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**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, 2016

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:

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
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
(Do not check if a smaller
reporting company)

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, 2016, the last business day of the registrant’s most recently completed second fiscal quarter, of \$33.73 per share was \$949 million. 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 22, 2017, 37,525,108 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 2017 annual meeting of stockholders to be filed no later than 120 days after the end of the registrant’s fiscal year ended December 31, 2016.

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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) and our other products; 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 use 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 trials 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 Skyepharm (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 in Parsippany, New Jersey.

Pacira®, EXPAREL®, DepoFoam®, DepoCyt® (United States (US) registration), DepoCyte® (European Union (EU) registration), DepoTXA®, 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 DepoCyte when discussed in the context of the EU.

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, manufacture and commercialization of 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 US Food and Drug Administration, or FDA, approved our New Drug Application, or NDA, for EXPAREL (bupivacaine liposome injectable suspension). EXPAREL consists of bupivacaine, an amide-type local anesthetic, encapsulated in DepoFoam and is indicated for single-dose infiltration into the surgical site to produce postsurgical analgesia. We believe EXPAREL addresses a significant medical need for a long-acting non-opioid postsurgical analgesic, resulting in simplified postsurgical pain management and reduced opioid consumption, and has the potential to result in 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 2016 were \$265.8 million. We believe EXPAREL is playing a significant role in opioid minimization strategies.

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 product candidates. For the years ended December 31, 2016, 2015 and 2014, sales of EXPAREL accounted for 96%, 96% and 95% of our total revenues, respectively.

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Our current product portfolio and product candidate pipeline, along with expected milestones, are summarized in the table below:

Proprietary Pipeline:		
Product / Product Candidates	Status	Next Expected Milestone
EXPAREL:		
Surgical infiltration	Approved (US)	Series of Phase 4 data readouts
Total knee arthroplasty (TKA)	Phase 4	Publication of Phase 4 trial
Spine	Phase 4	Report data from Phase 4 trial in second-half 2017
C-Section	Phase 4	Initiate Phase 4 trial in 2017
Colorectal	Phase 4	Initiate Phase 4 trial in 2017
Breast reconstruction	Phase 4	Initiate Phase 4 trial in 2017
Gynecologic oncology ¹	Phase 4	Report top-line data in 2018
Nerve block (NB)	Phase 3	Report top-line data from Phase 3 trials in mid-2017
EU Surgical infiltration/NB	Phase 3 (EU)	File EU Marketing Authorization Application in Q4 2017
Pediatrics	Phase 3	Finalize clinical strategy
DepoTranexamic Acid	Phase 2	Report data from Phase 2 trial in TKA
DepoMeloxicam	Preclinical	Submit Investigational New Drug (IND) application
Partnered Pipeline:		
Product / Product Candidates		
DepoCyt(e) (cytarabine liposome injection):		
Lymphomatous meningitis	Approved	Leadiant Biosciences Ltd. ² (US) and MundiPharma (EU)
NOCITA® (bupivacaine liposome injectable suspension):		
Surgical infiltration in dogs	Approved	Aratana Therapeutics

¹ - Trial being conducted at MD Anderson Cancer Center under a Pacira Grant

² - Formerly Sigma-Tau Rare Disease Ltd.

NOCITA® is a registered trademark of Aratana Therapeutics, Inc.

Our Strategy

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

- commercializing EXPAREL in the United States for postsurgical analgesia by infiltration;
- maintaining a streamlined commercial organization concentrating on major hospitals and ambulatory surgery centers in the US and targeting surgeons, anesthesiologists, pharmacists and nurses;
- utilizing strategic commercial partnerships to broaden the use of EXPAREL;
- 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;
- educating strategic commercial audiences for local infiltration procedures, including soft tissue, orthopedic, 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;
- manufacturing our DepoFoam-based products, including EXPAREL, in facilities compliant with the FDA’s current Good Manufacturing Practices, or cGMP, and expanding such manufacturing capacity to meet demand;

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- continuing to expand our marketed product portfolio through development of additional DepoFoam-based hospital products utilizing a Section 505(b)(2) strategy, which permits the reliance upon previous findings of safety and effectiveness for an approved product; and
- continuing research and development partnerships to provide DepoFoam-based products to enhance the duration of action and patient compliance for partner products.

EXPAREL

The US is in the midst of an opioid epidemic, with the Centers for Disease Control and Prevention (CDC) estimating that 91 people die every day from an opioid overdose. Unfortunately, research also shows that surgery has become an inadvertent gateway to opioid abuse and can put patients at serious risk for addiction and dependence. A 2016 survey found that one-in-ten patients prescribed an opioid following surgery report becoming addicted to or dependent on the drug. With an estimated 70 million procedures in the US providing access to opioids annually, these findings suggest that as many as 7 million patients could develop an opioid addiction or dependency this year.

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 care and outcomes, as well as enhanced hospital economics.

We are advancing a three-part growth strategy to expand the use of EXPAREL to fulfill our mission to provide an opioid alternative to as many appropriate patients as possible:

- First, we are advancing the understanding among our customers and patients that the operating room, in the absence of EXPAREL as part of a non-narcotic multimodal pain management, has served as a gateway to the opioid epidemic. In 2016, we initiated a robust public relations campaign that focuses on opioid-sparing solutions. We are educating patients about the availability of an opioid alternative and empowering them to talk to their healthcare providers about their pain treatment options. We are also working directly with healthcare providers to define opioid-sparing strategies to improve patient care, patient satisfaction and economic benefits.
- Second, we are investing in clinical trials in a number of key surgical procedures to expand the EXPAREL label to include nerve block, and to demonstrate procedure-specific pain reduction, opioid reduction and best-practice surgical infiltration techniques within the currently approved indication. In pursuit of a new indication in nerve block, we have initiated two pivotal Phase 3 trials comparing the effect of EXPAREL versus placebo through a femoral nerve block trial for total knee arthroplasty, or TKA, and a brachial plexus block trial for total shoulder arthroplasty, or rotator cuff repair procedures. We have reported positive topline results from our completed Phase 4 multicenter, randomized, double-blind, controlled, parallel group trial in TKA, we have initiated a spine study, we expect to initiate studies in 2017 in C-section, colorectal surgery and breast reconstruction and we have funded an ongoing study at MD Anderson Cancer Center in gynecologic oncology. We believe positive data from our Phase 4 studies will lead to improved patient outcomes and customer satisfaction.
- Third, we are forming strategic collaborations to expand education on the importance of non-opioid multimodal alternatives for post-surgical pain management and to broaden our commercial reach. These include agreements with industry partners, as well as healthcare providers and hospital systems to support their implementation of opioid-sparing enhanced recovery protocols. In January 2017, we announced a co-promotion agreement with DePuy Synthes Sales Inc., part of the Johnson & Johnson family of companies, to support the promotion, education and training of EXPAREL in orthopedics.

EXPAREL Clinical Benefits

EXPAREL can 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:

- provides long-lasting postsurgical analgesia;
- is a ready-to-use formulation;
- expands easily with saline or lactated Ringer's to reach a desired volume;

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- leverages existing postsurgical infiltration administration techniques; and
- facilitates treatment of both small and large surgical sites.

EXPAREL can 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 the 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.

EXPAREL can 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 barriers to earlier ambulation and may introduce catheter-related issues, including infection; and
- promotes maintenance of early postsurgical pain management, which may reduce the time spent in the intensive care unit.

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 the senior leadership of our hospital customers, group purchasing organizations, integrated health networks, quality improvement organizations, KOLs in the field of postsurgical pain management and leading influencer hospitals 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 Label Expansion

Nerve Block

We are pursuing additional indications to expand the label for EXPAREL. Our most advanced development program is evaluating EXPAREL for nerve block. Nerve block is a general term used to refer to the injection of local anesthetic onto or near nerves for pain control. Traditionally, nerve blocks are single injections of short-acting anesthetics and as a result, have a limited duration of action. When extended pain management is required, a catheter is used to deliver bupivacaine continuously using an external pump. EXPAREL is designed to provide extended pain management using a single injection.

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In the first quarter of 2016, we initiated two pivotal Phase 3 nerve block trials comparing the effect of EXPAREL versus placebo through a femoral nerve block trial for TKA and a brachial plexus block trial 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.

If our trials are successful, we intend to file a supplemental New Drug Application, or sNDA, for nerve block in the middle of 2017 for a six-month Prescription Drug User Fee Act, or PDUFA, review. We believe that this additional indication for EXPAREL will allow us to fully leverage our manufacturing and commercial infrastructure.

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 trials in all age groups for EXPAREL in the setting of wound infiltration and plan to conduct these pediatric trials as a post-marketing requirement, which was stated in the NDA approval letter for EXPAREL. We recently secured feedback from the FDA on the pediatric trial design in all age groups and we are in the process of finalizing our clinical strategy.

EXPAREL Phase 4 Clinical Trials

We are investing in a series of blinded, randomized, bupivacaine-comparator Phase 4 trials in key surgical procedures. These trials are designed to assess the differences in postsurgical pain and opioid use between patients receiving EXPAREL as the foundation of a multimodal analgesic regimen versus a bupivacaine-based multimodal analgesic regimen. Our Phase 4 trials are also designed to support clinician education on procedure-specific best-practice care.

For each of our Phase 4 trials we are taking the following approach:

- publishing procedure-specific technique and best-practice protocol to demonstrate (i) volume expansion to ensure proper coverage of the surgical field, (ii) admixing with bupivacaine to ensure pain relief that spans both the acute and later postsurgical periods and (iii) proper infiltration technique;
- creating KOL educational videos of proper technique;
- using virtual reality simulation to provide an immersive, hands-on training experience to reinforce recommended EXPAREL technique; and
- publishing trial results.

Third Molar Procedures and Introduction of 133mg Dose in a 10mL Vial

We have completed a Phase 4 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 September 2016, we launched EXPAREL to the oral and maxillofacial market by introducing a 133mg dose contained in a 10mL vial for use in patients undergoing third molar (wisdom teeth) extractions. We believe the 133mg dose will also find adoption among plastic surgeons. We introduced the 133mg dose in a 10-pack and a 4-pack so that oral surgeons and doctors at smaller surgical centers will have easier access to provide EXPAREL to their patients.

In 2017, we expect to introduce the 133mg dose into the hospital and ambulatory surgery marketplaces. To date, EXPAREL has only been available in the hospital and ambulatory surgery marketplaces in a 266mg dose contained in a 20mL vial. The 266mg dose, containing twice as much pain relieving drug as the 133mg dose, provides greater pain relief over a longer duration of time. However, we believe the 133mg dose in a 10mL vial could gain adoption in smaller surgical wounds such as foot and ankle surgeries, where 10mL covers the area of the surgery and where the larger 266mg dose in a 20mL vial is too much volume for the wound site.

Total Knee Arthroplasty

We recently announced positive top-line results from a Phase 4 multicenter, randomized, double-blind, controlled, parallel group trial in patients undergoing a primary unilateral TKA. The trial compared EXPAREL-based local analgesia infiltration to

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standard bupivacaine-based local analgesia infiltration, each as part of a standard multi-modal analgesic protocol. Patients were randomized to receive local infiltration analgesia with EXPAREL admixed with bupivacaine and expanded in volume to local infiltration analgesia with bupivacaine expanded in volume. The trial met its co-primary endpoints for postsurgical pain ($p=0.0381$) and opioid reduction ($p=0.0048$). We plan to report the statistical results for certain key secondary endpoints from this study in the first quarter of 2017. The full results will be submitted for publication in a peer-reviewed medical journal.

Spinal Fusion

We are advancing a Phase 4 multicenter, randomized, double-blind, controlled trial of EXPAREL for postsurgical pain management in patients undergoing open lumbar spinal fusion surgery. Patients will be randomized to receive local infiltration analgesia with EXPAREL admixed with bupivacaine and expanded in volume or local infiltration analgesia with bupivacaine expanded in volume. The primary objective of this trial is to compare postsurgical pain control and the secondary objectives will compare additional efficacy, safety and health economic outcomes. We expect to report top-line data from this trial in the second half of 2017.

Soft Tissue Trials

In 2017, we plan to initiate a series of Phase 4 trials in soft tissue procedures with EXPAREL as part of an Enhanced Recover After Surgery, or ERAS, protocol. These will include a C-Section trial with a two-point TAP, a colorectal trial evaluating a four-point TAP and a unilateral breast reconstruction trial. These trials will evaluate opioid use and postsurgical pain control, as well as a number of additional efficacy, safety and health economic outcomes.

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 \$7.2 million from our commercial partners in 2016.

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 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 15 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;

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- *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.

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

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 preventing the breakdown of a clot. 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 vigor in patients while decreasing overall costs to the hospital system.

DepoTXA is currently in Phase 2 clinical development.

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.

We expect to submit an Investigational New Drug, or IND, application and subsequently initiate a Phase 1 clinical trial of DepoMLX in 2017.

Research and Development

In the years ended December 31, 2016, 2015 and 2014, we spent \$45.7 million, \$28.7 million and \$18.7 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 US. 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.

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;

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- working in tandem with hospital staff, such as registered nurses, surgeons, heads of quality, pharmacists and 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;
- 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;
- 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; and
- collaborating with surgeons towards improving the knowledge and management of pain in surgical patients with a focus on opioid risk and non-opioid alternatives and engaging our field-based medical teams in system-wide partnerships to address the national opioid epidemic, with a goal of studying alternative postsurgical pain management options that focus on optimization and opioid alternative strategies.

DePuy Synthes Sales Inc.

In January 2017, we entered into a co-promotion agreement with DePuy Synthes Sales Inc., or DePuy Synthes, to market and promote the use of EXPAREL for orthopedic procedures in the US market. Through this collaboration, we believe we can accelerate the EXPAREL growth strategy by quickly leveraging the broad reach of DePuy Synthes and their established relationships and scale within hospitals and ambulatory surgery centers.

DePuy Synthes field representatives, specializing in joint reconstruction, spine, sports medicine and trauma, will collaborate with, and supplement, our field teams by expanding the reach and frequency of EXPAREL education in the hospital surgical suite and ambulatory surgery center settings. DePuy Synthes will also include EXPAREL in their Orthopedic Episode of Care Approach for health systems and surgeons. In addition to supporting DePuy Synthes, we will focus on soft tissue surgeons in key specialties and anesthesiologists, and continue to act as the overall EXPAREL account manager.

We will also work with DePuy Synthes to develop ERAS protocols to improve procedure-specific patient care and to then rapidly communicate opportunities to utilize EXPAREL-based multimodal pain strategies to minimize opioids and improve patient satisfaction and hospital economics.

DePuy Synthes is entitled to commissions on sales of EXPAREL under the agreement, subject to conditions, limitations and adjustments. The initial term of the agreement commences on January 24, 2017 and ends on December 31, 2021, with the option to extend the agreement in 12 month increments upon mutual agreement of the parties, subject to certain conditions.

We and DePuy Synthes have mutual termination rights under the agreement, subject to certain terms, conditions, and advance notice requirements; provided that we or DePuy Synthes generally may not terminate the agreement, without cause, within three years of the effective date of the agreement. We also have additional unilateral termination rights under certain circumstances. The agreement contains customary representations, warranties, covenants and confidentiality provisions, and also contains mutual indemnification obligations. DePuy Synthes is also subject to certain obligations and restrictions, including required compliance with certain laws and regulations and our policies, in connection with fulfilling their obligations under the agreement.

Other 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 DepoBupivacaine products collected, including EXPAREL, and certain other yet-to-be-developed products as well as milestone payments for DepoBupivacaine products, including EXPAREL as follows:

- (i) \$10.0 million upon first commercial sale in the United States (met April 2012);
- (ii) \$4.0 million upon first commercial sale in a major EU country (United Kingdom, France, Germany, Italy and Spain);
- (iii) \$8.0 million when annual net sales collected reach \$100.0 million (met September 2014);
- (iv) \$8.0 million when annual net sales collected reach \$250.0 million (met June 2016); and

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(v) \$32.0 million when annual net sales collected reach \$500.0 million.

For purposes of meeting future potential 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 DepoBupivacaine products, including 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. Cumulatively through December 31, 2016, Skyepharma has earned \$22.8 million of percentage payments on net sales of EXPAREL and other DepoBupivacaine products 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 or the last valid patent claim expires.

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.

Leadiant Biosciences Limited (Formerly Sigma-Tau Rare Disease Limited)

In December 2002, we entered into a supply and distribution agreement with Enzon Pharmaceuticals Inc., or Enzon, regarding the promotion and distribution 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, with successive two year renewal periods. In January 2010, Sigma-Tau Rare Disease, Ltd., or Sigma-Tau, acquired the rights to sell DepoCyt from Enzon for the United States and Canada. In December 2016, Sigma-Tau changed their name to Leadiant Biosciences, Ltd., or Leadiant. We and Leadiant are currently operating under the terms of the agreement. Under the supply and distribution agreement, we supply unlabeled DepoCyt vials to Leadiant. 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 Leadiant 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 Leadiant. Leadiant may terminate the agreement if, as a result of a settlement or a final court or regulatory action, the manufacture, use or sale of DepoCyt in the United States is prohibited.

Mundipharma International Holdings Limited

In June 2003, we entered into an agreement granting Mundipharma International Holdings Limited, or Mundipharma, exclusive marketing and distribution rights to DepoCyt in the European Union and certain other European countries. 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 DepoCyt 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 DepoCyt in any three countries in the territory covered in the agreement by a final non-appealable judgment in respect of infringement by DepoCyt of any third-party intellectual property rights.

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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. In August 2016, the FDA's Center for Veterinary Medicine approved NOCITA® (bupivacaine liposome injectable suspension) as a local post-operative analgesia for cranial cruciate ligament surgery in dogs. Aratana began purchasing bupivacaine liposome injectable suspension product in the third quarter of 2016.

In connection with its entry into the license agreement, we received a one-time payment of \$1.0 million. In December 2013, we received a \$0.5 million milestone payment under the agreement. In June 2016, we recorded \$1.0 million in milestone revenue for Aratana's filing of an FDA Administrative New Animal Drug Application, or ANADA, and in August 2016 recorded \$1.0 million related to the FDA's approval of the ANADA. We are eligible to receive up to an additional aggregate \$40.0 million upon the achievement of commercial milestones. Aratana is required to 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 be required to 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.

NOCITA® is a registered trademark of Aratana Therapeutics, Inc.

CrossLink BioScience, LLC

In October 2013, we formed a five-year arrangement with CrossLink BioScience, LLC, or CrossLink, for the promotion and sale of EXPAREL, pursuant to the terms of a Master Distributor Agreement. On June 30, 2016, we provided notice to CrossLink electing to terminate the agreement (as amended) effective as of September 30, 2016. In connection with the termination, a fee based on a percentage of earned performance-based fees is due to CrossLink. This fee of \$7.1 million is payable to CrossLink quarterly over two years, and is recorded in selling, general and administrative expense in the consolidated statements of operations.

Significant Customers

We had three customers each comprising 10% or more of our total revenue for the year ended December 31, 2016: Cardinal Health, Inc., McKesson Drug Company and AmerisourceBergen Health Corporation, which accounted for 32%, 28% and 26% of our revenues, respectively. These customers are wholesalers that process orders for EXPAREL under a drop-ship program. EXPAREL is delivered directly to end-users without the wholesalers ever taking physical possession of the product.

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 research and development 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 2017, we expect Suite A to be used for both commercial production of EXPAREL and for the production of clinical material for development products. We are expanding our EXPAREL manufacturing capacity directly and through agreements with a third-party, Patheon U.K. Limited, or Patheon, as demand for EXPAREL increases, as explained below.

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 research and development 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 entered into a Strategic Co-Production Agreement, Technical Transfer and Service Agreement and Manufacturing and Supply Agreement (the "Patheon Agreements") to collaborate in the manufacture of

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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 late 2018.

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 and 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 and Supply Agreement in the event of the breach or bankruptcy of the other party.

Upon termination of the Technical Transfer and Service Agreement (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, 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 US 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, 2016, 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 non-provisional filing unless referring to an earlier filed application. Some of our expired US 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. Certain pending patent applications may qualify for patent term adjustment that, if granted, would provide patent protection for EXPAREL beyond 2018. We received an issue notification from the United States Patent and Trademark Office, or USPTO, stating that a patent relating to product-by-process and process claims in connection with the production of multivesicular liposomes will issue on March 7, 2017. This patent will be listed on the Orange Book for EXPAREL, and includes patent term adjustment that equates to an expiration date of December 24, 2021.

Issued patents for EXPAREL 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 expired in January 2017 and will expire in September 2018, respectively. Pursuant to 35 U.S.C. § 156, an application for patent term extension was filed with the USPTO in October 2016 in connection with the regulatory approval of Aratana Therapeutics, Inc.'s NOCITA[®]. A US 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 US applications relating to the process for making the product candidate, if granted, would expire in November 2018 or later. 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. In Europe, a patent relating to methods of modifying the rate of drug release of the product candidate expires in January 2018. A pending application in Europe relating to the process for making the product candidate, if granted, would expire in November 2018. In April 2010, a provisional patent was filed relating to a new process to manufacture EXPAREL and other DepoFoam-

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based products. The process offers many advantages to the current process, including larger scale production and lower manufacturing costs. In April 2011, we filed an international patent application providing the basis for several non-provisional patent applications, for example in the US, Europe, China and Japan which, if granted, could potentially prevent others from using this process until 2031. In 2016, one such application was granted as a patent in Japan. Also, in 2015, a patent in the People's Republic of China directed to an apparatus for use in this process was granted. 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.

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, 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

In the United States, 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. Outside the United States, prescription drug products are regulated by comparable agencies, laws and regulations. Failure to comply with applicable regulatory requirements in the United States or elsewhere 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 the Company.

United States Regulatory Environment

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 (21 CFR 58);
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin for unapproved use 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 an NDA to the FDA;
- satisfactory completion of an FDA pre-approval inspection of the product's manufacturing facility or facilities to assess compliance with cGMP requirements 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
- 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 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. Thus, submission of an IND does not by itself automatically result in FDA authorization to commence a clinical trial. In addition, the FDA requires us 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 along with informed consent information for subjects before the clinical trial commences at that center. The IRB also must monitor the clinical trial until it is completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any 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 trial 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

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requirement that all research subjects provide their informed consent for their participation in any clinical trial. Sponsors of clinical trials generally must register at the NIH-maintained website www.clinicaltrials.gov and report key findings and parameters. 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 trials may be overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial. The process of completing clinical testing and obtaining FDA approval for a new drug is likely to take a number of years and requires 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.

US 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 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 of an NDA, the FDA has 60 days to determine whether it 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 ("refuse to file") 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. If the FDA accepts the submission for substantive review, the FDA typically reviews the NDA in accordance with established timeframes. Under the Prescription Drug User Fee Act, or 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 address and unmet medical need by offering major advances in treatment or providing a treatment where no adequate therapy currently exists. Standard Review applies to all applications that are not eligible for Priority Review. The FDA aims to complete Standard Reviews of NDAs within ten months of submission and Priority Reviews within 6 months. Review processes may sometimes extend beyond these target completion dates due to FDA requests for additional information or clarification, difficulties scheduling an advisory committee meeting, negotiations regarding REMS or FDA workload issues, but in general under PDUFA the FDA is supposed to complete its reviews within the target timeframes despite these factors. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to the application's approval. The recommendations of an advisory committee do not bind the FDA, but the FDA generally follows such recommendations.

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

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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 approve an NDA contingent 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 preclinical and/or clinical trials not conducted by or for the applicant. 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 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 trials, 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.

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

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

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

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

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

In December 2015 we announced that we achieved an amicable resolution with the United States in our lawsuit filed in September 2015 against the FDA and other governmental defendants. The resolution confirms that EXPAREL is, and has been since 2011, broadly indicated for administration into the surgical site to provide postsurgical analgesia.

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 US 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

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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 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

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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 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 US, 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

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subject to the penalty provisions of the pertinent federal and state laws and regulations. Outside the US, other countries have implemented requirements for disclosure of financial interactions with healthcare providers and additional countries may consider or implement such laws.

In April 2015, we received a subpoena from the US Department of Justice, US 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.

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, 2016, we had 503 employees. All of our employees are located in the United States except for six 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 2016, sales of EXPAREL constituted the vast majority of our total revenue, and we expect it will do so for the foreseeable future. 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.

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 five 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 or to encourage use of a lower cost dose than a surgeon would otherwise choose 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.

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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 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.

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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 trials 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 FDA's Office of Prescription Drug Promotion, or 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

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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, in January 2017, we entered into a co-promotion agreement with DePuy Synthes to market and promote the use of EXPAREL for orthopedic procedures in the US market. The initial term of the agreement commences on January 24, 2017 and ends on December 31, 2021, with the option to extend the agreement in 12 month increments upon mutual agreement of the parties, subject to certain conditions. 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 US 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. 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, 2016, we had 503 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

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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 management team, including David Stack, our Chief Executive Officer and Chairman, James Scibetta, our President and Charles A. Reinhart, III, our 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;

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- 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.

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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 timely 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 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 and 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 late 2018. If the construction of the Patheon suites is delayed, if Patheon experiences unanticipated cost overruns, or if the Patheon suites do not receive or maintain 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.

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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, including our current product candidates DepoMLX and DepoTXA. 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;
- 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. We may also not be successful in developing or commercializing our current product candidates

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DepoMLX and DepoTXA. Such efforts may require the dedication of significant financial and personnel resources, and any diversion of resources may also disrupt our management from expanding on EXPAREL sales. 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 US 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 trial. 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.

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. 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 US Department of Justice, US 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 trials 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

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Fifth Amendments of the US Constitution. The lawsuit sought a declaration and injunctive relief to permit us to promote EXPAREL consistent with its approved indication and pivotal trials 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 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 trial and that EXPAREL may be admixed with bupivacaine, provided certain medication ratios are observed. We and the FDA have agreed that, in future interactions, the parties will deal with each other in an open, forthright and fair manner.

We are unable to predict whether any future 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.

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:

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- 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 trials 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 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;

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

The design, development, manufacture, supply and distribution of EXPAREL and DepoCyt(e) is highly complex. As part of our routine stability monitoring that occurred in October 2016, it came to our attention that one of two test batches of EXPAREL made in early 2016 had fallen slightly out of specification for one of the 21 acceptance criteria measured during testing. This test result was unexpected and suggestive of some deviation from a consistency of manufacturing output. As a result, we have been in discussions with the FDA about both a modification of that specification as well as the potential development of a new analytical test for this attribute. Until that process is completed, we have agreed with the FDA that all EXPAREL manufactured beginning in October 2016 will include 12 month expiration dating. In connection with this issue, in 2016, we recorded a \$20.7 million charge to cost of goods sold. If we are unable to manufacture EXPAREL in compliance with our specifications, we may be subject to product exchanges or other corrective measures.

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

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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 US 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.

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-

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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.

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 US patent application relating to our product candidates or a similar invention, we may have to participate in interference proceedings declared by the USPTO 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 US 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

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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 US 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 US 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”, “DepoCyte” and “DepoTXA” marks with the USPTO. 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 US 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:

- 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. We had a net loss of \$37.9 million for the year ended December 31, 2016, net income of \$1.9 million for the year ended December 31, 2015 and a net loss of \$13.7 million for the year ended December 31, 2014. As of December 31, 2016, we had an accumulated deficit of \$346.2 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 and were not profitable in 2016. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses.

We may not return to profitability.

Our ability to return to profitability 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 return to profitability. If we are unable to generate additional revenues, we will not be able to do so 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.

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;
- in-license and develop additional product candidates; and

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- refinance our current convertible senior notes, due February 2019.

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;
- 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.

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 2017 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.

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 28, 2017, 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 US equity markets;
- developments concerning our sources of manufacturing supply;
- disputes or other developments relating to patents or other proprietary rights;

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- 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 our shares.

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, 2016, 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. We have completed other immaterial 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.

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.

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, 2016, the average per day trading volume of our common stock was 857,234 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 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.

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.

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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 April 2015, we received a subpoena from the US Department of Justice, US 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:

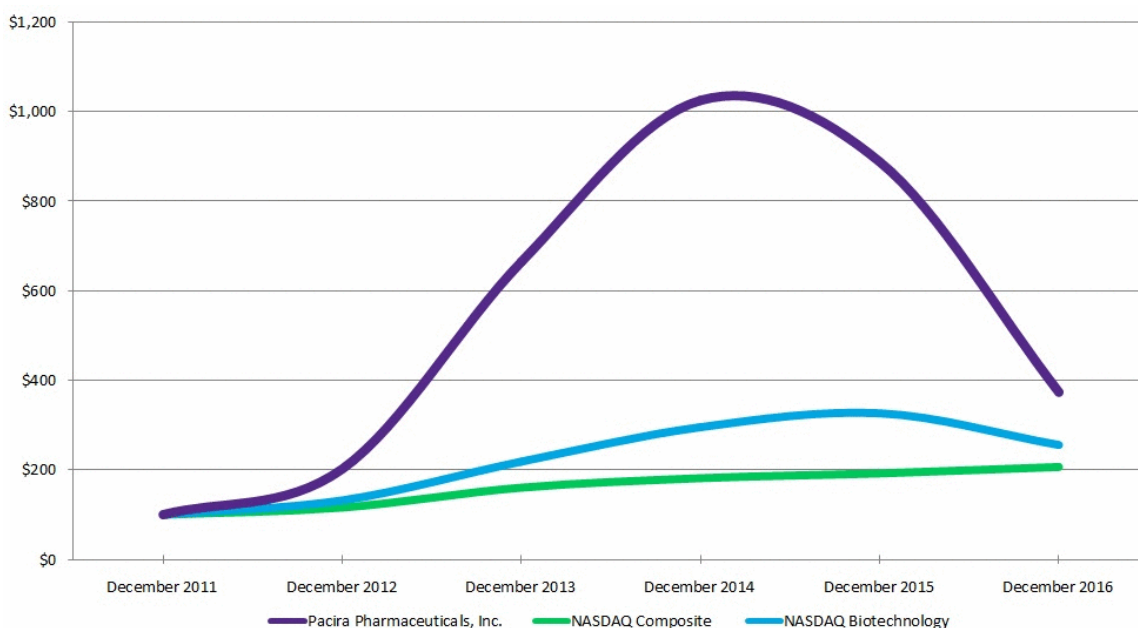
Year Ended 2016	High	Low
Fourth Quarter	\$ 38.20	\$ 29.95
Third Quarter	46.22	32.16
Second Quarter	65.64	31.08
First Quarter	76.75	44.15
Year Ended 2015	High	Low
Fourth Quarter	\$ 80.25	\$ 35.78
Third Quarter	72.98	39.29
Second Quarter	93.22	65.00
First Quarter	121.95	82.00

On February 22, 2017, the closing price of our common stock as reported on The NASDAQ Global Select Market was \$43.15 per share and we had approximately 13 holders of record of our common stock.

Performance Graph

The following graph shows the value of an investment of \$100 on December 31, 2011, 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



Cumulative Total Return

	Dec 31, 2011	Dec 31, 2012	Dec 31, 2013	Dec 31, 2014	Dec 31, 2015	Dec 31, 2016
Pacira Pharmaceuticals, Inc. (PCRX)	\$ 100.00	\$ 201.97	\$ 664.62	\$ 1,024.97	\$ 887.75	\$ 373.41
NASDAQ Composite (^IXIC)	100.00	115.91	160.32	181.44	192.21	206.63
NASDAQ Biotechnology (^NBI)	100.00	131.91	218.45	295.37	326.39	255.62

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 tables provide selected consolidated financial data. We have prepared this information using our audited consolidated financial statements as of and for the years ended December 31, 2016, 2015, 2014, 2013 and 2012. 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,				
	2016	2015	2014	2013	2012
Statement of Operations Data	(In thousands, except per share data)				
Revenues:					
Net product sales	\$ 270,073	\$ 244,487	\$ 193,526	\$ 81,956	\$ 18,191
Collaborative licensing and milestone revenue	3,426	1,426	1,287	972	18,390
Royalty revenue	2,872	3,084	2,855	2,623	2,503
Total revenues	276,371	248,997	197,668	85,551	39,084
Operating expenses:					
Cost of goods sold	110,104 ¹	71,837	77,440	54,772	32,139
Research and development	45,678	28,662	18,731	21,560	9,937
Selling, general and administrative	152,613 ²	139,043	106,662	62,508	46,306
Total operating expenses	308,395	239,542	202,833	138,840	88,382
Income (loss) from operations	(32,024)	9,455	(5,165)	(53,289)	(49,298)
Other (expense) income:					
Interest income	1,323	678	382	259	275
Interest expense	(7,061)	(7,725)	(8,278)	(7,253)	(1,807)
Loss on early extinguishment of debt	—	(52)	—	(3,398)	(1,062)
Royalty interest obligation	—	(71)	(323)	(623)	(278)
Other, net	(82)	(165)	(159)	(47)	(111)
Total other expense, net	(5,820)	(7,335)	(8,378)	(11,062)	(2,983)
Income (loss) before income taxes	(37,844)	2,120	(13,543)	(64,351)	(52,281)
Income tax (expense) benefit	(105)	(264)	(173)	442	—
Net income (loss)	\$ (37,949)	\$ 1,856	\$ (13,716)	\$ (63,909)	\$ (52,281)

Net income (loss) per share:

Basic net income (loss) per common share	\$ (1.02)	\$ 0.05	\$ (0.39)	\$ (1.93)	\$ (1.72)
Diluted net income (loss) per common share	\$ (1.02)	\$ 0.04	\$ (0.39)	\$ (1.93)	\$ (1.72)

Weighted average common shares outstanding:

Basic	37,236	36,540	35,299	33,182	30,332
Diluted	37,236	41,301	35,299	33,182	30,332

1 - Includes a \$20.7 million charge for inventory and related reserves for the cost of EXPAREL batches impacted by a routine stability test that did not meet required specifications. For further discussion of this charge, see Note 4, *Inventories*, to our consolidated financial statements included herein.

2 - Includes a \$7.1 million contract termination charge due to CrossLink Bioscience, LLC. For further discussion of this charge, see Note 15, *Commercial Partners and Other Agreements*, to our consolidated financial statements included herein.

	December 31,				
	2016	2015	2014	2013	2012
Balance Sheet Data	(In thousands)				
Cash and cash equivalents, restricted cash, short-term and long-term investments	\$ 172,597	\$ 172,427	\$ 182,598	\$ 73,785	\$ 42,573
Working capital (deficit) ³	198,251	102,794	71,715	(18,345)	46,766
Total assets ³	391,466	387,735	323,540	166,668	111,722
Long-term liabilities ³	127,652	19,555	14,917	6,628	32,376
Accumulated deficit	(346,238)	(308,289)	(310,145)	(296,429)	(232,520)
Total stockholders' equity	218,976	218,392	171,145	41,249	65,855

3 - Includes a reclassification in prior periods of deferred financing costs per Accounting Standards Update 2015-03 *Interest—Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*, which requires debt issuance costs related to a recognized debt liability be presented on the balance sheet as a direct deduction from the carrying amount of the related debt liability instead of being presented as an asset. This retrospective application is described further in Note 3, *Recent Accounting Pronouncements*, to our consolidated financial statements included herein.

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, manufacture and commercialization of 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, 2016, our product portfolio includes two commercial stage products—EXPAREL® and DepoCyt(e), and two earlier-stage compounds—DepoTranexamic Acid, or DepoTXA and DepoMeloxicam, or DepoMLX.

- 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. EXPAREL was approved by the United States Food and Drug Administration, or FDA, on October 28, 2011 and commercially launched in April 2012. We drop-ship EXPAREL directly to end users based on orders placed to wholesalers or directly to us. We do not have any 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 our inception, we have incurred significant operating losses. We expect to continue to incur significant expenses as we further commercialize EXPAREL; pursue expanded uses of EXPAREL in additional indications and opportunities; advance the development of DepoFoam-based product candidates, such as DepoMLX and DepoTXA; 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; expand and enhance our manufacturing capacity for EXPAREL and support regulatory and legal matters.

Recent Highlights and Developments

- Total revenues increased \$27.4 million, or 11%, in the year ended December 31, 2016, as compared to 2015, primarily driven by EXPAREL product sales of \$265.8 million, net of allowances for sales returns, prompt payment discounts, volume rebates, chargebacks and distribution service fees payable to wholesalers.
- In March 2017, we announced positive top-line results from a Phase 4 multicenter, randomized, double-blind, controlled, parallel group trial in patients undergoing a primary unilateral TKA. The trial compared EXPAREL-based local analgesia infiltration to standard bupivacaine-based local analgesia infiltration, each as part of a standard multi-modal analgesic protocol. Patients were randomized to receive local infiltration analgesia with EXPAREL admixed with bupivacaine and expanded in volume to local infiltration analgesia with bupivacaine expanded in volume. The trial met its co-primary endpoints for postsurgical pain control ($p=0.0381$) and opioid reduction ($p=0.0048$). We plan to report the statistical results for certain key secondary endpoints from this study in the first quarter of 2017. The full results will be submitted for publication in a peer-reviewed medical journal.
- In February 2017, we received an issue notification from the United States Patent and Trademark Office stating that a patent relating to product-by-process and process claims in connection with the production of multivesicular liposomes will issue on March 7, 2017. This patent will be listed on the Orange Book for EXPAREL, and includes a patent term adjustment that equates to an expiration date of December 24, 2021. For further discussion, see "Intellectual Property and Exclusivity" in Item 1. "Business" included in this report.
- In January 2017, we announced the initiation of an agreement with DePuy Synthes Sales, Inc., or DePuy Synthes, to market and promote the use of EXPAREL for orthopedic procedures in the United States market. DePuy Synthes field representatives, specializing in joint reconstruction, spine, sports medicine and trauma, will collaborate with, and supplement our field teams by expanding the reach and frequency of EXPAREL education in the hospital surgical suite and ambulatory surgery center settings. We believe our collaboration with DePuy Synthes will

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accelerate and enhance our education and training efforts with orthopedic customers as we aim to broaden and strengthen the adoption and use of EXPAREL. In addition to supporting DePuy Synthes, we will focus on soft tissue surgeons in key specialties and anesthesiologists, and continue to act as the overall EXPAREL account manager.

- In 2016, we recorded a \$20.7 million charge to cost of goods sold related to a stability out-of-specification test batch of EXPAREL. In October 2016, as part of our routine stability monitoring, it came to our attention that one of two test batches of EXPAREL made in early 2016 had fallen slightly (1%) out of specification for one of the 21 acceptance criteria. All other test attributes, many of which we believe are the most indicative of the product's performance and quality, are within specification and trending according to shelf life expectations. The other stability test batch remains fully within specifications. This test result was unexpected and an internal investigation has tied the result to a modification to the manufacturing process when this product was made, which has subsequently been corrected. We have reserved all impacted inventory on hand and exchanged a limited number of boxes that were sold from the impacted inventory.

Separately, as we have accumulated test data over the life of the product, it has become evident to us that one of the 21 stability acceptance criteria agreed to with the FDA upon product approval, and one that we believe has no bearing on product safety, presents a recurrent risk for testing outside the approved specification. As a result, we have recently been in discussions with the FDA about both a modification of that specification as well as the potential development of a new analytical test for this attribute. Until that process is completed, we have agreed with the FDA that all EXPAREL manufactured beginning in October 2016 will include 12-month expiration dating.

- In September 2016, we launched EXPAREL to the oral and maxillofacial market by introducing a 133mg dose contained in a 10mL vial for use in patients undergoing third molar (wisdom teeth) extractions. We believe the 133mg dose will also find adoption among plastic surgeons. We introduced these 10mL vials in a 10-pack and a 4-pack so that oral surgeons and doctors at smaller surgical centers will have easier access to provide EXPAREL to their patients.
- In June 2016, we enrolled the first patients in both of our EXPAREL Phase 3 trials for upper and lower extremity nerve blocks, specifically a femoral nerve block for patients undergoing TKA, and a brachial plexus nerve block for patients undergoing either total shoulder arthroplasty or rotator cuff repair procedures. We expect to report top-line data from these trials in mid-2017.

EXPAREL

We are investing in a series of blinded, randomized, bupivacaine-comparator Phase 4 trials in key surgical procedures. These trials are designed to assess the differences in postsurgical pain and opioid use between patients receiving EXPAREL as the foundation of a multimodal analgesic regimen versus a bupivacaine-based multimodal analgesic regimen. Our Phase 4 trials are also designed to support clinician education on procedure-specific best-practice care.

As noted above, we recently announced top-line data from a Phase 4 trial in TKA. We are also advancing a Phase 4 trial of EXPAREL for postsurgical pain management in patients undergoing spinal fusion surgery, and we expect to report top-line data in the second half of 2017.

In 2017, we plan to initiate a series of Phase 4 trials in soft tissue procedures. These will include a C-Section trial with a two-point transverse abdominis plane infiltration, or TAP, with EXPAREL added to the standard of care, a colorectal trial evaluating a four-point TAP with EXPAREL as part of an Enhanced Recovery After Surgery, or ERAS, protocol and a breast reconstruction trial. These trials will evaluate opioid use and postsurgical pain control, as well as a number of additional efficacy, safety and health economic outcomes.

In the first quarter of 2016, we initiated two pivotal Phase 3 nerve block trials comparing the effect of EXPAREL versus placebo through a femoral nerve block trial for TKA and a brachial plexus block trial 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.

If our trials are successful, we intend to file a supplemental New Drug Application, or sNDA, for nerve block in the middle of 2017 for a six-month Prescription Drug User Fee Act, or PDUFA, review. We believe that this additional indication for EXPAREL will allow us to fully leverage our manufacturing and commercial infrastructure.

Product Pipeline

DepoFoam is used to extend the release of active drug substances. With this technology, we are currently developing two new DepoFoam-based product candidates—DepoMLX, a non-steroidal anti-inflammatory drug, or NSAID, and DepoTXA, an antifibrinolytic. Completion of clinical trials may take several years or more. The length of time generally varies according to the type, complexity, novelty and intended use of a product candidate. We are also evaluating other potential DepoFoam products as pipeline candidates.

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 preventing the breakdown of a clot. However, the current formulation of TXA 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 vigor in patients while decreasing overall costs to the hospital system.

DepoTXA is currently in Phase 2 clinical development.

DepoMeloxicam

Our preclinical product candidate, DepoMLX, is a long-acting 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.

We expect to submit an Investigational New Drug application and subsequently initiate a Phase 1 clinical trial of DepoMLX in 2017.

Results of Operations***Comparison of Years Ended December 31, 2016, 2015 and 2014****Revenues*

Our net product sales primarily include sales of EXPAREL in the United States and DepoCyt(e) in the United States and Europe. We also earn royalties based on sales by commercial partners of DepoCyt(e) and license fees and milestone payments from third parties.

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

	Year Ended December 31,			2016 versus	2015 versus
	2016	2015	2014	2015	2014
				% Increase / (Decrease)	
Net product sales:					
EXPAREL	\$ 265,802	\$ 239,851	\$ 188,528	11 %	27 %
DepoCyt(e) and other product sales	4,271	4,636	4,998	(8)%	(7)%
Total net product sales	270,073	244,487	193,526	10 %	26 %
Collaborative licensing and milestone revenue	3,426	1,426	1,287	140 %	11 %
Royalty revenue	2,872	3,084	2,855	(7)%	8 %
Total revenues	\$ 276,371	\$ 248,997	\$ 197,668	11 %	26 %

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EXPAREL revenue grew 11% and 27% in the years ended December 31, 2016 and 2015, respectively, primarily due to increases in sales volume of 10% and 21% in each respective period. The 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 use in soft tissue and orthopedic procedures. The remaining increase in EXPAREL revenue was due to 5% price increases in April 2015 and May 2014, partially offset by lower pricing on government sales from our participation in the Federal Supply Schedule beginning in the third quarter of 2015.

DepoCyt(e) and other product sales decreased 8% in 2016 primarily due to fewer DepoCyt(e) lots sold to our domestic commercial partners compared to 2015, partially offset by net sales of bupivacaine liposome injectable suspension to serve animal health indications. 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.

The increase in collaborative licensing and milestone revenue of 140% in 2016 compared to 2015 was a result of \$2.0 million in milestones earned under our agreement with Aratana Therapeutics, Inc., or Aratana, for the development and commercialization of bupivacaine liposome injectable suspension for animal health indications. The increase in collaborative licensing and milestone revenue of 11% in 2015 versus 2014 was primarily driven by a full versus a partial year of amortized revenue on an \$8.0 million upfront payment received in May 2014 from Mundipharma International Corporation Limited, or Mundipharma. The payment, which is being recognized on a straight-line basis over the contractual term expiring in June 2033, was consideration for extending the term of the existing supply and distribution agreements and expanding the territory where Mundipharma can market and distribute DepoCyt(e).

Royalty revenue primarily 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,			2016 versus	2015 versus
	2016	2015	2014	2015	2014
				% Increase / (Decrease)	
Cost of goods sold	\$ 110,104	\$ 71,837	\$ 77,440	53%	(7)%
Gross margin	60%	71%	61%		

The 11 percentage point decrease in our gross margins in 2016 versus 2015 primarily reflects \$20.7 million for inventory and related reserves for the cost of EXPAREL batches impacted by a routine stability test that did not meet required specifications and for replacement product and other related costs. We also had a higher EXPAREL manufacturing cost per vial due to lower planned production, partially offset by a shift to utilizing a portion of our manufacturing lines in support of new pipeline product development opportunities at our Science Center Campus in San Diego, California starting mid-year 2015. In addition, gross margins decreased due to higher costs of \$3.0 million related to expansion of our manufacturing capacity in Swindon, England, in partnership with Patheon U.K. Limited, or Patheon and increases of \$2.9 million for unplanned manufacturing shutdown charges in 2016 versus 2015.

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.

Research and Development Expenses

Research and development expenses consist primarily of costs attributable to clinical trials and related outside services, stock-based compensation expenses and other research and development costs, including Phase 4 trials that are required as a

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condition of FDA approval or are conducted to generate new data such as dosing and administration techniques. Clinical trial expenses include costs for clinical personnel, services 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,			2016 versus	2015 versus
	2016	2015	2014	2015	2014
				% Increase / (Decrease)	
Clinical development	\$ 23,566	\$ 12,609	\$ 5,518	87 %	129 %
Product development and other	18,815	10,919	6,723	72 %	62 %
Stock-based compensation	3,297	5,134	6,490	(36)%	(21)%
Total research and development expense	\$ 45,678	\$ 28,662	\$ 18,731	59 %	53 %
% of total revenue	17%	12%	9%		

Total research and development expenses increased 59% in 2016 versus 2015 largely due to an \$11.0 million increase in clinical development expenses driven by the enrollment of the Phase 4 infiltration trial in TKA and 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 procedures. We also incurred start-up expenses in our spine trial and costs for planning pediatric trials. Increased costs also include a larger clinical workforce, which is managing our increasing investment in research and development initiatives. The increase in clinical development expense was partially offset by a decrease in research grants. Product development and other expenses increased \$7.9 million which reflects our investments in the development of a new EXPAREL DepoFoam spray manufacturing process, DepoMLX and DepoTXA, the latter of which is now in Phase 2 clinical development, along with increased depreciation on our new research and development facility placed into service in August 2015. Expenses for investigational runs and development of a new analytical test for the stability testing attribute are also included in costs for product development and other. Stock-based compensation decreased 36%, which was largely attributable to the requirement to revalue non-employee grants.

Total research and development expenses increased 53% in 2015 versus 2014 driven by a \$7.1 million increase in clinical development, including the initiation of and enrollment in our Phase 4 trial in third molar procedures, start-up expenses for our Phase 4 infiltration trial in TKA, two Phase 3 trials in nerve block procedures which began in 2015, and Phase 4 trials in tonsillectomy and C-section. Product development and other increased \$4.2 million, reflecting our investments in the development of a new EXPAREL DepoFoam spray manufacturing process, DepoTXA, DepoMLX and additional pre-clinical expenses driven by DepoFoam toxicology trials. Stock-based compensation decreased 21%, which was largely attributable to the requirement to revalue non-employee grants.

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 our marketing partners 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,			2016 versus	2015 versus
	2016	2015	2014	2015	2014
				% Increase / (Decrease)	
Sales and marketing	\$ 89,218	\$ 77,733	\$ 65,010	15 %	20%
General and administrative	41,882	39,088	26,902	7 %	45%
Stock-based compensation	21,513	22,222	14,750	(3)%	51%
Total selling, general and administrative expenses	\$ 152,613	\$ 139,043	\$ 106,662	10 %	30%
% of total revenue	55%	56%	54%		

Total selling, general and administrative expenses increased 10% in 2016 versus 2015.

Sales and marketing expenses increased by 15% in 2016 versus 2015 primarily due to a \$7.1 million contract termination charge due to CrossLink BioScience, LLC, or CrossLink, which was recognized in June 2016, and is payable quarterly over two years beginning in the fourth quarter of 2016. In addition, we increased the number of our field-based hospital sales specialists and commercial personnel to better support and educate our customers, resulting in a \$2.1 million increase in salaries, benefits and other personnel-related costs. We also had a \$3.9 million increase in spending for EXPAREL, which included educational initiatives and programs to create product awareness among key orthopedic and soft tissue surgical markets, along with other selling initiatives and promotional activities to support the growth of EXPAREL. Included in the increased spending for EXPAREL was our “Choices Matter” campaign, a national patient education campaign launched in August 2016, focused on educating the patient population about postsurgical non-opioid options for pain relief. We also unveiled a virtual reality educational program to focus on the proper EXPAREL infiltration technique for TKA procedures. In the third quarter of 2016, we launched EXPAREL to the oral and maxillofacial market by introducing a 10mL vial for use in patients undergoing third molar (wisdom teeth) extractions. Commission-based payments to CrossLink decreased as a result of the mid-year contract termination.

General and administrative expenses increased 7% in 2016 versus 2015 largely due to increases of \$1.6 million in business development and \$1.5 million in regulatory activities. Business development costs increased commensurate with added personnel to support our strategic initiatives, including our recently executed co-promotion agreement with DePuy Synthes. Regulatory spend rose in order to begin preparation for our EXPAREL nerve block sNDA filing and to support activities for other product pipeline candidates. Expenditures also increased for the expansion of our New Jersey headquarters and in our finance and human resource functions. Legal costs decreased by \$2.6 million, reflecting a decrease of \$4.1 million in legal expenses related to the amicable resolution in December 2015 of a lawsuit with the FDA, which stemmed from a warning letter issued by the FDA’s Office of Prescription Drug Promotion, or OPDP, and legal costs related to an April 2015 subpoena from the US Department of Justice, US Attorney’s Office for the District of New Jersey, or DOJ. These decreases were partially offset by a \$1.1 million increase in intellectual property matters and pipeline protection and \$0.4 million in other legal matters.

Stock-based compensation decreased 3% in 2016 versus 2015, mostly as a result of lower grant-date fair values of equity awards.

Total selling, general and administrative expenses increased by 30% in 2015 versus 2014.

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 personnel-related costs. We also had a \$2.7 million increase in spending for EXPAREL, which included educational initiatives and programs to create product awareness within 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. 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 personnel as well as our 2015 grant of RSUs.

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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,			2016 versus	2015 versus
	2016	2015	2014	2015	2014
				% Increase / (Decrease)	
Interest income	\$ 1,323	\$ 678	\$ 382	95 %	77 %
Interest expense	(7,061)	(7,725)	(8,278)	(9)%	(7)%
Loss on early extinguishment of debt	—	(52)	—	(100)%	N/A
Royalty interest obligation	—	(71)	(323)	(100)%	(78)%
Other, net	(82)	(165)	(159)	(50)%	4 %
Total other expense, net	<u>\$ (5,820)</u>	<u>\$ (7,335)</u>	<u>\$ (8,378)</u>	(21)%	(12)%
% of total revenue	(2)%	(3)%	(4)%		

Total other expense, net decreased by 21% in 2016 versus 2015 largely due to a decrease in interest expense arising from a \$0.6 million increase in capitalized interest, primarily on construction of our new manufacturing suites and an increase in interest income as a result of higher average investment returns. We had no expenses for our DepoCyt(e) royalty obligation and loss on early extinguishment of debt in 2016.

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 our new manufacturing suites. The increase in interest income was due to higher investment balances and longer duration investments, and the decrease in our royalty interest obligation was due to our royalty interest assignment agreement with Paul Capital Advisors, LLC that ended on December 31, 2014.

Income Tax Expense

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

	Year Ended December 31,			2016 versus	2015 versus
	2016	2015	2014	2015	2014
				% Increase / (Decrease)	
Income tax expense	\$ 105	\$ 264	\$ 173	(60)%	53%
Effective tax rate	0 %	12%	(1)%		

We recorded tax provisions of \$0.1 million, \$0.3 million and \$0.2 million for the years ended December 31, 2016, 2015 and 2014, respectively. Since our deferred tax assets are fully offset by a valuation allowance, our total income tax expense includes only current tax expense. The 2016 and 2014 tax provisions consist principally of minimum state taxes. The 2015 tax provision reflects federal alternative minimum tax as well as state taxes.

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, 2016, we had an accumulated deficit of \$346.2 million, cash and cash equivalents and short-term investments of \$172.6 million and working capital of \$198.3 million.

Summary of Cash Flows

The following table summarizes our cash flows from operating, investing and financing activities for the years ended December 31, 2016, 2015 and 2014 (in thousands):

Consolidated Statement of Cash Flows Data:	Year Ended December 31,		
	2016	2015	2014
Net cash provided by (used in):			
Operating activities	\$ 33,453	\$ 28,021	\$ 26,564
Investing activities	(61,754)	(19,256)	(120,434)
Financing activities	7,261	10,699	118,875
Net increase (decrease) in cash and cash equivalents	\$ (21,040)	\$ 19,464	\$ 25,005

Operating Activities

In 2016, net cash provided by operating activities was \$33.5 million, which largely resulted from an 11% increase in EXPAREL net product sales and \$2.0 million in milestones earned under our agreement with Aratana. Our operating loss of \$37.9 million was more than offset by non-cash expenses of \$49.1 million, including \$31.2 million of stock-based compensation, \$17.5 million of depreciation and amortization expense and \$22.3 million of funds provided by net changes in our operating assets and liabilities. These net changes included a \$30.4 million decrease in inventory due to a \$20.5 million charge for inventory that did not meet routine stability test specifications and a \$9.9 million decrease in our inventory investment, partially offset by increases of \$4.1 million in accounts receivable and prepayments for clinical trials of \$3.2 million.

In 2015, net cash provided by operating activities was \$28.0 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 \$23.3 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 related FDA lawsuit which was amicably resolved in December 2015 and the DOJ inquiry.

In 2014, net cash provided by operating activities was \$26.6 million. Our net loss of \$13.7 million was more than offset by \$39.6 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.

Investing Activities

In 2016, net cash used in investing activities was \$61.8 million, which reflected purchases of fixed assets of \$24.7 million. Major capital projects included the continued expansion of our manufacturing capacity in Swindon, England in partnership with Patheon. We also purchased \$21.2 million of short-term investments (net of maturities) and made \$15.9 million of contingent consideration payments to Skyepharma related to the March 2007 acquisition, including an \$8.0 million milestone payment in connection with achieving \$250.0 million of EXPAREL net sales collected on an annual basis and \$7.9 million in percentage payments on collections of net sales of EXPAREL.

In 2015, net cash used in investing activities was \$19.3 million, which reflected purchases of fixed assets of \$40.3 million. Major capital projects included investing in a new research and development facility at our Science Center Campus 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 March 2007 acquisition. 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 March 2007 acquisition.

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Financing Activities

In 2016, net cash provided by financing activities was \$7.3 million, which reflected proceeds from the exercise of stock options of \$5.8 million and proceeds from the issuance of shares under our ESPP of \$1.5 million.

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.

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.

Equity Financings

From inception through December 31, 2016, we have raised approximately \$345 million of net proceeds from the sale of common stock and other equity securities via public offerings. 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

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, 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, 2016, the requirements with respect to the Consecutive Sales Price were not met and, as a result, the Notes are classified as a long-term obligation and are not convertible during the quarter ended March 31, 2017. The future convertibility and resulting balance sheet classification of this liability is monitored at each quarterly reporting date and is analyzed dependent upon market prices of our common stock during the prescribed measurement periods. 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 \$35.7 million of cash or issue approximately 1.1 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, 2016, causing dilution to our current shareholders and/or significant expenditures of our cash and liquid securities.

As of 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 governing the Notes) 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, 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. We have completed other immaterial conversion requests.

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 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 through March 1, 2018. 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, or we elect to redeem all or part of the Notes on or after February 1, 2017 in accordance with the terms of the indenture agreement;
- the cost and timing of potential milestone payments to Skyepharma, which could be up to an aggregate of \$36.0 million if certain milestones pertaining to net sales of DepoBupivacaine products, including 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, 2016 (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)	\$ 118,531	\$ —	\$ 118,531	\$ —	\$ —
Senior convertible notes - interest	8,026	3,852	4,174	—	—
Lease obligations (3)	39,356	7,880	16,335	7,596	7,545
Purchase obligations (4)	588	290	298	—	—
Total	\$ 166,501	\$ 12,022	\$ 139,338	\$ 7,596	\$ 7,545

(1) This table does not include potential future milestone payments to Skyepharma which could be up to an aggregate of \$36.0 million if certain milestones pertaining to net sales of DepoBupivacaine products, including EXPAREL are met, including \$32.0 million when annual net sales of DepoBupivacaine products, including EXPAREL collected reach \$500.0 million (measured on a rolling quarterly basis) and \$4.0 million upon the first commercial sale in a major European Union country. 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, including agreements to conduct clinical trials, and for consulting and other contracted services due to the cancelable nature of the services.

(2) The amounts displayed in the table above represent the February 2019 maturity 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, 2016, it would result in an approximate premium of 1.1 million shares, \$35.7 million of cash or a combination thereof, at the Company’s option.

(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 June 2016, we provided notice to CrossLink electing to terminate our Master Distributor Agreement (as amended) effective as of September 30, 2016. In connection with the termination of the Agreement, a termination fee based on a percentage of earned performance-based fees is due to CrossLink. This fee of \$7.1 million is payable to CrossLink quarterly over two years and was recorded in selling, general and administrative expense in the consolidated statements of operations. At December 31, 2016, \$5.3 million is classified in accrued expenses and \$1.8 million is classified in other liabilities.

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In April 2014, we and Patheon entered into a Strategic Co-Production Agreement, a Technical Transfer and Service Agreement and a Manufacturing and Supply 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 these agreements, we will make monthly base fee payments for services rendered. The agreements will remain in full effect unless and until they expire or are terminated. Upon termination of the Technical Transfer and Services 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.

Under the terms of the Manufacturing and Supply Agreement, following the FDA approval date of the suites, we have agreed to purchase EXPAREL product from Patheon. Unless earlier terminated by giving notice of up to three years (other than termination by us in the event of a material breach by Patheon), this agreement will expire on the 10th anniversary of the FDA approval date for the initial manufacturing suite.

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, inventory costs, liabilities and accruals, clinical trial expenses, stock-based compensation and the valuation of deferred tax assets. 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) to our commercial partners within 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 the FDA's 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 that 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 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 DepoCyt(e) returns have not been material.

[Table of Contents](#)*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.

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, 2016, 2015 and 2014 (in thousands):

	Returns Allowances	Prompt Payment Discounts	Wholesaler Service Fees	Volume Rebates and Chargebacks	Total
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
Provision	694	5,448	4,118	2,611	12,871
Payments/credits	(1,081)	(5,478)	(4,128)	(2,284)	(12,971)
Balance at December 31, 2016	<u>\$ 1,346</u>	<u>\$ 595</u>	<u>\$ 735</u>	<u>\$ 1,124</u>	<u>\$ 3,800</u>

Total reductions of gross product sales from sales-related allowances and accruals were \$12.9 million, \$10.7 million and \$8.3 million, or 4.6%, 4.2% and 4.1% of gross product sales, for the years ended December 31, 2016, 2015 and 2014, 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 increase in the percentage of sales-related allowances and accruals for the year ended December 31, 2016 was primarily related to an increase in volume related rebates and an increase in wholesaler fees as a result of higher service rates. The percentage of sales-related allowances remained fairly consistent from 2014 to 2015. During that time frame the percentage of volume-related rebates increased slightly, which was offset by a slight decrease in the returns allowance percentage.

Royalty Revenue

We recognize revenue from royalties based on our commercial partners' net sales of DepoCyt(e) and sales of bupivacaine liposome injectable suspension product to serve animal health indications. Royalties are recognized as earned in accordance with contract terms when they can be reasonably estimated and collection is reasonably assured. Based on historical product sales, royalty receipts and other relevant information, we accrue royalty revenue each quarter.

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.

Research and Development Expenses

Research and development expenses consist of costs associated with products and processes being developed, and include related personnel expenses, laboratory supplies, active pharmaceutical ingredients, manufacturing supplies, facilities costs, preclinical and clinical trial costs and other outside service fees. We expense research and development costs as incurred. We rely on third parties to conduct our preclinical and clinical trials 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 trials, 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 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, expected term, risk-free interest rate and expected dividend yield.

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 realization of our deferred tax assets. As of December 31, 2016, 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. There is significant doubt regarding our ability to utilize our net deferred tax assets and, therefore, we have recorded a full valuation allowance reducing our net deferred tax assets to zero at both December 31, 2016 and 2015.

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, 2016, 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, 2016 by \$0.5 million.

In January 2013, we issued \$120.0 million in aggregate principal amount of 3.25% convertible senior notes, which mature in February 2019. Both we and the holders may convert the 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, 2016, the estimated fair value of the Notes was \$1,406 per \$1,000 principal amount. 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, 2016, we had approximately \$0.6 million in receivables from customers denominated in Euros. A hypothetical 10% decrease in the value of the Euro relative to the United States dollar would have decreased our revenue by \$0.4 million for the year ended December 31, 2016.

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 reports of our independent registered public accounting firms, 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 Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Based on their evaluation as of December 31, 2016, our Chief Executive Officer and Chairman and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2016.

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 Chief Financial Officer, management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2016, 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, 2016.

The effectiveness of our internal control over financial reporting as of December 31, 2016 was audited by KPMG 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, 2016.

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, 2016, 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.'s internal control over financial reporting as of December 31, 2016, 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 the 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, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included 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 generally accepted accounting principles. 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 generally accepted accounting principles, 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. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of Pacira Pharmaceuticals, Inc. and subsidiaries as of December 31, 2016, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for the year ended December 31, 2016, and our report dated March 1, 2017 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

Short Hills, NJ
March 1, 2017

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 2017 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 2017 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 2017 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 2017 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 2017 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 KPMG LLP, Independent Registered Public Accounting Firm
Report of CohnReznick LLP, 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 consolidated 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.

Item 16. Form 10-K Summary

None.

**PACIRA PHARMACEUTICALS, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2016**

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Pacira Pharmaceuticals, Inc.:

We have audited the accompanying consolidated balance sheet of Pacira Pharmaceuticals, Inc. and subsidiaries as of December 31, 2016, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for the year ended December 31, 2016. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our 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 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 audit provides 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, 2016, and the results of their operations and their cash flows for the year ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Pacira Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2016, 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 March 1, 2017 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ KPMG LLP

Short Hills, NJ
March 1, 2017

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Pacira Pharmaceuticals, Inc.:

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

/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,	
	2016	2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 35,944	\$ 56,984
Short-term investments	136,653	101,981
Accounts receivable, net	29,937	25,855
Inventories, net	31,278	61,645
Prepaid expenses and other current assets	9,277	6,117
Total current assets	243,089	252,582
Long-term investments	—	13,462
Fixed assets, net	101,016	90,324
Goodwill	46,737	30,880
Intangibles, net	—	81
Other assets	624	406
Total assets	\$ 391,466	\$ 387,735
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 7,511	\$ 8,739
Accrued expenses	36,666	35,375
Convertible senior notes	—	104,040
Current portion of deferred revenue	595	1,426
Income taxes payable	66	208
Total current liabilities	44,838	149,788
Convertible senior notes	108,738	—
Deferred revenue	7,487	8,082
Other liabilities	11,427	11,473
Total liabilities	172,490	169,343
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, 2016 and 2015	—	—
Common stock, par value \$0.001 and 250,000,000 shares authorized; 37,480,952 shares issued and outstanding at December 31, 2016; 36,848,319 shares issued and outstanding at December 31, 2015	37	37
Additional paid-in capital	565,207	526,696
Accumulated deficit	(346,238)	(308,289)
Accumulated other comprehensive loss	(30)	(52)
Total stockholders' equity	218,976	218,392
Total liabilities and stockholders' equity	\$ 391,466	\$ 387,735

See accompanying notes to consolidated financial statements.

PACIRA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

	Year Ended December 31,		
	2016	2015	2014
Revenues:			
Net product sales	\$ 270,073	\$ 244,487	\$ 193,526
Collaborative licensing and milestone revenue	3,426	1,426	1,287
Royalty revenue	2,872	3,084	2,855
Total revenues	276,371	248,997	197,668
Operating expenses:			
Cost of goods sold	110,104	71,837	77,440
Research and development	45,678	28,662	18,731
Selling, general and administrative	152,613	139,043	106,662
Total operating expenses	308,395	239,542	202,833
Income (loss) from operations	(32,024)	9,455	(5,165)
Other (expense) income:			
Interest income	1,323	678	382
Interest expense	(7,061)	(7,725)	(8,278)
Loss on early extinguishment of debt	—	(52)	—
Royalty interest obligation	—	(71)	(323)
Other, net	(82)	(165)	(159)
Total other expense, net	(5,820)	(7,335)	(8,378)
Income (loss) before income taxes	(37,844)	2,120	(13,543)
Income tax expense	(105)	(264)	(173)
Net income (loss)	\$ (37,949)	\$ 1,856	\$ (13,716)
Net income (loss) per share:			
Basic net income (loss) per common share	\$ (1.02)	\$ 0.05	\$ (0.39)
Diluted net income (loss) per common share	\$ (1.02)	\$ 0.04	\$ (0.39)
Weighted average common shares outstanding:			
Basic	37,236	36,540	35,299
Diluted	37,236	41,301	35,299

See accompanying notes to consolidated financial statements.

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

(In thousands)

	Year Ended December 31,		
	2016	2015	2014
Net income (loss)	\$ (37,949)	\$ 1,856	\$ (13,716)
Other comprehensive income (loss):			
Net unrealized gain (loss) on investments	22	28	(85)
Total other comprehensive income (loss)	22	28	(85)
Comprehensive income (loss)	\$ (37,927)	\$ 1,884	\$ (13,801)

See accompanying notes to consolidated financial statements.

PACIRA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2016, 2015 AND 2014

(In thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
	Shares	Amount				
Balance at December 31, 2013	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)
Balance at December 31, 2014	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
Balance at December 31, 2015	36,848	37	526,696	(308,289)	(52)	218,392
Exercise of stock options	518	—	5,770	—	—	5,770
Vested restricted stock units	62	—	—	—	—	—
Shares issued under employee stock purchase plan	53	—	1,495	—	—	1,495
Stock-based compensation	—	—	31,248	—	—	31,248
Retirement of equity component of convertible senior notes	—	—	(2)	—	—	(2)
Net unrealized gain on investments	—	—	—	—	22	22
Net loss	—	—	—	(37,949)	—	(37,949)
Balance at December 31, 2016	37,481	\$ 37	\$ 565,207	\$ (346,238)	\$ (30)	\$ 218,976

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,		
	2016	2015	2014
Operating activities:			
Net income (loss)	\$ (37,949)	\$ 1,856	\$ (13,716)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation of fixed assets and amortization of intangibles	12,919	11,475	10,035
Amortization of unfavorable lease obligation and debt issuance costs	479	481	487
Amortization of debt discount	4,088	4,102	4,139
Loss on disposal of fixed assets	389	6	158
Loss on early extinguishment of debt	—	52	—
Stock-based compensation	31,248	33,368	24,822
Changes in operating assets and liabilities:			
Restricted cash	—	1,509	124
Accounts receivable, net	(4,082)	(3,489)	(7,776)
Inventories, net	30,367	(32,382)	(13,706)
Prepaid expenses and other assets	(3,377)	(2,007)	(1,621)
Accounts payable, accrued expenses and income taxes payable	710	8,966	15,349
Royalty interest obligation	—	(276)	(970)
Other liabilities	87	5,786	2,526
Deferred revenue	(1,426)	(1,426)	6,713
Net cash provided by operating activities	<u>33,453</u>	<u>28,021</u>	<u>26,564</u>
Investing activities:			
Purchases of fixed assets	(24,709)	(40,295)	(22,984)
Purchases of investments	(192,815)	(189,082)	(164,303)
Sales of investments	171,627	217,240	80,286
Payment of contingent consideration	(15,857)	(7,119)	(13,433)
Net cash used in investing activities	<u>(61,754)</u>	<u>(19,256)</u>	<u>(120,434)</u>
Financing activities:			
Proceeds from follow-on public offering, net	—	—	110,452
Proceeds from exercise of stock options and warrants	5,770	10,073	7,239
Proceeds from shares issued under employee stock purchase plan	1,495	2,093	1,184
Conversion of principal and equity component of convertible senior notes	(4)	(1,467)	—
Net cash provided by financing activities	<u>7,261</u>	<u>10,699</u>	<u>118,875</u>
Net increase (decrease) in cash and cash equivalents	(21,040)	19,464	25,005
Cash and cash equivalents, beginning of year	56,984	37,520	12,515
Cash and cash equivalents, end of year	<u>\$ 35,944</u>	<u>\$ 56,984</u>	<u>\$ 37,520</u>
Supplemental cash flow information:			
Cash paid for interest, including royalty interest obligation	\$ 3,852	\$ 4,224	\$ 5,193
Cash paid for income taxes, net of refunds	\$ 247	\$ 195	\$ 34
Non-cash investing and financing activities:			
Issuance of stock from conversion of convertible senior notes	\$ —	\$ 3,929	\$ —
Net increase (decrease) in accrued fixed assets	\$ (789)	\$ 1,393	\$ (1,095)

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, manufacture and commercialization of 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. The Company also sells its bupivacaine liposome injectable suspension product to a commercial partner to serve animal health indications.

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, inventory costs, impairments of goodwill and long-lived assets, liabilities and accruals, stock-based compensation and the 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 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 March 1, 2018. 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 England.

Revenue Recognition

The Company’s principal sources of revenue include (i) sales of EXPAREL in the United States, or US, (ii) sales of DepoCyt(e) to our commercial partners within the US and the European Union, or EU, (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 DepoCyt(e) and other product sales 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, inventory data and other related information which may become known in the future. 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 12 months following product expiration. The Company estimates its sales return reserve based on its 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 DepoCyt(e) 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, 2016, 2015 and 2014 (in thousands):

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

NOTE 2—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

	Returns Allowances	Prompt Payment Discounts	Wholesaler Service Fees	Volume Rebates and Chargebacks	Total
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
Provision	694	5,448	4,118	2,611	12,871
Payments/credits	(1,081)	(5,478)	(4,128)	(2,284)	(12,971)
Balance at December 31, 2016	\$ 1,346	\$ 595	\$ 735	\$ 1,124	\$ 3,800

Royalty Revenue

The Company recognizes revenue from royalties based on sales of its commercial partners' net sales of DepoCyt(e) and sales of bupivacaine liposome injectable suspension product to serve animal health indications.

Royalties are recognized as earned in accordance with contract terms when they can be reasonably estimated and collection is reasonably assured. Based on historical product sales, royalty receipts and other relevant information, the Company accrues royalty revenue each quarter.

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.

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. (i.e.,wholesalers or commercial partners) in each year presented:

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

NOTE 2—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

	Year Ended December 31,		
	2016	2015	2014
Largest customer	32%	33%	33%
Second largest customer	28%	29%	29%
Third largest customer	26%	28%	24%
	<u>86%</u>	<u>90%</u>	<u>86%</u>

Revenues from customers outside the US accounted for 1%, 2% and 2% of the Company's revenue for the years ended December 31, 2016, 2015 and 2014, respectively.

Research and Development Expenses

Research and development expenses consist of costs associated with products and processes being developed, 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.

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-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 loss until realized. Realized gains and losses are included in interest income in 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:

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

NOTE 2—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Asset Category	Useful Lives
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, 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 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. 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 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

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

NOTE 2—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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, 2016 and 2015, all deferred tax assets were fully offset by a valuation allowance 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 and warrants, the vesting of restricted stock units, or 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 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.

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. The Company used an expected term based on its historical data from stock option exercises. 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.

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

NOTE 3—RECENT ACCOUNTING PRONOUNCEMENTS

Recently Adopted

In April 2015, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2015-03, *Interest—Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*, which requires debt issuance costs related to a recognized debt liability be presented on 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. The Company adopted this standard on January 1, 2016. The Company applied the new guidance retrospectively to all prior periods presented in the financial statements to conform to the 2016 presentation. As a result, \$1.9 million of debt issuance costs related to the Company's convertible senior notes at December 31, 2015 were reclassified from other assets to a reduction in the carrying value of the Company's convertible senior notes.

Not Adopted as of December 31, 2016

In May 2014, the FASB issued 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. During the fiscal third quarter of 2015, the FASB approved a one year deferral to the effective date to be adopted by all public companies for all annual periods and interim reporting periods beginning after December 15, 2017. During 2016, the FASB issued additional guidance and clarification relating to identifying performance obligations, licensing, principal versus agent considerations, assessing collectability, presentation of sales taxes, noncash consideration and contract modifications and completed contracts at transition. These updates will replace existing revenue recognition guidance under GAAP when it becomes effective for the Company beginning January 1, 2018, and permits two methods of adoption: the full retrospective method, which requires the standard to be applied to each prior period presented, or the modified retrospective method, which requires the cumulative effect of adoption to be recognized as an adjustment to opening retained earnings in the period of adoption. While the Company is continuing to evaluate the impact of these updates on its consolidated financial statements, it does not expect the implementation of ASU 2014-09 and the subsequently issued related guidance to have a material impact on its 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 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 February 2016, the FASB issued ASU 2016-02, *Leases (ASC 842)*. This update requires lessees to recognize lease assets and lease liabilities on the balance sheet for those leases classified as operating leases under previous authoritative guidance. The lease liability will be equal to the present value of lease payments and the right-of-use asset will be based on the lease liability, subject to adjustment for items such as initial direct costs. For income statement purposes, the new standard retains a dual model similar to Accounting Standards Codification, or ASC, 840, requiring leases to be classified as either operating or financing. For lessees, operating leases will result in straight-line expense (similar to current accounting by lessees for operating leases under ASC 840) while financing leases will result in a front-loaded expense pattern (similar to current accounting by lessees for capital leases under ASC 840). This update also introduces new disclosure requirements for leasing arrangements. The standard is effective for annual reporting periods beginning after December 15, 2018 and interim periods within those annual periods. Early adoption is permitted. The Company is evaluating the impact of ASU 2016-02 on its consolidated financial statements. Refer to Note 17, *Commitments and Contingencies*, for further discussion on the Company's leases.

In March 2016, the FASB issued ASU 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. This update includes multiple provisions intended to simplify various aspects of

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

the accounting for share-based payment transactions including accounting for excess tax benefits and tax deficiencies, classification of excess tax benefits in the statement of cash flows and accounting for award forfeitures. The update also removes the present requirement to delay recognition of an excess tax benefit until it reduces current taxes payable, instead, it is required to be recognized at the time of settlement, subject to normal valuation allowance considerations. This update became effective for the Company beginning January 1, 2017. The Company will elect an accounting policy change to record forfeitures as they occur rather than estimating forfeitures during each period and will record a charge of approximately \$0.3 million to retained earnings as of January 1, 2017 related to the reversal of cumulative forfeiture estimates. The adoption of this standard also will result in the recognition of \$29.3 million of previously unrecognized excess tax benefits in deferred tax assets, fully offset by a valuation allowance. All tax-related cash flows resulting from stock-based compensation, including the excess tax benefits related to the settlement of stock-based awards, will be classified as cash flows from operating activities on the Company's consolidated statements of cash flows. Based on a preliminary assessment, the Company does not believe that any of the provisions in ASU 2016-09 will have a significant impact on its consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326)*, which requires entities to measure all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions and reasonable and supportable forecasts. Entities will now use forward-looking information to better form their credit loss estimates. This update also requires enhanced disclosures to help financial statement users better understand significant estimates and judgments used in estimating credit losses, as well as the credit quality and underwriting standards of an entity's portfolio. This ASU is effective for annual reporting periods beginning after December 15, 2019, with early adoption permitted. The Company is evaluating the impact of ASU 2016-13 on its consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, which clarifies existing guidance on how companies present and classify certain cash receipts and cash payments in the statement of cash flows by addressing specific cash flow issues in an effort to reduce diversity in practice, including guidance on debt prepayment or extinguishment costs and contingent consideration payments made after a business combination. This update is effective for annual reporting periods beginning after December 15, 2017, with early adoption permitted. The Company is currently evaluating the impact of ASU 2016-15 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,	
	2016	2015
Raw materials	\$ 11,742	\$ 16,712
Work-in-process	11,621	12,152
Finished goods	7,915	32,781
Total	<u>\$ 31,278</u>	<u>\$ 61,645</u>

The Company is required to perform ongoing stability testing on select lots of EXPAREL at various time intervals. In October 2016, as part of its ongoing stability testing, the Company identified that a single batch of EXPAREL, which was manufactured in early 2016, did not meet the required specification. An internal investigation has tied this unexpected result to a modification to the manufacturing process that existed when this product was made, which has subsequently been corrected. The Company reserved all impacted inventory on hand and exchanged a limited number of boxes that were sold from the impacted inventory. As a result, the Company recorded in 2016 a \$20.7 million charge to cost of goods sold related to this matter, of which \$20.5 million was recorded as an inventory reserve and \$0.2 million for replacement boxes and other related administrative costs.

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

NOTE 5—FIXED ASSETS

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

	December 31,	
	2016	2015
Machinery and laboratory equipment	\$ 34,309	\$ 29,864
Leasehold improvements	33,787	30,834
Computer equipment and software	5,623	4,007
Office furniture and equipment	1,606	1,439
Construction in progress	63,201	49,097
Total	138,526	115,241
Less: accumulated depreciation	(37,510)	(24,917)
Fixed assets, net	\$ 101,016	\$ 90,324

Depreciation expense for the years ended December 31, 2016, 2015 and 2014 was \$12.8 million, \$11.2 million and \$9.3 million, respectively. During the years ended December 31, 2016, 2015 and 2014, the Company capitalized interest of \$1.5 million, \$0.8 million and \$0.4 million, respectively. As of December 31, 2016 and 2015, total fixed assets, net, includes leasehold improvements and manufacturing process equipment located in England in the amount of \$33.7 million and \$25.9 million, respectively.

For the years ended December 31, 2016 and 2015, the Company has recorded an ARO of \$0.5 million and \$0.6 million, respectively, 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 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 DepoBupivacaine products collected, as well as milestone payments for DepoBupivacaine products, as follows:

- (i) \$10.0 million upon the first commercial sale in the United States (met April 2012);
- (ii) \$4.0 million upon the first commercial sale in a major EU country (United Kingdom, France, Germany, Italy and Spain);
- (iii) \$8.0 million when annual net sales collected reach \$100.0 million (met September 2014);
- (iv) \$8.0 million when annual net sales collected reach \$250.0 million (met June 2016); 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. In June 2016, the Company recorded an \$8.0 million milestone payment for achieving \$250.0 million of annual EXPAREL net sales collected. For purposes of meeting future potential milestone payments, with certain exceptions, annual net sales are measured on a rolling quarterly basis. Cumulatively through December 31, 2016, the Company has recorded an additional \$22.8 million as goodwill for earn-out payments which are based on a percentage of net sales of DepoBupivacaine products, including 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 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 related to contingent payments due under the Acquisition during the years ended December 31, 2016, and 2015, which are not deductible for income tax purposes.

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

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

NOTE 6—GOODWILL AND INTANGIBLE ASSETS (Continued)

	Carrying Value
Balance at December 31, 2014	\$ 23,761
Percentage payments on collections of net sales of DepoBupivacaine products	7,119
Balance at December 31, 2015	30,880
Milestone payment triggered by collections of net sales of DepoBupivacaine products	8,000
Percentage payments on collections of net sales of DepoBupivacaine products	7,857
Balance at December 31, 2016	\$ 46,737

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):

	December 31, 2016			December 31, 2015			Estimated Useful Life
	Gross Carrying Value	Accumulated Amortization	Intangible Assets, Net	Gross Carrying Value	Accumulated Amortization	Intangible Assets, Net	
Amortizable Intangible Assets:							
Core technology	\$ 2,900	\$ (2,900)	\$ —	\$ 2,900	\$ (2,819)	\$ 81	9 Years
Developed technology	11,700	(11,700)	—	11,700	(11,700)	—	7 Years
Trademarks and trade names	400	(400)	—	400	(400)	—	7 Years
Total intangible assets	\$ 15,000	\$ (15,000)	\$ —	\$ 15,000	\$ (14,919)	\$ 81	

Annual amortization expense for intangibles for the years ended December 31, 2016, 2015 and 2014 was \$0.1 million, \$0.3 million and \$0.8 million, respectively.

NOTE 7—ACCRUED EXPENSES

Accrued expenses consist of the following (in thousands):

	December 31,	
	2016	2015
Compensation and benefits	\$ 11,228	\$ 11,944
Accrued operating expenses	16,538	14,601
Accrued royalties	3,822	3,731
Accrued interest	1,605	1,605
Product returns, rebates and other fees	3,473	3,494
Total	\$ 36,666	\$ 35,375

NOTE 8—DEBT

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

	December 31,	
	2016	2015
3.25% convertible senior notes	\$ 118,531	\$ 118,533
Deferred financing costs	(1,276)	(1,888)
Discount on debt	(8,517)	(12,605)
Total debt, net of debt discount	\$ 108,738	\$ 104,040

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 the Notes, and entered into an indenture agreement, or the Indenture, with respect

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

NOTE 8—DEBT (Continued)

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.

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

(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, 2016, the requirements with respect to the Consecutive Sales Price were not met. As a result, the Notes are classified as a long-term obligation and are not convertible during the quarter ended March 31, 2017. As of December 31, 2016, the Notes had a market price of \$1,406 per \$1,000 principal amount, compared to an estimated conversion value of \$1,301 per \$1,000 principal amount. 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 \$35.7 million of cash or issue approximately 1.1 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, 2016, 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. The Company has completed other immaterial conversion requests.

The future convertibility and resulting balance sheet classification of this liability is monitored at each quarterly reporting date and is analyzed dependent upon market prices of the Company's common stock during the prescribed measurement periods. The Notes are classified on the Company's consolidated balance sheet at December 31, 2016 as a long-term obligation

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

NOTE 8—DEBT (Continued)

and at December 31, 2015 as a current obligation. In the event that the holders of the Notes have the election to convert, the Notes would then be considered a current obligation and classified as such.

As of 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 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 on the consolidated balance sheet at the issuance date and the equity 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):

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

NOTE 8—DEBT (Continued)

	Year Ended December 31,		
	2016	2015	2014
Contractual interest expense	\$ 3,852	\$ 3,856	\$ 3,900
Amortization of debt issuance costs	612	615	620
Amortization of debt discount	4,088	4,102	4,139
Capitalized interest (Note 5)	(1,491)	(848)	(381)
Total	<u>\$ 7,061</u>	<u>\$ 7,725</u>	<u>\$ 8,278</u>
Effective interest rate on the Notes	7.22%	7.21%	7.22%

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 Advisors, LLC, or Paul Capital, to raise \$30.0 million. Under the PLC Royalty 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, which are recorded as a royalty interest obligation in the Company's consolidated statements of operations. Payments began for product sales realized on or after January 1, 2003 and continued through December 31, 2014. The related financing arrangement with Paul Capital terminated on December 31, 2014, and 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, 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, 2016 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
December 31, 2016				
Convertible senior notes *	\$ 108,738	\$ —	\$ 166,672	\$ —

* The fair value of the Notes was based on the Company's closing stock price of \$32.30 per share at December 31, 2016 compared to a conversion price of \$24.82 per share which, if converted, would result in an approximate conversion premium of 1.1 million shares or \$35.7 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

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

NOTE 9—FINANCIAL INSTRUMENTS (Continued)

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, 2016, all of the Company's short-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, 2016, all short-term and long-term investments were rated A or better by Standard & Poor's.

The following summarizes the Company's investments at December 31, 2016 and 2015 (in thousands):

December 31, 2016	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value (Level 2)
Debt securities:				
Short-term:				
Asset-backed securities	\$ 9,012	\$ —	\$ (2)	\$ 9,010
Commercial paper	39,530	8	(15)	39,523
Corporate bonds	88,141	11	(32)	88,120
Total	<u>\$ 136,683</u>	<u>\$ 19</u>	<u>\$ (49)</u>	<u>\$ 136,653</u>
December 31, 2015	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value (Level 2)
Debt securities:				
Short-term:				
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
Long-term:				
Corporate bonds	13,501	—	(39)	13,462
Total	<u>\$ 115,495</u>	<u>\$ 33</u>	<u>\$ (85)</u>	<u>\$ 115,443</u>

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, 2016, 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, 2016, three customers accounted for over 10% of the Company's accounts receivable; 36%, 29% and 25%, respectively. At December 31, 2015, three customers accounted for over 10% of the Company's accounts receivable; 34%, 28% 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, 2016 and 2015, no allowances for doubtful accounts were deemed necessary by the Company on its accounts receivable.

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

NOTE 10—STOCKHOLDERS' EQUITY*Common Stock*

The Company is authorized to issue up to 250,000,000 shares of common stock, of which 37,480,952 and 36,848,319 were outstanding at December 31, 2016 and 2015, respectively.

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' over-allotment 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, 2016 or 2015.

Warrants

The Company had no warrants outstanding at December 31, 2016. At December 31, 2015, 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 loss (in thousands):

	Net Unrealized Gains (Losses) From Available For Sale Investments
Balance at December 31, 2014	\$ (80)
Other comprehensive income before reclassifications	28
Amounts reclassified from accumulated other comprehensive income (loss)	—
Balance at December 31, 2015	(52)
Other comprehensive income before reclassifications	22
Amounts reclassified from accumulated other comprehensive income (loss)	—
Balance at December 31, 2016	\$ (30)

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. Since the adoption of the 2011 Plan, any remaining shares available for issuance under a 2007 stock incentive plan, or 2007 Plan, are reallocated 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.

In June 2016, the Company's board of directors adopted an amendment to the 2011 Plan. Under the amendment, an additional 4,000,000 shares of common stock were authorized for issuance as equity awards under the plan. The amendment to the 2011 Plan was subsequently ratified by the Company's stockholders and became effective in June 2016.

All of the Company's stock option grants have an exercise price equal to the closing price 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). Since 2015, the Company has granted RSUs to employees and its Board of Directors. The Company uses authorized and unissued shares to satisfy its obligations under these plans.

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

NOTE 11—STOCK PLANS (Continued)

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 have the opportunity to elect to purchase shares of the Company’s common stock on the purchase dates 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.

The following table contains information about the Company’s plans at December 31, 2016:

Stock Incentive Plans	Awards Reserved for Issuance	Awards Issued	Awards Available for Grant
2007 Plan	2,022,837	2,022,837	—
2011 Plan	9,931,700	6,503,336	3,428,364
2014 Inducement plan	175,000	66,626	108,374
	<u>12,129,537</u>	<u>8,592,799</u>	<u>3,536,738</u>

Employee Stock Purchase Plan	Shares Reserved for Purchase	Shares Purchased	Shares Available for Purchase
2014 ESPP	500,000	103,620	396,380

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, 2016, 2015 and 2014 as follows (in thousands):

	Year Ended December 31,		
	2016	2015	2014
Cost of goods sold	\$ 6,438	\$ 6,012	\$ 3,582
Research and development	3,297	5,134	6,490
Selling, general and administrative	21,513	22,222	14,750
Total	<u>\$ 31,248</u>	<u>\$ 33,368</u>	<u>\$ 24,822</u>
Stock-based compensation from:			
Stock options (employee awards)	\$ 24,505	\$ 27,262	\$ 19,182
Stock options (consultant awards)	841	2,367	5,295
RSUs	5,117	2,887	—
ESPP	785	852	345
Total	<u>\$ 31,248</u>	<u>\$ 33,368</u>	<u>\$ 24,822</u>

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

NOTE 11—STOCK PLANS (Continued)

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.

The following table summarizes the Company’s stock option activity and related information for the period from January 1, 2014 to December 31, 2016:

	Number of Options	Weighted Average Exercise Price (Per Share)	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in Thousands)
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
Granted	1,656,598	38.20		
Exercised	(518,226)	11.13		\$ 21,750
Forfeited	(401,048)	70.27		
Expired	(175,303)	80.91		
Outstanding at December 31, 2016	5,207,743	\$ 42.16	7.39	\$ 37,581
Exercisable at December 31, 2016	2,798,083	\$ 35.30	5.93	\$ 37,403
Vested and expected to vest at December 31, 2016	4,858,131	\$ 41.92	7.25	\$ 37,567

As of December 31, 2016, \$57.1 million of total unrecognized compensation cost related to non-vested stock options is expected to be recognized over a weighted average period of 2.8 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, 2016, 2015 and 2014 was \$19.13, \$37.82 and \$42.62 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,		
	2016	2015	2014
Expected dividend yield	None	None	None
Risk free interest rate	1.03% - 2.48%	1.40% - 2.28%	0.02% - 2.16%
Expected volatility	53.5%	52.9%	57.2%
Expected term of options	5.77 years	5.76 years	5.86 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 the period from January 1, 2015 to December 31, 2016:

	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	216,198	78.59	\$ 16,602
Granted	256,631	40.21	
Vested	(61,487)	78.33	
Forfeited	(46,939)	68.84	
Unvested at December 31, 2016	364,403	\$ 52.85	\$ 11,824
Expected to vest at December 31, 2016	308,797	\$ 53.05	\$ 9,974

As of December 31, 2016, \$16.0 million of total unrecognized compensation cost related to non-vested RSUs is expected to be recognized over a weighted average period of 3.0 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 closing price of the fair market value of the Company’s common stock 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:

	Year Ended December 31,		
	2016	2015	2014
ESPP option fair value	\$10.57 - \$25.28	\$21.93 - \$25.24	\$23.27
Expected dividend yield	None	None	None
Risk free interest rate	0.37% - 0.49%	0.11% - 0.13%	0.37%
Expected volatility	63.4%	50.7%	28.2%
Expected term of ESPP share options	6 months	6 months	4 months

NOTE 12—NET INCOME (LOSS) PER SHARE

Basic net income (loss) per 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, 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. For purposes of calculating the dilutive impact of the conversion premium on the Notes, 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, 2016 and 2014, 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, 2016, 2015 and 2014 (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,		
	2016	2015	2014
Numerator:			
Net income (loss)	\$ (37,949)	\$ 1,856	\$ (13,716)
Denominator:			
Weighted average common shares outstanding—basic	37,236	36,540	35,299
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 common shares outstanding—diluted	37,236	41,301	35,299
Net income (loss) per share:			
Basic net income (loss) per common share	\$ (1.02)	\$ 0.05	\$ (0.39)
Diluted net income (loss) per common share	\$ (1.02)	\$ 0.04	\$ (0.39)

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

	Year Ended December 31,		
	2016	2015	2014
Weighted average number of stock options	4,482	1,891	3,534
Weighted average number of RSUs	290	99	—
Conversion premium on the Notes	2,022	—	2,483
Weighted average number of warrants	1	—	21
Weighted average ESPP purchase options	21	8	1
Total	6,816	1,998	6,039

NOTE 13—INCOME TAXES

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

	Year Ended December 31,		
	2016	2015	2014
Income (loss) before income taxes:			
Domestic	\$ (36,339)	\$ 3,760	\$ (13,271)
Foreign	(1,505)	(1,640)	(272)
Total income (loss) before income taxes	\$ (37,844)	\$ 2,120	\$ (13,543)
Current taxes:			
Federal	\$ 11	\$ 92	\$ —
State	94	172	173
Total income tax expense	\$ 105	\$ 264	\$ 173

The tax provision of \$0.1 million and \$0.2 million for the years ended December 31, 2016 and 2014, respectively, is principally the result of minimum state taxes. The tax provision of \$0.3 million for the year ended December 31, 2015 is the result of the federal alternative minimum tax and state taxes.

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

NOTE 13—INCOME TAXES (Continued)

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

	Year Ended December 31,		
	2016	2015	2014
U.S. federal statutory rate	35.00 %	35.00 %	35.00 %
State taxes	2.20 %	0.71 %	(32.62)%
Foreign taxes	(0.81)%	12.03 %	(0.13)%
Change in valuation allowance	(43.96)%	10.32 %	(17.71)%
Stock-based compensation	(0.54)%	7.26 %	(0.44)%
Tax credits	8.77 %	(30.63)%	5.49 %
Interest expense	5.75 %	(37.57)%	10.68 %
Effect of state blended rate changes	(4.65)%	— %	— %
Other	(2.04)%	15.33 %	(1.55)%
Effective tax rate	<u>(0.28)%</u>	<u>12.45 %</u>	<u>(1.28)%</u>

The Company's effective tax rates of (0.28)% and (1.28)% for the years ended December 31, 2016 and 2014, respectively, differed from the expected US statutory tax rate of 35.0%. This difference was primarily driven by pretax losses for which the Company concluded that a majority of its tax benefits are not more-likely-than-not to be realized, resulting in the recording of a full valuation allowance. The Company's effective tax rate of 12.45% for the year ended December 31, 2015 was favorably impacted by the utilization of domestic net operating loss carryforwards for which there was a full valuation allowance.

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, 2016 and 2015 are as follows (in thousands):

	December 31,	
	2016	2015
Deferred tax assets:		
Net operating loss carry-forwards	\$ 96,163	\$ 101,011
Federal and state credits	13,724	7,232
Depreciation and amortization	2,604	1,310
Accruals and reserves	14,004	5,558
Deferred revenue	3,023	3,530
Stock based compensation	21,890	17,201
Other	531	953
Total deferred tax assets	<u>151,939</u>	<u>136,795</u>
Deferred tax liabilities:		
Discount on convertible senior notes	(3,186)	(4,679)
	<u>148,753</u>	<u>132,116</u>
Less: valuation allowance	(148,753)	(132,116)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2016, the available federal net operating loss carryforwards, or NOLs, and the federal tax credit carryforwards totaled \$341.4 million and \$10.5 million, respectively. The Company also had state NOLs and state tax credit carryforwards of \$222.8 million and \$5.0 million, respectively, which are subject to change on an annual basis due to variations in the Company's annual state apportionment factors. The Company had non-US tax NOLs of \$3.4 million at December 31, 2016. The federal and state NOLs will begin expiring in 2025 and 2017, respectively, if the Company has not used them prior to that time. The Company applies the with-and-without approach to determine the sequence in which stock-based compensation

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

NOTE 13—INCOME TAXES (Continued)

deductions and NOLs are utilized. Accordingly, no excess tax benefit related to stock option exercises was recognized in the current year. \$78.2 million of the federal NOLs are related to excess tax benefits arising from the exercise of stock options.

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 \$192.4 million of federal net operating losses are subject to annual limitations. At December 31, 2016, \$120.1 million of these federal net operating losses were available. The Company estimates that an additional \$14.8 million will become available 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 previously suspended or limited the use of net operating loss carryforwards for certain taxable years, and certain states are considering similar future measures. As a result, the Company may incur higher state income tax expense in the future.

In accordance with ASC Topic 740, the Company establishes a valuation allowance for deferred tax assets that, in its judgment, are not more-likely-than-not realizable. These judgments are based on projections of future income, including tax-planning strategies, by individual tax jurisdictions. In each reporting period, the Company assesses the likelihood that its deferred tax assets will be realized and determines if adjustments to its valuation allowance is appropriate. As a result of this assessment, the Company had a net change in its valuation allowance totaling \$16.6 million, \$0.8 million and \$9.9 million during the years ended December 31, 2016, 2015 and 2014, 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 reducing its net deferred tax assets to zero at both December 31, 2016 and 2015.

The Company did not have a liability related to unrecognized tax benefits, or UTBs, as of December 31, 2016 and 2015. The Company believes its UTBs for uncertain tax positions are adequate, consistent with the principles of ASC Topic 740. The Company regularly assesses the likelihood of additional tax assessments by jurisdiction and, if necessary, adjusts its UTBs based on new information or developments. The Company recognizes interest and penalties related to UTBs as an income tax expense. No interest or penalties were recognized in income tax expense for the years ended December 31, 2016, 2015 or 2014, respectively.

The Company is currently subject to audit by the United States Internal Revenue Service, or IRS, for the years 2014 through 2016, and state tax jurisdictions for the years 2010 through 2016. 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 a year that remains subject to audit. The Company's previously filed income tax returns are not presently under audit by the IRS or state tax authorities.

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 \$1.5 million, \$1.7 million and \$1.0 million of related compensation expense for the years ended December 31, 2016, 2015 and 2014, respectively.

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, a Technical Transfer and Service Agreement and a Manufacturing and Supply 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 these agreements, the Company will make monthly base fee payments for services rendered. The agreements will remain in full effect unless and until they expire or are terminated. Upon termination of the Technical Transfer and Services 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

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

NOTE 15—COMMERCIAL PARTNERS AND OTHER AGREEMENTS (Continued)

occasioned by the removal of its manufacturing equipment and for Patheon's termination costs up to a maximum amount of \$2.4 million.

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 by giving notice of up to three years (other than termination by the Company in the event of a material breach by Patheon), this agreement will expire on the 10th anniversary of the FDA approval date for the initial manufacturing suite.

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 developed and obtained FDA approval for the use of the product in veterinary surgery to manage postsurgical pain. In connection with its entry into the license agreement, the Company received a one-time payment of \$1.0 million. In December 2013, the Company received a \$0.5 million milestone payment under the agreement. In June 2016, the Company recorded \$1.0 million in milestone revenue for Aratana's filing of an FDA Administrative New Animal Drug Application, or ANADA, and in August 2016 recorded \$1.0 million related to the FDA's approval of the ANADA. The Company is eligible to receive up to an additional aggregate \$40.0 million upon the achievement of commercial milestones. Aratana is 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. Unless terminated earlier pursuant to its terms, the license agreement is effective until December 2027, after which Aratana has the option to extend the agreement for an additional five-year term, subject to certain requirements.

Aratana began purchasing bupivacaine liposome injectable suspension product in the third quarter of 2016, which they will market under the trade name NOCITA® to serve animal health indications.

NOCITA® is a registered trademark of Aratana Therapeutics, Inc.

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 EU 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.

Leadiant Biosciences, Ltd.

In December 2002, the Company entered into a supply and distribution agreement with Enzon Pharmaceuticals Inc., subsequently acquired by Sigma-Tau Rare Disease, Ltd., subsequently known as Leadiant Biosciences, Ltd., or Leadiant, regarding the promotion and distribution of DepoCyt®. Pursuant to the agreement, Leadiant was appointed the exclusive distributor of DepoCyt in the United States and Canada for a ten-year term, with successive two year renewal periods. Under the supply and distribution agreement, the Company supplies unlabeled DepoCyt vials to Leadiant. 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. The Company and Leadiant are currently operating under the terms of the agreement.

CrossLink BioScience, LLC

In October 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 (as amended). On June 30, 2016, the Company provided notice to CrossLink electing to terminate the agreement effective as of September 30, 2016. In connection with the termination of the agreement, a termination fee based on a percentage of earned performance-based fees is

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

NOTE 15—COMMERCIAL PARTNERS AND OTHER AGREEMENTS (Continued)

due to CrossLink. This fee of \$7.1 million is payable to CrossLink quarterly over two years, beginning in the fourth quarter of 2016, and was recorded in selling, general and administrative expense in the consolidated statements of operations. At December 31, 2016, \$5.3 million is classified in accrued expenses and \$1.8 million is classified in other liabilities.

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 was 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 was in effect until January 2017.

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. The Company incurred related consulting expenses of \$0.1 million, \$0.3 million and \$0.5 million for the years ended December 31, 2016, 2015 and 2014, respectively. At December 31, 2016 there was nothing payable to MPM and at December 31, 2015, the amount payable to MPM was \$0.1 million. The Company's agreement with MPM expired on December 31, 2015. The Company contracted with Dr. Patou directly for his services for the first six months of 2016.

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. David Stack, the Company's Chief Executive Officer and Chairman is a managing director at MPM.

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. The Company recorded expenses under the consulting arrangement of less than \$0.1 million for each of the years ended December 31, 2016, 2015 and 2014. In 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. At December 31, 2016, there was nothing payable to Dr. Pace for consulting services and at December 31, 2015, less than \$0.1 million was payable to Dr. Pace for consulting services.

NOTE 17—COMMITMENTS AND CONTINGENCIES*Leases*

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

As of December 31, 2016, aggregate annual minimum payments due under the Company's lease obligations are as follows (in thousands):

Year	Aggregate Minimum Payments
2017	\$ 7,880
2018	8,063
2019	8,272
2020	6,389
2021	1,207
2022 through 2028	7,545
Total	\$ 39,356

Total rent expense, net of amortization of unfavorable lease obligations and tenant improvements, under all operating leases for the years ended December 31, 2016, 2015 and 2014 was \$6.0 million, \$5.7 million and \$4.9 million, respectively. Deferred rent at December 31, 2016 and 2015 was \$8.6 million and \$9.2 million, respectively. The Company's research and

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

NOTE 17—COMMITMENTS AND CONTINGENCIES (Continued)

development facility in San Diego, California included a lease incentive allowance of \$5.6 million for the payment of leasehold improvements, which the Company utilized completely in 2015 and 2016. The leasehold improvements were capitalized into fixed assets, net on the consolidated balance sheets and are 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 April 2015, the Company received a subpoena from the US Department of Justice, US 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.

Purchase Obligations

The Company has \$0.6 million of minimum, non-cancelable contractual commitments for the purchase of certain raw materials as of December 31, 2016.

Other Commitments and Contingencies

The FDA, as a condition of EXPAREL approval, has required the Company to study EXPAREL in pediatric patients. The Company was granted a deferral for the required pediatric trials in all age groups for EXPAREL in the setting of wound infiltration and plans to conduct these pediatric trials as a post-marketing requirement, which was stated in the New Drug Application approval letter for EXPAREL. The Company recently secured feedback from the FDA on the pediatric trial design in all age groups and is in the process of finalizing its clinical strategy.

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 \$36.0 million are for milestones not yet met. Additionally, the Company agreed to pay to Skyepharma a low single-digit percentage payment on collections of EXPAREL sales in the United States, Japan, 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 Company has the right to cease paying the low single-digit percentage payments in the event that Skyepharma breaches certain covenants not to compete contained in the stock purchase agreement or the last valid patent claim expires. Refer to Note 6, *Goodwill and Intangible Assets*, for further discussion.

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.

NOTE 18—SUBSEQUENT EVENTS

In January 2017, the Company announced the initiation of a Co-Promotion Agreement, or the Agreement, with DePuy Synthes Sales, Inc., or DePuy Synthes, to market and promote the use of EXPAREL for orthopedic procedures in the United States. DePuy Synthes field representatives, specializing in joint reconstruction, spine, sports medicine and trauma, will collaborate with, and supplement, the Company's field teams by expanding the reach and frequency of EXPAREL education in the hospital surgical suite and ambulatory surgery center settings.

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Under the five-year arrangement, DePuy Synthes will be the exclusive third-party distributor during the term of the Agreement to promote and sell EXPAREL for operating room use for orthopedic and spine surgeries (including knee, hip, shoulder, sports and trauma surgeries) in the United States. DePuy Synthes is entitled to a tiered commission ranging from low single-digits to double-digits on sales of EXPAREL under the Agreement, subject to conditions, limitations and adjustments. The initial term of the Agreement commenced on January 24, 2017 and ends on December 31, 2021, with the option to extend the Agreement in additional 12 month increments upon mutual agreement of the parties, subject to certain conditions.

The Company and DePuy Synthes have mutual termination rights under the Agreement, subject to certain terms, conditions and advance notice requirements; provided that the Company or DePuy Synthes generally may not terminate the Agreement, without cause, within three years of the effective date of the Agreement. The Company also has additional unilateral termination rights under certain circumstances. The Agreement contains customary representations, warranties, covenants and confidentiality provisions, and also contains mutual indemnification obligations. DePuy Synthes is also subject to certain obligations and restrictions, including required compliance with certain laws and regulations and the Company's policies, in connection with fulfilling their obligations under the Agreement.

NOTE 19—SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

The following tables present selected quarterly financial data for the years ended December 31, 2016 and 2015 (in thousands, except per share data):

	Three Months Ended			
	March 31, 2016	June 30, 2016	September 30, 2016	December 31, 2016
Total revenues	\$ 65,474	\$ 69,640	\$ 68,355	\$ 72,902
Cost of goods sold	20,278	23,053	43,152	23,621
Total operating expenses	67,728	76,084	89,220	75,363
Net income (loss)	(3,854)	(7,958)	(22,164)	(3,973)
Basic and diluted net loss per common share	\$ (0.10)	\$ (0.21)	\$ (0.59)	\$ (0.11)

	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)

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

Exhibit Number	Description
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 the Registrant 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, between the Registrant 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 the Registrant and LASDK Limited Partnership.(2)
10.13	Third Amendment, dated March 13, 2013, to the Industrial Real Estate Lease, dated December 8, 1994, between the Registrant and LASDK Limited Partnership.(4)
10.14	Employment Agreement between the Registrant and David Stack.(2)***
10.15	Amendment No. 1 to Executive Employment Agreement, dated March 13, 2013, between the Registrant and David Stack.(4)***
10.16	Amendment No. 2 to Executive Employment Agreement, dated June 30, 2015, between the Registrant and David Stack.(14)***
10.17	Employment Agreement between the Registrant and James Scibetta.(2)***
10.18	Amendment No. 1 to Executive Employment Agreement, dated March 13, 2013, between the Registrant and James Scibetta.(4)***
10.19	Amendment No. 2 to Executive Employment Agreement, dated June 30, 2015, between the Registrant and James Scibetta.(14)***
10.20	Employment Agreement, dated November 29, 2012, between the Registrant and Kristen Williams.(13)***
10.21	Amendment No. 1 to Employment Agreement, dated March 13, 2013, between the Registrant and Kristen Williams.(13)***
10.22	Amendment No. 2 to Employment Agreement, dated June 30, 2015, between the Registrant and Kristen Williams.(14)***
10.23	Executive Employment Agreement, dated May 2, 2016, between the Registrant and Charles A. Reinhart, III.(17)***
10.24	Executive Employment Agreement, dated June 11, 2015, between the Registrant and Scott Braunstein.(16)***
10.25	Executive Employment Agreement, dated August 24, 2015, between the Registrant and James Jones.(16)***
10.26	Form of Warrant to purchase common stock of the Registrant, dated January 22, 2009.(2)
10.27	Form of Warrant to purchase common stock of the Registrant, dated December 29, 2010.(2)
10.28	Form of Indemnification Agreement between the Registrant and its directors and officers.(2)***
10.29†	Commercial Outsourcing Services Agreement entered into as of August 25, 2011 by the Registrant and Integrated Commercialization Solutions, Inc.(5)

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10.30†	First Amendment to Commercial Outsourcing Services Agreement, dated August 1, 2013, between the Registrant and Integrated Commercialization Solutions, Inc.(7)
10.31†	Second Amendment to Commercial Outsourcing Services Agreement, dated August 25, 2014, between the Registrant and Integrated Commercialization Solutions, Inc.(12)
10.32†	Third Amendment to Commercial Outsourcing Services Agreement, dated April 29, 2015, between the Registrant and Integrated Commercialization Solutions, Inc.(14)
10.33	Amended and Restated 2011 Stock Incentive Plan.(8)***
10.34	Form of Nonstatutory Stock Option Agreement under the Amended and Restated 2011 Stock Incentive Plan.(8)***
10.35	Form of Restricted Stock Unit Award Agreement (Employees) under the Amended and Restated 2011 Stock Incentive Plan.(14)***
10.36	Form of Restricted Stock Unit Award Agreement (Non-Employee Directors) under the Amended and Restated 2011 Stock Incentive Plan.(14)***
10.37	License, Development and Commercialization Agreement, dated December 5, 2012 between the Registrant and Aratana Therapeutics, Inc.(9)
10.38	Supply Agreement, dated December 5, 2012 between the Registrant and Aratana Therapeutics, Inc.(9)
10.39	2014 Inducement Plan.(10)***
10.40	2014 Employee Stock Purchase Plan.(8)***
10.41†	Strategic Co-Production Agreement dated April 4, 2014, by and between the Registrant and Patheon UK Limited.(11)
10.42†	Manufacturing and Supply Agreement dated April 4, 2014, by and between the Registrant and Patheon UK Limited.(11)
10.43†	Technical Transfer and Service Agreement dated April 4, 2014, by and between the Registrant and Patheon UK Limited.(11)
10.44	Amended and Restated Consulting Agreement, dated April 3, 2012, between the Registrant and Gary Pace.(6)***
10.45	Second Amended and Restated Consulting Agreement, dated August 17, 2012, between the Registrant and Gary Pace.(15)***
10.46	Third Amendment to Consulting Agreement, dated September 11, 2013, between the Registrant and Gary Pace.(7)***
10.47	Fourth Amendment to Consulting Agreement, dated November 25, 2015, between Pacira Pharmaceuticals, Inc. and Gary Pace.(18)***
21.1	Subsidiaries of Registrant.*
23.1	Consent of KPMG LLP.*
23.2	Consent of CohnReznick LLP.*
31.1	Certification of Chief Executive Officer and Chairman pursuant to Exchange Act Rule 13a-14(a).*
31.2	Certification of 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 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.*

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- (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 Quarterly Report on Form 10-Q, filed on May 9, 2012.
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- (7) Incorporated by reference to the exhibits to the registrant's Quarterly Report on Form 10-Q, filed on October 31, 2013.
- (8) Incorporated by reference to the exhibits to the registrant's Current Report on Form 8-K, filed on June 4, 2014.
- (9) Incorporated by reference to the exhibits to the registrant's Annual Report on Form 10-K, filed on March 7, 2013.
- (10) Incorporated by reference to Exhibit 10.1 to the registrant's Quarterly Report on Form 10-Q, filed on May 1, 2014.
- (11) Incorporated by reference to the exhibits to the registrant's Quarterly Report on Form 10-Q, filed on July 31, 2014.
- (12) Incorporated by reference to the exhibits to the registrant's Quarterly Report on Form 10-Q, filed on October 30, 2014.
- (13) Incorporated by reference to the exhibits to the registrant's Quarterly Report on Form 10-Q, filed on April 30, 2015.
- (14) Incorporated by reference to the exhibits to the registrant's Quarterly Report on Form 10-Q, filed on July 30, 2015.
- (15) Incorporated by reference to the exhibits to the registrant's Quarterly Report on Form 10-Q, filed on November 1, 2012.
- (16) Incorporated by reference to the exhibits to the registrant's Quarterly Report on Form 10-Q, filed on May 2, 2016.
- (17) Incorporated by reference to the exhibits to the registrant's Quarterly Report on Form 10-Q, filed on August 4, 2016.
- (18) Incorporated by reference to Exhibit 10.57 to the registrant's Annual Report on Form 10-K, filed on February 25, 2016.

* 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.

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 the registration statements (Nos. 333-175101, 333-181986, 333-196542 and 333-212098) on Form S-8 and the registration statement (No. 333-195099) on Form S-3 of Pacira Pharmaceuticals, Inc. of our reports dated March 1, 2017, with respect to the consolidated balance sheet of Pacira Pharmaceuticals, Inc. as of December 31, 2016, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for the year ended December 31, 2016, and the effectiveness of internal control over financial reporting as of December 31, 2016, which reports appear in the December 31, 2016 annual report on Form 10-K of Pacira Pharmaceuticals, Inc.

/s/ KPMG LLP

Short Hills, NJ
March 1, 2017

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in Registration Statement Nos. 333-175101, 333-181986, 333-196542, and 333-212098 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 for each of the two years in the period ended December 31, 2015, included in this Annual Report on Form 10-K of Pacira Pharmaceuticals, Inc. for the year ended December 31, 2016.

/s/ CohnReznick LLP
Roseland, NJ
March 1, 2017

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: March 1, 2017

/s/ DAVID STACK

David Stack
Chief Executive Officer and Chairman
(Principal Executive Officer)

CERTIFICATION

I, Charles A. Reinhart, III, 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.

March 1, 2017

Date:

/s/ CHARLES A. REINHART, III

Charles A. Reinhart, III
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, 2016, 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: March 1, 2017

/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, 2016, 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: March 1, 2017

/s/ CHARLES A. REINHART, III

Charles A. Reinhart, III
Chief Financial Officer
(Principal Financial Officer)

