. Selected Financial Data**

The following table provides selected consolidated financial data. We have prepared this information using our audited consolidated financial statements for the years ended December 31, 2015, 2014, 2013, 2012 and 2011. The following consolidated financial data should be read in conjunction with our consolidated financial statements and related notes and Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in this report.

	Year Ended December 31,				
	2015	2014	2013	2012	2011
<b>Statement of Operations Data</b>					
(In thousands, except per share data)					
<b>Revenues:</b>					
Net product sales	\$ 244,487	\$ 193,526	\$ 81,956	\$ 18,191	\$ 6,895
Collaborative licensing and milestone revenue	1,426	1,287	972	18,390	5,074
Royalty revenue	3,084	2,855	2,623	2,503	3,720
Total revenues	<u>248,997</u>	<u>197,668</u>	<u>85,551</u>	<u>39,084</u>	<u>15,689</u>
<b>Operating expenses:</b>					
Cost of goods sold	71,837	77,440	54,772	32,139	16,739
Research and development	28,662	18,731	21,560	9,937	14,873
Selling, general and administrative	139,043	106,662	62,508	46,306	20,159
Impairment of long-lived assets	—	—	—	—	3,019
Total operating expenses	<u>239,542</u>	<u>202,833</u>	<u>138,840</u>	<u>88,382</u>	<u>54,790</u>
Income (loss) from operations	<u>9,455</u>	<u>(5,165)</u>	<u>(53,289)</u>	<u>(49,298)</u>	<u>(39,101)</u>
<b>Other (expense) income:</b>					
Interest income	678	382	259	275	255
Interest expense	(7,725)	(8,278)	(7,253)	(1,807)	(4,780)
Loss on early extinguishment of debt	(52)	—	(3,398)	(1,062)	—
Royalty interest obligation	(71)	(323)	(623)	(278)	227
Other, net	(165)	(159)	(47)	(111)	71
Total other expense, net	<u>(7,335)</u>	<u>(8,378)</u>	<u>(11,062)</u>	<u>(2,983)</u>	<u>(4,227)</u>
Income (loss) before income taxes	2,120	(13,543)	(64,351)	(52,281)	(43,328)
Income tax (expense) benefit	(264)	(173)	442	—	—
Net income (loss)	<u>\$ 1,856</u>	<u>\$ (13,716)</u>	<u>\$ (63,909)</u>	<u>\$ (52,281)</u>	<u>\$ (43,328)</u>
<b>Net income (loss) per share:</b>					
Basic net income (loss) per common share	\$ 0.05	\$ (0.39)	\$ (1.93)	\$ (1.72)	\$ (2.64)
Diluted net income (loss) per common share	\$ 0.04	\$ (0.39)	\$ (1.93)	\$ (1.72)	\$ (2.64)
<b>Weighted average common shares outstanding:</b>					
Basic	36,540	35,299	33,182	30,332	16,437
Diluted	41,301	35,299	33,182	30,332	16,437

	December 31,				
	2015	2014	2013	2012	2011
(In thousands)					
<b>Balance Sheet Data</b>					
Cash and cash equivalents, restricted cash, short-term and long-term investments	\$ 172,427	\$ 182,598	\$ 73,785	\$ 42,573	\$ 77,452
Working capital (deficit)	100,906	74,247	(15,192)	46,766	50,738
Total assets	389,623	326,072	169,820	112,054	113,490
Long-term liabilities	19,555	14,917	6,628	32,043	33,310
Accumulated deficit	(308,289)	(310,145)	(296,429)	(232,520)	(180,239)
Total stockholders' equity	218,392	171,145	41,249	65,855	48,269

## Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

*The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the notes to those financial statements appearing elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements.*

### Overview

We are a specialty pharmaceutical company focused on the development, commercialization and manufacture of proprietary pharmaceutical products, based on our proprietary DepoFoam extended release drug delivery technology, for use primarily in hospitals and ambulatory surgery centers. As of December 31, 2015, our commercial stage products are EXPAREL and DepoCyt(e):

- EXPAREL is a liposome injection of bupivacaine, an amide-type local anesthetic indicated for single-dose administration into the surgical site to produce postsurgical analgesia, which was approved by the United States Food and Drug Administration, or FDA, on October 28, 2011. We commercially launched EXPAREL in April 2012. We drop-ship EXPAREL directly to the end user based on orders placed to wholesalers or directly to us, and we have no product held by wholesalers.
- 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. We sell DepoCyt(e) to our commercial partners located in the United States and Europe.

Since inception, we have incurred significant operating losses. We expect to continue to incur significant expenses as we commercialize EXPAREL; pursue the use of EXPAREL in additional indications and opportunities; advance the development of product candidates, such as DepoMeloxicam and DepoTranexamic Acid; seek FDA approval for our product candidates that successfully complete clinical trials; develop our sales force and marketing capabilities to prepare for their commercial launch and expand and enhance our manufacturing capacity for EXPAREL.

### FDA Litigation

On December 15, 2015, we announced that we achieved an amicable resolution with the United States in our lawsuit filed on September 8, 2015, *Pacira Pharmaceuticals, Inc. et al v. United States Food & Drug Administration et al*, which claimed violations of the First and Fifth Amendments of the U.S. Constitution as well as violations of the Administrative Procedures Act. The resolution confirms that EXPAREL is, and has been since 2011, broadly indicated for administration into the surgical site to provide postsurgical analgesia. Following a series of productive and collaborative discussions, the FDA and Pacira agreed to the following key resolution terms:

- i) The FDA confirms that EXPAREL has, since its approval on October 28, 2011, been approved for "administration into the surgical site to produce postsurgical analgesia" in a variety of surgeries not limited to those studied in its pivotal trials.
- ii) The FDA approved a labeling supplement which amends the EXPAREL Package Insert to clarify and reinforce that:
  - The use, efficacy and safety of EXPAREL is not limited to any specific surgery type or site;
  - The proper dosage and administration of EXPAREL is based on various patient and procedure-specific factors, with the two surgical models utilized in the pivotal trials provided as examples for the purpose of providing general guidance;
  - There was a significant treatment effect for EXPAREL compared to placebo over the first 72 hours in the pivotal hemorrhoidectomy study. The description of that duration of effect now includes a graphical representation of the mean pain intensity scores over time for the EXPAREL and placebo groups for the full 72-hour efficacy period, as well as information about median time to first opioid use and percentage of opioid-free patients in each treatment group; and
  - EXPAREL may be admixed with bupivacaine—including co-administered in the same syringe—provided certain medication ratios are observed.

iii) The September 2014 FDA Warning Letter was formally withdrawn via a “Rescission Letter” from the Director of the FDA Center for Drug Evaluation and Research (CDER). At the request of Pacira, the Rescission Letter included FDA guidance related to two key procedures:

- Infiltration into the transversus abdominis plane, or TAP block, which is a field block technique covered by the approved indication for EXPAREL; and
- Infiltration to produce postsurgical analgesia at the site of oral surgery procedures including tooth extractions, which is also covered by the approved indication for EXPAREL.

iv) The United States acknowledged that the rescission of the Warning Letter and approval of the labeling supplement reflect the scope of the indication in the New Drug Application, or NDA, that the FDA approved on October 28, 2011.

#### **Recent Highlights and Developments**

- Total revenues increased \$51.3 million, or 26%, in the year ended December 31, 2015, as compared to 2014, primarily driven by EXPAREL product sales of \$239.9 million, net of allowances for sales returns, prompt payment discounts, volume rebates, chargebacks and distribution service fees payable to wholesalers.
- In February 2016, we announced topline results of a randomized controlled trial in third molar, or “wisdom teeth”, procedures, with a per-protocol analysis demonstrating statistical significance and an intention-to-treat analysis strongly trending towards significance in spite of the underpowered study size resulting from one of three clinical sites being eliminated for protocol violations. We plan to generate Phase 4 studies in additional oral and maxillofacial surgeries to provide clinical guidance to the oral and maxillofacial community. We anticipate a late third quarter 2016 launch for oral surgery.
- In May 2015, we received feedback from the FDA’s Division of Anesthesia, Analgesia and Addiction Products, or DAAAP, that the proposed approach to demonstrate comparability and to provide adequate data in support of our new DepoFoam spray process appears acceptable. Based on this feedback, we intend to pursue the manufacturing of DepoFoam-based products using the spray process.
- In April 2015, we delivered manufacturing process equipment to the first of two manufacturing suites dedicated to the production of EXPAREL at Patheon U.K. Limited’s, or Patheon, Swindon, England facility. We currently expect, subject to receipt of regulatory approvals, the first commercial manufacturing suite at Patheon’s facility to commence commercial production in 2017. We expect production capacity for EXPAREL at the first commercial manufacturing suite at Patheon’s facility to be similar to that of our Suite C manufacturing location in San Diego, California.
- In April 2015, we received a subpoena from the U.S. Department of Justice, or DOJ, U.S. Attorney’s Office for the District of New Jersey requiring the production of a broad range of documents pertaining to marketing and promotional practices related to EXPAREL. We are cooperating with the government’s inquiry. We can make no assurances as to the time or resources that will need to be devoted to this inquiry or its final outcome, or the impact, if any, of this inquiry or any proceedings on our business, financial condition, results of operations and cash flows.
- In March 2015, we received a Complete Response Letter from the FDA following a review of our sNDA for the use of EXPAREL in nerve block to provide postsurgical analgesia, and in May 2015 we conducted an end-of-review conference with the DAAAP. Based upon FDA guidance that the expected use of EXPAREL will be for a broad spectrum of nerve blocks and not limited to the narrow indication of a single nerve block, we plan to conduct additional Phase 3 studies for upper extremity and lower extremity nerve blocks, specifically a brachial plexus nerve block for patients undergoing total shoulder arthroplasty or rotator cuff repair and a femoral nerve block for patients undergoing total knee arthroplasty. As of February 2016, we have initiated these studies.

#### **EXPAREL**

We are pursuing several additional indications for EXPAREL. We plan to conduct Phase 3 studies for both upper and lower extremity nerve blocks, specifically a brachial plexus nerve block for patients undergoing total shoulder arthroplasty or rotator cuff repair and a femoral nerve block for patients undergoing total knee arthroplasty, or TKA. We believe that this additional indication for EXPAREL presents a method of pain control that has the potential to reduce the need for opioids and replace the costly and cumbersome perineural catheter, drug reservoir and pump with a single injection to continuously deliver

## [Table of Contents](#)

bupivacaine, and will allow us to fully leverage our manufacturing and commercial infrastructure. In addition to the nerve block indication, we are also pursuing studies for the expanded use of EXPAREL in chronic pain. For chronic pain, we intend to initiate a Phase 2 trial in 2016 with patients suffering from chronic lower back pain caused by facet joint dysfunction with EXPAREL as a single dose administration to define the duration of efficacy and determine the optimal dose, which will better inform the Phase 3 study design. We also plan on commencing pediatric trials, which have been required by the FDA.

We expect to continue to implement a variety of programs to educate customers about EXPAREL. Our commercial team, consisting of both sales representatives and scientific and medical affairs professionals, executes on a full range of activities for EXPAREL, including disseminating publications and abstracts evidencing the clinical efficacy and safety of EXPAREL, health outcomes and economic research and review articles on postsurgical pain management. We also provide resources for real world evidence data collection such as drug utilization and/or medication use evaluations and pharmaco-economic studies, which aid in demonstrating the true cost of opioid-based postsurgical pain control through retrospective and prospective analyses for our hospital customers utilizing their own hospital data. Finally, we intend to launch an integrated patient engagement and activation campaign focused on educating the patient population about their postsurgical analgesic options. The initiative is centered on empowering individuals to proactively discuss non-opioid options, including EXPAREL, with their clinicians prior to surgical procedures.

### ***Product Pipeline***

DepoFoam is used to extend the release of the active drug substances. With this technology, we are currently developing two new DepoFoam-based product candidates, DepoMeloxicam, or DepoMLX, a DepoFoam-based non-steroidal anti-inflammatory drug, or NSAID, and DepoTranexamic Acid, or DepoTXA, a DepoFoam-based antifibrinolytic. 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. There are other potential DepoFoam products being evaluated as pipeline candidates.

DepoMLX is a long-acting NSAID, designed to treat moderate to severe acute pain. A product designed for single dose local administration such as DepoMLX could provide a longer duration of pain relief at a significantly lower concentration of systemic NSAIDs, which are known to cause dose dependent gastrointestinal side effects. Meloxicam, which is currently available as an oral formulation, is a commonly used NSAID on the market today. We expect our customer audience for this drug to be similar to the target audience for EXPAREL infiltration. DepoMLX is currently in pre-clinical development, and we expect the initiation of a Phase 1 clinical study under an investigational new drug application, or IND, in the second half of 2016.

Tranexamic Acid, or TXA, is currently used as a systemic injection or as a topical application, and is used to treat or prevent excessive blood loss during surgery by promoting hemostasis. The current formulation of tranexamic acid, however, has a short-lived effect consisting of only a few hours, while the risk of bleeding continues for two to three days after surgery. We believe DepoTXA, a long acting local antifibrinolytic agent combining immediate and extended release TXA, could address the unmet, increasing need for rapid ambulation and discharge in the ambulatory surgery environment for joint surgery (primarily orthopedic surgery, including spine and trauma procedures and cardiothoracic surgery). Designed for single dose local administration into the surgical site, DepoTXA could provide enhanced hemostabilization for patients over the systemic use of TXA by reducing bleeding, the need for blood transfusions, swelling, soft-tissue hematomas and the need for postoperative drains, thereby increasing not only vigor in patients, but also by decreasing overall costs to the hospital system. DepoTXA is currently in pre-clinical development, and we expect an IND approval to be followed by the initiation of a Phase 2 clinical study in the second half of 2016.

### **Results of Operations**

#### ***Comparison of Years Ended December 31, 2015, 2014 and 2013***

##### *Revenues*

The following table provides information regarding our revenues during the periods indicated, including percent changes (dollar amounts in thousands):



[Table of Contents](#)

	Year Ended December 31,			2015 versus	2014 versus
	2015	2014	2013	2014	2013
				% Increase / (Decrease)	
Net product sales:					
EXPAREL	\$ 239,851	\$ 188,528	\$ 76,218	27 %	147 %
DepoCyt(e)	4,636	4,998	5,738	(7)%	(13)%
Total net product sales	244,487	193,526	81,956	26 %	136 %
Collaborative licensing and milestone revenue	1,426	1,287	972	11 %	32 %
Royalty revenue	3,084	2,855	2,623	8 %	9 %
Total revenues	\$ 248,997	\$ 197,668	\$ 85,551	26 %	131 %

EXPAREL revenue grew 27% and 147% in the years ended December 31, 2015 and 2014, respectively, primarily due to increases in sales volume of 21% and 135% in each respective period. The strong demand for EXPAREL has continued as a result of new accounts and growth within existing accounts, which has been driven by continued adoption of EXPAREL in soft tissue and orthopedic procedures. The remaining increase in EXPAREL revenue was due to 5% price increases in each of May 2014 and April 2015. In addition, as a result of both major hospital system formulary wins and the reduction of formulary restrictions, physician access has improved. The 2015 EXPAREL growth was partially offset by lower pricing on government sales resulting from our participation in the Federal Supply Schedule beginning in the third quarter of 2015.

DepoCyt(e) product sales decreased 7% in 2015 primarily due to the decrease in the value of the Euro reflected in European sales and a decrease in domestic DepoCyt(e) sales volume. DepoCyt(e) product sales decreased 13% in 2014 due to a lower number of DepoCyt(e) lots sold to our commercial partners.

The increase in collaborative licensing and milestone revenue of 11% in 2015 and 32% in 2014 was primarily driven by the receipt of an \$8.0 million upfront payment in May 2014 from Mundipharma International Corporation Limited, or Mundipharma, in connection with the extension of the term of existing supply and distribution agreements and the expansion of the territory where Mundipharma can market and distribute DepoCyt(e), which is being recognized on a straight-line basis over the contractual term which expires in June 2033.

Royalty revenue reflects royalties earned on collections of end user sales of DepoCyt(e) by our commercial partners.

*Cost of Goods Sold*

Cost of goods sold primarily relates to the costs to produce, package and deliver our products to customers. These expenses include labor, raw materials, manufacturing overhead and occupancy costs, depreciation of facilities, royalty payments, quality control and engineering.

The following table provides information regarding cost of goods sold during the periods indicated, including our gross margin percentage (dollar amounts in thousands):

	Year Ended December 31,			2015 versus	2014 versus
	2015	2014	2013	2014	2013
				% Increase / (Decrease)	
Cost of goods sold	\$ 71,837	\$ 77,440	\$ 54,772	(7)%	41%
Gross margin *	71%	61%	35%		

\* The gross margin calculation excludes collaborative licensing and milestone revenue.

Despite an increase in annual sales volume during 2015 of 21%, the 7% decrease in cost of goods sold versus 2014 was due to a lower manufacturing cost per vial, driven by increased utilization of our EXPAREL manufacturing facility located in San Diego, California, along with the absence of manufacturing line start-up costs which were incurred during 2014. In 2015, the full-year benefit of additional capacity from the 2014 introduction of two new manufacturing lines dedicated to EXPAREL and higher production contributed to the increased utilization of our facilities and lower manufacturing costs per vial, which is reflected in the improvement of our gross margin to 71% in 2015 versus 61% in 2014. The improvements in lower manufacturing costs per vial and gross margin percentage were sustained in spite of unplanned shutdown costs of \$3.0 million during 2015.

The increase in cost of goods sold in 2014 was due to the increase in net product sales discussed above. The improvement in gross margin to 61% in 2014 versus 35% in 2013 was driven by increased utilization of our facilities to manufacture

[Table of Contents](#)

EXPAREL. During 2014, we added two new manufacturing lines which offset the high fixed cost infrastructure at our EXPAREL manufacturing facility.

#### Research and Development Expenses

Research and development expenses consist primarily of costs related to clinical studies and related outside services, stock-based compensation expenses and other research and development costs, including Phase 4 studies that are required as a condition of FDA approval or are conducted to generate new data such as dosing and administration techniques. Clinical study expenses include costs for clinical personnel, clinical studies performed by third-party contract research organizations, materials and supplies, database management and other third-party fees. Product development and other expenses include development costs for our pipeline products and medical information expenses, which include personnel, equipment, materials and contractor costs for both new process development and new product candidates, toxicology studies and facility costs for our research space. Stock-based compensation expense relates to the costs of stock option grants to employees and non-employees, awards of restricted stock units, or RSUs, and our employee stock purchase plan, or ESPP.

The following table provides a breakout of our research and development expenses during the periods indicated, including percent changes (dollar amounts in thousands):

	Year Ended December 31,			2015 versus	2014 versus
	2015	2014	2013	2014	2013
				% Increase / (Decrease)	
Clinical development	\$ 10,001	\$ 5,518	\$ 11,202	81 %	(51)%
Product development and other	13,527	6,723	6,013	101 %	12 %
Stock-based compensation	5,134	6,490	4,345	(21)%	49 %
Total research and development expense	\$ 28,662	\$ 18,731	\$ 21,560	53 %	(13)%
% of total revenue	12%	9%	25%		

Research and development expenses increased 53% in 2015 versus 2014 largely due a \$6.8 million increase in product development and other expenses reflecting the development of a new EXPAREL DepoFoam spray manufacturing process, DepoTXA, DepoMLX and additional pre-clinical expenses driven by DepoFoam toxicology studies. Clinical development expenses increased by \$4.5 million primarily due to the initiation of and enrollment in our EXPAREL infiltration oral surgery trial. We also incurred start-up expenses in our infiltration TKA trial, expected to commence enrollment in early 2016, and in two Phase 3 nerve block trials, including a femoral nerve block in subjects undergoing TKA and a brachial plexus block in patients undergoing total shoulder arthroplasty or rotator cuff repair, both of which are expected to commence enrollment in early 2016. Stock-based compensation decreased 21%, which was largely attributable to the requirement to revalue non-employee grants.

Research and development expenses decreased 13% in 2014 versus 2013 primarily due to decreases in clinical expenses related to the conclusion of our Phase 2/3 pivotal trial of EXPAREL administered as a femoral nerve block for TKA and our Phase 3 pivotal trial of EXPAREL as an intercostal nerve block for thoracotomy. This decrease was partially offset by an increase in stock-based compensation expense, primarily due to the requirement to revalue non-employee options periodically until they vest. Over this timeframe the fair value of our stock options increased significantly, largely as a result of a corresponding increase in our stock price. The increase in other research and development expense reflects increased headcount for our medical information support function.

#### Selling, General and Administrative Expenses

Sales and marketing expenses primarily consist of compensation and benefits for our sales force and personnel that support our sales, marketing, medical and scientific affairs operations, commission payments to CrossLink BioScience, LLC, or CrossLink, for the promotion and sale of EXPAREL, expenses related to communicating health outcome benefits of EXPAREL patients and educational programs for our customers. General and administrative expenses consist of compensation and benefits for legal, finance, regulatory, compliance, information technology, human resources, executive management and other supporting personnel. It also includes professional fees for legal, audit, tax and consulting services. Stock-based compensation expense relates to the costs of stock option grants, RSU awards and our ESPP.

The following table provides information regarding selling, general and administrative expenses during the periods indicated, including percent changes (dollar amounts in thousands):

	Year Ended December 31,			2015 versus	2014 versus
	2015	2014	2013	2014	2013
				% Increase / (Decrease)	
Sales and marketing	\$ 77,733	\$ 65,010	\$ 39,298	20%	65%
General and administrative	39,088	26,902	17,568	45%	53%
Stock-based compensation	22,222	14,750	5,642	51%	161%
Total selling, general and administrative expenses	\$ 139,043	\$ 106,662	\$ 62,508	30%	71%
% of total revenue	56%	54%	73%		

Selling, general and administrative expenses increased 30% in 2015.

Sales and marketing expenses increased by 20% in 2015 versus 2014 primarily due to an increase in the number of our field-based medical and scientific affairs personnel to better support and educate our customers, resulting in a \$10.0 million increase in salaries, benefits and other headcount related costs. We also had a \$2.7 million increase in spending for EXPAREL, which included educational initiatives and programs to create product awareness among key orthopedic and soft tissue surgical markets, commission based payments to CrossLink, the initiation of a patient awareness campaign related to postsurgical analgesic options for pain relief and other selling initiatives and promotional activities to support the growth of EXPAREL.

General and administrative expenses increased 45% in 2015 versus 2014 largely due to increases in legal costs of \$7.8 million associated with the subpoena from the DOJ and our FDA activities, including expenses related to the warning letter issued by the FDA's Office of Prescription Drug Promotion, or OPDP, and our lawsuit against the FDA which claimed violations of the First and Fifth Amendments of the U.S. Constitution as well as the Administrative Procedures Act, the resolution of which is described in the *Overview* section above. Due to the growth of the business mainly in our business development and human resources groups, salaries and benefits increased by \$2.5 million. Additionally, there were increases in infrastructure costs and outside services in areas such as compliance and information technology to support the commercial and manufacturing growth of EXPAREL.

Stock-based compensation increased 51% in 2015 versus 2014 as a result of increases in headcount as well as our 2015 grant of RSUs.

Selling, general and administrative expenses increased by 71% in 2014.

Sales and marketing expenses increased by 65% in 2014 versus 2013 primarily due to a \$16.0 million increase in spending for EXPAREL, which included educational initiatives and programs to create product awareness in the orthopedic market, commission based payments to CrossLink, other selling initiatives and promotional activities to support the growth of EXPAREL. We also had an \$8.7 million increase in salaries and benefits driven by an increase in the number of our field-based medical and scientific affairs personnel to better support and educate our customers.

General and administrative expenses increased 53% in 2014 versus 2013 largely due to increases in salaries and benefits of \$3.6 million associated with our increased headcount, as well as increased infrastructure costs and outside services in areas such as regulatory affairs and pharmacovigilance, tax services and information technology to support the commercial and manufacturing growth of EXPAREL.

Stock-based compensation increased 161% in 2014 versus 2013 largely due to increases in headcount and significantly higher grant date fair values of our stock options as a result of a corresponding increase in our stock price.

[Table of Contents](#)

*Other Income (Expense)*

The following table provides information regarding other income (expense) during the periods indicated, including percent changes (dollar amounts in thousands):

	Year Ended December 31,			2015 versus	2014 versus
	2015	2014	2013	2014	2013
				% Increase / (Decrease)	
Interest income	\$ 678	\$ 382	\$ 259	77 %	47 %
Interest expense	(7,725)	(8,278)	(7,253)	(7)%	14 %
Loss on early extinguishment of debt	(52)	—	(3,398)	N/A	(100)%
Royalty interest obligation	(71)	(323)	(623)	(78)%	(48)%
Other, net	(165)	(159)	(47)	4 %	238 %
Total other expense, net	\$ (7,335)	\$ (8,378)	\$ (11,062)	(12)%	(24)%
% of total revenue	(3)%	(4)%	(13)%		

Total other expense, net decreased by 12% in 2015 versus 2014 primarily due to decreases in both interest expense and our royalty interest obligation and an increase in interest income. The decrease in interest expense was primarily due to a \$0.5 million increase in capitalized interest on the construction of new manufacturing suites. The increase in interest income is due to higher cash balances and longer duration investments. The decrease in our royalty interest obligation is due to our royalty interests assignment agreement with Paul Capital Advisors LLC ending on December 31, 2014.

Total other expense, net decreased by 24% in 2014 versus 2013 primarily due to the loss on the early extinguishment of our Oxford Credit Facility in January 2013, partially offset by an increase in interest expense. The increase in interest expense was due to an \$0.8 million decrease in capitalized interest on a manufacturing suite at our San Diego location, which was placed into service in 2014 and a \$0.2 million increase in interest expense arising from a full year's amortization of the discount on our convertible senior notes.

In 2013, we incurred a \$3.4 million loss on the early extinguishment of the Oxford Credit Facility.

*Income Tax Expense (Benefit)*

The following table provides information regarding our income tax expense (benefit) during the periods indicated, including percent changes (in thousands):

	Year Ended December 31,			2015 versus	2014 versus
	2015	2014	2013	2014	2013
				% Increase / (Decrease)	
Income tax expense (benefit)	\$ 264	\$ 173	\$ (442)	53%	N/A
Effective tax rate	12%	(1)%	1%		

We recorded tax provisions of \$0.3 million and \$0.2 million for the years ended December 31, 2015 and 2014, respectively. The \$0.1 million increase in 2015 versus 2014 is primarily attributable to the alternative minimum tax component of the federal tax provision. The 2015 tax provision reflects alternative minimum tax as well as minimum and apportionment state taxes. Prior to 2015, there was no provision for federal income taxes since we had incurred net operating losses since inception. The 2014 provision was the result of minimum and apportionment based state taxes. In 2013, the income tax benefit reflected the sale of our unused net operating losses through the State of New Jersey's Economic Development Authority Technology Business Tax Certificate Transfer Program.

**Liquidity and Capital Resources**

Since our inception in 2006, we have devoted most of our cash resources to manufacturing, research and development and selling, general and administrative activities related to the development and commercialization of EXPAREL. We are highly dependent on the commercial success of EXPAREL, which we launched in April 2012. We have financed our operations primarily with the proceeds from the sale of convertible senior notes, convertible preferred stock, common stock, secured and unsecured notes, borrowings under debt facilities, product sales and collaborative licensing and milestone revenue. As of December 31, 2015, we had an accumulated deficit of \$308.3 million, cash and cash equivalents, short-term investments and long-term investments of \$172.4 million and working capital of \$100.9 million.

[Table of Contents](#)**Summary of Cash Flows**

The following table summarizes our cash flows from operating, investing and financing activities for the years ended December 31, 2015, 2014 and 2013 (in thousands):

<b>Consolidated Statement of Cash Flows Data:</b>	<b>Year Ended December 31,</b>		
	<b>2015</b>	<b>2014</b>	<b>2013</b>
Net cash provided by (used in):			
Operating activities	\$ 28,996	\$ 26,564	\$ (43,838)
Investing activities	(20,231)	(120,434)	(42,938)
Financing activities	10,699	118,875	89,165
Net increase in cash and cash equivalents	\$ 19,464	\$ 25,005	\$ 2,389

**Operating Activities**

In 2015, net cash provided by operating activities was \$29.0 million, which largely resulted from increased revenues and improved gross margins versus 2014. Positive cash flow from operations reflected net income of \$1.9 million plus \$49.5 million in add backs of non-cash expenses comprised of \$33.4 million of stock-based compensation and \$16.1 million of depreciation and amortization, partially offset by a \$22.3 million net investment in operating assets and liabilities, including a substantial investment in inventory. Both net income and cash flow were negatively impacted by legal expenses related to the warning letter issued by the OPDP in September 2014, the DOJ inquiry and our lawsuit against the FDA which claimed violations of the First and Fifth Amendments of the U.S. Constitution as well as the Administrative Procedures Act, the resolution of which is described in the *Overview* section above.

In 2014, net cash provided by operating activities was \$26.6 million. Our net loss of \$13.7 million was more than offset by \$40.0 million in non-cash expenses comprised of \$24.8 million of stock-based compensation and \$14.7 million of depreciation and amortization. Cash flow benefited from higher EXPAREL product sales and significantly improved gross margins, which were partially offset by expenditures for additional field-based personnel and related educational, selling and promotional initiatives, as well as additional administrative support. We also received an \$8.0 million upfront payment from Mundipharma in connection with the extension of the term of existing supply and distribution agreements and the expansion of the territory where Mundipharma can market and distribute DepoCyte.

In 2013, net cash used in operating activities was \$43.8 million, largely due to a \$63.9 million loss offset by non-cash expenses of \$21.7 million, comprised of \$11.5 million in stock-based compensation and \$10.2 in depreciation and amortization.

**Investing Activities**

In 2015, net cash used in investing activities was \$20.2 million, which reflected purchases of fixed assets of \$41.3 million. Major capital projects included investing in a new research and development facility at our Science Center Campus in San Diego, California and continuing expenditures for expanding our manufacturing capacity in Swindon, England in partnership with Patheon. We also made contingent consideration payments to Skyepharma of \$7.1 million related to the acquisition in March 2007. These expenditures were offset by \$28.2 million of short-term investment maturities, net of purchases.

In 2014, net cash used in investing activities was \$120.4 million. This was due to a net investment of \$84.0 million in short-term and long-term investments, mainly purchased using the net proceeds from our April 2014 follow-on underwritten public offering. We spent \$23.0 million for purchases of fixed assets, which included major investments for an EXPAREL manufacturing fill line and our capacity expansion project with Patheon. We also paid \$13.4 million in contingent consideration payments to Skyepharma, which included an \$8.0 million milestone payment and \$5.4 million in percentage payments on collections of net sales of EXPAREL in connection with the 2007 acquisition.

In 2013, net cash used in investing activities was \$42.9 million. This was due to a net investment of \$28.7 million in short-term investments, \$12.2 million in investments in fixed assets related to the expansion of our manufacturing facilities at our Science Center Campus and \$2.0 million in percentage payments on collections of net sales of EXPAREL in connection with the 2007 acquisition.

**Financing Activities**

In 2015, net cash provided by financing activities was \$10.7 million, which reflected proceeds from the exercise of stock options of \$10.1 million and proceeds from the issuance of shares under our ESPP of \$2.1 million. The increase was offset by the cash settlement of \$1.5 million in principal on a conversion of our convertible senior notes.

## [Table of Contents](#)

In 2014, net cash provided by financing activities was \$118.9 million which was largely attributable to our April 2014 follow-on underwritten public offering with net proceeds of \$110.5 million after deducting underwriters' fees and expenses. We also received \$7.2 million and \$1.2 million of proceeds from the exercise of stock options/warrants and our ESPP, respectively.

In 2013, net cash provided by financing activities of \$89.2 million was primarily attributable to our private offering of our convertible senior notes, which, after deducting financing costs, provided net proceeds of \$115.3 million. We used \$30.0 million of the net proceeds from the offering to repay in full the \$27.5 million outstanding balance on the Oxford Credit Facility, as well as a \$1.7 million end of term fee and an \$0.8 million early prepayment penalty. We also received \$3.9 million from the exercise of stock options and warrants.

### ***Equity Financings***

From inception through December 31, 2015, we have raised approximately \$345 million of net proceeds from the sale of common stock and other equity securities.

#### *Common Stock*

In April 2014, we sold 1,840,000 shares of common stock at a price of \$64.00 per share in a follow-on underwritten public offering for proceeds of \$110.5 million, net of underwriters' fees and related expenses.

### ***Debt Facilities***

#### *January 2013 Convertible Senior Notes*

On January 23, 2013, we completed a private offering of \$120.0 million in aggregate principal, 3.25% convertible senior notes due 2019, or Notes, which are classified as a current liability as discussed in Note 8, *Debt*, to our consolidated financial statements included herein. The net proceeds from the Notes offering were \$115.3 million, after deducting the initial purchasers' discounts and commissions as well as offering expenses.

On or after August 1, 2018, until the close of business on the second scheduled trading day immediately preceding February 1, 2019, holders may convert their Notes at any time. Upon conversion, holders will receive cash up to the principal amount of the Notes and, with respect to any excess conversion value, cash, shares of our common stock or a combination of cash and shares of our common stock, at our option. The conversion rate for the Notes is initially 40.2945 shares of common stock per \$1,000 principal amount, which is equivalent to an initial conversion price of approximately \$24.82 per share of our common stock. The conversion rate will be subject to adjustment for some events, but will not be adjusted for any accrued and unpaid interest. Additionally, during any calendar quarter, the holders have the right to convert if our stock price closes at or above 130% of the conversion price then applicable (the "Consecutive Sales Price") during a period of at least 20 out of the last 30 consecutive trading days of any given quarter. During the three months ended December 31, 2015 the requirements with respect to the Consecutive Sales Price were met and, as a result, the Notes are classified as a current obligation and are convertible until March 31, 2016. The future convertibility and resulting balance sheet classification of the Notes will be monitored on a quarterly basis. Prior to February 1, 2018, in the event such requirements are not met in a given quarter, the Notes would be reclassified as a long-term liability. In the event that all of the Notes are converted, we would be required to repay the \$118.5 million in outstanding principal and approximately \$248 million of cash or issue approximately 3.2 million shares of our common stock (or a combination of cash and shares of our common stock at our option) to settle the conversion premium as of December 31, 2015, causing dilution to our current shareholders and/or significant expenditures of our cash and liquid securities.

On or after February 1, 2017, we may redeem for cash all or part of the Notes if the last reported sale price (as defined in the Indenture) of our common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading-day period, ending within five trading days prior to the date on which we provide notice of redemption. If we decide to call the Notes on or after February 1, 2017, we currently intend, subject to market conditions and the trading price of our common stock, to provide holders of the Notes with the maximum 60 day redemption notice provided for in the Indenture.

In February 2015, we received notice of an election for conversion from a holder of the Notes. The principal amount of the conversion request was \$1.5 million which was paid in cash in April 2015 pursuant to the terms of an indenture agreement with respect to the Notes. We elected to settle the conversion premium by issuing 44,287 shares of our common stock, calculated based on a daily volume-weighted average price over a 40 trading-day observation period which ended on April 8, 2015.

See Note 8, *Debt*, to our consolidated financial statements included herein for further discussion of the Notes.

**Future Capital Requirements**

We believe that our existing cash and cash equivalents, short-term and long-term investments and cash received from product sales will be sufficient to enable us to fund our operating expenses, capital expenditure requirements, payment of the principal on any conversions of the Notes and to service our indebtedness for at least the next 12 months. Our future use of operating cash and capital requirements will depend on many forward-looking factors, including, but not limited to, the following:

- our ability to successfully continue to expand the commercialization of EXPAREL;
- the cost and timing of expanding our manufacturing facilities for EXPAREL and our other product candidates, including costs associated with certain technical transfer activities and the construction of manufacturing suites at Patheon’s Swindon, England facility;
- the timing of and extent to which the holders of our Notes elect to convert the Notes;
- the cost and timing of potential milestone payments to Skyepharma, which could be up to an aggregate of \$44.0 million if certain milestones pertaining to net sales of EXPAREL are met;
- costs related to legal and regulatory issues;
- the costs of performing additional clinical trials for EXPAREL, including the pediatric trials required by the FDA as a condition of approval, and costs of development for our other product candidates; and
- the extent to which we acquire or invest in products, businesses and technologies.

We may require additional debt or equity financing to meet our future operating and capital requirements. We have no committed external sources of funds, and additional equity or debt financing may not be available on acceptable terms, if at all.

**Contractual Obligations**

The table below presents a summary of our contractual obligations as of December 31, 2015 (in thousands):

Contractual Obligations (1)	Payments Due by Period				
	Total	Less Than One Year	1-3 Years	3-5 Years	More Than 5 Years
Senior convertible notes - principal (2)	\$ 118,533	\$ —	\$ —	\$ 118,533	\$ —
Senior convertible notes - interest	11,878	3,852	7,705	321	—
Lease obligations (3)	47,156	7,743	15,959	14,723	8,731
Purchase obligations (4)	869	281	588	—	—
<b>Total</b>	<b>\$ 178,436</b>	<b>\$ 11,876</b>	<b>\$ 24,252</b>	<b>\$ 133,577</b>	<b>\$ 8,731</b>

(1) This table does not include potential future milestone payments to Skyepharma which could be up to an aggregate of \$44.0 million if certain milestones pertaining to net sales of EXPAREL are met, including \$8.0 million when annual net sales of EXPAREL collected reach \$250.0 million (measured on a rolling quarterly basis). This contingency is described further in Note 6, *Goodwill and Intangible Assets*, of our consolidated financial statements included herein. In addition, this table does not include various agreements that we have entered into for services with third party vendors due to the cancelable nature of these services.

(2) The amounts displayed in the table above represent management’s best estimate of timing with respect to the future convertibility of these instruments. See Note 8, *Debt*, of our consolidated financial statements included herein for further discussion. Additionally, it excludes any conversion premium on the Notes, which may be settled in cash or stock at the Company’s discretion. If the Notes were converted at December 31, 2015, it would result in an approximate premium of 3.2 million shares, \$248 million of cash or a combination thereof.

(3) The amounts consist of operating leases for our corporate headquarters in Parsippany, New Jersey and manufacturing, research and development and warehouse space in San Diego, California.

(4) The amounts consist of minimum non-cancelable contractual commitments for the purchase of certain raw materials.

In October 2013, we and CrossLink commenced a five-year arrangement for the promotion and sale of EXPAREL, pursuant to the terms of a Master Distributor Agreement. In February 2015, we entered into a Third Amendment to the Master Distributor Agreement (the “Third Amendment”) with CrossLink to, among other things, amend certain payment terms of the agreement and specify certain sub-distributors that may promote and sell EXPAREL under the agreement. Under the terms of the Third Amendment, Pacira and CrossLink have mutual termination rights under the Agreement, and we are permitted to terminate the Agreement without cause effective September 30, 2016, subject to certain terms and conditions set forth in the Agreement. In the event we terminate the agreement, a termination payment based on a percentage of earned performance-based fees will be due to CrossLink.

[Table of Contents](#)

In April 2014, we and Patheon entered into a Strategic Co-Production Agreement and Technical Transfer and Service Agreement to collaborate in the manufacture of EXPAREL. Under the terms of the Technical Transfer and Service Agreement, Patheon has agreed to undertake certain technical transfer activities and construction services needed to prepare its Swindon, England facility for the manufacture of EXPAREL in two dedicated manufacturing suites. Upon an early termination of this agreement (other than termination by us in the event that Patheon does not meet the construction and manufacturing milestones or for a breach by Patheon), we will pay for the make good costs occasioned by the removal of our manufacturing equipment and for Patheon's termination costs up to a maximum amount of \$2.4 million.

**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 require 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 revenue recognition, clinical trial expenses and stock-based compensation. We base our estimates on historical experience, contract terms and on other factors we believe to be appropriate under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are more fully discussed in Note 2, *Summary of Significant Accounting Policies*, to our audited consolidated financial statements included in this filing. The following accounting policies, which may include significant judgments and estimates, were used in the preparation of our consolidated financial statements.

***Revenue Recognition***

Our principal sources of revenue include (i) sales of EXPAREL in the United States, (ii) sales of DepoCyt(e) in the United States and Europe, (iii) royalties based on sales by commercial partners of DepoCyt(e) and (iv) license fees and milestone payments. We recognize revenue when there is persuasive evidence that an arrangement exists, title has passed, collection is reasonably assured and the price is fixed or determinable.

***Net Product Sales***

We sell EXPAREL through a drop-ship program under which orders are processed through wholesalers based on orders of the product placed by end users which include hospitals, ambulatory surgery centers and doctors. EXPAREL is delivered directly to the end user without the wholesaler ever taking physical possession of the product. We record revenue at the time the product is delivered to the end user. We also recognize revenue from products manufactured and supplied to commercial partners, such as DepoCyt(e), upon shipment. Prior to the shipment of manufactured products, we conduct initial product release and stability testing in accordance with current Good Manufacturing Practices, or cGMP.

Revenues from sales of products are recorded net of returns allowances, prompt payment discounts, wholesaler service fees and volume rebates and chargebacks. The calculation of some of these items requires management to make estimates based on sales data, contracts, inventory data and other related information which may become known in the future. We review the adequacy of our provisions on a quarterly basis.

***Returns Allowances***

We allow customers to return product that is damaged or received in error. In addition, we allow EXPAREL to be returned beginning six months prior to, and twelve months following, product expiration. We estimate our sales returns reserve based on return history from other hospital-based products with similar distribution models and our historical return rates, which we believe is the best estimate of the anticipated product to be returned. The returns reserve is recorded at the time of sale as a reduction to gross product sales and an increase in accrued expenses.

Our commercial partners can return DepoCyt(e) within contractually specified timeframes if the product does not meet the applicable inspection tests. We estimate our returns reserves based on our experience with historical return rates. Historically, our product returns have not been material.

***Prompt Payment Discounts***

The prompt payment reserve is based upon discounts offered to wholesalers as an incentive to meet certain payment terms. We accrue discounts to wholesalers based on contractual terms of agreements and historical experience. We account for these discounts at the time of sale as a reduction to gross product sales and a reduction to accounts receivable.



[Table of Contents](#)*Wholesaler Service Fees*

Our customers include major and regional wholesalers with whom we have contracted a fee for service based on a percentage of gross product sales. This fee for service is recorded as a reduction to gross product sales and an increase to accrued expenses at the time of sale, and is recorded based on the contracted percentage.

*Volume Rebates and Chargebacks*

Volume rebates and chargeback reserves are based upon contracted discounts and promotional offers we provide to certain end users such as members of group purchasing organizations. Volume rebates are recorded at the time of sale as a reduction to gross product sales and an increase in accrued expenses. Chargeback reserves are recorded at the time of sale as a reduction to gross product sales and a reduction to accounts receivable.

The following table provides a summary of activity with respect to our sales related allowances and accruals for the years ended December 31, 2015, 2014 and 2013 (in thousands):

	<b>Returns Allowances</b>	<b>Prompt Payment Discounts</b>	<b>Wholesaler Service Fees</b>	<b>Volume Rebates and Chargebacks</b>	<b>Total</b>
Balance at January 1, 2013	\$ 134	\$ 80	\$ 68	\$ 111	\$ 393
Provision	802	1,559	1,078	590	4,029
Payments/credits	(39)	(1,326)	(880)	(299)	(2,544)
Balance at December 31, 2013	897	313	266	402	1,878
Provision	829	3,833	2,780	881	8,323
Payments/credits	(167)	(3,571)	(2,458)	(962)	(7,158)
Balance at December 31, 2014	1,559	575	588	321	3,043
Provision	339	4,905	3,482	2,020	10,746
Payments/credits	(165)	(4,855)	(3,325)	(1,544)	(9,889)
Balance at December 31, 2015	\$ 1,733	\$ 625	\$ 745	\$ 797	\$ 3,900

Total reductions of gross product sales from sales-related allowances and accruals were \$10.7 million, \$8.3 million and \$4.0 million, or 4.2%, 4.1% and 4.7% of gross product sales, for the years ended December 31, 2015, 2014 and 2013, respectively. The overall increase in sales-related allowances and accruals was directly related to the increase in product sales since the commercial launch of EXPAREL in April 2012. The percentage of sales-related allowances remained fairly consistent from 2014 to 2015. In that time frame the percentage of volume rebates increased slightly, which was offset by a slight decrease in the returns allowance percentage. The decrease in the percentage of sales-related allowances and accruals from 2013 to 2014 related primarily to a reduction in our estimate of product returns based on historical returns experience and a reduction in volume rebates and chargebacks due to a reduced percentage of sales purchased through group purchasing organizations. As a percentage of gross product sales, the prompt payment discounts and wholesaler service fees remained consistent from 2013 to 2014.

*Royalty Revenue*

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 collection 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 our royalty revenue when we receive royalty reports from our commercial partners.

*Collaborative Licensing and Milestone Revenue*

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 notification of the termination of a collaboration agreement, any remaining non-refundable license fees received by us, which had been deferred, are recognized over the remaining contractual term. If the termination is immediate and no additional services are to be performed, the deferred revenue is generally

recognized in full. All such recognized revenues are included in collaborative licensing and milestone 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 collection is reasonably assured. If these criteria are not met, we recognize milestone payments ratably over the remaining period of our performance obligations under the applicable collaboration agreement.

#### ***Cost of Goods Sold***

Our cost of goods sold consist of the costs associated with our products sold and include the following:

- manufacturing overhead and fixed costs associated with running two cGMP manufacturing facilities, including allocated rent, utilities, insurance, depreciation and salaries and related costs of personnel, including stock-based compensation;
- costs of active pharmaceutical ingredients;
- royalties due to third parties on our revenues;
- packaging, testing and freight;
- amortization of our intangible assets; and
- costs associated with excess manufacturing capacity.

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

We expense 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, direct pass-through costs, clinical site fees 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 prepaid or accrued expenses related to these costs.

#### ***Convertible Debt Transactions***

We separately account for the liability and equity components of convertible debt instruments by allocating the proceeds from the issuance between the liability component and the embedded conversion option, or equity component. This is done in accordance with accounting for convertible debt instruments that may be settled in cash (including partial cash settlement) upon conversion. The value of the equity component is calculated by first measuring the fair value of the liability component, using the interest rate of a similar liability that does not have a conversion feature, as of the issuance date. The difference between the initial proceeds from the convertible debt issuance and the fair value of the liability component is recorded as the carrying amount of the equity component. We recognize the amortization of the resulting discount as part of interest expense in our consolidated statement of operations.

Upon settlement of the convertible senior notes, the liability component is measured at fair value. We allocate a portion of the fair value of the total settlement consideration transferred to the extinguishment of the liability component equal to the fair value of that component immediately prior to the settlement. Any difference between the consideration attributed to the liability component and the net carrying amount of the liability component, including any unamortized debt issuance costs, is recognized as a gain or loss in the consolidated statement of operations. Any remaining consideration is allocated to the reacquisition of the equity component and is recognized as a reduction of additional paid-in capital.

#### ***Stock-Based Compensation***

We account for stock-based compensation by measuring and recognizing compensation expense for employee stock-based awards based on their 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 for stock options, RSUs and the offering period for our ESPP. Because the valuation of stock options is inherently subjective, we estimate the fair value

## [Table of Contents](#)

of our stock-based awards 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:

- *Expected Volatility*—Since our initial public offering, we have utilized our available historic volatility data combined with a publicly traded peer group’s historic volatility to determine our expected volatility over the expected option term. The peer group was developed based on companies in the pharmaceutical and biotechnology industry in a similar stage of development. The expected volatility rate used to value ESPP options is based solely on our historic volatility data.
- *Expected Term*—In 2015, we used an expected term based on a weighted average combination of our historical data from stock option exercises and the simplified method. In prior years, we utilized the “simplified” method for “plain vanilla” options to estimate the expected term of stock option grants. Under that approach, the weighted average expected life was 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 is based on zero coupon United States Department of the Treasury instruments for periods commensurate 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.

### **Income Tax Expense (Benefit)**

Our income tax expense, deferred tax assets and liabilities and reserves for unrecognized tax benefits reflect management’s assessment of estimated future taxes to be paid. Significant judgments and estimates are required in determining the consolidated income tax expense. As of December 31, 2015, we have significant federal and state income tax net operating loss and credit carry forwards, the use of which may be limited by historic and future ownership changes within the meaning of Section 382 of the Internal Revenue Code. Based on the positive and negative evidence available, we believe that it is more likely than not that the benefit from deferred tax assets will not be realized. In recognition of this risk, we have provided a full valuation allowance against our deferred tax assets net of deferred tax liabilities that will generate taxable income during the reversal period.

### **Recent Accounting Pronouncements**

See Note 3, *Recent Accounting Pronouncements*, to the Notes to Consolidated Financial Statements in Item 15 below for further discussion of recent accounting pronouncements.

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

We do not have any material off-balance sheet arrangements as of December 31, 2015, except for operating leases, nor do we have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities. None of our operating leases have, or are reasonably likely to have, a current or future material effect on our financial condition or changes in financial condition.

### **Item 7A. Quantitative and Qualitative Disclosures about Market Risk**

The primary objective of our cash equivalent and investment activities is to preserve principal while at the same time maximizing the income that we receive from our investments without significantly increasing risk. We invest in corporate bonds, commercial paper and asset-backed securities, which are reported at fair value. These securities are subject to interest rate risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the interest rate later rises, we expect that the fair value of our investment will decline. A hypothetical 100 basis point increase in interest rates would have reduced the fair value of our available-for-sale securities at December 31, 2015 by \$0.3 million.

In January 2013, we issued \$120.0 million in aggregate principal amount of 3.25% convertible senior notes, which mature in February 2019. Holders may convert their notes prior to maturity under certain circumstances. Upon conversion, holders will receive cash up to the principal amount of the Notes and, with respect to any excess conversion value, cash, shares of our common stock or a combination of cash and shares, at our option. The fair value of the Notes is impacted by both the fair value of our common stock and interest rate fluctuations. As of December 31, 2015, the estimated fair value of the Notes was \$3,121 per \$1,000 principal amount. We do not have interest rate exposure related to the Notes, as they have a fixed annual interest

[Table of Contents](#)

rate. See Note 8, *Debt*, to the Notes to Consolidated Financial Statements in Item 15 below for additional information on the Notes.

Most of our transactions are conducted in United States dollars. We do have certain agreements with commercial partners located outside the United States which have transactions conducted in Euros. As of December 31, 2015, we had approximately \$0.4 million in receivables from customers denominated in Euros. A hypothetical 10% decrease in the value of the United States dollar relative to the Euro would have decreased our revenue by less than \$0.1 million for the quarter ended December 31, 2015.

Additionally, our accounts receivable are concentrated with three large regional wholesalers of pharmaceutical products. In the event of non-performance or non-payment, there may be a material adverse impact on our financial condition, results of operations or net cash flow.

**Item 8. Financial Statements and Supplementary Data**

Our consolidated financial statements required by this item, together with the report of our independent registered public accounting firm, appear on pages F-1 through F-33 of this Annual Report on Form 10-K.

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None.

**Item 9A. Controls and Procedures**

**Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures, as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, which are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chairman and President and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Based on their evaluation as of December 31, 2015, our Chief Executive Officer and Chairman and President and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2015.

**Management's Report on Internal Control over Financial Reporting**

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chairman and President and Chief Financial Officer, management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2015, based on the criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based upon the results of the evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2015.

The effectiveness of our internal control over financial reporting as of December 31, 2015 was audited by CohnReznick LLP, our independent registered public accounting firm, as stated in their report appearing below, which expressed an unqualified opinion on the effectiveness of our internal control over financial reporting as of December 31, 2015.

**Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2015, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders  
Pacira Pharmaceuticals, Inc.

We have audited Pacira Pharmaceuticals, Inc. and Subsidiaries' internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Pacira Pharmaceuticals, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on Pacira Pharmaceuticals, Inc.'s internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Pacira Pharmaceuticals, Inc. has maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015 based on the COSO criteria.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements of Pacira Pharmaceuticals, Inc. and Subsidiaries as of December 31, 2015 and 2014, and for each of the three years in the period ended December 31, 2015 and our report dated February 25, 2016 expressed an unqualified opinion thereon.

/s/ CohnReznick LLP

Roseland, New Jersey  
February 25, 2016

**Item 9B. Other Information**

None.

**PART III**

**Item 10. Directors, Executive Officers and Corporate Governance**

Information required by this item will be included in the proxy statement for our 2016 annual stockholders' meeting and is incorporated by reference into this report.

**Item 11. Executive Compensation**

Information required by this item will be included in the proxy statement for our 2016 annual stockholders' meeting and is incorporated by reference into this report.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholders Matters**

Information required by this item will be included in the proxy statement for our 2016 annual stockholders' meeting and is incorporated by reference into this report.

**Item 13. Certain Relationships and Related Transactions, and Director Independence**

Information required by this item will be included in the proxy statement for our 2016 annual stockholders' meeting and is incorporated by reference into this report.

**Item 14. Principal Accounting Fees and Services**

Information required by this item will be included in the proxy statement for our 2016 annual stockholders' meeting and is incorporated by reference into this report.

**PART IV**

**Item 15. Exhibits, Financial Statement Schedules**

(a) Documents filed as part of Form 10-K.

(1) Financial Statements

Report of Independent Registered Public Accounting Firm  
Consolidated Balance Sheets  
Consolidated Statements of Operations  
Consolidated Statements of Comprehensive Income (Loss)  
Consolidated Statements of Stockholders' Equity  
Consolidated Statements of Cash Flows  
Notes to Consolidated Financial Statements

(2) Schedules

All financial statement schedules have been omitted because they are not required, are not applicable or the information is included in the financial statements or related notes thereto.

(3) Exhibits

The Exhibits listed in the Exhibit Index are filed with, or incorporated by reference in this Form 10-K.



**PACIRA PHARMACEUTICALS, INC.  
ANNUAL REPORT ON FORM 10-K  
FOR THE YEAR ENDED DECEMBER 31, 2015**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

<a href="#">Report of Independent Registered Public Accounting Firm</a>	<a href="#">F-2</a>
<a href="#">Consolidated Balance Sheets as of December 31, 2015 and 2014</a>	<a href="#">F-3</a>
<a href="#">Consolidated Statements of Operations for the years ended December 31, 2015, 2014 and 2013</a>	<a href="#">F-4</a>
<a href="#">Consolidated Statements of Comprehensive Income (Loss) for the years ended December 31, 2015, 2014 and 2013</a>	<a href="#">F-5</a>
<a href="#">Consolidated Statements of Stockholders' Equity for the years ended December 31, 2015, 2014 and 2013</a>	<a href="#">F-6</a>
<a href="#">Consolidated Statements of Cash Flows for the years ended December 31, 2015, 2014 and 2013</a>	<a href="#">F-7</a>
<a href="#">Notes to Consolidated Financial Statements</a>	<a href="#">F-8</a>



**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders  
Pacira Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Pacira Pharmaceuticals, Inc. and Subsidiaries as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended December 31, 2015. Pacira Pharmaceuticals, Inc.'s management is responsible for these consolidated financial statements. 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, 2015 and 2014, and their results of operations and cash flows for each of the three years in the period ended December 31, 2015, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Pacira Pharmaceuticals, Inc. and Subsidiaries' internal control over financial reporting as of December 31, 2015 based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated February 25, 2016, expressed an unqualified opinion thereon.

/s/ CohnReznick LLP

Roseland, New Jersey  
February 25, 2016

**PACIRA PHARMACEUTICALS, INC.  
CONSOLIDATED BALANCE SHEETS**

(In thousands, except share and per share amounts)

	December 31,	
	2015	2014
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 56,984	\$ 37,520
Restricted cash	—	1,509
Short-term investments	101,981	119,138
Accounts receivable, net	25,855	22,366
Inventories, net	61,645	29,263
Prepaid expenses and other current assets	6,117	4,461
Total current assets	252,582	214,257
Long-term investments	13,462	24,431
Fixed assets, net	90,324	60,632
Goodwill	30,880	23,761
Intangibles, net	81	403
Other assets	2,294	2,588
Total assets	\$ 389,623	\$ 326,072
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 8,739	\$ 6,758
Accrued expenses	35,375	28,311
Convertible senior notes	105,928	103,100
Current portion of royalty interest obligation	—	276
Current portion of deferred revenue	1,426	1,426
Income taxes payable	208	139
Total current liabilities	151,676	140,010
Deferred revenue	8,082	9,508
Other liabilities	11,473	5,409
Total liabilities	171,231	154,927
Commitments and contingencies (Note 17)		
Stockholders' equity:		
Preferred stock, par value \$0.001; 5,000,000 shares authorized, none issued and outstanding at December 31, 2015 and 2014	—	—
Common stock, par value \$0.001 and 250,000,000 shares authorized; 36,848,319 shares issued and outstanding at December 31, 2015; 36,150,620 shares issued and outstanding at December 31, 2014	37	36
Additional paid-in capital	526,696	481,334
Accumulated deficit	(308,289)	(310,145)
Accumulated other comprehensive loss	(52)	(80)
Total stockholders' equity	218,392	171,145
Total liabilities and stockholders' equity	\$ 389,623	\$ 326,072

*See accompanying notes to consolidated financial statements.*

**PACIRA PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

(In thousands, except per share amounts)

	Year Ended December 31,		
	2015	2014	2013
<b>Revenues:</b>			
Net product sales	\$ 244,487	\$ 193,526	\$ 81,956
Collaborative licensing and milestone revenue	1,426	1,287	972
Royalty revenue	3,084	2,855	2,623
<b>Total revenues</b>	<b>248,997</b>	<b>197,668</b>	<b>85,551</b>
<b>Operating expenses:</b>			
Cost of goods sold	71,837	77,440	54,772
Research and development	28,662	18,731	21,560
Selling, general and administrative	139,043	106,662	62,508
<b>Total operating expenses</b>	<b>239,542</b>	<b>202,833</b>	<b>138,840</b>
<b>Income (loss) from operations</b>	<b>9,455</b>	<b>(5,165)</b>	<b>(53,289)</b>
<b>Other (expense) income:</b>			
Interest income	678	382	259
Interest expense	(7,725)	(8,278)	(7,253)
Loss on early extinguishment of debt	(52)	—	(3,398)
Royalty interest obligation	(71)	(323)	(623)
Other, net	(165)	(159)	(47)
<b>Total other expense, net</b>	<b>(7,335)</b>	<b>(8,378)</b>	<b>(11,062)</b>
<b>Income (loss) before income taxes</b>	<b>2,120</b>	<b>(13,543)</b>	<b>(64,351)</b>
Income tax (expense) benefit	(264)	(173)	442
<b>Net income (loss)</b>	<b>\$ 1,856</b>	<b>\$ (13,716)</b>	<b>\$ (63,909)</b>
<b>Net income (loss) per share:</b>			
Basic net income (loss) per common share	\$ 0.05	\$ (0.39)	\$ (1.93)
Diluted net income (loss) per common share	\$ 0.04	\$ (0.39)	\$ (1.93)
<b>Weighted average common shares outstanding:</b>			
Basic	36,540	35,299	33,182
Diluted	41,301	35,299	33,182

*See accompanying notes to consolidated financial statements.*

**PACIRA PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)**

(In thousands)

	Year Ended December 31,		
	2015	2014	2013
Net income (loss)	\$ 1,856	\$ (13,716)	\$ (63,909)
Other comprehensive income (loss):			
Net unrealized gain (loss) on investments	28	(85)	(22)
Total other comprehensive income (loss)	28	(85)	(22)
Comprehensive income (loss)	\$ 1,884	\$ (13,801)	\$ (63,931)

*See accompanying notes to consolidated financial statements.*

**PACIRA PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
**Years Ended December 31, 2015, 2014 and 2013**

(In thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Treasury Stock	Accumulated Other Comprehensive Income (Loss)	Total
	Shares	Amount					
<b>Balances at December 31, 2012</b>	32,623	\$ 33	\$ 298,317	\$ (232,520)	\$ (2)	\$ 27	\$ 65,855
Exercise of stock options	741	1	3,855	—	—	—	3,856
Cashless exercise of warrants	271	—	—	—	—	—	—
Stock-based compensation	—	—	11,513	—	—	—	11,513
Net unrealized loss on investments	—	—	—	—	—	(22)	(22)
Equity component of convertible senior notes, net of issuance costs	—	—	23,956	—	—	—	23,956
Issuance of common stock from treasury	1	—	(2)	—	2	—	—
Net loss	—	—	—	(63,909)	—	—	(63,909)
<b>Balances at December 31, 2013</b>	33,636	34	337,639	(296,429)	—	5	41,249
Follow-on public offering, net	1,840	2	110,450	—	—	—	110,452
Exercise of stock options	624	—	7,239	—	—	—	7,239
Shares issued under employee stock purchase plan	16	—	1,184	—	—	—	1,184
Cashless exercise of warrants	35	—	—	—	—	—	—
Stock-based compensation	—	—	24,822	—	—	—	24,822
Net unrealized loss on investments	—	—	—	—	—	(85)	(85)
Net loss	—	—	—	(13,716)	—	—	(13,716)
<b>Balances at December 31, 2014</b>	36,151	36	481,334	(310,145)	—	(80)	171,145
Exercise of stock options	618	1	10,072	—	—	—	10,073
Shares issued under employee stock purchase plan	35	—	2,093	—	—	—	2,093
Stock-based compensation	—	—	33,368	—	—	—	33,368
Issuance of common stock upon conversion of convertible senior notes	44	—	3,929	—	—	—	3,929
Retirement of equity component of convertible senior notes	—	—	(4,100)	—	—	—	(4,100)
Net unrealized gain on investments	—	—	—	—	—	28	28
Net income	—	—	—	1,856	—	—	1,856
<b>Balances at December 31, 2015</b>	36,848	\$ 37	\$ 526,696	\$ (308,289)	\$ —	\$ (52)	\$ 218,392

*See accompanying notes to consolidated financial statements.*

**PACIRA PHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)

	Year Ended December 31,		
	2015	2014	2013
<b>Operating activities:</b>			
Net income (loss)	\$ 1,856	\$ (13,716)	\$ (63,909)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation of fixed assets and amortization of intangibles	11,475	10,035	5,747
Amortization of unfavorable lease obligation and debt issuance costs	481	487	459
Amortization of debt discount	4,102	4,139	3,959
Loss on disposal of fixed assets	6	158	32
Loss on early extinguishment of debt	52	—	3,398
Stock-based compensation	33,368	24,822	11,513
Changes in operating assets and liabilities:			
Restricted cash	1,509	124	(110)
Accounts receivable, net	(3,489)	(7,776)	(10,238)
Inventories	(32,382)	(13,706)	(3,480)
Prepaid expenses and other assets	(2,007)	(1,621)	(972)
Accounts payable and accrued expenses	9,941	15,349	9,622
Royalty interest obligation	(276)	(970)	(434)
Other liabilities	5,786	2,526	1,047
Deferred revenue	(1,426)	6,713	(472)
Net cash provided by (used in) operating activities	<u>28,996</u>	<u>26,564</u>	<u>(43,838)</u>
<b>Investing activities:</b>			
Purchases of fixed assets	(41,270)	(22,984)	(12,172)
Purchases of investments	(189,082)	(164,303)	(114,299)
Sales of investments	217,240	80,286	85,564
Payment of contingent consideration	(7,119)	(13,433)	(2,031)
Net cash used in investing activities	<u>(20,231)</u>	<u>(120,434)</u>	<u>(42,938)</u>
<b>Financing activities:</b>			
Proceeds from follow-on public offering, net	—	110,452	—
Proceeds from exercise of stock options and warrants	10,073	7,239	3,856
Proceeds from shares issued under employee stock purchase plan	2,093	1,184	—
Conversion of principal and equity component of convertible senior notes	(1,467)	—	—
Proceeds from convertible senior notes	—	—	120,000
Repayment of debt	—	—	(27,500)
Payment of debt issuance and financing costs	—	—	(7,191)
Net cash provided by financing activities	<u>10,699</u>	<u>118,875</u>	<u>89,165</u>
Net increase in cash and cash equivalents	19,464	25,005	2,389
Cash and cash equivalents, beginning of year	37,520	12,515	10,126
Cash and cash equivalents, end of year	<u>\$ 56,984</u>	<u>\$ 37,520</u>	<u>\$ 12,515</u>
<b>Supplemental cash flow information:</b>			
Cash paid for interest, including royalty interest obligation	\$ 4,224	\$ 5,193	\$ 3,500
Cash paid for income taxes, net of refunds	\$ 195	\$ 34	\$ —
<b>Non-cash investing and financing activities:</b>			
Equity component of convertible senior notes	\$ —	\$ —	\$ 24,936
Issuance of stock from conversion of convertible senior notes	\$ 3,929	\$ —	\$ —
Net increase (decrease) in accrued fixed assets	\$ 418	\$ (1,095)	\$ 622

*See accompanying notes to consolidated financial statements.*

**PACIRA PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**NOTE 1—DESCRIPTION OF BUSINESS**

Pacira Pharmaceuticals, Inc. and its subsidiaries (collectively, the “Company” or “Pacira”) is a specialty pharmaceutical company focused on the development, commercialization and manufacture of proprietary pharmaceutical products, based on its proprietary DepoFoam® extended release drug delivery technology, for use primarily in hospitals and ambulatory surgery centers. The Company’s lead product, EXPAREL® (bupivacaine liposome injectable suspension), which consists of bupivacaine encapsulated in DepoFoam, was approved by the United States Food and Drug Administration, or FDA, on October 28, 2011 and launched commercially in April 2012. DepoFoam is also the basis for the Company’s other FDA-approved product, DepoCyt(e), which the Company manufactures for its commercial partners.

Pacira 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 products, reliance on a single manufacturing site, new technological innovations, dependence on key personnel, reliance on third-party service providers and sole source suppliers, protection of proprietary technology and compliance with government regulations.

**NOTE 2—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

***Basis of Presentation and Principles of Consolidation***

The consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America, or GAAP, and in accordance with the rules and regulations of the Securities and Exchange Commission, or SEC. The accounts of wholly owned subsidiaries are included in the consolidated financial statements. All intercompany balances and transactions have been eliminated in consolidation. Certain reclassifications were made to conform to the current presentation.

***Use of Estimates***

The preparation of financial statements in conformity with GAAP 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 financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates are used for, among other things, revenue recognition, impairment of long-lived assets, stock-based compensation and valuation of deferred tax assets. 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 could differ from these estimates.

***Liquidity***

Management believes that the Company’s existing cash and cash equivalents, short-term and long-term investments and cash flows generated from product sales will be sufficient to enable the Company to meet its planned operating expenses, capital expenditure requirements, payment of the principal on any conversions of the Company’s convertible senior notes and to service its indebtedness at least through December 31, 2016. However, changing circumstances may cause the Company to expend cash significantly faster than currently anticipated, and the Company may need to spend more cash than currently expected because of circumstances beyond its control. See Note 8, *Debt*, for further discussion of the Company’s convertible senior notes and conversion elections. The Company expects to continue to incur substantial additional expenditures as it continues to commercialize EXPAREL, develops and seeks regulatory approval for its product candidates, and expands its manufacturing facilities for EXPAREL and its other product candidates including costs associated with certain technical transfer activities and construction of two dedicated manufacturing suites in the United Kingdom.

***Revenue Recognition***

The Company’s principal sources of revenue include (i) sales of EXPAREL in the United States, or U.S., (ii) sales of DepoCyt(e) in the U.S. and the European Union, or E.U., (iii) royalties based on sales by commercial partners of DepoCyt(e) and (iv) license fees and milestone payments. The Company recognizes revenue when there is persuasive evidence that an arrangement exists, title has passed, collection is reasonably assured and the price is fixed or determinable.

**PACIRA PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**NOTE 2—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

*Net Product Sales*

The Company sells EXPAREL through a drop-ship program under which orders are processed through wholesalers based on orders of the product placed by end users which include hospitals, ambulatory surgery centers and doctors. EXPAREL is delivered directly to the end user without the wholesaler ever taking physical possession of the product. The Company records revenue at the time the product is delivered to the end user. The Company also recognizes revenue from products manufactured and supplied to commercial partners, such as DepoCyt(e), upon shipment. Prior to the shipment of manufactured products, the Company conducts initial product release and stability testing in accordance with current Good Manufacturing Practices.

Revenues from sales of products are recorded net of returns allowances, prompt payment discounts, wholesaler service fees and volume rebates and chargebacks. The calculation of some of these items requires management to make estimates based on sales data, contract terms and experience. The Company reviews the adequacy of its provisions on a quarterly basis.

*Returns Allowances*

The Company allows customers to return product that is damaged or received in error. In addition, the Company allows EXPAREL to be returned beginning six months prior to, and twelve months following product expiration. The Company estimates its sales return reserve based on return history from other hospital-based products with similar distribution models and its experience with historical return rates, which management believes is the best estimate of the anticipated product to be returned. The returns reserve is recorded at the time of sale as a reduction to gross product sales and an increase in accrued expenses.

The Company's commercial partners can return DepoCyt(e) within contractually specified timeframes if the product does not meet the applicable inspection tests. The Company estimates its returns reserve based on its experience with historical return rates. Historically, the Company's product returns have not been material.

*Prompt Payment Discounts*

The prompt payment reserve is based upon discounts offered to wholesalers as an incentive to meet certain payment terms. The Company accrues discounts to wholesalers based on contractual terms of agreements and historical experience. The Company accounts for these discounts at the time of sale as a reduction to gross product sales and a reduction to accounts receivable.

*Wholesaler Service Fees*

The Company's customers include major and regional wholesalers with whom the Company has contracted a fee for service based on a percentage of gross product sales. This fee for service is recorded as a reduction to gross product sales and an increase to accrued expenses at the time of sale, and is recorded based on the contracted percentage.

*Volume Rebates and Chargebacks*

Volume rebates and chargeback reserves are based upon contracted discounts and promotional offers the Company provides to certain end users such as members of group purchasing organizations. Volume rebates are recorded at the time of sale as a reduction to gross product sales and an increase in accrued expenses. Chargeback reserves are recorded at the time of sale as a reduction to gross product sales and a reduction to accounts receivable.

The following table provides a summary of activity with respect to the Company's accrued rebates and chargebacks, returns, wholesaler service fees and prompt pay discounts for the years ended December 31, 2015, 2014 and 2013 (in thousands):



**PACIRA PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**NOTE 2—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

	<u>Beginning of Period</u>	<u>Accruals</u>	<u>Payments (Credits)</u>	<u>End of Period</u>
<b>Year Ended December 31, 2015</b>				
Accrued rebates and chargebacks (1)	\$ 321	\$ 2,020	\$ (1,544)	\$ 797
Accrued returns	1,559	339	(165)	1,733
Accrued wholesaler service fees	588	3,482	(3,325)	745
Subtotal	<u>2,468</u>	<u>5,841</u>	<u>(5,034)</u>	<u>3,275</u>
Reserves for prompt pay discounts	575	4,905	(4,855)	625
Total	<u>\$ 3,043</u>	<u>\$ 10,746</u>	<u>\$ (9,889)</u>	<u>\$ 3,900</u>
<b>Year Ended December 31, 2014</b>				
Accrued rebates and chargebacks	\$ 402	\$ 881	\$ (962)	\$ 321
Accrued returns	897	829	(167)	1,559
Accrued wholesaler service fees	266	2,780	(2,458)	588
Subtotal	<u>1,565</u>	<u>4,490</u>	<u>(3,587)</u>	<u>2,468</u>
Reserves for prompt pay discounts	313	3,833	(3,571)	575
Total	<u>\$ 1,878</u>	<u>\$ 8,323</u>	<u>\$ (7,158)</u>	<u>\$ 3,043</u>
<b>Year Ended December 31, 2013</b>				
Accrued rebates and chargebacks (1)	\$ 111	\$ 590	\$ (299)	\$ 402
Accrued returns	134	802	(39)	897
Accrued wholesaler service fees	68	1,078	(880)	266
Subtotal	<u>313</u>	<u>2,470</u>	<u>(1,218)</u>	<u>1,565</u>
Reserves for prompt pay discounts	80	1,559	(1,326)	313
Total	<u>\$ 393</u>	<u>\$ 4,029</u>	<u>\$ (2,544)</u>	<u>\$ 1,878</u>

(1) - Includes reserves for chargebacks of \$0.2 million at December 31, 2015 and \$0.3 million at December 31, 2013, recorded as a contra asset. There was no reserve for chargebacks at December 31, 2014.

*Royalty Revenue*

The Company recognizes revenue from royalties based on sales of its commercial partners' net sales of DepoCyt(e).

Royalties are recognized as earned in accordance with contract terms when they can be reasonably estimated and collection 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 and subsequently adjusts its royalty revenue when it receives royalty reports from its commercial partners.

*Collaborative Licensing and Milestone Revenue*

The Company recognizes revenues from non-refundable up-front license fees received under collaboration agreements ratably over the performance period as determined under the 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 notification of a termination of a collaboration agreement, any remaining non-refundable license fees received by the Company, which had been deferred, are recognized over the remaining contractual term. If the termination is immediate and no additional services are to be performed, the deferred revenue is generally recognized in full. All such recognized revenues are included in collaborative licensing and milestone revenue in the Company's consolidated statements of operations.

**PACIRA PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**NOTE 2—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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 collection 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 applicable agreements.

**Concentration of Major Customers**

The Company's customers are national and regional wholesalers of pharmaceutical products as well as commercial, collaborative and licensing partners. The Company sells EXPAREL through a drop-ship program under which orders are processed through wholesalers (including AmerisourceBergen Health Corporation, Cardinal Health, Inc., and McKesson Drug Company), but shipments of the product are sent directly to individual accounts, such as hospitals, ambulatory surgery centers and individual doctors. The table below includes the percentage of revenue comprised by the three largest customers (i.e., wholesalers or commercial partners) in each year presented:

	Year Ended December 31,		
	2015	2014	2013
Largest customer	33%	33%	33%
Second largest customer	29%	29%	28%
Third largest customer	28%	24%	18%
	90%	86%	79%

Revenues from customers outside the U.S. accounted for 2%, 2% and 5% of the Company's revenue for the years ended December 31, 2015, 2014 and 2013, respectively.

**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 development activities are outsourced to third parties, including contract research organizations. In such cases, the Company may be required to estimate related service fees to be accrued.

**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 8, *Debt*, the Company had entered into a financing agreement with Paul Capital Advisors LLC, or Paul Capital, for the sale of a royalty interest in its DepoCyt(e) and DepoDur<sup>®</sup> product revenue and royalties. The royalty interest agreement pertained only to DepoCyt(e) and the Company's previously-marketed product, DepoDur, and does not include revenue related to EXPAREL or any other product candidates. As part of this financing agreement, the Company and Paul Capital maintained a lockbox, where all DepoCyt(e) and DepoDur product revenue and royalties were received. The Company had no minimum payment obligations under this agreement. Commencing on April 1 of every year, the first \$2.5 million received in the lockbox was restricted and was 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, was remitted to the Company. The Paul Capital financing agreement terminated on December 31, 2014 and the final payment was made in March 2015.

**Short-Term and Long-Term Investments**

Short-term investments consist of asset-backed securities collateralized by credit card receivables, investment grade commercial paper and corporate bonds with initial maturities of greater than three months at the date of purchase, but less than one year. Long-term investments consist of corporate bonds with initial maturities greater than one year at the date of purchase. The Company determines the appropriate classification of its investments at the time of purchase and reevaluates such determination at each balance sheet date. The Company's investment policy sets minimum credit quality criteria and maximum maturity limits on its investments to provide for preservation of capital, liquidity and a reasonable rate of return. Available-for-

**PACIRA PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**NOTE 2—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

sale securities are recorded at fair value, based on current market valuations. Unrealized holding gains and losses on available-for-sale securities are excluded from net loss and are reported as a separate component of accumulated other comprehensive income (loss) until realized. Realized gains and losses are included in non-operating other income (expense) on the consolidated statements of operations and are derived using the specific identification method for determining the cost of the securities sold.

***Inventories***

Inventories consist of finished goods held for sale and distribution, raw materials and work in process. Inventories are stated at the lower of cost, which includes amounts related to material, labor and overhead, or market (net realizable) value and is determined using the first-in, first-out (“FIFO”) method. The Company periodically reviews its inventory to identify obsolete, slow-moving, or otherwise unsalable inventories, and establishes allowances for situations in which the cost of the inventory is not expected to be recovered.

***Fixed Assets***

Fixed assets 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 fixed assets 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 remaining lease terms. Useful lives by asset category are as follows:

<b>Asset Category</b>	<b>Useful Lives</b>
Computer equipment and software	1 to 3 years
Office furniture and equipment	5 years
Manufacturing and laboratory equipment	5 to 10 years

***Asset Retirement Obligations***

The Company has contractual obligations stemming from certain of its lease agreements to return leased space to its original condition upon termination of the lease agreement. The Company records an asset retirement obligation, or ARO, liability along with a corresponding capital asset in an amount equal to the estimated fair value of the ARO. In subsequent periods, the Company records interest expense to accrete the ARO liability to full value. Each ARO capital asset is depreciated over the depreciable term of the associated asset.

***Goodwill and Intangible 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. The Company evaluates the recoverability of intangible assets periodically and takes into account events and circumstances which may indicate that impairment exists. Goodwill represents the excess of purchase price over fair value acquired in a business combination and is not amortized, but subject to impairment at least annually or when a triggering event occurs that could indicate a potential impairment.

***Impairment of Long-Lived Assets***

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.

***Convertible Debt Transactions***

The Company separately accounts for the liability and equity components of convertible debt instruments by allocating the proceeds from the issuance between the liability component and the embedded conversion option, or equity component. This is done in accordance with accounting for convertible debt instruments that may be settled in cash (including partial cash

**PACIRA PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**NOTE 2—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

settlement) upon conversion. The value of the equity component is calculated by first measuring the fair value of the liability component, using the interest rate of a similar liability that does not have a conversion feature, as of the issuance date. The difference between the initial proceeds from the convertible debt issuance and the fair value of the liability component is recorded as the carrying amount of the equity component. The Company recognizes the amortization of the resulting discount as part of interest expense in its consolidated statements of operations.

Upon settlement of the convertible senior notes, the liability component is measured at fair value. The Company allocates a portion of the fair value of the total settlement consideration transferred to the extinguishment of the liability component equal to the fair value of that component immediately prior to the settlement. Any difference between the consideration attributed to the liability component and the net carrying amount of the liability component, including any unamortized debt issuance costs, is recognized as a gain or loss in the consolidated statements of operations. Any remaining consideration is allocated to the reacquisition of the equity component and is recognized as a reduction of additional paid-in capital.

***Foreign Currencies***

The Company receives payment from certain commercial partners relating to accounts receivable and royalties on DepoCyte® in Euros. Gains and losses from foreign currency transactions are reflected in the consolidated statements of operations and were not significant in any period. 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 basis 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. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. As of December 31, 2015 and 2014, all deferred tax assets were fully offset by a valuation allowance.

In February 2013, the Company received \$0.4 million from the sale of unused net operating losses through the State of New Jersey's Economic Development Authority Technology Business Tax Certificate Transfer Program. As a result, the Company recorded an income tax benefit by reversing the valuation allowance for the related net deferred tax assets. The Company continues to maintain a full valuation allowance on its remaining net deferred tax assets because there is significant doubt regarding the Company's ability to utilize such net deferred tax assets.

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.

***Per Share Data***

Basic net income (loss) per common share is computed by dividing net income (loss) available (attributable) to common stockholders by the weighted average number of shares of common stock outstanding during the period.

Diluted net income (loss) per common share is calculated by dividing net income (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, warrants and the purchase of shares from the employee stock purchase plan (using the treasury stock method) as well as the conversion of the excess conversion value on the Company's convertible senior notes. Potential common shares in the diluted net loss per share computation are excluded to the extent that they would be anti-dilutive. For periods where the Company reported a net loss, no potentially dilutive securities were included in the computation of diluted net loss per share.

***Stock-Based Compensation***

The Company's stock-based compensation program includes grants of stock options and restricted stock units to employees, consultants, and non-employee directors in addition to the opportunity for employees to participate in an employee stock purchase plan. 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 under the applicable vesting terms or the length of an offering period.

**PACIRA PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**NOTE 2—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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 valuation model, or Black-Scholes model, which requires the consideration of the following variables for purposes of estimating fair value:

- Expected term of the option
- Expected volatility
- Expected dividends
- Risk-free interest rate

Since its initial public offering, the Company utilizes its available historic volatility data combined with a publicly traded peer group's historic volatility to determine expected volatility over the expected option term. In 2015, the Company used an expected term based on a weighted average combination of its historical data from stock option exercises and the simplified method. In prior years the Company utilized the "simplified" method for "plain vanilla" options to estimate the expected term of stock option grants. Under that approach, the weighted average expected life was presumed to be the average of the vesting term and the contractual term of the option. The risk-free interest rate is based on the implied yield on United States Department of the Treasury zero coupon bonds for periods commensurate with the expected term of the options. The dividend yield on the Company's common stock is estimated to be zero as the Company has not paid any dividends since inception, nor does it have any intention to do so in the foreseeable future. The Company estimates the level of award forfeitures expected to occur based on its historical data and records compensation cost only for those awards that are ultimately expected to vest.

**Segment Reporting**

The Company operates in one reportable segment and, accordingly, no segment disclosures have been presented.

**NOTE 3—RECENT ACCOUNTING PRONOUNCEMENTS**

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2014-09, *Revenue from Contracts with Customers*, which requires that an entity recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to its customers. In order to achieve this core principle, an entity should apply the following steps: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract and (5) recognize revenue when (or as) the entity satisfies a performance obligation. In August 2015, the FASB issued Accounting Standards Update 2015-14, *Revenue from Contracts with Customers: Deferral of the Effective Date*. This latest standard defers the effective date of revenue standard ASU 2014-09 by one year and permits early adoption on a limited basis. This update will replace existing revenue recognition guidance under GAAP when it becomes effective for the Company beginning January 1, 2018, with early adoption permitted in the first quarter of 2017. The updated standard will permit the use of either the retrospective or cumulative effect transition method. The Company is continuing to evaluate the impact of these updates on its consolidated financial statements.

In April 2015, the FASB issued ASU 2015-03, *Interest—Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*, which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of the related debt liability instead of being presented as an asset. Debt disclosures will include the face amount of the debt liability and the effective interest rate. The update requires retrospective application and represents a change in accounting principle. The update is effective for fiscal years beginning after December 15, 2015. Early adoption is permitted for financial statements that have not been previously issued. The adoption of ASU 2015-03 is not expected to have a material impact on the Company's consolidated financial statements.

In July 2015, the FASB issued ASU 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory*. The standard requires entities to measure most inventory "at the lower of cost and net realizable value," thereby simplifying the current guidance under which an entity must measure inventory at the lower of cost or market (market in this context is defined as one of three different measures, one of which is net realizable value). The standard is effective for the Company

**PACIRA PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

prospectively beginning January 1, 2017. The adoption of ASU 2015-11 is not expected to have a material impact on the Company's consolidated financial statements.

In November 2015, the FASB issued ASU 2015-17, *Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes*. The standard eliminates the current requirement for an entity to separate deferred income tax liabilities and assets into current and non-current amounts in a classified balance sheet. Instead, this guidance requires deferred tax liabilities, deferred tax assets and valuation allowances be classified as non-current in a classified balance sheet. This ASU is effective for annual reporting periods beginning after December 15, 2016 and interim periods within those annual periods. Early adoption is permitted. Additionally, this guidance may be applied either prospectively or retrospectively to all periods presented. The Company is evaluating the impact of ASU 2015-17 on its consolidated financial statements.

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.

**NOTE 4—INVENTORIES**

The components of inventories are as follows (in thousands):

	December 31,	
	2015	2014
Raw materials	\$ 16,712	\$ 9,263
Work-in-process	12,152	8,617
Finished goods	32,781	11,383
Total	<u>\$ 61,645</u>	<u>\$ 29,263</u>

**NOTE 5—FIXED ASSETS**

Fixed assets, net summarized by major category, consist of the following (in thousands):

	December 31,	
	2015	2014
Machinery and laboratory equipment	\$ 29,864	\$ 29,697
Leasehold improvements	30,834	26,350
Computer equipment and software	4,007	3,754
Office furniture and equipment	1,439	1,001
Construction in progress	49,097	19,944
Total	115,241	80,746
Less: accumulated depreciation	(24,917)	(20,114)
Fixed assets, net	<u>\$ 90,324</u>	<u>\$ 60,632</u>

Depreciation expense for the years ended December 31, 2015, 2014 and 2013 was \$11.2 million, \$9.3 million and \$3.7 million, respectively. During the years ended December 31, 2015, 2014 and 2013, the Company capitalized interest of \$0.8 million, \$0.4 million and \$1.1 million, respectively. Included in total fixed assets, net, is \$25.9 million of leasehold improvements and manufacturing process equipment located in Swindon, England.

As of December 31, 2015, the Company has recorded an ARO of \$0.6 million, included in other liabilities on its consolidated balance sheet, for costs associated with returning leased space to its original condition upon the termination of certain lease agreements.

**NOTE 6—GOODWILL AND INTANGIBLE ASSETS**

In March 2007, the Company acquired from SkyePharma Holding, Inc., or Skyepharma, its California operating subsidiary, or Pacira California, referred to herein as the Acquisition. The Company's goodwill arose in April 2012 from a contingent milestone payment to Skyepharma in connection with the Acquisition. The Acquisition was accounted for under

**PACIRA PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**NOTE 6—GOODWILL AND INTANGIBLE ASSETS (Continued)**

Statement of Financial Accounting Standards 141, *Accounting for Business Combinations*, which was the effective GAAP at the Acquisition date. In connection with the Acquisition, the Company agreed to certain earn-out payments based on a percentage of net sales of EXPAREL collected and certain other yet-to-be-developed products as well as milestone payments for EXPAREL as follows:

- (i) \$10.0 million upon the first commercial sale in the United States;
- (ii) \$4.0 million upon the first commercial sale in a major E.U. country (United Kingdom, France, Germany, Italy and Spain);
- (iii) \$8.0 million when annual net sales collected reach \$100.0 million;
- (iv) \$8.0 million when annual net sales collected reach \$250.0 million; and
- (v) \$32.0 million when annual net sales collected reach \$500.0 million.

The first milestone was met in April 2012 resulting in a \$10.0 million payment to Skyepharma. The Company recorded this payment net of a \$2.0 million contingent consideration liability recognized at the time of the Acquisition, resulting in \$8.0 million recorded as goodwill. In September 2014, the Company made an \$8.0 million milestone payment to Skyepharma in connection with achieving \$100.0 million of annual EXPAREL net sales collected. For purposes of meeting future milestone payments, with certain exceptions, annual net sales are measured on a rolling quarterly basis. Cumulatively through December 31, 2015, the Company has recorded an additional \$14.9 million as goodwill for earn-out payments which are based on a percentage of net sales of EXPAREL collected. Any remaining earn-out payments will also be treated as additional costs of the Acquisition and, therefore, recorded as goodwill if and when each contingency is resolved.

The change in the carrying value of goodwill is summarized as follows (in thousands):

	<b>Carrying Value</b>
Balance at December 31, 2013	\$ 10,328
Milestone payment triggered by collections of net sales of EXPAREL	8,000
Percentage payments on collections of net sales of EXPAREL	5,433
Balance at December 31, 2014	23,761
Percentage payments on collections of net sales of EXPAREL	7,119
Balance at December 31, 2015	\$ 30,880

Intangible assets, net, consist of core technology, developed technology and trademarks and trade names acquired in the Acquisition and are summarized as follows (in thousands):

<b>December 31, 2015</b>	<b>Gross Carrying Value</b>	<b>Accumulated Amortization</b>	<b>Intangible Assets, Net</b>	<b>Estimated Useful Life</b>
<b>Amortizable intangible assets:</b>				
Core technology	\$ 2,900	\$ (2,819)	\$ 81	9 Years
Developed technology	11,700	(11,700)	—	7 Years
Trademarks and trade names	400	(400)	—	7 Years
<b>Total intangible assets</b>	<b>\$ 15,000</b>	<b>\$ (14,919)</b>	<b>\$ 81</b>	
<b>December 31, 2014</b>				
<b>Amortizable intangible assets:</b>				
Core technology	\$ 2,900	\$ (2,497)	\$ 403	9 years
Developed technology	11,700	(11,700)	—	7 years
Trademarks and trade names	400	(400)	—	7 years
<b>Total intangible assets</b>	<b>\$ 15,000</b>	<b>\$ (14,597)</b>	<b>\$ 403</b>	

Annual amortization expense for intangibles for the years ended December 31, 2015, 2014 and 2013 was \$0.3 million, \$0.8 million and \$2.1 million, respectively.

The remaining net value of core technology of \$0.1 million will be fully amortized in 2016.

**PACIRA PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**NOTE 7—ACCRUED EXPENSES**

Accrued expenses consist of the following (in thousands):

	December 31,	
	2015	2014
Compensation and benefits	\$ 11,944	\$ 8,909
Accrued operating expenses	14,984	12,094
Accrued royalties	3,731	3,213
Accrued interest	1,605	1,625
Product returns, rebates and other fees	3,111	2,470
Total	<u>\$ 35,375</u>	<u>\$ 28,311</u>

**NOTE 8—DEBT**

The composition of the Company's debt and financing obligations is as follows (in thousands):

	December 31,	
	2015	2014
Debt:		
Convertible senior notes	\$ 118,533	\$ 120,000
Discount on debt	(12,605)	(16,900)
Total debt, net of discount	105,928	103,100
Royalty interest obligation	—	276
Total debt and financing obligations	<u>\$ 105,928</u>	<u>\$ 103,376</u>

*Convertible Senior Notes*

On January 23, 2013, the Company completed a private placement of \$120.0 million in aggregate principal amount of 3.25% convertible senior notes due 2019, or Notes, and entered into an indenture agreement, or Indenture, with respect to the Notes. The Notes accrue interest at a fixed rate of 3.25% per year, payable semiannually in arrears on February 1 and August 1 of each year. The Notes mature on February 1, 2019.

The net proceeds from the offering were \$115.3 million after deducting the initial purchasers' discounts, commissions and the offering expenses payable by the Company. The net proceeds from the Notes were used by the Company to repay the entire balance of the Company's then existing credit facility. In connection with the early extinguishment of the credit facility, the Company prepaid the remaining principal amount of \$27.5 million, a \$1.7 million end of term fee, an \$0.8 million early prepayment penalty and \$0.2 million of accrued interest. The Company recorded a loss on early extinguishment of debt of \$3.4 million, comprised of the early prepayment penalty, the remaining unamortized debt issuance costs and end of term fee.

Holders may convert their Notes prior to the close of business on the business day immediately preceding August 1, 2018, only under the following circumstances:

(i) during any calendar quarter, if the last reported sales price of the Company's common stock for at least 20 trading days during the period including the last 30 consecutive trading days of the quarter (ending on the last trading day of the immediately preceding calendar quarter) is greater than 130% of the conversion price then applicable (the "Consecutive Sales Price"), on each applicable trading day;

(ii) during the five business-day period after any five consecutive trading-day period (the "measurement period") in which the trading price (as defined in the Indenture) per \$1,000 principal amount of Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such trading day;

(iii) upon the occurrence of specified corporate events, including a merger or a sale of all or substantially all of the Company's assets; or



**PACIRA PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**NOTE 8—DEBT (Continued)**

(iv) if the Company calls the Notes for redemption until the close of business on the business day immediately preceding the redemption date.

On or after August 1, 2018, until the close of business on the second scheduled trading day immediately preceding February 1, 2019, holders may convert their Notes at any time, regardless of the foregoing circumstances. Upon conversion, holders will receive cash up to the principal amount of the Notes and, with respect to any excess conversion value, cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock, at the Company's option. The initial conversion rate for the Notes was 40.2945 shares of common stock per \$1,000 principal amount, which is equivalent to an initial conversion price of approximately \$24.82 per share of the Company's common stock. The conversion rate will be subject to adjustment for some events, but will not be adjusted for any accrued and unpaid interest. The initial conversion price of the Notes represented a premium of approximately 32.5% to the closing sale price of \$18.73 per share of the Company's common stock on The NASDAQ Global Select Market on January 16, 2013, the date that the Company priced the private offering of the Notes.

During the quarter ended December 31, 2015, the requirements with respect to the Consecutive Sales Price were met. As a result, the Notes are classified as a current obligation and will be convertible until March 31, 2016. As of December 31, 2015, the Notes had a market price of \$3,121 per \$1,000 principal amount, compared to an estimated conversion value of \$3,094. In the event of conversion, holders would forgo all future interest payments, any unpaid accrued interest and the possibility of further stock price appreciation. Upon the receipt of conversion requests, the settlement of the Notes will be paid pursuant to the terms of the Indenture, which state that the principal must be settled in cash. In the event that all of the Notes are converted, the Company would be required to repay the \$118.5 million in principal value and approximately \$248 million of cash or issue approximately 3.2 million shares of its common stock (or a combination of cash and shares of its common stock at the Company's option) to settle the conversion premium as of December 31, 2015, causing dilution to the Company's shareholders and/or significant expenditures of the Company's cash and liquid securities.

In February 2015, the Company received notice of an election for conversion from one of the holders of the Notes. The principal amount of the conversion request was \$1.5 million, which was paid in cash pursuant to the terms of the Indenture in April 2015. The Company elected to settle the conversion premium by issuing 44,287 shares of its common stock, calculated based on a daily volume-weighted adjusted price over a 40 trading-day observation period which ended on April 8, 2015. The Company realized a \$0.1 million loss on the early extinguishment of the converted Notes.

While the Notes are classified in the Company's consolidated balance sheets at December 31, 2015 and 2014 as a current obligation, the future convertibility and resulting balance sheet classification of this liability will be monitored at each quarterly reporting date and will be analyzed dependent upon market prices of the Company's common stock during the prescribed measurement periods. In the event that the holders of the Notes continue to have the election to convert the Notes at any time during the prescribed measurement period, the Notes will continue to be considered a current obligation and classified as such. Prior to August 1, 2017, in the event that none of the conversion conditions are satisfied in a given quarter, the Notes would be reclassified as a long-term liability.

Prior to February 1, 2017, the Company may not redeem the Notes. On or after February 1, 2017, the Company may redeem for cash all or part of the Notes if the last reported sale price (as defined in the Indenture) of the Company's common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading-day period ending within five trading days prior to the date on which the Company provides notice of redemption. The redemption price will equal the sum of (i) 100% of the principal amount of the Notes being redeemed, plus (ii) accrued and unpaid interest, including additional interest, if any, to, but excluding, the redemption date, plus (iii) a "make-whole premium" payment in cash equal to the sum of the present values of the remaining scheduled payments of interest that would have been made on the Notes to be redeemed had such Notes remained outstanding from the redemption date to the maturity date (excluding interest accrued to, but excluding, the redemption date that is otherwise paid pursuant to the preceding clause (ii)). The present values of the remaining interest payments will be computed using a discount rate equal to 2.0%. The Company must make the make-whole premium payments on all Notes called for redemption prior to the maturity date, including Notes converted after the date the Company provides the notice of redemption. No sinking fund is provided for the Notes, which means that the Company is not required to redeem or retire the Notes periodically.

If the Company undergoes a fundamental change as defined in the Indenture, subject to certain conditions, holders of the Notes may require the Company to repurchase for cash all or part of their Notes at a repurchase price equal to 100% of the

**PACIRA PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**NOTE 8—DEBT (Continued)**

principal amount of the Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

The Notes are senior unsecured obligations of the Company and will rank senior in right of payment to the Company's future indebtedness, if any, that is expressly subordinated in right of payment to the Notes and equal in right of payment to the Company's existing and future unsecured indebtedness that is not so subordinated. The Notes are effectively junior in right of payment to any secured indebtedness of the Company to the extent of the value of the assets securing such indebtedness and are structurally junior to all existing and future indebtedness and other liabilities (including trade payables) incurred by the Company's subsidiaries.

The Notes do not contain any financial or operating covenants or any restrictions on the payment of dividends, the incurrence of other indebtedness or the issuance or repurchase of securities by the Company. The Indenture contains customary events of default with respect to the Notes, including that upon certain events of default, 100% of the principal of and accrued and unpaid interest on the Notes will automatically become due and payable.

Under Accounting Standards Codification 470-20, *Debt with Conversion and Other Options*, an entity must separately account for the liability and equity components of convertible debt instruments (such as the Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. The equity component is recorded in additional paid-in capital in the consolidated balance sheet at the issuance date and the liability component is treated as a discount on the liability component of the Notes. The initial carrying value of the liability component of \$95.1 million was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The carrying value of the equity component, representing the conversion option, was determined by deducting the fair value of the liability component from the par value of the Notes. The equity component is not re-measured as long as it continues to meet the conditions for equity classification.

The Company allocated the total transaction costs of \$4.7 million related to the issuance of the Notes to the liability and equity components of the Notes based on their relative values. Transaction costs attributable to the liability component are amortized to interest expense over the six-year term of the Notes, and transaction costs attributable to the equity component are netted with the equity components in stockholders' equity.

The following table sets forth the total interest expense recognized by the Company (in thousands):

	Year Ended December 31,		
	2015	2014	2013
Contractual interest expense	\$ 3,856	\$ 3,900	\$ 3,833
Amortization of debt issuance costs	615	620	593
Amortization of debt discount	4,102	4,139	3,959
Capitalized interest	(848)	(381)	(1,132)
Total	\$ 7,725	\$ 8,278	\$ 7,253
Effective interest rate on the Notes	7.21%	7.22%	7.22%

*Oxford Loan Facility*

On May 2, 2012, the Company entered into a definitive loan and security agreement with Oxford Finance LLC, and borrowed the principal amount of \$27.5 million, or the Loan Facility, at a fixed rate of 9.75%, with the first principal payment due December 1, 2013. The term loan under the Loan Facility was repaid and terminated in January 2013, and the Company recorded a loss on early extinguishment of debt of \$3.4 million comprised of the early prepayment penalty and the remaining unamortized debt issuance costs.

*Sale of Royalty Interests*

In 2000, prior to the Acquisition, Pacira California and SkyePharma PLC entered into a Royalty Interests Assignment Agreement, or PLC Royalty Agreement, with an affiliate of Paul Capital to raise \$30.0 million. Under the PLC Royalty

**PACIRA PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**NOTE 8—DEBT (Continued)**

Agreement, Paul Capital had the right to receive a royalty interest in four of SkyePharma PLC’s product sales including product sales of, and other payments related to DepoCyt(e) and the no-longer marketed DepoDur. Payments began for product sales realized on or after January 1, 2003 and continued through December 31, 2014. The final payment to Paul Capital occurred in March 2015.

**NOTE 9—FINANCIAL INSTRUMENTS**

*Fair Value Measurements*

Fair value is defined as the price that would be received to sell an asset or be paid to transfer a liability in the principal or most advantageous market in an orderly transaction. To increase consistency and comparability in fair value measurements, the FASB established a three-level hierarchy which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The three levels of fair value measurements are:

- *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.

The carrying value of financial instruments including cash and cash equivalents, restricted cash, accounts receivable and accounts payable approximate their respective fair values due to the short-term nature of these items. The fair value of the Company’s Notes at December 31, 2015 are calculated utilizing market quotations from an over-the-counter trading market for these notes (Level 2). The carrying amount and fair value of the Notes are as follows (in thousands):

Financial Liabilities Carried at Historical Cost	Carrying Value	Fair Value Measurements Using		
		Level 1	Level 2	Level 3
<b>December 31, 2015</b>				
Convertible senior notes *	\$ 105,928	\$ —	\$ 369,971	\$ —

\* The fair value of the Notes was based on the Company’s closing stock price of \$76.79 per share at December 31, 2015 compared to a conversion price of \$24.82 per share which, if converted, would result in an approximate conversion premium of 3.2 million shares or \$248 million of cash. The maximum conversion premium that can be due on the Notes is 4.8 million shares, which assumes no increases in the conversion rate for certain corporate events.

Short-term investments consist of asset-backed securities collateralized by credit card receivables, investment grade commercial paper and corporate bonds with maturities greater than three months, but less than one year. Long-term investments consist of corporate bonds with maturities greater than one year. The net unrealized gains from the Company’s short-term and long-term investments are reported in other comprehensive income (loss). At December 31, 2015, all of the Company’s short-term and long-term investments are classified as available for sale investments and are determined to be Level 2 instruments, which are measured at fair value using standard industry models with observable inputs. The fair value of the commercial paper is measured based on a standard industry model that uses the three-month Treasury bill rate as an observable input. The fair value of the asset-backed securities and corporate bonds is principally measured or corroborated by trade data for identical issues in which related trading activity is not sufficiently frequent to be considered a Level 1 input or that of comparable securities. At December 31, 2015, all short-term and long-term investments were rated A or better by Standard & Poor’s. All long-term investments mature within 18 months of December 31, 2015.

The following summarizes the Company’s investments at December 31, 2015 and 2014 (in thousands):

**PACIRA PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**NOTE 9—FINANCIAL INSTRUMENTS (Continued)**

<b>December 31, 2015</b>	<b>Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value (Level 2)</b>
<b>Debt securities:</b>				
<b>Short-term:</b>				
Asset-backed securities	\$ 27,484	\$ —	\$ (15)	\$ 27,469
Commercial paper	35,191	31	—	35,222
Corporate bonds	39,319	2	(31)	39,290
Subtotal	101,994	33	(46)	101,981
<b>Long-term:</b>				
Corporate bonds	13,501	—	(39)	13,462
<b>Total</b>	<b>\$ 115,495</b>	<b>\$ 33</b>	<b>\$ (85)</b>	<b>\$ 115,443</b>

<b>December 31, 2014</b>	<b>Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value (Level 2)</b>
<b>Debt securities:</b>				
<b>Short-term:</b>				
Asset-backed securities	\$ 15,009	\$ —	\$ (9)	\$ 15,000
Commercial paper	1,747	3	—	1,750
Corporate bonds	102,430	—	(42)	102,388
Subtotal	119,186	3	(51)	119,138
<b>Long-term:</b>				
Corporate bonds	24,463	10	(42)	24,431
<b>Total</b>	<b>\$ 143,649</b>	<b>\$ 13</b>	<b>\$ (93)</b>	<b>\$ 143,569</b>

Certain assets and liabilities are measured at fair value on a nonrecurring basis, including assets and liabilities acquired in a business combination and long-lived assets, which would be recognized at fair value if deemed to be impaired or if reclassified as assets held for sale. The fair value in these instances would be determined using Level 3 inputs. At December 31, 2015, the Company had no financial instruments that were measured using Level 3 inputs.

*Credit Risk*

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents, short-term investments, long-term investments and accounts receivable. The Company maintains its cash and cash equivalents with high-credit quality financial institutions. At times, such amounts may exceed federally-insured limits. The Company performs ongoing credit evaluations of its customers as warranted and generally does not require collateral.

As of December 31, 2015, three customers accounted for over 10% of the Company's accounts receivable; 34%, 28% and 27%, respectively. At December 31, 2014, three customers accounted for over 10% of the Company's accounts receivable; 33%, 29% and 27%, respectively. Revenues are primarily derived from major wholesalers and pharmaceutical companies which 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, 2015 and 2014, no allowances for doubtful accounts were deemed necessary by the Company on its accounts receivable.

**NOTE 10—STOCKHOLDERS' EQUITY**

*Common Stock*

The Company is authorized to issue up to 250,000,000 shares of common stock, of which 36,848,319 and 36,150,620 were outstanding at December 31, 2015 and 2014, respectively.

**PACIRA PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**NOTE 10—STOCKHOLDERS' EQUITY (Continued)**

In April 2014, the Company completed a follow-on underwritten public offering of 1,840,000 shares of common stock, including the shares issued to cover the underwriters' overallotment option, at \$64.00 per share. The Company received proceeds of \$110.5 million as a result of the offering, net of underwriters' fees and related expenses.

*Preferred Stock*

The Company is authorized to issue up to 5,000,000 shares of preferred stock. No preferred stock was outstanding at December 31, 2015 or 2014.

*Warrants*

At both December 31, 2015 and 2014, the Company had 7,216 warrants outstanding at a weighted average exercise price of \$13.44.

*Accumulated Other Comprehensive Income (Loss)*

The following table illustrates the changes in the balances of the Company's accumulated other comprehensive income (loss) (in thousands):

	<b>Net Unrealized Gains (Losses) From Available For Sale Investments</b>
Balance at December 31, 2013	\$ 5
Other comprehensive loss before reclassifications	(85)
Amounts reclassified from accumulated other comprehensive income (loss)	—
Balance at December 31, 2014	(80)
Other comprehensive loss before reclassifications	28
Amounts reclassified from accumulated other comprehensive income (loss)	—
Balance at December 31, 2015	\$ (52)

**NOTE 11—STOCK PLANS***Stock Incentive Plans*

The Company's amended and restated 2011 stock incentive plan, or 2011 Plan, was adopted by its Board of Directors and approved by its stockholders in June 2014. The 2011 Plan allows the granting of incentive stock options, non-statutory stock options, restricted stock awards and other stock-based awards. The remaining shares available for issuance under a 2007 stock incentive plan, or 2007 Plan, were reallocated to the 2011 Plan. Any shares forfeited or canceled from the 2007 Plan are transferred to the 2011 Plan. In April 2014, the Company's Board of Directors adopted the 2014 Inducement Plan which authorized 175,000 shares of common stock to be granted as equity awards to new employees.

All of the Company's stock option grants have an exercise price equal to the closing price of the fair market value of the Company's common stock on the date of grant, generally have a 10-year contractual term and vest in increments (generally over four years from the date of grant although the Company may occasionally grant options with different vesting terms). The Company uses authorized and unissued shares to satisfy its obligations under these plans.

*2014 Employee Stock Purchase Plan*

In April 2014, the Company's Board of Directors adopted the 2014 Employee Stock Purchase Plan, or ESPP, which was subsequently approved by the Company's stockholders in June 2014. The purpose of the ESPP is to provide a vehicle for eligible employees to purchase shares of the Company's common stock at a discounted price and to help retain and motivate current employees as well as attract new talent. Under the ESPP, up to 500,000 shares of common stock may be sold under the ESPP which expires in June 2024. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Internal Revenue Code. The maximum fair market value of stock which can be purchased by a participant in a calendar year is \$25,000. Six-month offering periods begin on January 1 and July 1 of each year. During an offering period, eligible employees will have the opportunity to elect to purchase shares of the Company's common stock on the purchase dates

**PACIRA PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**NOTE 11—STOCK PLANS (Continued)**

of June 30 and December 31. The per share purchase price will be equal to the lesser of 85% of the fair market value of the Company's common stock on either the offering date or the purchase date.

*Restricted Stock Units*

In June 2015, the Company granted a mix of stock options and restricted stock units, or RSUs, to employees and its Board of Directors. The RSUs are authorized as part of the 2011 Plan.

The following table contains information about the Company's plans at December 31, 2015:

<b>Stock Incentive Plans</b>	<b>Awards Reserved for Issuance</b>	<b>Awards Issued</b>	<b>Awards Available for Grant</b>
2007 Plan	2,022,837	2,022,837	—
2011 Plan	5,931,700	5,213,023	718,677
2014 Inducement plan	175,000	67,000	108,000
	<u>8,129,537</u>	<u>7,302,860</u>	<u>826,677</u>

<b>Employee Stock Purchase Plan</b>	<b>Shares Reserved for Purchase</b>	<b>Shares Purchased</b>	<b>Shares Available for Purchase</b>
2014 ESPP	500,000	50,700	449,300

*Stock-Based Compensation*

Compensation expense for stock options and RSUs granted to employees and directors is based on the estimated grant date fair value of options recognized over the requisite service period on a straight-line expense attribution method. Compensation expense for options and RSUs granted to non-employees is based on the fair value of options, which are revalued each reporting period until vested and are recognized as expense over the requisite service period. Compensation expense for ESPP options is based on the grant date fair value of the ESPP shares and the grant date number of shares that can be purchased, which is recognized as expense over the length of an offering period.

The Company recognized stock-based compensation expense (net of forfeitures) in its consolidated statements of operations for the years ended December 31, 2015, 2014 and 2013 as follows (in thousands):

	<b>Year Ended December 31,</b>		
	<b>2015</b>	<b>2014</b>	<b>2013</b>
Cost of goods sold	\$ 6,012	\$ 3,582	\$ 1,526
Research and development	5,134	6,490	4,345
Selling, general and administrative	22,222	14,750	5,642
Total	<u>\$ 33,368</u>	<u>\$ 24,822</u>	<u>\$ 11,513</u>
Stock-based compensation from:			
Stock options (employee awards)	\$ 27,262	\$ 19,182	\$ 7,133
Stock options (consultant awards)	2,367	5,295	4,380
RSUs	2,887	—	—
ESPP	852	345	—
Total	<u>\$ 33,368</u>	<u>\$ 24,822</u>	<u>\$ 11,513</u>

In November 2014, the Company's Board of Directors approved amendments to stock options held by a departing Vice President. The amendments accelerated the vesting of nine months' worth of options and as a result the Company recognized an additional \$0.6 million in stock-based compensation expense for the year ended December 31, 2014. In September 2013, the Company's Board of Directors approved amendments to stock options held by two departing directors. The amendments (i) accelerated the vesting of the unvested portion of certain options and (ii) extended the period during which each departing

**PACIRA PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**NOTE 11—STOCK PLANS (Continued)**

director could exercise all vested options to September 30, 2015. As a result of these amendments, the Company recognized an additional \$0.2 million in stock-based compensation for the year ended December 31, 2013.

The following table summarizes the Company's stock option activity and related information for the period from January 1, 2013 to December 31, 2015:

	Number of Options	Weighted Average Exercise Price (Per Share)	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in Thousands)
Outstanding at January 1, 2013	4,003,166	\$ 7.86	8.66	\$ 38,485
Granted	918,915	30.42		
Exercised	(742,211)	5.19		\$ 21,679
Forfeited	(338,145)	10.93		
Expired	(1,687)	7.24		
Outstanding at December 31, 2013	3,840,038	13.50	8.01	\$ 168,905
Granted	1,638,575	79.68		
Exercised	(624,229)	11.60		\$ 45,289
Forfeited	(175,967)	44.32		
Expired	(561)	21.70		
Outstanding at December 31, 2014	4,677,856	35.78	7.86	\$ 248,276
Granted	906,706	75.35		
Exercised	(618,434)	16.29		\$ 39,401
Forfeited	(294,880)	64.29		
Expired	(25,526)	81.94		
Outstanding at December 31, 2015	4,645,722	\$ 44.03	7.31	\$ 162,340
Exercisable at December 31, 2015	2,618,881	\$ 26.08	6.32	\$ 135,576
Vested and expected to vest at December 31, 2015	4,499,941	\$ 43.08	7.26	\$ 161,272

As of December 31, 2015, \$66.3 million of total unrecognized compensation cost related to non-vested stock options is expected to be recognized over a weighted average period of 2.7 years. The Company's stock options have a maximum expiration date of ten years from the date of grant.

The weighted average fair value of stock options granted for the years ended December 31, 2015, 2014 and 2013 was \$37.82, \$42.62 and \$19.22 per share, respectively. The fair values of stock options granted were estimated using the Black-Scholes model with the following weighted average assumptions:

	Year Ended December 31,		
	2015	2014	2013
Expected dividend yield	None	None	None
Risk free interest rate	1.40 - 2.28%	0.02 - 2.16%	0.33 - 2.83%
Expected volatility	52.9%	57.2%	68.7%
Expected term of options	5.76 years	5.86 years	6.22 years

**PACIRA PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**NOTE 11—STOCK PLANS (Continued)**

The following table summarizes the Company’s RSU activity and related information for 2015:

	Number of Units	Weighted Average Grant Date Fair Value (Per Share)	Aggregate Intrinsic Value (in Thousands)
Unvested at December 31, 2014	—	\$ —	\$ —
Granted	232,046	78.65	
Vested	—	—	
Forfeited	(15,848)	79.43	
Unvested at December 31, 2015	<u>216,198</u>	<u>\$ 78.59</u>	<u>\$ 16,602</u>
Expected to vest at December 31, 2015	<u>194,290</u>	<u>\$ 78.61</u>	<u>\$ 14,920</u>

As of December 31, 2015, \$14.1 million of total unrecognized compensation cost related to non-vested RSUs is expected to be recognized over a weighted average period of 3.4 years. The Company’s RSUs have a maximum vest date of four years from the date of grant. The fair values of RSUs awarded are equal to the common stock price on the date of grant.

The fair values of the ESPP share options granted are estimated using the Black-Scholes model with the following weighted average assumptions:

Grant Date	Per Share Fair Value	Expected Dividend Yield	Risk Free Interest Rate	Expected Volatility	Expected Term
September 2014	\$ 23.27	None	0.37%	28.2%	4 months
January 2015	25.24	None	0.11%	45.0%	6 months
July 2015	21.93	None	0.13%	58.2%	6 months

**NOTE 12—NET INCOME (LOSS) PER SHARE**

Basic net income (loss) per common share is calculated by dividing the net income (loss) attributable to common shares by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per common share is calculated by dividing the net income (loss) attributable to common shares by the weighted average number of common shares outstanding plus dilutive potential common stock outstanding during the period. Potential common shares include the shares of common stock issuable upon the exercise of outstanding stock options and warrants, the vesting of RSUs and the purchase of shares from the employee stock purchase plan (using the treasury stock method) as well as the conversion of the excess conversion value on the Notes. As discussed in Note 8, *Debt*, the Company must settle the principal of the Notes in cash upon conversion, and it may settle any conversion premium in either cash or stock at the Company’s discretion. For purposes of calculating the dilutive impact, it is presumed that the conversion premium will be settled in common stock.

Potential common shares are excluded from the diluted net income (loss) per share computation to the extent that they would be antidilutive. Because the Company reported a net loss for the years ended December 31, 2014 and 2013, no potentially dilutive securities have been included in the computation of diluted net loss per share for those periods.

The following table sets forth the computation of basic and diluted net income (loss) per share for the years ended December 31, 2015, 2014 and 2013 (in thousands except per share amounts):



**PACIRA PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**NOTE 12—NET INCOME (LOSS) PER SHARE (Continued)**

	Year Ended December 31,		
	2015	2014	2013
<b>Numerator:</b>			
Net income (loss)	\$ 1,856	\$ (13,716)	\$ (63,909)
<b>Denominator:</b>			
Weighted average shares of common stock outstanding—basic	36,540	35,299	33,182
Computation of diluted securities:			
Dilutive effect of stock options	1,638	—	—
Dilutive effect of RSUs	3	—	—
Dilutive effect of conversion premium on the Notes	3,113	—	—
Dilutive effect of warrants	6	—	—
Dilutive effect of ESPP	1	—	—
Weighted average shares of common stock outstanding—diluted	41,301	35,299	33,182
<b>Net income (loss) per share:</b>			
Basic net income (loss) per share of common stock	\$ 0.05	\$ (0.39)	\$ (1.93)
Diluted net income (loss) per share of common stock	\$ 0.04	\$ (0.39)	\$ (1.93)

The following outstanding stock options, RSUs, conversion premium on the Notes, warrants and ESPP units are antidilutive in the periods presented (in thousands):

	Year Ended December 31,		
	2015	2014	2013
Weighted average number of stock options	1,891	3,534	3,980
Weighted average number of RSUs	99	—	—
Conversion premium on the Notes	—	2,483	1,194
Weighted average number of warrants	—	21	204
Weighted average purchase options under ESPP	8	1	—
Total	1,998	6,039	5,378

**NOTE 13—INCOME TAXES**

Income (loss) before income taxes and the related tax (expense) benefit is as follows (in thousands):

	Year Ended December 31,		
	2015	2014	2013
Income (loss) before income taxes:			
Domestic	\$ 4,033	\$ (13,271)	\$ (64,351)
Foreign	(1,913)	(272)	—
Total income (loss) before income taxes	\$ 2,120	\$ (13,543)	\$ (64,351)
Current taxes:			
Federal	\$ (92)	\$ —	\$ —
State	(172)	(173)	442
Total income tax (expense) benefit	\$ (264)	\$ (173)	\$ 442

**PACIRA PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**NOTE 13—INCOME TAXES (Continued)**

A reconciliation of income taxes at the U.S. federal statutory rate to the provision for income taxes is as follows:

	Year Ended December 31,		
	2015	2014	2013
U.S. federal statutory rate	35.00 %	35.00 %	35.00 %
State taxes	0.71 %	(32.62)%	4.79 %
Foreign taxes	12.03 %	(0.13)%	— %
Increase (decrease) in valuation allowance	10.32 %	(17.71)%	(42.91)%
Stock-based compensation	7.26 %	(0.44)%	1.72 %
Tax credits	(30.63)%	5.49 %	1.69 %
Interest expense	(37.57)%	10.68 %	0.30 %
Other permanent items	15.33 %	(1.55)%	0.10 %
Effective tax rate	<u>12.45 %</u>	<u>(1.28)%</u>	<u>0.69 %</u>

The tax provision of \$0.3 million for the year ended December 31, 2015 reflects alternative minimum tax as well as minimum and apportionment state taxes. The Company's effective tax rate for 2015 was 12.45%, which was impacted by the expected utilization of domestic net operating loss carryforwards to offset current year taxable income. Prior to 2015, there was no provision for federal income taxes since the Company has incurred net operating losses since inception. The income tax provision of \$0.2 million for the year ended December 31, 2014 was the result of minimum and apportionment based state taxes. In 2013, the Company sold a portion of its unused New Jersey State net operating losses through a program sponsored by the New Jersey Economic Development Authority. Cash proceeds of \$0.4 million were received by the Company resulting in a state tax benefit recognized during the year ended December 31, 2013.

Deferred taxes reflect the tax effects of the differences between the amounts recorded as assets and liabilities for financial reporting purposes and the comparable amounts recorded for income tax purposes. Significant components of the Company's deferred tax assets and liabilities at December 31, 2015 and 2014 are as follows (in thousands):

	December 31,	
	2015	2014
Deferred tax assets:		
Net operating loss carry-forwards	\$ 101,011	\$ 111,086
Federal and state research credits	7,140	6,043
Depreciation and amortization	1,310	3,494
Accruals and reserves	5,558	3,861
Deferred revenue	3,530	4,065
Stock based compensation	17,201	8,487
Other	1,045	588
Total deferred tax assets	<u>136,795</u>	<u>137,624</u>
Deferred tax liabilities:		
Discount on convertible senior notes	(4,679)	(6,283)
	132,116	131,341
Less: valuation allowance	<u>(132,116)</u>	<u>(131,341)</u>
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2015, the available federal net operating loss carryforward and the federal research and development tax credit carryforwards totaled \$335.0 million and \$5.1 million, respectively. \$72.9 million of the federal net operating loss carryforward related to excess tax benefits arising from the exercise of stock options for which future tax benefits will be credited to equity when realized through a reduction in taxes payable. The Company also had state net operating loss carryforwards and state research and development tax credit carryforwards of \$197.9 million and \$3.2 million, respectively,

**PACIRA PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**NOTE 13—INCOME TAXES (Continued)**

which are subject to change on an annual basis due to variations in the Company's annual state apportionment factors. The Company had non-U.S. tax net operating loss carry forwards of \$2.2 million at December 31, 2015.

The net operating loss carryforwards will begin expiring in 2025 for federal purposes and 2016 for state purposes if the Company has not used them prior to that time.

Since the Company had cumulative changes in ownership of more than 50% within a three-year period, under Internal Revenue Code sections 382 and 383, the Company's ability to use certain net operating loss and credit carryforwards to offset taxable income or tax will be limited. Such ownership changes were triggered by the initial acquisition of the Company's stock in 2007 as well as cumulative ownership changes arising as a result of the completion of the initial public offering and other financing transactions. As a result of these ownership changes, the Company estimates that approximately \$192.8 million of federal net operating losses are subject to annual limitations. At December 31, 2015, \$94.1 million of these federal net operating losses were available. The Company estimates that an additional \$26.4 million will become available in 2016, \$14.8 million in 2017, \$10.3 million annually from 2018 through 2022, and the remaining \$6.0 million through 2025. In addition, California and certain states have suspended the use of net operating loss carryforwards for certain taxable years, and other states are considering similar measures. As a result, the Company may incur higher state income tax expense in the future.

The valuation allowance for deferred tax assets increased by approximately \$0.8 million, \$9.9 million and \$17.5 million during the years ended December 31, 2015, 2014 and 2013, respectively. There is significant doubt regarding the Company's ability to utilize its net deferred tax assets and, therefore, the Company has recorded a full valuation allowance.

The 2007 Acquisition was treated as a stock acquisition for tax purposes and, therefore, the acquired intangibles for book purposes are not deductible for income tax purposes. The Company also recorded goodwill relating to contingent payments due under the Acquisition during the years ended December 31, 2015 and 2014, which are not deductible for income tax purposes. See Note 6, *Goodwill and Intangible Assets*, for further discussion.

In connection with the adoption of stock-based compensation guidance in 2006, the Company elected to follow the with-and-without approach to determine the sequence in which deductions and net operating loss carryforwards are utilized. Accordingly, no tax benefit related to stock options was recognized in the current year.

The Company evaluates its uncertain tax positions 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% likelihood of being realized upon ultimate settlement.

The Company did not have a liability related to unrecognized tax benefits as of December 31, 2015 and 2014 due to operating losses but has reduced its deferred tax assets by \$0.4 million at December 31, 2015 and 2014. Further, because the Company has recorded a full valuation allowance on its net deferred tax assets, the effect of implementing ASC 740 has been a reduction of the tax valuation allowance by the amount above.

The Company recognizes interest and penalties related to unrecognized tax benefits as tax expense. No interest or penalties were accrued for 2015, 2014 or 2013. The Company is currently open for audit by the United States Internal Revenue Service, or IRS, and state tax jurisdictions for 2009 through 2015. However, the IRS or states may still examine and adjust a net operating loss arising from a closed year to the extent it is utilized in an open tax year. The American Tax Relief Act of 2012, enacted on January 2, 2013, retroactively reinstated the research and development tax credit for 2012. The Company reported credits of approximately \$0.2 million for federal income tax purposes in the first quarter of 2013 related to 2012.

**NOTE 14—OTHER EMPLOYEE BENEFITS**

The Company sponsors a 401(k) savings plan. Under the plan, employees may make contributions which are eligible for a discretionary percentage match as defined in the plan and determined by the Board of Directors. The Company recognized \$1.7 million, \$1.0 million and \$0.6 million of related compensation expense for the years ended December 31, 2015, 2014 and 2013, respectively.

**PACIRA PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**NOTE 15—COMMERCIAL PARTNERS AND OTHER AGREEMENTS**

***Commercial Partners***

*Patheon UK Limited*

In April 2014, the Company and Patheon UK Limited, or Patheon, entered into a Strategic Co-Production Agreement and Technical Transfer and Service Agreement to collaborate in the manufacture of EXPAREL. Under the terms of the Technical Transfer and Service Agreement, Patheon has agreed to undertake certain technical transfer activities and construction services needed to prepare its Swindon, England facility for the manufacture of EXPAREL in two dedicated manufacturing suites. Under the agreements, the Company will make monthly base fee payments for services rendered. This agreement will remain in full effect unless and until it expires or is terminated. Upon termination of this agreement (other than termination by the Company in the event that Patheon does not meet the construction and manufacturing milestones or for a breach by Patheon), the Company will pay for the make good costs occasioned by the removal of its manufacturing equipment and for Patheon's termination costs up to a maximum amount of \$2.4 million.

The Company also entered into a Manufacturing and Supply Agreement with Patheon. Under the terms of the Manufacturing and Supply Agreement, following the FDA approval date of the suites, the Company has agreed to purchase EXPAREL product from Patheon. Unless earlier terminated, this agreement will expire on the 10th anniversary of the FDA approval date for the initial manufacturing suite.

Future expenditures associated with the aforementioned agreements are primarily driven by the potential commercial requirements and demand for the Company's products which cannot be fully determined at this time.

*Aratana Therapeutics, Inc.*

On December 5, 2012, the Company entered into a worldwide license, development and commercialization agreement with Aratana Therapeutics, Inc., or Aratana. Under the agreement, the Company granted Aratana an exclusive royalty-bearing license, including the limited right to grant sublicenses, for the development and commercialization of the Company's bupivacaine liposome injectable suspension product for animal health indications. Under the agreement, Aratana will develop and seek approval for the use of the product in veterinary surgery to manage postsurgical pain, focusing initially on developing the product for cats and dogs. In connection with its entry into the license agreement, the Company received a one-time payment of \$1.0 million and is eligible to receive up to an additional aggregate \$42.5 million upon the achievement of development and commercial milestones. Once the product has been approved by the FDA for sale in the United States, Aratana will be required to pay the Company a tiered double digit royalty on net sales made in the United States. If the product is approved by foreign regulatory agencies for sale outside of the United States, Aratana will be required to pay the Company a tiered double digit royalty on such net sales. Royalty rates will be reduced by a certain percentage upon the entry of a generic competitor for animal health indications into a jurisdiction or if Aratana must pay royalties to third parties under certain circumstances. In December 2013, the Company received a \$0.5 million milestone payment under the agreement.

*Mundipharma International Corporation Limited*

In June 2003, the Company entered into an agreement granting Mundipharma International Corporation Limited, or Mundipharma, exclusive marketing and distribution rights to DepoCyt in the E.U. and certain other European countries. Under the agreement, as amended, and a separate supply agreement, the Company receives a fixed payment for supplying vials of DepoCyt and a double-digit royalty, net of supply price, on sales in the applicable territories. In April 2014, the Company and Mundipharma amended their agreements to, among other things, (i) extend the term of such agreements by an additional 15 years to June 2033 and (ii) expand the territories where Mundipharma can market and distribute DepoCyt to all countries other than the United States of America, Canada and Japan. In connection with the agreements, the Company received a non-refundable upfront payment of \$8.0 million in May 2014 which was deferred and is being recognized over the contractual term.

*Sigma-Tau Pharmaceuticals, Inc.*

In December 2002, the Company entered into a supply and distribution agreement with Enzon Pharmaceuticals Inc., subsequently acquired by Sigma-Tau Pharmaceuticals, Inc., or Sigma-Tau, regarding the sale of DepoCyt®. Pursuant to the agreement, Sigma-Tau was appointed the exclusive distributor of DepoCyt in 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.

**PACIRA PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**NOTE 15—COMMERCIAL PARTNERS AND OTHER AGREEMENTS (Continued)**

Under these agreements, the Company receives a fixed payment for supplying the vials of DepoCyt and a double-digit royalty on sales, net of supply price, in the United States and Canada.

*CrossLink BioScience, LLC*

Effective October 1, 2013, the Company and CrossLink BioScience, LLC, or CrossLink, commenced a five-year arrangement for the promotion and sale of EXPAREL pursuant to the terms of a Master Distributor Agreement. Under the agreement, the Company appointed CrossLink as a third-party distributor during the term to promote and sell EXPAREL to orthopedic surgeons in the United States, with the exception of certain geographical areas and accounts. The prices and purchasing terms related to sales of EXPAREL are determined by the Company, and all orders are subject to acceptance or rejection by the Company. CrossLink is entitled to receive commissions on its sales of EXPAREL in the applicable territories, subject to certain conditions and adjustments. CrossLink may receive additional performance-based payments if it achieves certain sales goals. The Company may terminate the agreement if CrossLink fails to meet certain minimum performance metrics or if the Company pays a termination fee. Effective March 1, 2015, the agreement was amended to, among other things, amend certain payment terms and specify certain sub-distributors that may promote and sell EXPAREL under the agreement. Under the terms of the Third Amendment, the Company and CrossLink have mutual termination rights under the Agreement, and the Company is permitted to terminate the Agreement without cause effective September 30, 2016, subject to certain terms and conditions set forth in the Agreement. In the event the Company terminates the agreement, a termination payment based on a percentage of earned performance-based fees will be due to CrossLink.

*Research Development Foundation*

Pursuant to an agreement with Research Development Foundation, or RDF, the Company is required to pay RDF a low single-digit royalty on the collection of revenues from its DepoFoam-based products, for as long as certain patents assigned to the Company under the agreement remain valid. RDF has the right to terminate the agreement for an uncured material breach by the Company, in connection with its bankruptcy or insolvency or if it directly or indirectly opposes or disputes the validity of the assigned patent rights.

*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 provided 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. The development and licensing agreement with Amylin remains in effect until January 2017, however, neither party is currently performing any activities under the agreement.

**NOTE 16—RELATED PARTY TRANSACTIONS**

The Company's former Chief Medical Officer, Dr. Gary Patou, is a partner of MPM Asset Management LLC, or MPM, an investor in the Company. David Stack, the Company's Chief Executive Officer and Chairman is also a managing director at MPM. The Company contracted with MPM and Dr. Patou for the services of Dr. Patou, or Consultant. MPM earned monthly consulting fees between \$16,000 and \$26,000 in exchange for 50% to 80% of the Consultant's business time. The Company executed an Amendment with MPM effective April 1, 2015, for an increase to \$21,000 in exchange for 50% of the Consultant's business time. The Company incurred expenses of \$0.3 million, \$0.5 million and \$0.3 million for the years ended December 31, 2015, 2014 and 2013, respectively. At December 31, 2015 and 2014, the amount payable to MPM was \$0.1 million and \$0.2 million, respectively. The Company's agreement with MPM expired on December 31, 2015.

In December 2012, the Company entered into a worldwide license, development and commercialization agreement with Aratana as discussed in Note 15, *Commercial Partners and Other Agreements*. MPM and its affiliates are holders of capital stock of Aratana.

In April 2012, the Company entered into a consulting agreement with Dr. Gary Pace, a director of the Company, whereby Dr. Pace would provide consulting services. Pursuant to the consulting agreement and subsequent amendments, the consulting services are paid at the rate of \$5,000 to \$15,000 per month based on the number of days worked. The Company recorded expenses under the consulting arrangement of \$0.1 million for each of the years ended December 31, 2015, 2014 and 2013. In

**PACIRA PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**NOTE 16—RELATED PARTY TRANSACTIONS (Continued)**

connection with the consulting arrangement, Dr. Pace received an option to purchase 20,000 shares of common stock at an exercise price of \$11.02 per share and an option to purchase 70,000 shares of common stock at an exercise price of \$16.67 per share. The amounts payable at December 31, 2015 and 2014 to Dr. Pace for the consulting services were less than \$0.1 million.

**NOTE 17—COMMITMENTS AND CONTINGENCIES***Leases*

The Company leases research and development, manufacturing and warehouse facilities in San Diego, California which expire in August 2020 and its corporate headquarters in Parsippany, New Jersey which expires in March 2028.

As of December 31, 2015, the aggregate annual minimum payments due under the Company's lease obligations are as follows (in thousands):

Year	Annual Minimum Payments Due
2016	\$ 7,743
2017	7,878
2018	8,081
2019	8,303
2020	6,420
2021 through 2028	8,731
Total	\$ 47,156

Total rent expense, net of amortization of unfavorable lease obligations and tenant improvements, under all operating leases for the years ended December 31, 2015, 2014 and 2013 was \$5.7 million, \$4.9 million and \$4.9 million, respectively. Deferred rent at December 31, 2015 and 2014 was \$9.2 million and \$4.5 million, respectively.

The Company's research and development facility in San Diego, California included a lease incentive allowance of \$5.7 million for the payment of leasehold improvements. The Company has utilized \$4.6 million of this lease incentive allowance, which was capitalized into fixed assets, net on the consolidated balance sheets and depreciated over the lease term.

*Litigation*

From time to time, the Company has been and may again become involved in legal proceedings arising in the ordinary course of its business, including those related to patents, product liability and government investigations. Except as described below, the Company is not presently a party to any litigation which it believes to be material, and is not aware of any pending or threatened litigation against the Company which it believes could have a material adverse effect on its business, operating results, financial condition or cash flows.

In September 2014, the FDA's Office of Prescription Drug Promotion issued Pacira a warning letter related to certain promotional materials. Pacira took actions to address the immediate FDA concerns and minimize further disruption to its business, but ultimately sought a court order to defend against any retroactive attempt to limit the broad indication for EXPAREL and restrict communications supported by the approved label. On September 8, 2015, the Company, along with two independent physicians, filed a lawsuit in the U.S. District Court for the Southern District of New York against the FDA and other governmental defendants seeking to exercise its lawful right to communicate truthful and non-misleading information about EXPAREL. The complaint outlined the Company's belief that the FDA's warning letter and regulations restricting the Company's truthful and non-misleading speech about EXPAREL violated the Administrative Procedure Act and the First and Fifth Amendments of the U.S. Constitution. The lawsuit sought a declaration and injunctive relief to permit the Company to promote EXPAREL consistent with its approved indication and pivotal studies that supported FDA approval. On December 15, 2015, the Company's lawsuit against the FDA was amicably resolved. The FDA approved a revised label for EXPAREL confirming that EXPAREL has, since its approval on October 28, 2011, been approved for administration into the surgical site to produce postsurgical analgesia in a variety of surgeries not limited to those studied in its pivotal trials, and issued a rescission letter withdrawing its previously issued warning letter.

**PACIRA PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

**NOTE 17—COMMITMENTS AND CONTINGENCIES (Continued)**

In April 2015, the Company received a subpoena from the U.S. Department of Justice, U.S. Attorney's Office for the District of New Jersey, requiring the production of a broad range of documents pertaining to marketing and promotional practices related to EXPAREL. The Company is cooperating with the government's inquiry. The Company can make no assurances as to the time or resources that will need to be devoted to this inquiry or the impact, if any, of this inquiry or any proceedings on its business, financial condition, results of operations and cash flows.

On October 3, 2014, a purported class action lawsuit was filed in the U.S. District Court for the District of New Jersey against the Company and several of its current officers, *Nicholas R. Lovallo v. Pacira Pharmaceuticals, Inc., et al.*, Case No. 2:14-cv-06172-WHW-CLW. The plaintiff amended the lawsuit on May 29, 2015. The lawsuit asserted claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and is premised on allegedly false and/or misleading statements, and non-disclosure of material facts, regarding the Company's business, operations, prospects and performance during the proposed class period of February 24, 2014 to April 29, 2015. On November 19, 2015, the suit was dismissed with leave to re-plead by a New Jersey federal judge. On January 22, 2016, the parties agreed to and filed a Stipulation of Dismissal with Prejudice.

*Purchase Obligations*

The Company has \$0.9 million of minimum, non-cancelable contractual commitments for the purchase of certain raw materials as of December 31, 2015.

*Other Commitments and Contingencies*

The FDA, as a condition of the approval of EXPAREL, has required the Company to study EXPAREL in pediatric patients. The Company has agreed to a trial timeline where, over several years, it will study pediatric patient populations in descending order starting with 12-18 year olds and ending with children under two years of age. The cost to complete the trial may be significant.

In addition to the initial \$19.6 million purchase price for the Acquisition, the Company entered into an earn-out agreement with Skyepharma which was based on the Company reaching certain revenue milestones following the Acquisition. Pursuant to this agreement, the Company is required to pay Skyepharma milestone payments up to an aggregate of \$62.0 million, of which \$18.0 million has been paid. Additionally, the Company agreed to pay to Skyepharma a 3% percentage payment on collections of EXPAREL sales in the United States, Japan, the United Kingdom, France, Germany, Italy and Spain.

Such obligations to make percentage payments 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. The expiration date of the last valid claim will occur in 2018. The Company has the right to cease paying the 3% percentage payments in the event that Skyepharma breaches certain covenants not to compete contained in the stock purchase agreement. Refer to Note 6, *Goodwill and Intangible Assets*, for further discussion.

**NOTE 18—SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)**

The following table presents selected quarterly financial data for the years ended December 31, 2015 and 2014 (in thousands, except per share data):

	Three Months Ended			
	March 31, 2015	June 30, 2015	September 30, 2015	December 31, 2015
Total revenues	\$ 58,316	\$ 59,148	\$ 62,213	\$ 69,320
Cost of goods sold	17,580	18,929	15,901	19,427
Total operating expenses	54,975	57,330	57,104	70,133
Net income (loss)	1,260	8	3,086	(2,498)
Basic and diluted net income (loss) per common share	\$ 0.03	\$ 0.00	\$ 0.08	\$ (0.07)

**PACIRA PHARMACEUTICALS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)**

	<b>Three Months Ended</b>			
	<b>March 31, 2014</b>	<b>June 30, 2014</b>	<b>September 30, 2014</b>	<b>December 31, 2014</b>
Total revenues	\$ 36,662	\$ 47,165	\$ 52,048	\$ 61,793
Cost of goods sold	18,127	19,954	20,391	18,968
Total operating expenses	45,920	50,007	53,033	53,873
Net income (loss)	(11,477)	(5,037)	(3,004)	5,802
Basic net income (loss) per common share	\$ (0.34)	\$ (0.14)	\$ (0.08)	\$ 0.16
Diluted net income (loss) per common share	\$ (0.34)	\$ (0.14)	\$ (0.08)	\$ 0.14

For periods where the Company reported a net loss, no potentially dilutive securities were included in the computation of diluted net loss per share.



**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
3.1	Amended and Restated Certificate of Incorporation of the Registrant.(1)
3.2	Amended and Restated Bylaws of the Registrant.(1)
4.1	Specimen Certificate evidencing shares of common stock.(2)
4.2	Indenture (including form of Notes), dated January 23, 2013, between the Registrant and Wells Fargo Bank, National Association, as trustee.(3)
10.1	Second Amended and Restated 2007 Stock Option/Stock Issuance Plan.(2)***
10.2	Form of Stock Option Agreement under the Second Amended and Restated 2007 Stock Option/Stock Issuance Plan.(2)***
10.3	Investors' Rights Agreement, dated March 23, 2007, among the Registrant and the parties named therein.(2)
10.4	Assignment Agreement, dated February 9, 1994, amended April 15, 2004, between the Registrant and Research Development Foundation.(2)
10.5	Stock Purchase Agreement, dated January 8, 2007, between SkyePharma, Inc. and the Registrant.(2)
10.6	Supply Agreement, dated June 30, 2003, between SkyePharma, Inc. and Mundipharma Medical Company.(2)
10.7	Distribution Agreement, dated June 30, 2003, between SkyePharma, Inc. and Mundipharma International Holdings Limited.(2)
10.8	Distribution Agreement, dated July 27, 2005, between SkyePharma, Inc. and Mundipharma International Holdings Limited.(2)
10.9	DepoCyt Supply and Distribution Agreement, dated December 31, 2002, between SkyePharma, Inc. and Enzon Pharmaceuticals, Inc.(2)
10.10	Industrial Real Estate Triple Net Lease, dated August 17, 1993, between Pacira Pharmaceuticals, Inc. and HCP TPSP, LLC.(2)
10.11	Fifth Amendment, dated March 13, 2013, to the Industrial Real Estate Triple Net Lease, dated August 17, 1993, among the Registrant, Pacira Pharmaceuticals, Inc. and HCP TPSP, LLC (and successor-in-interest to Equitable Life Assurance Society of the United States).(4)
10.12	Industrial Real Estate Lease, dated December 8, 1994, amended July 2, 2009, between Pacira Pharmaceuticals, Inc. and LASDK Limited Partnership.(2)
10.13	Third Amendment, dated March 13, 2013, to the Industrial Real Estate Lease, dated December 8, 1994, among the Registrant, Pacira Pharmaceuticals, Inc. and LASDK Limited Partnership.(4)
10.14	Services Agreement, dated October 28, 2010, between the Registrant, MPM Asset Management LLC and Gary Patou.(2)***
10.15	Amendment to Services Agreement, dated October 28, 2010, between the Registrant, MPM Asset Management LLC and Gary Patou. (6)***
10.16	Amendment #2 to Services Agreement, between the Registrant and MPM Asset Management LLC, and Gary Patou, dated November 29, 2012.(10)***
10.17	Amendment #3 to Services Agreement, dated September 11, 2013, among the Registrant, MPM Asset Management LLC, and Gary Patou. (8)***
10.18	Amendment #4 to Services Agreement, dated November 17, 2014, among the Registrant, MPM Asset Management LLC, and Gary Patou. (16)***
10.19	Amendment #5 to Services Agreement, dated March 17, 2015, among the Registrant, MPM Asset Management LLC, and Gary Patou. (16)***
10.20	Employment Agreement between the Registrant and David Stack.(2)***
10.21	Amendment No. 1 to Executive Employment Agreement, dated March 13, 2013, between the Registrant and David Stack.(4)***
10.22	Amendment No. 2 to Executive Employment Agreement, dated June 30, 2015, between the Registrant and David Stack.(17)***
10.23	Employment Agreement between the Registrant and James Scibetta.(2)***
10.24	Amendment No. 1 to Executive Employment Agreement, dated March 13, 2013, between the Registrant and James Scibetta.(4)***
10.25	Amendment No. 2 to Executive Employment Agreement, dated June 30, 2015, between the Registrant and James Scibetta.(17)***
10.26	Executive Employment Agreement, dated November 1, 2010, between the Registrant and Tania Markvicka.(7)***
10.27	Amendment No. 1 to Executive Employment Agreement, dated March 13, 2013, between the Registrant and Tania Markvicka.(4)***

## [Table of Contents](#)

10.28	Amendment No. 2 to Executive Employment Agreement, dated June 30, 2015, between the Registrant and Taunia Markvicka.(17)***
10.29	Employment Agreement, dated November 29, 2012, between the Registrant and Kristen Williams.(16)***
10.30	Amendment No. 1 to Employment Agreement, dated March 13, 2013, between the Registrant and Kristen Williams.(16)***
10.31	Amendment No. 2 to Employment Agreement, dated June 30, 2015, between the Registrant and Kristen Williams.(17)***
10.32	Form of Warrant to purchase common stock of the Registrant, dated January 22, 2009.(2)
10.33	Form of Warrant to purchase common stock of the Registrant, dated December 29, 2010.(2)
10.34	Form of Indemnification Agreement between the Registrant and its directors and officers.(2)***
10.35†	Commercial Outsourcing Services Agreement entered into as of August 25, 2011 by the Registrant and Integrated Commercialization Solutions, Inc.(5)
10.36†	First Amendment to Commercial Outsourcing Services Agreement, dated August 1, 2013, between the Registrant and Integrated Commercialization Solutions, Inc.(8)
10.37†	Second Amendment to Commercial Outsourcing Services Agreement, dated August 25, 2014, between Pacira Pharmaceuticals, Inc. and Integrated Commercialization Solutions, Inc.(15)
10.38†	Third Amendment to Commercial Outsourcing Services Agreement, dated April 29, 2015, between Pacira Pharmaceuticals, Inc. and Integrated Commercialization Solutions, Inc.(17)
10.39	Amended and Restated 2011 Stock Incentive Plan.(9)***
10.40	Form of Nonstatutory Stock Option Agreement under the Amended and Restated 2011 Stock Incentive Plan.(9)***
10.41	Form of Restricted Stock Unit Award Agreement (Employees) under the Amended and Restated 2011 Stock Incentive Plan.(17)***
10.42	Form of Restricted Stock Unit Award Agreement (Non-Employee Directors) under the Amended and Restated 2011 Stock Incentive Plan.(17)***
10.43†	License, Development and Commercialization Agreement, dated December 5, 2012 between the Registrant and Aratana Therapeutics, Inc.(11)
10.44†	Supply Agreement, dated December 5, 2012 between the Registrant and Aratana Therapeutics, Inc.(11)
10.45†	Master Distributor Agreement, dated March 11, 2013, between the Registrant and CrossLink BioScience, LLC.(12)
10.46†	First Amendment to Master Distributor Agreement, dated April 1, 2013, between the Registrant and CrossLink BioScience, LLC.(12)
10.47†	Second Amendment to Master Distributor Agreement, dated September 5, 2013, between the Registrant and Crosslink BioScience, LLC.(12)
10.48†	Third Amendment to Master Distributor Agreement, dated February 20, 2015, between the Registrant and Crosslink BioScience, LLC.(16)
10.49	2014 Inducement Plan.(13)***
10.50	2014 Employee Stock Purchase Plan.(9)***
10.51†	Strategic Co-Production Agreement dated April 4, 2014, by and between Pacira Pharmaceuticals, Inc. and Patheon UK Limited.(14)
10.52†	Manufacturing and Supply Agreement dated April 4, 2014, by and between Pacira Pharmaceuticals, Inc. and Patheon UK Limited.(14)
10.53†	Technical Transfer and Service Agreement dated April 4, 2014, by and between Pacira Pharmaceuticals, Inc. and Patheon UK Limited.(14)
10.54	Amended and Restated Consulting Agreement, dated April 3, 2012, between the Registrant and Gary Pace.(7)***
10.55	Second Amended and Restated Consulting Agreement, dated August 17, 2012, between the Registrant and Gary Pace.(18)***
10.56	Third Amendment to Consulting Agreement, dated September 11, 2013, between the Registrant and Gary Pace.(8)***
10.57	Fourth Amendment to Consulting Agreement, dated November 25, 2015, between Pacira Pharmaceuticals, Inc. and Gary Pace.***
21.1	Subsidiaries of Registrant.*
23.1	Consent of CohnReznick LLP.*
31.1	Certification of Chief Executive Officer and Chairman pursuant to Exchange Act Rule 13a-14(a).*

---

## [Table of Contents](#)

31.2	Certification of President and Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a).*
32.1	Certification of Chief Executive Officer and Chairman pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
32.2	Certification of President and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
101.INS	XBRL Instance Document.*
101.SCH	XBRL Taxonomy Schema Document.*
101.CAL	XBRL Taxonomy Calculation Linkbase Document.*
101.LAB	XBRL Taxonomy Label Linkbase Document.*
101.PRE	XBRL Taxonomy Presentation Linkbase Document.*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.*

- (1) Incorporated by reference to the registrant's Current Report on Form 8-K, filed on February 11, 2011.
- (2) Incorporated by reference to the exhibits to the registrant's Registration Statement on Form S-1 (SEC File 333-170245).
- (3) Incorporated by reference to Exhibit 4.1 to the registrant's Current Report on Form 8-K, filed on January 23, 2013.
- (4) Incorporated by reference to the exhibits to the registrant's Current Report on Form 8-K, filed on March 18, 2013.
- (5) Incorporated by reference to the exhibits to the registrant's Quarterly Report on Form 10-Q, filed on October 31, 2011.
- (6) Incorporated by reference to the exhibits to the registrant's Current Report on Form 8-K, filed on December 9, 2011.
- (7) Incorporated by reference to the exhibits to the registrant's Quarterly Report on Form 10-Q, filed on May 9, 2012.
- (8) Incorporated by reference to the exhibits to the registrant's Quarterly Report on Form 10-Q, filed on October 31, 2013.
- (9) Incorporated by reference to the exhibits to the registrant's Current Report on Form 8-K, filed on June 4, 2014.
- (10) Incorporated by reference to the exhibits to the registrant's Current Report on Form 8-K, filed on December 4, 2012.
- (11) Incorporated by reference to the exhibits to the registrant's Annual Report on Form 10-K, filed on March 7, 2013.
- (12) Incorporated by reference to the exhibits to the registrant's Annual Report on Form 10-K, filed on February 25, 2014.
- (13) Incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q, filed on May 1, 2014.
- (14) Incorporated by reference to the exhibits to the registrant's Quarterly Report on Form 10-Q, filed on July 31, 2014.
- (15) Incorporated by reference to the exhibits to the registrant's Quarterly Report on Form 10-Q, filed on October 30, 2014.
- (16) Incorporated by reference to the exhibits to the registrant's Quarterly Report on Form 10-Q, filed on April 30, 2015.
- (17) Incorporated by reference to the exhibits to the registrant's Quarterly Report on Form 10-Q, filed on July 30, 2015.
- (18) Incorporated by reference to the exhibits to the registrant's Quarterly Report on Form 10-Q, filed on November 1, 2012.

\* Filed herewith.

\*\* Furnished herewith.

\*\*\* Denotes management contract or compensatory plan or arrangement.

† Confidential treatment has been granted as to certain portions, which portions were omitted and filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Request.

**FOURTH AMENDMENT TO CONSULTING AGREEMENT**

This fourth Amendment to the Consulting Agreement (this "Amendment"), is entered into as of November 27, 2015, by and among Pacira Pharmaceuticals, Inc., a California corporation (the "Company") and Gary Pace ("Consultant").

This Amendment amends the Third Amendment and Restated Consulting Agreement dated August 17, 2012 by and among the Company, and Consultant (the "Original Agreement"). If there is any conflict between the provisions of this Amendment and those in the Original Agreement, the provisions of this Amendment govern. Except as expressly stated in this Amendment, capitalized terms used and not defined herein have the same meanings defined in the Original Agreement. Except as expressly amended herein, all other terms and provisions of the Original Agreement remain in full force and effect.

**AGREEMENT**

NOW, THEREFORE, in consideration of the representations, warranties and agreements contained in this Agreement and for other good and valuable consideration, the receipt of which the parties hereby acknowledge, the parties agree as follows

- Exhibit A to the Original Agreement is hereby amended in its entirety and replaced with the Exhibit A attached hereto.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives, effective as of the date first written above.

**PACIRA PHARMACEUTICALS, INC.**

**GARY PACE**

/s/ Daina Borteck

/s/ Gary W. Pace

Daina Borteck  
Assistant General Counsel  
December 22, 2015

Gary W. Pace  
Consultant  
November 27, 2015

---

**EXHIBIT A**

Scope of Services of Consultant:

The scope of consulting work contemplated by this Agreement shall be as follows: Consultant will act as a Technical advisor to the professional responsible for the management of the Science Center activities relating to the Company's product development and manufacturing functions. Consultant will work as needed on an hourly basis with a maximum of \$5,000 per month.

Consulting Fees:

Consultant shall be compensated at the rate of \$400 per hour, to be billed monthly via invoice. Invoices must be sent electronically to \_\_\_\_\_ with copy to Pacira contact and shall be paid within thirty (30) days of receipt at Pacira of a correct and undisputed invoice.

Total charges of all billing not to exceed \$5,000.00 per month.

Payment shall be made by direct deposit (preferred method - complete Exhibit B), wire transfer or by check payable to the following address:

Name & Address:

Gary W. Pace

Electronic Payment:

ON FILE

Company name:

Bank name:

Account number:

Routing ABA #

If paid by ACH remittance can be emailed to \_\_\_\_\_.

---

## **EXHIBIT B**

Complete and return Form W-9—Request for Taxpayer Identification Number and Certification along with the Consulting Agreement.

### Reimbursement of Expenses:

- Pacira Pharmaceuticals will reimburse consultant for all pre-approved travel and related expenses.
- The consultant is responsible for making all travel arrangements through his/her travel agent, unless otherwise instructed.
- Expense reports should be submitted to Pacira with corresponding receipts within five (5) days of the completed travel.

### Pacira Pharmaceuticals Contact:

Name: James Scibetta  
Title: President & CFO  
Pacira Pharmaceuticals, Inc.  
5 Sylvan Way, Suite 300  
Parsippany, NJ 07054  
Tel: (973) 254-3560  
Fax: (973) 254-0060

**SUBSIDIARIES OF THE REGISTRANT**

Pacira Pharmaceuticals, Inc., a California corporation

Pacira Pharmaceuticals International, Inc., a Delaware corporation

Pacira Ltd., a company organized under the laws of the United Kingdom

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in Registration Statement Nos. 333-175101, 333-181986 and 333-196542 on Form S-8 and Registration Statement No. 333-195099 on Form S-3 of our report dated February 25, 2016, on our audits of the consolidated financial statements of Pacira Pharmaceuticals, Inc. and Subsidiaries as of December 31, 2015 and 2014, and for each of the three years in the period ended December 31, 2015 and our report on our audit of the internal control over financial reporting of Pacira Pharmaceuticals, Inc. and Subsidiaries as of December 31, 2015, dated February 25, 2016, included in this Annual Report on Form 10-K of Pacira Pharmaceuticals, Inc. for the year ended December 31, 2015.

/s/ CohnReznick LLP  
Roseland, New Jersey  
February 25, 2016



## CERTIFICATION

I, David Stack, certify that:

1. I have reviewed this annual report on Form 10-K of Pacira Pharmaceuticals, Inc. (the "Registrant");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
  - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and
5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: February 25, 2016

/s/ DAVID STACK  
David Stack  
*Chief Executive Officer and Chairman*  
*(Principal Executive Officer)*

## CERTIFICATION

I, James Scibetta, certify that:

1. I have reviewed this annual report on Form 10-K of Pacira Pharmaceuticals, Inc. (the “Registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
  - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) evaluated the effectiveness of the Registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) disclosed in this report any change in the Registrant’s internal control over financial reporting that occurred during the Registrant’s most recent fiscal quarter (the Registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant’s internal control over financial reporting; and
5. The Registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant’s auditors and the audit committee of the Registrant’s board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant’s ability to record, process, summarize and report financial information; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant’s internal control over financial reporting.

Date: February 25, 2016

/s/ JAMES SCIBETTA  
James Scibetta  
*President and Chief Financial Officer*  
*(Principal Financial Officer)*

**STATEMENT PURSUANT TO 18 U.S.C. §1350**

Pursuant to 18 U.S.C. §1350, the undersigned certifies that this Annual Report on Form 10-K of Pacira Pharmaceuticals, Inc. for the year ended December 31, 2015, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in this report fairly presents, in all material respects, the financial condition and results of operations of Pacira Pharmaceuticals, Inc.

Date: February 25, 2016

/s/ DAVID STACK  
David Stack  
*Chief Executive Officer and Chairman*  
*(Principal Executive Officer)*

**STATEMENT PURSUANT TO 18 U.S.C. §1350**

Pursuant to 18 U.S.C. §1350, the undersigned certifies that this Annual Report on Form 10-K of Pacira Pharmaceuticals, Inc. for the year ended December 31, 2015, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in this report fairly presents, in all material respects, the financial condition and results of operations of Pacira Pharmaceuticals, Inc.

Date: February 25, 2016

/s/ JAMES SCIBETTA  
James Scibetta  
*President and Chief Financial Officer*  
*(Principal Financial Officer)*

