Pacira Pharmaceuticals, Inc.
Form 10-K
February 25, 2014
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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, 2013

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 51-0619477
(State or Other Jurisdiction of Incorporation or Organization) Identification No.)

5 Sylvan Way, Suite 100 Parsippany, New Jersey 07054 (Address of Principal Executive Offices) (Zip Code)

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

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

Title of each class

Name of each exchange on which registered

The NASDAQ Global Select

Common Stock, \$0.001 par value

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 o No x

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 o No x

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 x No o Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, 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 x No o

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. x 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 o

Accelerated filer x

Non-accelerated filer o

Smaller reporting company o

(Do not check if a smaller

reporting company)

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

The aggregate market value of 20,909,360 shares of 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 28, 2013, the last business day of the registrant's most recently completed second fiscal quarter, of \$29.00 per share was \$606,371,440. 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 14, 2014, 33,714,015 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 2014 annual meeting of stockholders to be filed no later than 120 days after the end of the registrant's fiscal year ended December 31, 2013.

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Forward-Looking Statements

This Annual Report on Form 10-K and certain other communications made by us contains 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; the rate and degree of market acceptance of EXPAREL; the size and growth of the potential markets for EXPAREL and our ability to serve those markets; the Company's plans to expand the indications of EXPAREL, including nerve block and the related timing and success of a supplemental U.S. Food and Drug Administration New Drug Application; the Company's plans to evaluate and pursue additional DepoFoam-based product candidates; clinical studies in support of an existing or potential DepoFoam based product; the Company's plans to continue to manufacture and provide support services for its commercial partners who have licensed DepoCyt(e); and our commercialization and marketing capabilities. 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 the

Company's 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 our 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. is the holding company for our California operating subsidiary of the same name, which we refer to as PPI-California. In March 2007, we acquired PPI-California from SkyePharma Holding, Inc. (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., and its subsidiaries. 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 Europe. Corporate Information

We were incorporated in Delaware under the name Blue Acquisition Corp. in December 2006 and changed our name to Pacira, Inc. in June 2007. In October 2010, we changed our name to Pacira Pharmaceuticals, Inc. Our principal executive offices are located at 5 Sylvan Way, Suite 100, Parsippany, New Jersey 07054, and our telephone number is (973) 254-3560.

Pacira®, DepoFoam®, DepoCyt® (U.S. registration), DepoCyte® (EU registration), EXPAREL®, 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. This Annual Report on Form 10-K contains additional trade names, trademarks and service marks of other companies. Overview

We are a specialty pharmaceutical company focused on the development, commercialization and manufacture of pharmaceutical products, based on our proprietary DepoFoam® drug delivery technology, for use primarily in hospitals and ambulatory surgery centers. We operate in one reportable segment. On October 28, 2011, the United States Food and Drug Administration, or FDA, approved our New Drug Application, or NDA, for our lead product candidate, EXPAREL®, a liposome injection of bupivacaine, an amide-type local anesthetic indicated for infiltration into the surgical site to produce postsurgical analgesia for up to 72 hours. We believe EXPAREL addresses a significant unmet medical need for a long-acting non-opioid postsurgical analgesic, resulting in simplified postsurgical pain management and reduced opioid consumption, leading to improved patient outcomes and enhanced hospital economics. We have developed an internal sales force entirely dedicated to commercializing EXPAREL, which we commercially launched in April 2012. In addition, following a pilot program, effective October 1, 2013, we appointed CrossLink BioScience, LLC, or CrossLink, for a term of five years as the exclusive third-party distributor to promote and sell EXPAREL for orthopedic and spine surgeries in the United States, with the exception of certain geographical areas and accounts subject to change and adjustments by mutual agreement.

Our net sales for EXPAREL in 2013 were \$76.2 million, and our net sales for EXPAREL in our fiscal quarter ended December 31, 2013, which was the seventh quarter of our launch, were \$30.5 million. A total of 2,106 accounts have ordered EXPAREL since launch through December 31, 2013, with approximately 250 accounts having ordered more than \$100,000 of EXPAREL by the end of 2013. During the fourth quarter of 2013, we added 374 new accounts, averaging 29 new accounts per week. We believe EXPAREL will ultimately become a major hospital pharmaceutical brand.

In addition to EXPAREL, DepoFoam is also the basis for our other FDA-approved commercial product, DepoCyt(e), which we manufacture for our commercial partners, as well as our other product candidates. For the years ended December 31, 2013, 2012 and 2011 sales of EXPAREL accounted for 89%, 37% and 0% of total revenues and Depocyt(e) 10%, 15% and 66%, respectively.

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

Product(s)/Product Candidate(s)	Primary Indication(s)	Status	Commercialization Rights
EXPAREL	Postsurgical analgesia by infiltration	Marketed in U.S.	Pacira (worldwide)
	Postsurgical analgesia-nerve block	Phase 3	Pacira (worldwide)
	Č	Filed INAD	

Bupivacaine Liposome Injectable Veterinary postsurgical Aratana Therapeutics, Inc. Suspension analgesia (worldwide)

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Product(s)/Product Candidate(s) Primary Indication(s) Status Commercialization Rights
DepoCyt(e) Lymphomatous meningitis Marketed in U.S. Sigma-Tau Pharmaceuticals

Marketed in E.U. Mundipharma International

DepoNSAID Acute pain Preclinical Pacira (worldwide)
DepoMethotrexate Oncology Preclinical Pacira (worldwide)

Our Strategy

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

commercializing EXPAREL in the United States for postsurgical analgesia by infiltration;

building a streamlined commercial organization concentrating on major hospitals and ambulatory surgery centers in the United States and targeting surgeons, anesthesiologists, pharmacists and nurses;

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 influence hospitals in conducting Phase 4 retrospective and prospective trials and drug utilization evaluations;

servicing the commercial audiences that are rapidly adopting EXPAREL in local infiltration procedures, including not only the soft tissue surgical audiences that were the focus of the launch, but more recently expanding our education to audiences including the orthopedic, spine, and anesthesia (infiltration into the transverse abdominus plane—iTAP) who require similar education and training to ensure consistent, proper and safe use of the product;

obtaining FDA approval for nerve block indication for EXPAREL;

leveraging the development success of EXPAREL in the animal health market through our commercial partner for Bupivacaine Liposome Injectable Suspension to serve the companion animal market;

manufacturing all our DepoFoam-based products, including EXPAREL, in facilities compliant with current Good Manufacturing Practices, or cGMP;

continuing to expand our marketed product portfolio through development of additional DepoFoam-based hospital products utilizing a 505(b)(2) strategy, which permits us to rely upon the FDA's previous findings of safety and effectiveness for an approved product. A 505(b)(2) strategy may not succeed if there are successful challenges to the FDA's interpretation of Section 505(b)(2); and

continuing research and development partnerships to provide DepoFoam-based products to enhance the duration of action and patient compliance for partner products.

### **EXPAREL-Our Lead Product**

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

Our EXPAREL strategy has several principal elements:

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

extends postsurgical analgesia for up to 72 hours, from approximately eight hours or less;

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utilizes existing postsurgical infiltration administration techniques;

dilutes easily with saline to reach desired volume;

is a ready-to-use formulation; and

facilitates treatment of both small and large surgical sites.

Become the foundation of a long- acting postsurgical pain management regimen in order to reduce and delay opioid 2)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;

delays first opioid usage to approximately 14 hours post-surgery, compared to approximately one hour for placebo;

significantly increases the percentage of patients requiring no opioid rescue medication through 72 hours post-surgery, to 28% compared to 10% for placebo;

results in 45% less opioid usage at 72 hours post-surgery compared to placebo; and

increases the percentage of patients who are pain free at 24 hours post-surgery compared to placebo.

- 3) 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 considered as part of a multimodal postsurgical pain regimen;

reduces the need for patients to be constrained by elastomeric bags and PCA systems, which are clumsy, difficult to use and may introduce catheter-related issues, including infection;

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

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

presents a low-cost opportunity for clinical development; and

enables us to fully leverage our manufacturing and sales infrastructure.

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

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

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

#### Phase 4 Clinical Studies

We recently completed our IMPROVE program, a series of open-label prospective Phase 4 clinical studies evaluating the differences in postsurgical opioid use and health economic outcomes in patients undergoing open colectomy, ileostomy reversal, and lap colectomy. Findings consistently showed reduction in median length of hospital stay, mean hospitalization costs, and mean opioid consumption.

Additionally, we conducted a Phase 4 study (the "TRANSCEND" trial) in patients undergoing gynecologic or colorectal surgery. Prior to surgery, patients received either EXPAREL or sham (normal saline) iTAP as part of a multimodal pain regimen. The study goal was to demonstrate the utility of EXPAREL by achieving either co-primary endpoint of Day 3 Overall Benefit of Analgesia Score (OBAS) or total opioid rescue. A pre-planned interim analysis was performed on the first 39 patients recruited, which revealed a signal in one of the co-primary endpoints (OBAS), but poor compliance with the algorithm for total opioid rescue in the protocol and no signal for that co-primary endpoint. As a result, the decision was made not to continue the trial, but rather to analyze all of the patients recruited up to that point (n=67). In this analysis, the total opioid rescue continued to show no signal (with only 35 percent of patients protocol compliant), while the OBAS demonstrated an advantage for EXPAREL (P<0.05) compared to the sham-treated group.

### **EXPAREL Regulatory Plan**

The NDA for EXPAREL was approved on October 28, 2011, using a 505(b)(2) application. The initial FDA approval of EXPAREL is for single-dose infiltration into the surgical site to produce postsurgical analgesia.

EXPAREL consists of bupivacaine encapsulated in DepoFoam, both of which are used in FDA-approved products: Bupivacaine, a well-characterized generic anesthetic/analgesic, has an established safety profile and over 20 years of use in the United States.

DepoFoam, modified to meet the requirements of each product, is used to extend the release of the active drug substances in the products DepoCyt(e) and the no-longer marketed DepoDur.

The FDA, as a condition of EXPAREL approval, 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 to 18 year olds and ending with children under two years of age.

### **Additional Indications**

We are pursuing several additional indications for EXPAREL and expect to submit a supplemental U.S. Food and Drug Administration New Drug Application, or sNDA, for nerve block administration. We believe that this additional indication for EXPAREL presents a low-cost opportunity for clinical development and will allow us to fully leverage our manufacturing and commercial infrastructure.

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

In 2012, we initiated two pivotal nerve block trials comparing the effect of EXPAREL versus placebo through a femoral nerve block study for total knee arthroplasty and an intercostal block study for posterolateral thoracotomy procedures. In May 2013, we reported positive findings from the first part of our femoral nerve block study for total knee arthroplasty; the final part of this study is still ongoing. In August 2013, we reported that the intercostal nerve block study for posterolateral thoracotomy did not achieve its primary endpoint. The FDA has previously indicated to us at its end of Phase 2 meeting that a single pivotal trial meeting its primary endpoint would be sufficient to gain approval for the nerve block indication, assuming demonstration of adequate safety. We plan to submit data from the ongoing femoral nerve block study to demonstrate efficacy and safety, as well as safety data from the intercostal nerve block study, for an sNDA, anticipated in early 2014. 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.

### Sales and Marketing

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

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

providing publications and abstracts showing the EXPAREL clinical program efficacy and safety, health outcomes program and review articles on pain management;

working in tandem with hospital staff, such as registered nurses, surgeons, heads of quality, pharmacists and C-level executives, to provide access and resources for drug utilization (DUE) or medication use evaluations (MUE), 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; and

undertaking education initiatives such as center of excellence programs, preceptorship programs, pain protocols and predictive models for enhanced patient care, interactive discussion forums, web-based training and virtual launch programs.

Initially at launch, we outsourced our dedicated commercial sales force through our relationship with Quintiles Commercial US, Inc., or Quintiles. On January 28, 2013, this sales force transitioned from Quintiles employees to Pacira employees. They are supported by our current marketing team as well as teams of healthcare professionals, including medical affairs, scientific affairs and nursing teams, who support our formulary approval and customer education initiatives. Additionally, on October 1, 2013, we entered into an agreement with CrossLink to act as a local agent and lead partner in collaboration with additional distributors to promote and sell EXPAREL in select territories in the United States for postsurgical pain management following orthopedic and spine procedures.

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

The primary target audience for EXPAREL is healthcare practitioners who influence pain management decisions, including surgeons, anesthesiologists, pharmacists and nurses.

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

Convenience. Our DepoFoam products are ready to use and do not require reconstitution or mixing with another solution, and can be used with patient-friendly narrow gauge needles and pen systems;

Multiple regulatory precedents. Our current and past DepoFoam products, including DepoCyt(e) and DepoDur, have been approved in the United States and Europe, making regulatory authorities familiar with our DepoFoam

technology;

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Extensive safety history. Our DepoFoam products have over ten years of safety data as DepoCyt(e) has been sold in the United States since 1999;

Proven manufacturing capabilities. We make the DepoFoam-based products, EXPAREL and DepoCyt(e) in our cGMP facilities;

Flexible time release. Encapsulated drug releases over a desired period of time, from 1 to 30 days;

Favorable pharmacokinetics. Decrease in adverse events associated with high peak blood levels, thereby improving the utility of the product;

Shortened development timeline. Does not alter the native molecule, potentially enabling the filing of a 505(b)(2) application; and

Aseptic manufacturing and filling. Enables use with proteins, peptides, nucleic acids, vaccines and small molecules. Other Products

DepoCyt(e)

DepoCyt(e) is a sustained-release liposomal formulation of the chemotherapeutic agent cytarabine utilizing our DepoFoam technology. DepoCyt(e) is indicated for the intrathecal treatment of lymphomatous meningitis, a life-threatening complication of lymphoma, a cancer of the immune system. Lymphomatous meningitis can be controlled with conventional cytarabine, but because of the drug's short half-life, a spinal injection is required twice per week, whereas DepoCyt(e) is dosed once every two weeks in an outpatient setting. DepoCyt(e) was granted accelerated approval by the FDA in 1999 and full approval in 2007. We recognized revenue from DepoCyt(e) of \$8.4 million from our commercial partners in 2013.

**Product Candidates** 

**DepoNSAID** 

Our preclinical product candidates, extended release formulations of NSAIDs, are designed to provide the benefits of injectable NSAIDs with a prolonged duration of action in order to improve patient care and ease of use in the acute pain environment. Currently available injectable systemic products provide a four to six hour duration of action. We believe that there is an unmet medical need for a product which could provide a local infiltration since the mode of action for NSAIDs is by local activity. A product developed for local infiltration should provide pain relief with a much lower dose of NSAID and potentially avoid the side effects commonly associated with the systemic use of these agents. We have DepoFoam formulations for several NSAIDs, and we expect to select a lead product candidate in 2014.

Commercial Partners and Agreements

SkyePharma Holdings, Inc.

In connection with the stock purchase agreement related to the Acquisition, we agreed to pay SkyePharma Holdings, Inc., or Skyepharma, specified contingent milestone payments related to EXPAREL sales as set forth below:

(i)\$10.0 million upon first commercial sale in the United States;

(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;

(iv)\$8.0 million when annual net sales collected reach \$250.0 million; and

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

The first contingency was resolved in April 2012, resulting in a \$10.0 million payment to Skyepharma. Additionally, we agreed to pay to Skyepharma 3% of net sales of EXPAREL collected in the United States, Japan, the United Kingdom, France, Germany, Italy and Spain. Such obligations to make percentage payments will continue for

the term in which such sales related to EXPAREL are covered by a valid claim in certain patent rights related to EXPAREL and other

biologics products. The expiration date of the last valid claim will occur in 2018. Cumulatively through December 31, 2013, Skyepharma has earned \$2.4 million of percentage payments on net sales of EXPAREL collected. We have the right to cease paying the 3% percentage payments in the event that Skyepharma breaches certain covenants not to compete contained in the stock purchase agreement. In the event that we cease to sell EXPAREL and begin marketing a similar replacement product for EXPAREL, we would no longer be obligated to make percentage payments, but we may be required to make certain milestone payments upon reaching certain sales milestones.

For additional information related to the Skyepharma agreement, please refer to Note 6, Goodwill and Intangible Assets, in the Consolidated Financial Statements.

Research Development Foundation

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

Sigma-Tau Pharmaceuticals, Inc.

In December 2002, we entered into a supply and distribution agreement with Enzon Pharmaceuticals Inc. regarding the sale of DepoCyt. Pursuant to the agreement, Enzon was appointed the exclusive distributor of DepoCyt in the United States and Canada for a ten-year term. In January 2010, Sigma-Tau Pharmaceuticals, Inc., or Sigma-Tau, acquired the rights to sell DepoCyt from Enzon Pharmaceuticals for the United States and Canada. Under the supply and distribution agreement, we supply unlabeled DepoCyt vials to Sigma-Tau for finished packaging. Under these agreements, we receive a fixed payment for manufacturing the vials of DepoCyt and an additional royalty payment, if Sigma-Tau's quarterly net sales exceed a certain amount, which brings total payments in the thirty percent range on sales by Sigma-Tau in the United States and Canada.

We and Sigma-Tau have the right to terminate the agreement for an uncured material breach by the other party or in the event that a generic pharmaceutical product that is therapeutically equivalent to DepoCyt is commercialized. We may terminate the agreement if certain minimum sales targets are not met by Sigma-Tau. Sigma-Tau may terminate the agreement if, as a result of a settlement or a final court or regulatory action, the manufacture, use or sale of DepoCyt in the United States is prohibited.

Mundipharma International Holdings Limited

In June 2003, we entered into an agreement granting Mundipharma International Holdings Limited, or Mundipharma, exclusive marketing and distribution rights to DepoCyte in the European Union and certain other European countries. This agreement has a term of 15 years, and after that term expires, continues year to year unless terminated by us or by Mundipharma upon no less than 12 months written notice.

Under the agreement, as amended, and a separate supply agreement, we receive a fixed payment for manufacturing the vials of DepoCyte, as well as a royalty in addition to the fixed sum per vial supplied to Mundipharma, if Mundipharma's quarterly net sales exceed a certain amount, and a mid single-digit royalty on all annual sales exceeding a certain amount. 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 we do not expect to receive the remaining €7.5 million.

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

Paul Capital Advisors LLC

On March 23, 2007, we entered into an amended and restated royalty interests assignment agreement with Paul Capital Advisors LLC, or Paul Capital, pursuant to which we assigned to Paul Capital the right to receive a portion of our

royalty payments from DepoCyt(e) and DepoDur. The original agreement was entered into prior to the Acquisition by Skyepharma in order to monetize certain royalty payments from DepoCyt(e) and DepoDur. In connection with the Acquisition, the original agreement with Paul Capital was amended and restated and the responsibility to pay the royalty interest in product sales of DepoCyt(e) and DepoDur was transferred to us and we were required to make payments to Paul Capital upon the occurrence of certain events. For additional information, see "Management's Discussion and Analysis of Financial Condition and Results of Operations-Liquidity and Capital Resources-Royalty Interests Assignment Agreement" and "Risk Factors-Risks Related to Our Financial Condition and Capital Requirements." Under our financing arrangement with Paul Capital, upon the occurrence of certain events, Paul Capital may require us to repurchase the right to receive royalty payments that we assigned to it, or may foreclose on certain assets that secure our obligations to Paul Capital. Any exercise by Paul Capital of its right to cause us to repurchase the assigned right or any foreclosure by Paul Capital would adversely affect our results of operations and our financial condition. This financing arrangement terminates on December 31, 2014.

Aratana Therapeutics, Inc.

On December 5, 2012 we entered into an Exclusive License, Development and Commercialization Agreement and related Supply Agreement with Aratana Therapeutics, Inc. or Aratana. Under the agreements, we granted Aratana an exclusive royalty-bearing license, including the limited right to grant sublicenses, for the development and commercialization of our bupivacaine liposome injectable suspension product for animal health indications. Under the agreement, Aratana will develop and seek approval for the use of the product in veterinary surgery to manage postsurgical pain, focusing initially on developing it for cats, dogs and other companion animals.

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

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

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

Effective October 1, 2013, we and CrossLink commenced a five-year arrangement for the promotion and sale of EXPAREL, pursuant to the terms of a Master Distributor Agreement (as amended, the "Agreement"). We entered into the Agreement on March 11, 2013, which provided for an initial small-scale pilot period commencing on April 1, 2013 and ending on September 30, 2013 (the "Pilot Period"), during which CrossLink was appointed as the exclusive distributor of EXPAREL for certain specified accounts. The Agreement permitted either party to terminate the Agreement within 15 days prior to the expiration of the Pilot Period, and unless such termination was effected, the

Agreement would automatically renew for a term of five years, commencing on October 1, 2013 and ending on September 30, 2018 (the "Term"). Neither party provided notice of termination, and upon the commencement of the Term, certain performance metrics and payment terms became effective, and CrossLink's distribution territory expanded.

Under the Agreement, we appointed CrossLink as the exclusive third-party distributor during the Term to promote and sell EXPAREL for orthopedic and spine surgeries in the United States, with the exception of certain geographical areas and

accounts (the "Territory"). The prices and purchasing terms related to sales of EXPAREL are determined by us, and all orders are subject to acceptance or rejection by us. CrossLink is entitled to receive commissions on its sales of EXPAREL in the Territory, subject to certain conditions and adjustments. CrossLink may receive additional performance-based payments if it achieves certain sales goals, and we may terminate the Agreement if CrossLink fails to meet certain minimum performance metrics.

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

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

### Significant Customers

We had three customers each comprising 10% or more of our total revenue for the year ended December 31, 2013. AmerisourceBergen Health Corporation, Cardinal Health, Inc. and McKesson Drug Company accounted for 33%, 28%, and 18% of our revenues, respectively. These customers are wholesalers that process orders for EXPAREL under a drop-ship program.

### Manufacturing

We manufacture EXPAREL and DepoCyt(e) in two manufacturing facilities that we refer to as the Science Center Campus 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. Our facilities are inspected regularly and approved for pharmaceutical manufacturing by the FDA, the European Medicines Agency, or the EMA, the Medicines and Healthcare Products Regulatory Agency, or the MHRA, the Drug Enforcement Administration, or the DEA, and the Environmental Protection Agency, or the EPA.

We 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 any control over the process or timing of the acquisition of these raw materials from our suppliers.

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

Building 1 is an approximately 84,000 square foot concrete structure located on a five acre site. It was custom built as a pharmaceutical R&D and manufacturing facility in August 1995. Activities in this facility include the manufacture of EXPAREL bulk pharmaceutical product candidate in a dedicated production line and its fill/finish into vials, microbiological and quality control testing, product storage, development of analytical methods, research and development, the coordination of clinical and regulatory functions, and general administrative functions. To date, the bulk manufacturing of all EXPAREL product sold to the marketplace has occurred in a manufacturing line housed in what we refer to as Suite A. We are currently working to expand our manufacturing capacity and anticipate receiving FDA approval for our newly installed manufacturing line, referred to as Suite C, in the second quarter of 2014. Combined with Suite A, we expect Suite C to significantly increase our manufacturing capacity and ability to meet the growing demand for EXPAREL. We plan to further expand our manufacturing capacity either directly or through

third parties as demand for EXPAREL increases.

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.

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).

Intellectual Property and Exclusivity

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

Patents and Patent Applications

We seek to protect the proprietary position of our product candidates by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. As of December 31, 2013, there are over 14 families of patents and patent applications relating to various aspects of the DepoFoam delivery technology. Patents have been issued in numerous countries, with an emphasis on the North American, European and Japanese markets. These patents generally have a term of 20 years from the date of the nonprovisional filing unless referring to an earlier filed application. Some of our U.S. patents have a term from 17 years from the grant date. Our issued patents expire at various dates in the future, with the last currently issued patent expiring in 2019.

In regards to patents providing protection for EXPAREL, issued patents in the United States relating to the composition of the product candidate and methods for modifying the rate of drug release of the product candidate expire in September 2018 and January 2017, respectively. A patent relating to compositions including EXPAREL, but not EXPAREL specifically, expired in November 2013. Pending U.S. applications relating to the composition of the product candidate and the process for making the product candidate, if granted, would expire in September 2018 and November 2018, respectively. In Europe, granted patents related to the composition of the product candidate expire in November 2014 and September 2018. Pending applications in Europe relating to methods of modifying the rate of drug release of the product candidate and the process for making the product candidate, if granted, would expire in January 2018 and November 2018, respectively. In April 2010, a provisional patent was filed relating to a new process to manufacture EXPAREL and other DepoFoam-based products. The process offers many advantages to the current process, including larger scale production and lower manufacturing costs. In April 2011, we filed a non-provisional patent application which, if granted, could prevent others from using this process until 2031. Furthermore, a non-exclusively licensed patent of ours relating to EXPAREL was allowed in Europe with an expiration date in October 2021 and was extended in the United States until October 2023.

### Trade Secrets and Proprietary Information

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

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or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

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

EXPAREL is competing with elastomeric pump/catheter devices intended to provide bupivacaine over several days. I-FLOW Corporation (acquired by Kimberly-Clark Corporation in 2009) has marketed these medical devices in the United States since 2004. In addition, we anticipate that EXPAREL will compete with currently marketed bupivacaine and opioid analgesics such as morphine.

Government Regulation

Federal Food, Drug and Cosmetic Act

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

New Drug Applications

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

completion of preclinical laboratory and animal testing and formulation studies in compliance with the FDA's Good Laboratory Practice, or GLP, regulations;

submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin in the United States;

approval by an independent institutional review board, or IRB, at each clinical trial site before each trial may be initiated;

performance of human clinical trials, including adequate and well-controlled clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each intended use;

submission of an NDA to the FDA;

satisfactory completion of an FDA pre-approval inspection of the product's manufacturing facility or facilities to assess compliance with the FDA's cGMP regulations, and to ensure that the facilities, methods and controls are adequate to preserve the drug's identity, quality and purity;

satisfactory completion of an FDA advisory committee review, if applicable; and

approval by the FDA of the NDA.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that the FDA will grant approvals for any of our product candidates on a timely basis, if at all. Preclinical tests include laboratory evaluation of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals. The results of preclinical tests, together with manufacturing information, analytical data and a proposed clinical trial protocol and other information, are submitted as part of an IND application to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the trial on a clinical hold because of, among other things, concerns about the conduct of the clinical trial or about exposure of human research subjects to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Our submission of an IND may not result in FDA authorization to commence a clinical trial. In addition, the FDA requires to amend an existing IND for each successive clinical trial conducted during product development. Further, an independent institutional review board, or IRB, covering each medical center proposing to conduct the clinical trial must review and approve the plan for any clinical trial and informed consent information for subjects before the clinical trial commences at that center, and it must monitor the clinical trial until completed. The FDA, the IRB or the sponsor may suspend a clinical trial at any time, or from time to time, on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

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

Phase 1: sponsors initially conduct clinical trials in a limited population to test the product candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients, such as cancer patients.

Phase 2: sponsors conduct clinical trials generally in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted indications and to determine dose tolerance and optimal dosage. Sponsors may conduct multiple Phase 2 clinical trials to obtain information prior to beginning larger and more extensive Phase 3 clinical trials.

Phase 3: these include expanded controlled and uncontrolled trials, including pivotal clinical trials. When Phase 2 evaluations suggest the effectiveness of a dose range of the product and acceptability of such product's safety profile, sponsors undertake Phase 3 clinical trials in larger patient populations to obtain additional information needed to evaluate the overall benefit and risk balance of the drug and to provide an adequate basis to develop labeling.

In addition, sponsors may elect to conduct, or be required by the FDA to conduct, 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.

Sponsors submit the results of product development, preclinical studies and clinical trials to the FDA as part of an NDA. NDAs must also contain extensive information relating to the product's pharmacology, chemistry, manufacture, controls and proposed labeling, among other things. In addition, 505(b)(2) applications must contain a patent certification for each patent listed in FDA's "Orange Book" that covers the drug referenced in the application and upon which the third-party studies were conducted. For some drugs, the FDA may require risk evaluation and mitigation strategies, or REMS, which could include medication guides, physician communication plans, or restrictions on distribution and use, such as limitations on who may prescribe the drug or where it may be dispensed or administered. Upon receipt, the FDA has 60 days to determine whether the NDA is sufficiently complete to initiate a substantive review. If the FDA identifies deficiencies that would preclude substantive review, the FDA will refuse to accept the NDA and will inform the sponsor of the deficiencies that must be corrected prior to resubmission. If the FDA accepts the submission for substantive review, the FDA typically reviews the NDA in accordance with established

timeframes. Under PDUFA, the FDA agrees to specific goals for NDA review time through a two-tiered classification system, Priority Review and Standard Review. A Priority Review designation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. For a Priority Review application, the FDA aims to complete the initial review cycle for New Molecular Entities, or NMEs, within six months of the 60 day filing date, and for Non-NMEs within six months of the date of receipt. Standard Review applies to all applications that are not eligible for Priority Review. The FDA aims to complete Standard Review NDAs for NMEs within ten-months of the 60 day filing date, and for Non-NMEs within ten months of the date of receipt. Review processes often extend significantly beyond anticipated completion dates due to FDA requests for additional information or clarification, difficulties scheduling an advisory committee meeting, negotiations regarding REMS, or FDA workload issues. The FDA may refer the application to an advisory committee

for review, evaluation and recommendation as to the application's approval. The recommendations of an advisory committee do not bind the FDA, but the FDA generally follows such recommendations.

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

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

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

Section 505(b)(2) New Drug Applications

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

Section 505(b)(2) applications are subject to any non-patent exclusivity period applicable to the referenced product, which may delay approval of the 505(b)(2) application even if FDA has completed its substantive review and determined the drug should be approved. In addition, 505(b)(2) applications must include patent certifications to any patents listed in the Orange Book as covering the referenced product. If the 505(b)(2) applicant seeks to obtain approval before the expiration of an applicable listed patent, the 505(b)(2) applicant must provide notice to the patent owner and NDA holder of the referenced product. If the patent owner or NDA holder bring a patent infringement lawsuit within 45 days of such notice, the 505(b)(2) application cannot be approved for 30 months or until the 505(b)(2) applicant prevails, whichever is sooner. If the 505(b)(2) applicant loses the patent infringement suit, FDA may not approve the 505(b)(2) application until the patent expires, plus any period of pediatric exclusivity. In the NDA submissions for our product candidates, we intend to follow the development and approval pathway permitted under the FDCA that we believe will maximize the commercial opportunities for these product candidates. Post-Approval Requirements

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

If new safety issues are identified following approval, the FDA can require the NDA sponsor to revise the approved labeling to reflect the new safety information; conduct post-market studies or clinical trials to assess the new safety

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

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. If after approval the FDA determines that the product does not meet applicable regulatory requirements or poses unacceptable safety risks, the FDA may take other regulatory actions, including initiating suspension or withdrawal of the NDA approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;

fines, warning letters or holds on post-approval clinical trials;

refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;

• product seizure or detention, or refusal to permit the import or export of products; or

injunctions or the imposition of civil or criminal penalties.

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

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

In addition to regulations in the United States, we are subject to a variety of foreign regulations governing clinical trials and the commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of foreign countries before we can

commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

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

The Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the EMA, and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

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

As with FDA approval, we may not be able to secure regulatory approvals in Europe in a timely manner, if at all. Additionally, as in the United States, post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution, would apply to any product that is approved in Europe, and failure to comply with such obligations could have a material adverse effect on our ability to successfully commercialize any product. The conduct of clinical trials in the EU is governed by the EU Clinical Trials Directive (Directive 2001/20/EC of 4 April 2001, of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use). The provisions of the EU Clinical Trials Directive were required to be implemented and applied by the EEA Member States before May 2004. The EU Clinical Trials Directive harmonizes the regulatory requirements of the Member States of the EEA for the conduct of clinical trials in their respective territories. The EU Clinical Trials Directive requires sponsors of clinical trials to submit formal applications to, and to obtain the approval of, national ethics committees and regulatory authorities prior to the initiation of clinical trials.

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

Third Party Payer Coverage and Reimbursement

The commercial success of our 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, which could impact our ability to sell our products at a price level high enough to realize an appropriate return on our investment.

For example, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, which we refer to collectively as the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The Health Care Reform Law 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 Health Reform Law also established a new Medicare Part D coverage gap discount program, in which drug manufacturers must provide 50% point-of-sale discounts on products covered under Part D beginning in 2011. Further, also beginning in 2011, the new law 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. Some details of the Health Care Reform Law are yet to be determined, as applicable federal and state agencies must issue regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs, Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products.

In addition, other legislative changes have been proposed and adopted since the Health Care Reform Law was enacted, which could result in reductions in Medicare payments to providers. The full impact on our business of these legislative actions is uncertain. Nor is it clear whether other legislative changes will be adopted, if any, or how such changes would affect the demand for our products.

The cost of pharmaceuticals continues to generate substantial governmental and third-party payer interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Our results of operations could be adversely affected by current and future healthcare reforms. Ongoing federal and state government initiatives directed at lowering the total cost of health care will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid payment systems. Examples of how limits on drug coverage and reimbursement in the United States may cause reduced payments for drugs in the future include:

changing Medicare reimbursement methodologies;

fluctuating decisions on which drugs to include in formularies;

revising covered outpatient drug rebate calculations under the Medicaid program; and

reforming drug importation laws.

Some third-party payers also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers that use such therapies or place limits on the amount of reimbursement. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and to operate at a reasonable return on investment. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. There can be no assurance that our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third-party payers, or that an adequate level or reimbursement will be available so that the third-party

payers' reimbursement policies will not adversely affect our ability to sell our products profitably. Marketing/Data Exclusivity

The FDA may grant three or five years of marketing exclusivity in the United States for the approval of new or supplemental NDAs, including Section 505(b)(2) NDAs, for, among other things, new indications, dosages or dosage forms of an existing drug, if new clinical investigations that were conducted or sponsored by the applicant are essential to the approval

of the application. Additionally, six months of marketing exclusivity in the United States is available under Section 505A of the FDCA if, in response to a written request from the FDA, a sponsor submits and the agency accepts requested information relating to the use of the approved drug in the pediatric population. This six month pediatric exclusivity period is not a standalone exclusivity period, but rather is added to any existing patent or non-patent exclusivity period for which the drug product is eligible. Based on our clinical trial program for EXPAREL, FDA granted three years of marketing exclusivity to EXPAREL, which expires on October 28, 2014. Manufacturing Requirements

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

## Healthcare Fraud and Abuse Laws

We are subject to various federal, state and local laws targeting fraud and abuse in the healthcare industry. For example, in the United States, there are federal and state anti-kickback laws that prohibit the offer, payment or receipt of kickbacks, bribes or other remuneration intended to induce the purchase or recommendation of healthcare products and services or reward purchases or recommendations. Violations of these laws can lead to civil and criminal penalties, including fines, imprisonment and exclusion from participation in federal healthcare programs. These laws are potentially applicable to manufacturers of products regulated by the FDA and reimbursed by federal healthcare programs, such as us, and to hospitals, physicians and other potential purchasers of such products. In particular, the federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. The term "remuneration" is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, including gifts, discounts, the provision of goods and services, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. In addition, the Health Care Reform Law, among other things, amends the intent requirement of the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 U.S.C. § 1320a-7b. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the Health Care Reform Law provides that the federal government may assert that a reimbursement claim for items or services resulting from a violation of 42 U.S.C. § 1320a-7b constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute, which imposes a penalty of \$5,000 against any person who is determined to have presented or caused to be presented claims to a federal health care program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Moreover, the lack of uniform court interpretation of the Anti-Kickback Statute makes compliance with the law difficult.

Recognizing that the federal Anti-Kickback Statute is broad and may prohibit innocuous or beneficial arrangements within the healthcare industry, the statute establishes certain exemptions from the statutory prohibition and authorizes additional exemptions by regulation. Pursuant to this authority, the U.S. Department of Health and Human Services'

Office of Inspector General, or OIG, issued regulations in July of 1991, and periodically since that time, which the OIG refers to as "safe harbors." These safe harbor regulations set forth certain provisions which, if met in form and substance, will assure pharmaceutical companies, healthcare providers and other parties that they will not be prosecuted under the federal Anti-Kickback Statute. Although full compliance with these provisions ensures against prosecution under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued. However,

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

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

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

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

In addition, under California law, pharmaceutical companies must adopt a comprehensive compliance program that is in accordance with both the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, or OIG Guidance, and the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals, or the PhRMA Code. The PhRMA Code seeks to promote transparency in relationships between health care professionals and the pharmaceutical industry and to ensure that pharmaceutical marketing activities comport with the highest ethical standards. The PhRMA Code contains strict limitations on certain interactions between health care professionals and the pharmaceutical industry relating to gifts, meals, entertainment and speaker programs, among others. Also, certain states, such as Massachusetts, Minnesota, Vermont and others, have imposed restrictions on the types of interactions that pharmaceutical and medical device

companies or their agents (e.g., sales representatives) may have with health care professionals, including bans or strict limitations on the provision of meals, entertainment, hospitality, travel and lodging expenses, and other financial support, including funding for continuing medical education activities.

Healthcare Privacy and Security Laws

We may be subject to, or our marketing activities may be limited by, HIPAA, and its implementing regulations, which established uniform standards for certain "covered entities" (healthcare providers, health plans and healthcare clearinghouses) governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health

information. The American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, included sweeping expansion of HIPAA's privacy and security standards called the Health Information Technology for Economic and Clinical Health Act, or HITECH, which became effective on February 17, 2010. Among other things, the new law makes HIPAA's privacy and security standards directly applicable to "business associates"-independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions.

### **Environmental Matters**

Our research and development processes and our manufacturing processes involve the controlled use of hazardous materials, 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, 2013, we had 310 employees, of which two were part-time. All of our employees are located in the United States. None of our employees are represented by a labor union, and we consider our current employee relations to be good.

# **Available Information**

Item 1A. Risk Factors

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.

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 2013, sales of EXPAREL constituted a significant portion of our total revenue, and our success depends on our ability to continue to effectively commercialize EXPAREL. Our ability to effectively generate revenues from EXPAREL will depend on our ability to, among other things:

create market demand for EXPAREL through our marketing and sales activities and other arrangements established for the promotion of EXPAREL;

train, deploy and support a qualified sales force;

secure formulary approvals for EXPAREL at a substantial number of targeted hospitals;

manufacture EXPAREL in sufficient quantities in compliance with requirements of the FDA and similar foreign regulatory agencies and at acceptable quality and pricing levels in order to meet commercial demand;

implement and maintain agreements with wholesalers, distributors and group purchasing organizations on commercially reasonable terms;

receive adequate levels of coverage and reimbursement for EXPAREL from commercial health plans and governmental health programs;

maintain compliance with regulatory requirements;

obtain regulatory approvals for additional indications for the use of EXPAREL;

ensure that our entire supply chain efficiently and consistently delivers EXPAREL to our customers; and maintain and defend our patent protection and regulatory exclusivity for EXPAREL.

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

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

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

If EXPAREL does not achieve broad market acceptance, the revenues that we generate from its sales will be limited. The degree of market acceptance of EXPAREL also depends on a number of other factors, including: changes in the standard of care for the targeted indications for EXPAREL, which could reduce the marketing impact of any claims that we can make:

the relative efficacy, convenience and ease of administration of EXPAREL;

the prevalence and severity of adverse events associated with EXPAREL;

cost of treatment versus economic and clinical benefit, both in absolute terms and in relation to alternative treatments; the availability of adequate coverage or reimbursement by third parties, such as insurance companies and other healthcare payers, and by government healthcare programs, including Medicare and Medicaid;

the extent and strength of our marketing and distribution of EXPAREL;

the safety, efficacy and other potential advantages over, and availability of, alternative treatments, including, in the case of EXPAREL, a number of products already used to treat pain in the hospital setting; and distribution and use restrictions imposed by the FDA or to which we agree as part of a mandatory risk evaluation and mitigation strategy or voluntary risk management plan.

Our ability to effectively promote and sell EXPAREL and any product candidates that we may develop, license or acquire in the hospital marketplace will also depend on pricing and cost effectiveness, including our ability to produce a product at a competitive price and therefore achieve acceptance of the product onto hospital formularies, and our ability to obtain sufficient third-party coverage or reimbursement. Since many hospitals are members of group purchasing organizations, which leverage

the purchasing power of a group of entities to obtain discounts based on the collective buying power of the group, our ability to attract customers in the hospital marketplace will also depend on our ability to effectively promote our product candidates to group purchasing organizations. We will also need to demonstrate acceptable evidence of safety and efficacy, as well as relative convenience and ease of administration. Market acceptance could be further limited depending on the prevalence and severity of any expected or unexpected adverse side effects associated with our product candidates.

In addition, the labeling approved by the FDA does not contain claims that EXPAREL is safer or more effective than competitive products and does not permit us to promote EXPAREL as being superior to competing products. Further, the availability of inexpensive generic forms of postsurgical pain management products may also limit acceptance of EXPAREL among physicians, patients and third-party payers. If EXPAREL does not achieve an adequate level of acceptance among physicians, patients and third-party payers, we may not generate meaningful revenues from EXPAREL and we may not become profitable.

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

The pharmaceutical and biotechnology industries are intensely competitive and subject to rapid and significant technological change. Our major competitors include organizations such as major multinational pharmaceutical companies, established biotechnology companies and specialty pharmaceutical and generic drug companies. Many of our competitors have greater financial and other resources than we have, such as larger research and development staff, more extensive marketing, distribution, sales and manufacturing organizations and experience, more extensive clinical trial and regulatory experience, expertise in prosecution of intellectual property rights and access to development resources like personnel and technology. As a result, these companies may obtain regulatory approval more rapidly than we are able to and may be more effective in selling and marketing their products. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis technologies and drug products that are more effective or less costly than EXPAREL or any product candidate that we are currently developing or that we may develop, which could render our products obsolete and noncompetitive or significantly harm the commercial opportunity for EXPAREL or our product candidates.

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

EXPAREL competes with well-established products with similar indications. Competing products available for postsurgical pain management include opioids such as morphine, fentanyl, meperidine and hydromorphone, each of which is available generically from several manufacturers, and several of which are available as proprietary products using novel delivery systems. Ketorolac, an injectable non-steroidal anti-inflammatory drug, or NSAID, is also available generically in the United States from several manufacturers, and Caldolor (ibuprofen for injection), an NSAID, has been approved by the FDA for pain management and fever in adults. In addition, EXPAREL 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) has marketed these medical devices in the United States since 2004.

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

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

In addition to our internal marketing and sales efforts, we have entered into agreements with third party distributors to promote and sell EXPAREL in certain territories. For example, following a pilot program, effective October 1, 2013, we appointed CrossLink as our exclusive third-party distributor to promote and sell EXPAREL for orthopedic and spine surgeries

in the U.S., with the exception of certain geographical areas and accounts, for a five year term. We may seek additional distribution arrangements in the future, including arrangements with third party distributors to commercialize and sell EXPAREL in certain foreign countries. The use of distributors involves certain risks, including risks that such distributors will:

not effectively distribute or support our products;

not provide us with accurate or timely information regarding their inventories, the number of accounts using our products or complaints about our products;

fail to comply with their obligations to us;

fail to comply with laws and regulations to which they are subject, whether in the U.S. or in foreign jurisdictions; reduce or discontinue their efforts to sell or promote our products; or rease 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, and financial management and information technology services. In addition, most of our inventory is stored at a single warehouse maintained by one such service provider. 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 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, 2013, we had 310 employees. We may need to expand our personnel resources in order to manage our operations and sales of EXPAREL. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. In addition, we may not be able to recruit and retain qualified personnel in the future, particularly marketing positions, due to competition for personnel among pharmaceutical businesses, and the failure to do so could have a significant negative impact on our future product revenues and business results. Our need to effectively manage our operations, growth and various projects requires that we:

continue the hiring and training of an effective commercial organization for the commercialization of EXPAREL, and establish appropriate systems, policies and infrastructure to support that organization;

continue to establish and maintain effective relationships with distributors and commercial partners for the promotion and sale of our products;

ensure that our distributors, partners, suppliers, consultants and other service providers successfully carry out their contractual obligations, provide high quality results, and meet expected deadlines;

manage our development efforts and clinical trials effectively;

expand our manufacturing capabilities;

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 president, chief executive officer and chairman. If we lose one or more of these key employees, our ability to successfully implement our business strategy could be seriously harmed. Replacing key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate additional key personnel.

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

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

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for DepoCyt(e), 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. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

loss of revenue from decreased demand for our products and/or product candidates;

impairment of our business reputation or financial stability;

costs of related litigation;

substantial monetary awards to patients or other claimants;

diversion of management attention;

loss of revenues;

withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs; and the inability to commercialize our product candidates.

We have obtained limited product liability insurance coverage for our products and our clinical trials with a \$10.0 million annual aggregate coverage limit. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage 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 and 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 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 drug 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.

In addition to expanding our internal manufacturing facilities, we may enter into arrangements with third parties to manufacture, supply, test and/or store EXPAREL or our other products. Entering into such arrangements requires testing and compliance inspections, FDA approvals, and development of the processes 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, financial risks in connection with our investment in setting up a third party manufacturing process and inabilities to fulfill our commercial needs.

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

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

We are currently the sole manufacturer of EXPAREL and DepoCyt(e). 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 Medicines and Healthcare products Regulatory Agency, or 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 (EU) 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.

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

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

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

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

significant capital expenditures;

difficulty or inability to secure financing to fund development activities for such development, acquisition or in-licensed products or technologies;

incurrence of substantial debt or dilutive issuances of securities to pay for development, acquisition or in-licensing of new products;

disruption of our business and diversion of our management's time and attention;

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 likely will have access to greater financial resources, research and development staffs and facilities than us and may have greater expertise in identifying and evaluating new opportunities. We may not be successful in locating and acquiring or in-licensing additional desirable product candidates on acceptable terms or at all. Moreover, we may devote resources to potential development, acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts.

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

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

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

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, human error, unauthorized access, natural disasters, intentional acts of vandalism, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed clinical trials for EXPAREL could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of our product candidates may be delayed. Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our product candidates.

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

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

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

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, and other regulatory authorities in the U.S. 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 that could delay or prevent us from receiving regulatory approval or commercializing our drug products. In addition, the results of pre-clinical studies and early-stage clinical trials of

our drug products do not necessarily predict the results of later-stage clinical trials. Later-stage clinical trials may fail to demonstrate that a drug product is safe and effective despite having progressed through initial clinical testing. Even if we believe the data collected from clinical trials of our drug products is promising, such data may not be sufficient to support approval by the FDA or any other U.S. or foreign regulatory approval. 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 that conduct the clinical testing may devote to our clinical trials. 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 will be unable to complete these trials or to complete them as planned, 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 good clinical practices, 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. Regulatory Risks

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 products, which would be time-consuming and 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 will be 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 may be 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 drug as a result of undesirable side effects identified during clinical testing, the FDA may decline to approve the drug at the end of the NDA review period or issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve the drug. The number of such requests for additional data or information issued by the FDA in recent years has increased, and resulted in substantial delays in the approval of several new drugs. Undesirable side effects caused by EXPAREL or any product candidate could also result in the inclusion of unfavorable information in our product labeling, imposition of distribution or use restrictions, a requirement to conduct post-market studies or to implement a risk evaluation and mitigation strategy, denial, suspension or withdrawal of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing and generating revenues from the sale of EXPAREL or any product candidate.

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

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

regulatory authorities may require the addition of unfavorable labeling statements, specific warnings or contraindications (including boxed warnings);

regulatory authorities may suspend or withdraw their approval of the product, or require it to be removed from the market:

regulatory authorities may impose restrictions on the distribution or use of the product;

we may be required to change the way the product is administered, conduct additional clinical trials, reformulate the product, change the labeling of the product or change or obtain re-approvals of manufacturing facilities;

sales of the product may be significantly decreased from projected sales;

we may be subject to government investigations, product liability claims and litigation; and our reputation may suffer.

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

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

Any regulatory approval is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA. For example, the FDA-approved label for EXPAREL does not include an indication in obstetrical paracervical block anesthesia. In addition to the FDA approval required for new formulations, any new

indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products and product candidates, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. Although recent court decisions

suggest that certain off-label promotional activities may be protected under the First Amendment, the scope of any such protection is unclear. If our promotional activities fail to comply with the FDA's regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating 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 fail to comply with federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

As a pharmaceutical company, even though we do not provide healthcare services or receive payments directly from or bill directly to Medicare, Medicaid or other third-party payers for our products, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We would be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include: the federal Anti-Kickback Statute, which constrains our marketing practices, educational programs, pricing policies and relationships with healthcare providers or other entities, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under federally funded healthcare programs, such as the Medicare and Medicaid programs;

federal civil and criminal false claims and false statement laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent or making any materially false statement in connection with the delivery or payment for healthcare benefits, items, or services; the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended, which created federal criminal and civil statutes that prohibit executing a scheme to defraud any healthcare benefit program; federal physician self-referral laws, such as the Stark law, which prohibit a physician from making a referral to a provider of certain health services with which the physician or the physician's family member has a financial interest, and prohibit submission of a claim for reimbursement pursuant to a prohibited referral;

HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under the U.S. federal Anti-Kickback Statute, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Moreover, recent health care reform legislation has strengthened these laws. For example, the Health Care Reform Law, among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes; a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Health Care Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. Recently, several pharmaceutical and other healthcare companies have been prosecuted under the federal false claims laws for allegedly inflating drug prices they report to pricing services, which in turn are used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal

programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. To the extent that any product we make is sold in a foreign country, we may be subject to similar foreign laws and regulations.

Further, there has been a recent trend in the increase of federal and state laws and regulations regarding consulting arrangements with physicians. The Health Care Reform Law imposes new requirements to report certain financial arrangements with physicians and others, including reporting any "transfer of value" made or distributed to prescribers and other healthcare providers and reporting any investment interests held by physicians and their immediate family members during each calendar year beginning in 2013, subject to federal implementation and enforcement policies. In addition, some states such as California, Massachusetts and Vermont, mandate that we comply with a state code of conduct, adopt a company code of conduct under state criteria, disclose marketing payments made to physicians, and/or report compliance information to

the state authorities. Some states, such as Massachusetts, have created an internet database to provide disclosed information on certain transactions with physicians to the public. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply in multiple jurisdictions with different compliance and reporting requirements increases the possibility that a pharmaceutical company may run afoul of one or more of the requirements.

If our past or present operations, or those of our distributors are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in U.S. federal or state health care programs, and the curtailment or restructuring of our operations. Similarly, if the healthcare providers, distributors or other entities with whom we do business are found to be out of compliance with applicable laws and regulations, they may be subject to sanctions, which could also have a negative impact on us. The risk of being found to have violated such laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any penalties, damages, fines, curtailment or restructuring of our operations could materially adversely affect our ability to operate our business and our financial results. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

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

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

The manufacturing techniques and facilities used for the manufacture and supply of our products must be operated in conformity with cGMP and other FDA, DEA 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 would also require conformity with cGMP and other FDA, DEA and MHRA regulations. In complying with these requirements, we, along with our suppliers, must continually expend time, money and effort in production, record keeping, and quality assurance and control to ensure that our products meet applicable specifications and other requirements for safety, efficacy and quality. In addition, we, along with our suppliers, are subject to unannounced inspections by the FDA, 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. If we fail to comply with the extensive regulatory requirements to which we and our products, EXPAREL and DepoCyt(e), are subject, such products could be subject to restrictions or withdrawal from the market and we could be subject to penalties.

The testing, manufacturing, quality control, labeling, safety, effectiveness, advertising, promotion, storage, sales, distribution, import, export and marketing, among other things, of our products EXPAREL and DepoCyt(e) are subject to extensive regulation by governmental authorities in the United States and elsewhere throughout the world. Quality control and manufacturing procedures regarding EXPAREL and DepoCyt(e) must conform to cGMP.

Regulatory authorities, including the FDA and the MHRA, periodically inspect manufacturing facilities to assess compliance with cGMP. Our failure, or the failure of any contract manufacturers with whom we may work in the future, to comply with the laws administered by the FDA, the MHRA or other governmental authorities could result in, among other things, any of the following:

product recall or seizure;

suspension or withdrawal of an approved product from the market;

interruption of production;

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

fines and other monetary penalties;

eriminal 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 we may develop, license or acquire, if any, are unavailable, or if hospitals choose to use therapies that are less expensive, our revenue and prospects for profitability will be limited.

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

Third-party payers, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. 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.

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

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

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an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, beginning in 2011;

an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1% and 13.0% of the average manufacturer price for most branded and generic drugs, respectively;

a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50.0% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D, beginning in 2011;

extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, effective March 23, 2010;

expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in April 2010 and by adding new mandatory eligibility categories for certain individuals with income at or below 133.0% of the Federal Poverty Level beginning in 2014, thereby potentially increasing both the volume of sales and manufacturers' Medicaid rebate liability; expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program, effective in January 2010;

- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians, effective April 1, 2012, subject to federal implementation and enforcement policies;
- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;

creation of the Independent Payment Advisory Board which, beginning in 2014, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations; and establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending, beginning by January 1, 2011.

These measures could result in decreased net revenues from our pharmaceutical products and decrease potential returns from our development efforts. Congress has also proposed a number of legislative initiatives, including possible repeal of the Health Care Reform Law. At this time, it remains unclear whether there will be any changes made to the Health Care Reform Law, whether to certain provisions or its entirety. In addition, some details regarding the implementation of the Health Care Reform Law are yet to be determined, and at this time, the full effect that the Health Care Reform Law would have on our business remains unclear.

In addition, other legislative changes have been proposed and adopted since the Health Care Reform Law was enacted. For example, on August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. As a result of the failure of the Joint Select Committee to propose, and of Congress to enact, deficit reduction measures of at least \$1.2 trillion for the years 2013 through 2021, the Budget Control Act provides for automatic cuts to be made to most federal government programs, which, with respect to Medicare, would include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. Pursuant to the American Taxpayer Relief Act of 2012, which was enacted by Congress on January 1, 2013, the imposition of these automatic cuts was delayed until March 1, 2013. On March 1, 2013, the President signed an executive order implementing the automatic budget reductions. Pursuant to that order, payments to Medicare providers for services furnished on or after April 1, 2013 were reduced by 2%. In addition, the new law, among other things, reduces Medicare inpatient payment amounts to hospitals and increases the statute of limitations for recovering overpayments from three years to five years. The full impact on our business of this new law, assuming it is implemented, is uncertain. Nor is it clear whether other legislative changes will be adopted or how such changes would affect the demand for our products.

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

In July 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act, or FDASIA. This law makes several significant changes to the Federal Food, Drug, and Cosmetic Act and FDA's processes for reviewing marketing applications that could have a significant impact on the pharmaceutical industry, including, among other things, the following:

reauthorizes the Prescription Drug User Fee Act, or PDUFA, increases the amount of associated user fees, and, for certain types of applications, increases the expected time frame for FDA review of the application; permanently reauthorizes and makes some revisions to the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, which provides for pediatric exclusivity and mandated pediatric assessments for certain types of applications, respectively;

revises certain standards and requirements for FDA inspections of manufacturing facilities and the importation of drug products from foreign countries;

ereates incentives for the development of certain antibiotic drug products;

modifies the standards for accelerated approval of certain new medical treatments;

expands the reporting requirements for potential and actual drug shortages;

requires the FDA to issue a report on, among other things, ensuring safe use of prescription drugs that have the potential for abuse;

requires the FDA to hold a public meeting regarding the potential rescheduling of drug products containing hydrocodone, which was held in January 2013; and

requires electronic submission of certain marketing applications following the issuance of final FDA regulations.

The full impact of FDASIA on our business is uncertain.

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: (1) there is no patent information listed in the FDA's Orange Book with respect to our NDA for EXPAREL; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third-

party's generic drug product. A certification that the new product will not infringe the Orange Book-listed patents for EXPAREL, or that such patents are invalid, is called a paragraph IV certification. If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third-party's ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third-party's ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party. If we do not file a patent infringement lawsuit within the required 45-day period, the third-party's ANDA will not be subject to the 30-month stay. Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business, and may result in unfavorable results that could adversely impact our ability to prevent third parties from competing with our products.

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

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for EXPAREL, DepoCyt(e), 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;

•t 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 U.S. patent application relating to our product candidates or a similar invention, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be

substantial and it is possible that our efforts would be unsuccessful, resulting in a material adverse effect on our U.S. patent position. Furthermore, we may not have identified all United States and foreign patents or published applications that affect our business either by blocking our ability to commercialize our drugs or by covering similar technologies that affect our drug market.

In addition, some countries, including many in Europe, do not grant patent claims directed to methods of treating humans, and in these countries patent protection may not be available at all to protect our product candidates. Even if patents issue, we cannot guarantee that the claims of those patents will be valid and enforceable or provide us with any significant protection against competitive products, or otherwise be commercially valuable to us. 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 patent application has been granted and provides protection through November 2018. In the United States, our application is pending, and if granted, would provide protection for EXPAREL in the United States through November 2018, an existing formulation patent for EXPAREL will expire in November 2013. Once our patents covering EXPAREL have expired, we will be more reliant on trade secrets to protect against generic competition.

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

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

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

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

Our ability to develop, manufacture, market and sell EXPAREL, our DepoFoam drug delivery technology or any product candidates that we may develop, license or acquire depends upon our ability to avoid infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the general fields of pain management and cancer treatment and cover the use of numerous compounds and formulations in our targeted markets. Because of the uncertainty inherent in any patent or other litigation involving proprietary rights, we and our licensors may not be successful in defending intellectual property claims by third parties, which could have a material adverse effect on our results of operations. Regardless of the outcome of any litigation, defending the litigation may be expensive, time-consuming and distracting to management. In addition, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that EXPAREL or DepoCyt(e) may infringe. There could also be existing patents of which we are not aware that EXPAREL or DepoCyt(e) may inadvertently infringe.

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

infringement and other intellectual property claims which, with or without merit, can be expensive and time consuming to litigate and can divert management's attention from our core business;

substantial damages for past infringement which we may have to pay if a court decides that our product infringes on a competitor's patent;

a court prohibiting us from selling or licensing our product unless the patent holder licenses the patent to us, which it would not be required to do;

if a license is available from a patent holder, we may have to pay substantial royalties or grant cross licenses to our patents; and

redesigning our processes so they do not infringe, which may not be possible or could require substantial funds and time.

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

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used

or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Our Financial Condition and Capital Requirements

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

We are a specialty pharmaceutical company with a limited operating history. We have focused primarily on developing and commercializing EXPAREL. We have incurred losses in each year since our inception in December 2006, including net losses of \$63.9 million, \$52.3 million and \$43.3 million, for the years ended December 31, 2013, 2012 and 2011, respectively. As of December 31, 2013, we had an accumulated deficit of \$296.4 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 expect to continue to incur significant losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. We may never become profitable.

Our ability to become profitable depends upon our ability to generate revenue from EXPAREL. 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. We also do not anticipate that we will achieve profitability for a period of time after generating material revenues, if ever. If we are unable to generate revenues, we will not become profitable and may be unable to continue operations without continued funding.

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

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

Our 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) and DepoDur. 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 and outsource the commercial-scale manufacturing of our products under cGMP; and in-license and develop additional product candidates.

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

the costs of maintaining a commercial organization to sell, market and distribute EXPAREL;

the success of the commercialization of EXPAREL;

the cost and timing of manufacturing sufficient supplies of EXPAREL to meet customer demand, including the cost of expanding our manufacturing facilities to produce EXPAREL;

the rate of progress and costs of our efforts to prepare for the submission of an NDA for any product candidates that we may in-license or acquire in the future, and the potential that we may need to conduct additional clinical trials to support applications for regulatory approval;

the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates, including any such costs we may be required to expend if our licensors are unwilling or unable to do so;

the effect of competing technological and market developments;

the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish; and the potential that we may be required to file a lawsuit to defend our patent rights or regulatory exclusivities from challenges by companies seeking to market generic versions of extended-release liposome injection of bupivacaine.

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

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

Our quarterly operating results may fluctuate significantly.

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

our ability to establish and maintain the necessary commercial infrastructure to sell EXPAREL without substantial delays, including engaging additional sales and marketing personnel and contracting with third parties for warehousing, distribution, cash collection and related commercial activities;

maintaining our existing manufacturing facilities and expanding our manufacturing capacity, including installing specialized processing equipment for the manufacturing of EXPAREL;

our execution of other collaborative, licensing, 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;

regulatory developments affecting EXPAREL or the product candidates of our competitors; and

the level of underlying hospital demand for EXPAREL and wholesaler buying patterns.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of

our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

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

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

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

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on the effectiveness of our internal control over financial reporting. The internal control report must contain (i) a statement of management's responsibility for establishing and maintaining adequate internal control over financial reporting, (ii) a statement identifying the framework used by management to conduct the required evaluation of the effectiveness of our internal control over financial reporting and (iii) management's assessment of the effectiveness of our internal control over financial reporting as of the end of our most recent fiscal year, including a statement as to whether or not internal control over financial reporting is effective.

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

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

We have significant federal and state net operating loss carryforwards and federal and state research and development tax credit carryforwards. Our net operating loss carryforwards and research and development tax credits may expire and not be used. Our net operating loss carryforwards will begin expiring in 2026 for federal purposes and 2015 for state purposes if we have not used them prior to that time, and our federal tax credits will begin expiring in 2028 unless previously used. Our state tax credits carry forward indefinitely. Additionally, our ability to use any net operating loss and credit carryforwards to offset taxable income or tax, respectively, in the future will be limited under Internal Revenue Code Sections 382 and 383 because we experienced a cumulative change in ownership of more than 50% within a three-year period. Such an ownership change was triggered by the cumulative ownership changes arising as a result of the completion of our initial public offering and our other financing transactions. Because of the ownership change, we will be limited regarding the amount of net operating loss carryforwards and research tax credits that we can utilize annually in the future to offset taxable income or tax, respectively. Such an annual limitation will significantly reduce the utilization of the net operating loss carryforwards and research tax credits before they expire. In addition, California and certain states have suspended use of net operating loss carryforwards for certain taxable years, and other states are considering similar measures. As a result, we may incur higher state income tax expense in the future. Depending on our future tax position, continued suspension of our ability to use net operating loss carryforwards in states in which we are subject to income tax could have an adverse impact on our results of operations and financial condition.

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

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

Risks Related 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 14, 2014, the trading prices of our stock have ranged from \$6.16 to \$71.92 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; general economic and market conditions and overall fluctuations in U.S. equity markets;

developments concerning our sources of manufacturing supply;

disputes or other developments relating to patents or other proprietary rights;

additions or departures of key scientific or management personnel;

issuances of debt, equity or convertible securities;

changes in the market valuations of similar companies; and

the other factors described in this "Risk Factors" section.

In addition, the stock market in general, and the market for small pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. Fluctuations in our stock price could, among other things, adversely impact the trading price of the Notes and our shares issuable upon conversion of the Notes.

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

Our ability to make scheduled 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, 2013, our total consolidated gross indebtedness was \$120.0 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.

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

Under certain circumstances, holders of the Notes are entitled to convert the Notes to common stock at any time during specified periods at their option. If one or more holders elect to convert their Notes, we would be required to settle any converted principal through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their Notes, we have reclassified all of the outstanding principal of the Notes as a current rather than long-term liability, which has resulted in a material reduction of our net working capital. Conversion of the Notes may dilute the ownership interest of existing stockholders, including holders who had previously converted their Notes, or may otherwise depress the price of our common stock.

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

In the future, we may sell additional shares of our common stock to raise capital. Except under limited circumstances, we are not restricted from issuing additional common stock, including securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. The issuance of additional shares of our common stock or convertible securities, including upon exercise of our outstanding options or otherwise, will dilute the ownership interest of our common stockholders. In addition, our greater than 5% stockholders may sell a substantial number of their shares in the public market, which could also affect the market price for our common stock. We cannot predict the size of future sales or issuances of our common stock or the effect, if any, that they may have on the market price for our common stock. The liquidity and trading volume of our common stock is limited. For the three months ended December 31, 2013, the average per day trading volume of our common stock was 490,136 shares. The issuance and/or sale of substantial amounts of common stock, or the perception that such issuances and/or sales may occur, could adversely affect the market price of our common stock and the trading price of the Notes and impair our ability to raise capital through the sale of additional equity or debts securities.

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

In May 2008, the Financial Accounting Standards Board, which we refer to as 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, which we refer to as ASC 470-20. Under ASC 470-20, an entity must separately account for the liability and equity components of the convertible debt instruments (such as the Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. The effect of ASC 470-20 on the accounting for the Notes is that the equity component is required to be included in the additional paid-in capital section of stockholders' equity on our consolidated balance sheet at the issuance date and the value of the equity component would be treated as debt discount for purposes of accounting for the debt component of the Notes. As a result, we are required to record a greater amount of non-cash interest expense in current periods presented as a result of the amortization of the discounted carrying value of the Notes to

their face amount over the term of the Notes. We will report larger net losses in our financial results because ASC 470-20 will require interest to include both the current period's amortization of the debt discount and the instrument's coupon interest, which could adversely affect our reported or future financial results, the trading price of our common stock and the trading price of the Notes.

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

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

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

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

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

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

prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;

eliminating the ability of stockholders to call a special meeting of stockholders; and

establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

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

We have never declared or paid cash dividends on our common stock. We currently intend to retain our future earnings, if any, to finance the further development and expansion of our business and do not intend to pay cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of

directors and will depend upon our financial condition, results of operations, capital requirements, restrictions contained in future financing instruments and such other factors as our board of directors deems relevant. Item 1B. Unresolved Staff Comments

None.

### Item 2. Properties

Our research and development and manufacturing facilities are located in San Diego, California, where we occupy two facilities totaling approximately 106,000 square feet under leases expiring in August 2020. We use these facilities for research and development, manufacturing and general and administrative purposes. We also occupy a warehouse in San Diego primarily used for the storage of inventory under a lease expiring 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 13,000 square feet under a lease expiring in July 2017.

We believe that our manufacturing facilities will be sufficient for our needs with Suites A and C. We intend to add new facilities or expand existing facilities as we add employees, expand our geographic markets and as 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. 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.

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 has been listed under the symbol "PCRX" on The NASDAQ Global Select Market since January 2, 2013. Our common stock was listed on The NASDAQ Global Market from our initial public offering on February 3, 2011 until January 1, 2013. Prior to our initial public offering, there was no public market for our common stock. The following table sets forth, for the periods indicated, the high and low intraday sales prices of our common stock as reported by NASDAQ:

Year Ended 2013	High	Low
Fourth Quarter	\$58.22	\$45.68
Third Quarter	49.45	28.79
Second Quarter	32.36	24.70
First Quarter	30.94	17.15
Year Ended 2012	High	Low
Fourth Quarter	\$19.09	\$15.07
Third Quarter	19.31	14.00
Second Quarter	16.93	9.60
First Quarter	12.01	7.38

On February 14, 2013, the closing price of our common stock as reported on The NASDAQ Global Select Market was \$68.02 per share and we had approximately 23 holders of record of our common stock.

Comparison of Cumulative Total Returns Since Our IPO \*

C1		T-4-1	D -4
Cumu	iative	i otai	Return

	February 3, 2011	December 31, 2011	December 31, 2012	December 31, 2013
Pacira Pharmaceuticals, Inc. (PCRX)	\$100.00	\$123.22	\$248.86	\$818.95
NASDAQ Composite (^IXIC)	100.00	94.60	109.65	151.66
NASDAQ Biotechnology (^NBI)	100.00	111.01	146.42	242.49

<sup>\*</sup> Assumes \$100 invested on February 3, 2011, the date of our IPO (including reinvestment of dividends). DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain earnings, if any, to finance the growth and development of our business. We do not expect to pay any cash dividends on our common stock in the foreseeable future. Payment of future dividends, if any, will be at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, restrictions contained in future financing instruments, provisions of applicable law and other factors the board deems relevant.

# Item 6. Selected Financial Data

The table below provides selected consolidated financial data. We have prepared this information using our audited consolidated financial statements for the years ended December 31, 2013, 2012, 2011, 2010 and 2009. The following consolidated financial data should be read in conjunction with our consolidated financial statements and related notes included in this report and "Item 7 - Management's Discussion and Analysis of Financial Condition and Results of Operations" of this annual report.

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	2013		December 31 2012 s, except shar		2011 and per shar	e o	2010 data)		2009	
Statement of Operations Data										
Revenues:	ΦΩ1.056		<b>#10.101</b>		Φ.C. 0.0.7		Φ7. 640		Φ. 6. 2.2.4	
Net product sales	\$81,956		\$18,191		\$6,895		\$7,640		\$6,324	
Collaborative licensing and development revenue	972		18,390		5,074		3,217		4,638	
Royalty revenue	2,623		2,503		3,720		3,705		4,044	
Total revenues	85,551		39,084		15,689		14,562		15,006	
Operating expenses:	05,551		37,004		13,007		17,502		13,000	
Cost of revenues	54,772		32,139		16,739		12,276		12,301	
Research and development	21,560		9,937		14,873		18,628		26,233	
Selling, general and administrative	62,508		46,306		20,159		6,367		5,020	
Impairment of long-lived assets			<del></del>		3,019		<del></del>		J,020 —	
Total operating expenses	138,840		88,382		54,790		37,271		43,554	
Loss from operations	(53,289	)	(49,298	`	(39,101	`	(22,709	)	(28,548	)
Other (expense) income:	(33,20)	,	(47,270	,	(3),101	,	(22,70)	,	(20,540	,
Interest income	259		275		255		146		77	
Interest expense	(7,253	)	(1,807	`	(4,780	`	(3,959	)	(1,723	)
Loss on early extinguishment of debt	(3,398		(1,062	)	— —	,	(184	)	(1,723	,
Royalty interest obligation	(623	<i>)</i>	(278	)	227		(930	<i>)</i>	(1,880	)
Other, net	(47	<i>)</i>	(111	<i>)</i>	71		487	,	367	,
Total other expense, net	(11,062	) )	(2,983	)	(4,227	`	(4,440	)	(3,159	)
Loss before income taxes	(64,351	) )	(52,281	)	(43,328		(27,149)	)	(31,707	)
Income tax benefit	442	,	(32,201	,	( <del>4</del> 3,320	,	(27,14)	,	(31,707	,
Net loss	\$(63,909	)	\$(52,281	`	\$(43,328	`	\$(27,149	)	\$(31,707	)
Net loss per share:	Ψ(03,707	,	ψ(32,201	,	ψ(+3,326	,	Ψ(27,14)	,	Φ(31,707	,
Basic and diluted net loss per common share	\$(1.93	)	\$(1.72	)	\$(2.64	)	\$(47.29	)	\$(55.32	)
Weighted average common shares outstanding	•	,	ψ(1.72	,	φ(2.04	,	ψ(+7.2)	,	φ(33.32	,
Basic and diluted	33,181,895	5	30,331,965		16,437,464	_	574,072		573,118	
	Decemb				-,, -		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		,	
	2013		2012		2011		2010		2009	
	(In thou	sai			_011		2010		_00)	
Balance Sheet Data	(=== ==== ===									
Cash and cash equivalents, restricted cash and		_	+							
short-term investments	\$73,785	)	\$42,573		\$77,452		\$27,447		\$8,293	
Working capital (deficit)	(15,192		) 46,766		50,738		14,733		(1,868	)
Total assets	169,820		112,054		113,490		66,562		43,954	,
Long-term liabilities	6,628		32,043		33,310		98,623		52,486	
Accumulated deficit	(296,429	9	) (232,520		) (180,239		) (136,911	)	(109,762	)
Total stockholders' equity (deficit)	41,249		65,855		48,269		(48,383		(22,949	)
1,,	- ,—		,		- ,		( - )		, ,	,

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

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

We are a specialty pharmaceutical company focused on the development, commercialization and manufacture of proprietary pharmaceutical products, based on our proprietary DepoFoam drug delivery technology, for use in hospitals and ambulatory surgery centers. As of December 31, 2013, our commercial stage products are EXPAREL and DepoCyt(e).

EXPAREL is a liposome injection of bupivacaine, an amide-type local anesthetic, indicated for administration into the surgical site to produce postsurgical analgesia and was approved by the FDA on October 28, 2011. We commercially launched EXPAREL in April 2012. We ship EXPAREL directly to the end user based on orders placed to wholesalers or directly to us and have no product held by wholesalers.

DepoCyt(e) is a sustained release liposomal formulation of the chemotherapeutic agent cytarabine and is indicated for the intrathecal treatment of lymphomatous meningitis. DepoCyt(e) was granted accelerated approval by the FDA in 1999 and full approval in 2007. We sell DepoCyt(e) to our commercial partners located in the U.S. and Europe. Since inception, we have incurred significant operating losses. We expect to continue to incur significant expenses as we commercialize EXPAREL; advance the development of product candidates; pursue the use of EXPAREL in additional indications such as nerve block; seek FDA approval for our product candidates that successfully complete clinical trials; and develop our sales force and marketing capabilities to prepare for their commercial launch. 2013 Highlights and Developments

Since the commercial launch of EXPAREL in April 2012 through December 31, 2013, 2,106 accounts have ordered EXPAREL, and during the year ended December 31, 2013, we added 1,287 new accounts. We believe the strong demand for EXPAREL has continued due to major hospital formulary wins and orders from orthopedic centers.

Total revenues increased \$46.5 million, or 119%, in the year ended December 31, 2013, as compared to 2012, primarily driven by product sales of EXPAREL of \$76.2 million, net of allowances for sales returns, prompt payment discounts, volume rebates and distribution service fees payable to wholesalers, for the year ended December 31, 2013.

In January 2013, we completed a private placement of \$120.0 million in aggregate principal amount of 3.25% convertible senior notes, or Notes. The net proceeds from the offering, including net proceeds from the exercise in full by the initial purchasers of their option to purchase an additional \$10.0 million in aggregate principal amount of the Notes, were \$115.3 million, after deducting the initial purchasers' discounts and commissions and the offering expenses payable by us.

We internalized the approximately 60-person sales force previously employed by Quintiles Commercial US, Inc., or Quintiles, and further developed a sales and marketing team entirely dedicated to commercializing EXPAREL.

In May 2013, we reported positive findings from the first part of our femoral nerve block study comparing the effect of EXPAREL versus placebo for total knee arthroplasty, which was initiated in 2012. The final part of this study is still ongoing and we expect to have final data in March 2014.

In August 2013, we reported that the intercostal nerve block study for posterolateral thoracotomy, which was also initiated in 2012, did not achieve its primary endpoint. However, the FDA has previously indicated to us at its end of Phase 2 meeting that a single pivotal trial meeting its primary endpoint would be sufficient to gain approval for the nerve block indication, assuming demonstration of adequate safety. We plan to submit data from the ongoing

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femoral nerve block study to demonstrate efficacy and safety, as well as safety data from the intercostal nerve block study, for an sNDA, which is anticipated in the second quarter of 2014.

Following a pilot program, effective October 1, 2013, we appointed CrossLink BioScience, LLC, or CrossLink, for a term of five years as the exclusive third-party distributor to promote and sell EXPAREL for orthopedic and spine surgeries in the United States, with the exception of certain geographical areas and accounts.

We continued the expansion of our manufacturing facility located in San Diego, California, and we anticipate receiving FDA approval for our newly installed manufacturing facility, referred to as Suite C, in the second quarter of 2014. Combined with our current facility, we expect this facility to significantly increase our manufacturing capacity and ability to meet the growing demand for EXPAREL.

Research and development expenses increased by \$11.6 million, or 117%, for the year ended December 31, 2013, as compared to 2012, driven by, among other things, an increase in clinical development expenses relating to our nerve block trials, described above. We expect to incur additional research and development expenses as we accelerate the development of EXPAREL in additional indications, including nerve block and the pediatric trials required by the FDA for EXPAREL.

Financial Operations Overview

### Revenue

Our net product sales are derived from EXPAREL, which we commercially launched in April 2012 in the United States, and DepoCyt(e), which we sell to commercial partners in the United States and Europe. We ship EXPAREL directly to the end user based on orders placed to wholesalers or directly to us. No product is held by wholesalers. We reported EXPAREL product sales of \$76.2 million for the year ended December 31, 2013, which is net of allowances for sales returns, prompt payment discounts, volume rebates and distribution service fees payable to wholesalers. DepoCyt(e) net product sales of \$5.7 million for the year ended December 31, 2013 were derived from a contractual price on shipments to our commercial partners.

We also generate collaborative licensing and development revenue from our collaborations with third parties who seek to use our DepoFoam technology to develop extended release formulations of their products and product candidates. Royalties are recognized as the product is sold by our commercial partners and are calculated as a percentage of the net selling price, which is typically net of discounts, returns and allowances incurred by our commercial partners, and net of the agreed upon supply price.

# Cost of Revenues

Our cost of revenues consists of the costs associated with our products sold and research and development services provided to our collaboration partners and include the following:

manufacturing overhead and fixed costs associated with running two current Good Manufacturing Practices, or •GMP, manufacturing facilities, including allocated rent, utilities, insurance, depreciation and salaries and related costs of personnel, including stock-based compensation, involved with our manufacturing activities;

cost of active pharmaceutical ingredients;

royalties due to third parties on our revenues;

packaging, testing and freight;

amortization of our intangible assets;

regulatory and pharmacovigilance costs; and

cost associated with excess manufacturing capacity and any non-routine shutdown of our facilities, which are charged to cost of revenue as incurred.

Our cost of revenues increased significantly following FDA approval of EXPAREL in October 2011, when we shifted EXPAREL manufacturing expenses on a prospective basis from research and development to cost of revenues.

Research and Development Expenses

Our historical research and development expenses primarily consist of expenses incurred in developing, testing, manufacturing and seeking regulatory approval of EXPAREL, including:

expenses associated with regulatory submissions, clinical trials and manufacturing, including additional expenses to prepare for the commercial manufacture of EXPAREL prior to FDA approval;

payments to third-party contract research organizations, contract laboratories and independent contractors;

payments made to consultants who perform research and development on our behalf and assist us in the preparation of regulatory filings;

personnel related expenses, such as salaries, benefits, travel and other related expenses, including stock-based compensation;

payments made to third-party investigators who perform research and development on our behalf and clinical sites where such research and development is conducted; and

allocated rent and utilities, depreciation and amortization, and other related expenses.

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

From the acquisition date through December 31, 2013, we incurred research and development expenses of \$145.2 million, which has primarily been for EXPAREL. We have also incurred expenses for our product candidates, including DepoNSAID and DepoMethotrexate. We expect to incur additional research and development expenses as we accelerate the development of EXPAREL in additional indications including nerve block and the pediatric trials required by the FDA for EXPAREL. Completion of clinical trials may take several years or more and the length of time generally varies according to the type, complexity, novelty and intended use of a product candidate. We are currently unable to determine our future research and development expenses related to EXPAREL because the requirements of any additional clinical trials of EXPAREL for additional indications have yet to be determined. For example, the FDA has required that we complete a post-approval clinical trial for EXPAREL in pediatric patients. The cost of clinical development may vary significantly due to factors such as the scope, rate of progress, expense and outcome of our clinical trials and other development activities.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries, benefits and other related costs, including stock-based compensation, for personnel serving in our sales and marketing, executive, finance, legal, information technology, compliance and human resource functions. Our selling, general and administrative expenses also include facility and related costs, professional fees for legal, patent expenses, consulting, tax and accounting services, insurance, depreciation and general corporate expenses.

Our selling, general and administrative costs have increased significantly since we have focused significant resources on building our commercial team for the launch and commercial sale of EXPAREL. Following approval of EXPAREL in October 2011, we hired and trained our Quintiles sales force which was comprised of approximately 60 representatives, whom we transitioned to our employees on January 28, 2013. In 2013, we also hired CrossLink to promote and sell EXPAREL for orthopedic and spine surgeries. We continue to run prospective outcome studies designed for commercial purposes, which do not have any regulatory endpoints and are included in selling, general and administrative expenses. We expect to continue to incur significant selling, general and administrative expenses as we continue to execute our marketing and sales strategies for EXPAREL and implement a variety of programs to educate customers about EXPAREL.

Interest Income (Expense)

Interest income consists of interest earned on our cash and cash equivalents and short-term investments. Interest expense primarily consists of cash and non-cash interest costs related to our debt holdings. We capitalize interest based on the construction costs for our Suite C manufacturing lines. During 2011, we also incurred interest

expense associated with our secured and unsecured notes issued to certain of our investors that converted into common stock upon completion of our initial public offering and negotiated rent deferral payments.

Loss on Early Extinguishment of Debt

Loss on early extinguishment of debt consists of any remaining unamortized debt issuance costs, warrants and end of term fee, as well as any prepayment penalties, resulting from the prepayment of debt.

**Royalty Interest Obligation** 

Our royalty interest obligation is due under an Amended and Restated Royalty Interests Assignment Agreement, further discussed in "Liquidity and Capital Resources," which provides Paul Capital a right to receive an interest in end user sales relating to DepoCyt(e) and our previously-marketed product, DepoDur. The obligations under the agreement are composed of (i) the difference in the revaluation of our obligations between each reporting period and (ii) the actual royalty interest payments payable for such reporting period.

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

Our income tax expense, deferred tax assets and liabilities, and reserves for unrecognized tax benefits reflect management's assessment of estimated future taxes to be paid. Significant judgments and estimates are required in determining the consolidated income tax expense. As of December 31, 2013, we have significant federal and state income tax net operating loss and credit carry forwards, the use of which may be limited by historic and future ownership changes within the meaning of Section 382 of the Internal Revenue Code. Based on the positive and negative evidence available, we believe that it is more likely than not that the benefit from deferred tax assets will not be realized. In recognition of this risk, we have provided a full valuation allowance against our deferred tax assets net of deferred tax liabilities that will generate taxable income during the reversal period.

Critical Accounting Policies and Use of Estimates

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

While our significant accounting policies are more fully discussed in Note 2 to our audited consolidated financial statements included in this filing, we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our consolidated financial statements. Revenue Recognition

Our principal sources of revenue include (i) sales of EXPAREL in the United States, (ii) sales of DepoCyt(e) in the United States and Europe, (iii) royalties based on sales by commercial partners of DepoCyt(e), and (iv) license fees, milestone payments and reimbursement for development work to third parties. 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 with the wholesaler never 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 cGMP.

At the time we recognize revenue, we also record certain sales reserves and allowances as a reduction of revenue. These reserves and allowances include a prompt payment reserve, return reserves, volume rebates, chargeback reserve and wholesaler service fee. Due to estimates and assumptions inherent in determining some of our sales reserves, the actual amount of volume rebates, chargebacks and returns may be different from our estimates, at which time we would adjust our reserves accordingly.

# Prompt Payment Reserve

The prompt payment reserve is based upon discounts offered to wholesalers as an incentive to meet certain payment terms. We account for these discounts at the time the sale is made and reduce accounts receivable accordingly.

Returns Reserve

We allow customers to return product that is damaged or received in error. In addition, we allow for product to be returned beginning six months prior to, and twelve months following product expiration. As EXPAREL is a new commercially available product, we are estimating our sales return reserve based on return history from other hospital based products with similar distribution models, 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 sales and an increase in returns liability. Our commercial partners can return the products within contractually specified timeframes if the products do not meet the applicable inspection tests. We estimate our return reserves based on our experience with historical return rates. Historically, our product returns have not been material.

### Volume Rebates and Chargeback Reserve

Volume rebates and chargeback reserve are based upon contracted discounts and promotional offers we provide to certain end users such as members of group purchasing organizations. The volume rebates and chargeback reserve are recorded as a reduction to sales and a customer payable and reduction to receivables, respectively.

### Wholesaler Service Fee

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

## Royalty Revenue

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

# Collaborative Licensing and Development Revenue

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

We recognize revenues from non-refundable up-front license fees received under collaboration agreements ratably over the performance period as determined under the collaboration agreement (estimated development period in the case of development agreements, and contract period or longest patent life in the case of supply and distribution agreements). If the estimated performance period is subsequently modified, we will modify the period over which the up-front license fee is recognized accordingly on a prospective basis. Upon 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 development revenue in our consolidated statements of operations.

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

# Research and Development Expenses

We expense all research and development costs as incurred. We rely on third parties to conduct our preclinical and clinical studies and to provide services, including data management, statistical analysis and electronic compilation for our clinical trials. We track and record information regarding third-party research and development expenses for each study or trial that we conduct and recognize these expenses based on the estimated progress towards completion at the end of each reporting period. Factors we consider in preparing these estimates include the number of subjects enrolled in studies, milestones achieved and other criteria related to the efforts of our vendors. Historically, any adjustments we have made to these assumptions have not been material. Depending on the timing of payments to vendors and estimated services provided, we may record prepaid or accrued expenses related to these costs.

# **Stock-Based Compensation**

We account for stock-based compensation by measuring and recognizing compensation expense for all stock-based awards based on estimated grant date fair values. We use the straight-line method to allocate compensation cost to reporting periods over each optionee's requisite service period, which is generally the vesting period. 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, the calculation of expected term, and the fair value of the underlying common stock on the date of grant, among other inputs.

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

	Year Ended December 31,					
	2013	2012	2011			
Expected dividend yield	None	None	None			
Risk free interest rate	0.33 - 2.83%	0.84 - 1.70%	1.1 - 2.7%			
Expected volatility	68.7%	74.0%	76.8%			
Expected term of options	6.22 years	6.76 years	6.73 years			

Expected Volatility—The expected volatility rate used to value stock option grants is based on volatilities of a peer group of similar companies whose share prices are publicly available. Since our initial public offering, we have utilized our available historic volatility data combined with the publicly traded peer historic volatility to determine expected volatility over the expected option term. The peer group was developed based on companies in the pharmaceutical and biotechnology industry in a similar stage of development.

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

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

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

# **Results of Operations**

Comparison of Years Ended December 31, 2013, 2012 and 2011

### Revenues

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

	Year Ended December 31,			2013 versus 2012		2012 versus 2011	
	2013	2012	2011	% Incre	ease /	(Decrea	se)
Net product sales:							
EXPAREL	\$76,218	\$14,591	\$—	422	%	N/A	
DepoCyt(e)	5,738	3,537	6,812	62	%	(48	)%
DepoDur		63	83	(100	)%	(24	)%
Total net product sales	81,956	18,191	6,895	351	%	164	%
Collaborative licensing and development revenue	972	18,390	5,074	(95	)%	262	%
Royalty revenue	2,623	2,503	3,720	5	%	(33	)%
Total revenues	\$85,551	\$39,084	\$15,689	119	%	149	%

Total revenues increased \$46.5 million, or 119%, in the year ended December 31, 2013, as compared to 2012, and net product sales increased \$63.8 million, or 351%, in the year ended December 31, 2013, as compared to 2012. These increases were driven primarily from the increase in sales of EXPAREL by \$61.6 million, or 422%, in 2013, as compared to 2012, resulting from both a full year of EXPAREL sales in 2013 and continued penetration into the soft tissue and orthopedic markets. Since the launch of EXPAREL in April of 2012 through the year ended December 31, 2013, 2,106 accounts have ordered EXPAREL. During the year ended December 31, 2013, we added 1,287 new accounts. The strong demand for EXPAREL has continued as a result of major hospital system formulary wins due to rapid adoption in orthopedic procedures as well as continued adoption of infiltration into the transversus abdominis plane, or iTAP, for abdominal and genitourinary surgeries. There have also been positive indications of demand growth due to approval for use of EXPAREL at major military institutions, as well as the completion of drug evaluations leading to a reduction of restrictions and thus improved physician access. DepoCyt(e) product sales increased \$2.2 million in the year ended December 31, 2013, as compared to 2012, driven by the lifting of a selective recall recommended by the European Medicines Agency where DepoCyt(e) was not considered to be an "essential medicinal product," which resulted in decreased sales in 2012.

The decrease in collaborative licensing and development revenue of \$17.4 million, or 95%, in the year ended December 31, 2013, as compared to 2012, was primarily driven by the recognition of deferred revenue in connection with the termination of certain licensing agreements in 2012, which included (i) \$11.6 million for EKR Therapeutics, Inc, or EKR, (ii) \$4.0 million for Novo Nordisk AS, or Novo, and (iii) \$1.8 million for Flynn Pharmaceuticals Limited, or Flynn. We recognized any unamortized deferred revenue related to any milestones received under these agreements over the remaining contract periods, which ended in 2012.

Total revenues increased \$23.4 million, or 149%, in the year ended December 31, 2012, as compared to 2011. Net product sales increased \$11.3 million, or 164%, in the year ended December 31, 2012, as compared to 2011. In April 2012, we commercially launched EXPAREL resulting in \$14.6 million of net product sales during 2012. The increase in EXPAREL product sales was partially offset by a \$3.3 million decrease in DepoCyt(e) product sales primarily driven by the selective recall of DepoCyt(e) in Europe.

The increase in collaborative licensing and development revenue of \$13.3 million, or 262%, in the year ended December 31, 2012, as compared to 2011 was primarily driven by the recognition of deferred revenue in connection with the termination of certain licensing agreements, which included increases of (i) \$10.7 million for EKR, (ii) \$1.1 million for Novo and (iii) \$1.5 million for Flynn. We recognized any unamortized deferred revenue related to any milestones received under these agreements over the remaining contract periods, which ended in 2012. Royalty revenue decreased \$1.2 million, or 33%, in the year ended December 31, 2012, as compared to 2011 due to lower end user sales by our commercial partners due to the selective recall of DepoCyt(e) in Europe.

#### Cost of Revenues

The following table provides information regarding our cost of revenues during the periods indicated, including changes as a percentage (dollar amounts in thousands):

	Year Ended December 31,			2013 v	ersus 2012 v 2011	ersus
	2013	2012	2011	% Incre	ease / (Decrea	se)
Cost of goods sold	\$54,772	\$31,744	\$15,310	73	% 107	%
Cost of collaborative licensing and development		395	1,429	(100	)% (72	)%
Total cost of revenues	\$54,772	\$32,139	\$16,739	70	% 92	%

Total cost of revenues increased \$22.6 million, or 70% in the year ended December 31, 2013 as compared to 2012. Cost of goods sold increased primarily due to a higher volume of EXPAREL sales. The improvement in cost of goods sold as a percentage of net product sales during the year ended December 31, 2013 as compared to 2012 was driven by (i) increased utilization of our facility to manufacture EXPAREL, (ii) a decrease in consulting costs, (iii) the significant increase in EXPAREL sales to offset the substantial level of fixed cost infrastructure for operating two cGMP facilities and (iv) the resumption of production of DepoCyt(e). This improvement was partially offset by the impact of producing Suite C batches in preparation for FDA approval submission, which cannot be sold for commercial use and resulted in \$3.7 million of expense during the year ended December 31, 2013. There was no cost of collaborative licensing and development revenue for the year ended December 31, 2013 due to the termination of services performed under a licensing agreement with Novo in 2012.

Total cost of revenues increased \$15.4 million, or 92% in the year ended December 31, 2012 as compared to 2011. Cost of goods sold increased by \$16.4 million primarily due to (i) the cost of goods for EXPAREL sales which we commercially launched in April 2012, (ii) approximately \$3.2 million of expense for the voluntary but non-routine shutdown periods of the EXPAREL manufacturing site for repairs and maintenance and deployment of new manufacturing skids for our Suite C manufacturing expansion project, (iii) \$1.3 million charge for corrective actions taken on the DepoCyt(e) manufacturing line based on the remediation plan, inventory replacement and reserve costs due to action taken in response to the report issued by the European Medicines Agency and (iv) EXPAREL production costs, which were previously expensed as incurred until March 2012 when the first commercial batch was produced. We have a substantial level of infrastructure cost relating to running two cGMP facilities and any extended or non-routine shutdown results in these costs being charged directly to cost of goods sold.

Cost of collaborative licensing and development revenue decreased by \$1.0 million in the year ended December 31, 2012 as compared to 2011 due to decreased services performed under the agreement with Novo for which we received a notice of termination in June 2012.

### Research and Development Expenses

The following table provides information regarding research and development expenses during the periods indicated, including changes as a percentage (dollar amounts in thousands):

	Year Ende	d Decembe	er 31,	2013 versus 2012	2012 vers 2011	sus
	2013	2012	2011	% Increase /	(Decrease)	
Research and development	\$21,560	\$9,937	\$14,873	117	% (33	)%
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Research and development expenses increased by \$11.6 million, or 117%, for the year ended December 31, 2013, as compared to 2012, primarily due to the following:

Salaries and benefits increased by \$3.6 million driven by a \$3.2 million increase in stock-based compensation expense;

Clinical development expenses increased by \$6.2 million relating to our Phase 2/3 pivotal trial of EXPAREL administered as a femoral nerve block for total knee arthroplasty and our Phase 3 pivotal trial of EXPAREL as an intercostal nerve block for thoracotomy;

•

Product development expenses increased by \$0.8 million related to a potential new manufacturing process for EXPAREL; and

Pre-clinical expenses increased by \$0.7 million related to toxicity studies in animals.

Research and development expenses decreased by \$4.9 million, or 33%, for the year ended December 31, 2012 as compared to 2011 primarily due to a shift of \$10.6 million in EXPAREL related manufacturing development expenses to cost of goods sold following the approval of EXPAREL by the FDA in October 2011. This decrease was partially offset by an increase of \$3.6 million in clinical development expenses primarily for the initiation of our Phase 2/3 pivotal trial of EXPAREL administered as a single-dose injection femoral nerve block for total knee arthroplasty surgery, in which the first patient was dosed in September 2012, and start-up costs for our Phase 3 pivotal trial of EXPAREL for intercostal nerve block for thoracotomy. We also had an increase of \$2.2 million of research and development expenses on a potential new manufacturing process for EXPAREL.

Selling, General and Administrative Expenses

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

	Year Ended December 31,			2013 versus 2012	2012 versi 2011	us
	2013	2012	2011	% Increase	(Decrease)	
Sales and marketing	\$41,549	\$30,332	\$10,123	37	% 200	%
General and administrative	20,959	15,974	10,036	31	% 59	%
Total selling, general and administrative	\$62,508	\$46,306	\$20,159	35	% 130	%
expenses						

Selling, general and administrative expenses increased by \$16.2 million, or 35%, in the year ended December 31, 2013 as compared to 2012 primarily due to the following:

Sales and marketing expenses increased by \$11.2 million to \$41.5 million in the year ended December 31, 2013, as compared to \$30.3 million in the year ended December 31, 2012, due to a \$8.0 million increase in project spend for EXPAREL, which included educational initiatives and programs to create product awareness in the orthopedic market, commission based payments to CrossLink, our Phase 4 trial for infiltration into iTAP, along with other selling initiatives and promotional activities to support the growth of EXPAREL, and a \$3.2 million increase in salaries and benefits driven by an increase in the number of our field-based medical health science personnel; and General and administrative expenses increased by \$5.0 million to \$21.0 million in the year ended December 31, 2013, as compared to \$16.0 million in the year ended December 31, 2012, primarily due to increases in salaries and benefits, including \$1.4 million of stock-based compensation expense, associated with our increased headcount, as well as infrastructure costs and outside services in areas such as information technology, human resources and finance to support the commercial and manufacturing growth of EXPAREL.

Selling, general and administrative expenses increased by \$26.1 million, or 130%, in the year ended December 31, 2012, as compared to 2011, primarily due to the following:

Sales and marketing expenses increased by \$20.2 million to \$30.3 million in the year ended December 31, 2012, as compared to \$10.1 million in the year ended December 31, 2011, due to a \$12.4 million increase in salaries and benefits associated with our sales force entirely dedicated to commercializing EXPAREL, which was comprised of approximately 60 hospital specialists, seven regional directors and a national sales director; and a \$4.6 million increase in project spending of which \$3.0 million was promotional costs to support the launch of EXPAREL, including simulcasts, speaker trainings, educational programs, publications, promotional materials and health outcomes collaboratives; and

General and administrative expenses increased by \$5.9 million to \$16.0 million in the year ended December 31, 2012, as compared to \$10.0 million in the year ended December 31, 2011, due to increases of \$3.1 million in salaries and benefits associated with our increased headcount, and \$2.0 million in consulting costs primarily to support our information technology structure and recruiting efforts.

Impairment of Long-Lived Assets

The following table provides information regarding impairment of long-lived assets during the periods indicated, including changes as a percentage (dollar amounts in thousands):

	Year End	ded Decembe	er 31,	2013 versi 2012	us 2012 versu 2011	IS
	2013	2012	2011	% Increas	e / (Decrease)	
Impairment of long-lived assets	<b>\$</b> —	<b>\$</b> —	\$3,019	N/A	(100	)%

During the year ended December 31, 2011, an impairment loss of \$3.0 million was recognized relating to the following:

- \$1.7 million impairment of intangible assets and certain property, plant and equipment relating to DepoDur due to the notification by EKR in December 2011 of its intent to terminate our licensing, distribution and marketing agreement; and
- \$1.3 million impairment of property, plant and equipment due to our decision made during the fourth quarter of 2011 to change the automation technology process in our EXPAREL production line to expand capacity resulting in certain software and equipment that were no longer utilizable.

Other Income (Expense)

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

	Year Ended December 31,			2013 versus 2012	2013 versus 2012 ve 2012 2011	
	2013	2012	2011	% Increase	/ (Decrease	2)
Interest income	\$259	\$275	\$255	(6	)% 8	%
Interest expense	(7,253	) (1,807	) (4,780	) 301	% (62	)%
Loss on early extinguishment of debt	(3,398	) (1,062	) —	220	% N/A	
Royalty interest obligation	(623	) (278	) 227	124	% *	
Other, net	(47	) (111	) 71	(58	)% *	
Total other expense, net	\$(11,062	) \$(2,983	) \$(4,227	) 271	% (29	)%

<sup>\*</sup> We do not believe the percentage change is meaningful.

Total other expense, net increased by \$8.1 million, or 271%, to \$11.1 million in the year ended December 31, 2013 as compared to \$3.0 million in 2012, primarily due to a \$5.4 million increase in interest expense. The increase in interest expense is due to the following:

- \$3.5 million increase driven by the amortization of the debt discount related to the equity component of the Notes;
- \$1.0 million increase related to interest expense on higher debt balances; and
- \$0.9 million decrease in capitalized interest related to our Suite C manufacturing expansion project due to a lower interest rate on our Notes as compared to our term loan under the Oxford Credit Facility, which we repaid with the proceeds from the Notes offering.

Additionally, in 2013 we incurred a \$3.4 million loss on the extinguishment of the Oxford Credit Facility in January 2013 as compared to a \$1.1 million loss on extinguishment of the Hercules Credit Facility in May 2012.

Total other expense, net decreased by \$1.2 million, or 29%, to \$3.0 million in the year ended December 31, 2012 as compared to \$4.2 million in 2011, primarily due to a \$3.0 million decrease in interest expense. The decrease in interest expense is due to the following:

- \$1.2 million increase in capitalized interest mostly related to our Suite C manufacturing expansion project;
- \$1.1 million decrease in warrant expense recognized during the first quarter of 2011 in connection with the conversion of these warrants upon our initial public offering; and

\$0.3 million decrease in interest expense associated with our 2009 and 2010 convertible and secured debt facilities which were converted to common shares in connection with our initial public offering in February 2011.

Additionally, the decrease in interest expense was offset by a \$1.1 million loss on the extinguishment of the Hercules Credit Facility in May 2012. We also recognized a \$0.5 million increase in royalty interest obligation expense due to a forecast

reduction in end user DepoCyt(e) sales that occurred in 2011 based on plateauing sales trends for DepoCyt(e), the weakening

Euro exchange rate and termination of the EKR agreement.

Income Tax Benefit

The following table provides information regarding our income tax benefit during the periods indicated (in thousands):

	Year Ended Decem	nber 31,		2013 versus 2012	2012 versus 2011
	2013	2012	2011	% Increase / (Decre	ease)
Income tax benefit	\$442	<b>\$</b> —	<b>\$</b> —	N/A	N/A

2012

2012

In February 2013, we received \$0.4 million from the sale of our unused net operating losses through the State of New Jersey's Economic Development Authority Technology Business Tax Certificate Transfer Program. Liquidity and Capital Resources

Since our inception in 2007, we have devoted most of our cash resources to manufacturing, research and development and selling, general and administrative activities primarily related to EXPAREL. We have financed our operations primarily with the proceeds from the sale of convertible preferred stock and common stock, secured and unsecured notes and borrowings under debt facilities, and revenues.

We are highly dependent on the commercial success of EXPAREL, which we launched in April 2012. We have incurred losses and generated negative cash flows from operations since inception. As of December 31, 2013, we had an accumulated deficit of \$296.4 million, cash and cash equivalents, restricted cash and short-term investments of \$73.8 million and a working capital deficit of \$15.2 million.

The following table summarizes our cash flows from operating, investing and financing activities for the years ended December 31, 2013, 2012 and 2011 (in thousands):

	Year Ended December 31,			
	2013	2012	2011	
Consolidated Statement of Cash Flows Data:				
Net cash provided by (used in):				
Operating activities	\$(43,216	) \$(70,130	) \$(31,000	)
Investing activities	(43,560	) (29,522	) (36,123	)
Financing activities	89,165	63,610	87,158	
Net increase (decrease) in cash and cash equivalents	\$2,389	\$(36,042	) \$20,035	
Operating Activities				

For the years ended December 31, 2013, 2012 and 2011, our net cash used in operating activities was \$43.2 million, \$70.1 million and \$31.0 million, respectively. The \$26.9 million decrease in net cash used in operating activities in 2013 as compared to 2012 was primarily driven by a \$57.2 million increase in collections from EXPAREL net product sales, partially offset by increased operating expenses incurred for commercial manufacturing and the Phase 2/3 EXPAREL nerve block trials, increases in the number of our field-based medical health science personnel, and various promotional and educational programs to support EXPAREL.

The \$39.1 million increase in net cash used in operations in 2012 as compared to 2011 was primarily driven by (i) higher selling, marketing and administrative expenses driven by the launch of EXPAREL in April 2012, including the hiring of our sales force dedicated to EXPAREL and our Phase 4 and retrospective studies, (ii) increased manufacturing costs and an increase in inventory in connection with our commercial launch of EXPAREL, and

(iii) initiation of our Phase 2/3 EXPAREL nerve block trials.

#### **Investing Activities**

For the years ended December 31, 2013, 2012 and 2011, our net cash used in investing activities was \$43.6 million, \$29.5 million and \$36.1 million, respectively. The \$14.0 million increase in net cash used in investing activities in 2013 as compared to 2012 was primarily due to a \$27.8 million net increase in investment of the net proceeds from our Notes in short-term investments, partially offset by a \$8.3 million decrease in contingent consideration payments to Skyepharma and a \$5.5 million decrease in purchases of fixed assets.

The \$6.6 million decrease in net cash used in investing activities for 2012 as compared to 2011 was primarily driven by a \$29.0 million decrease in the purchases, net of redemptions, of short-term investments from the proceeds of our public offerings, partially offset by a (i) \$10.0 million contingent milestone payment made in April 2012 to Skyepharma in connection with the first commercial sale of EXPAREL, and a (ii) \$12.1 million increase in the purchase of fixed assets relating to the construction of our Suite C manufacturing lines for EXPAREL, which we re-commenced following approval from the FDA in October 2011.

### Financing Activities

For the years ended December 31, 2013, 2012 and 2011, our net cash provided by financing activities was \$89.2 million, \$63.6 million and \$87.2 million, respectively. During the year ended December 31, 2013, our net cash provided by financing activities was primarily attributable to our private offering of the Notes, which, after deducting financing costs, provided net proceeds of \$115.3 million. We used \$30.2 million of the net proceeds from the offering of the Notes to repay in full the \$27.5 million outstanding balance on the Oxford Credit Facility, as well as a \$1.7 million end of term fee, a \$0.8 million early prepayment penalty, and \$0.2 million of accrued interest. In April 2012, we raised \$62.9 million in net proceeds through a follow-on public offering. Additionally, in May 2012, we borrowed a principal amount of \$27.5 million from Oxford Finance LLC and used the funds primarily to repay the remaining principal on the Hercules Credit Facility of \$24.2 million, an early prepayment penalty of \$0.3 million and the end of term fee of \$0.6 million.

## **Equity Financings**

From inception through December 31, 2013, we raised approximately \$235 million of net proceeds from the sale of common stock and other equity securities.

#### Common Stock

In April 2012, we sold 6,900,000 shares at a price of \$9.75 per share in a registered public offering of common stock. We raised approximately \$62.9 million in net proceeds after deducting underwriting discounts and offering expenses. Debt Facilities

## January 2013 Convertible Notes

On January 23, 2013, we completed our private offering of the Notes. The net proceeds from the offering were \$115.3 million, after deducting the initial purchasers' discounts and commissions and the offering expenses payable by us. 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 and will mature on February 1, 2019.

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 commencing after the calendar quarter ending June 30, 2013, the holders have the right to convert when 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 (whether or not consecutive) out of the last 30 consecutive trading days of any given quarter. During the three months ended December 31, 2013, the requirements with respect to the Consecutive Sale Price were met and, as a result, the Notes are redeemable until March 31, 2014. The future convertibility and resulting balance sheet classification of the Notes will be monitored on a quarterly basis. In the event such requirements are not met in a given quarter, the Notes would be reclassified as a long-term liability. See Note 8, Debt, to our consolidated financial

statements included herein for additional details.

#### Royalty Interests Assignment Agreement

On March 23, 2007, we entered into the Amended and Restated Royalty Interests Assignment Agreement with Paul Capital, pursuant to which we assigned to Paul Capital the right to receive up to approximately 20% of our royalty payments from DepoCyt(e) and the no-longer marketed DepoDur. The original agreement was entered into prior to the acquisition by the Predecessor in order to monetize certain royalty payments from DepoCyt(e) and DepoDur. In connection with the Acquisition, the original agreement with Paul Capital was amended and restated and the responsibility to pay the royalty interest in product sales of DepoCyt(e) and DepoDur was transferred to us and we were required to make payments to Paul Capital upon the occurrence of certain events. To secure our obligations to Paul Capital, we granted Paul Capital a security interest in collateral which includes the royalty payments we are entitled to receive with respect to sales of DepoCyt(e) and DepoDur, as well as to bank accounts to which such payments are deposited. Under our arrangement with Paul Capital, upon the occurrence of certain events, including if we experience a change of control, undergo certain bankruptcy events of us or our subsidiary, transfer any or substantially all of our rights in DepoCyt(e) and/or DepoDur, transfer all or substantially all of our assets, breach certain of the covenants, representations or warranties under the Amended and Restated Royalty Interests Assignment Agreement, or sales of DepoCyt(e) and/or DepoDur are suspended due to an injunction or if we elect to suspend sales of DepoCyt(e) and/or DepoDur as a result of a lawsuit filed by certain third parties, Paul Capital may require us to repurchase the rights we assigned to it at a cash price equal to (a) 50% of all cumulative payments made by us to Paul Capital under the Amended and Restated Royalty Interests Assignment Agreement during the preceding 24 months, multiplied by (b) the number of days from the date of Paul Capital's exercise of such option until December 31, 2014, divided by 365. Under the terms of the Amended and Restated Royalty Interests Assignment Agreement, our initial public offering did not constitute a change of control.

## Future Capital Requirements

We believe that our existing cash and cash equivalents and revenue from product sales will be sufficient to enable us to fund our operating expenses, capital expenditure requirements and service our indebtedness for at least the next 12 months. However, the holders of the Notes have the ability to elect to convert the Notes at any time during the quarter ended March 31, 2014. We do not believe such action will be taken since the market price of the Notes is currently above the estimated conversion value, and in the event of conversion, holders would forgo all future interest payments and the possibility of further stock price appreciation. In the event conversion of the Notes did occur, we may not have enough cash on hand to pay the holders the principal plus the conversion premium and may need to raise additional capital or refinance the Notes, although there is no assurance we would be able to do so on acceptable terms or at all.

We may require additional debt or equity financing to meet our working capital requirements. Our need for additional external sources of funds will depend significantly on the level and timing of our sales of EXPAREL. We expect to continue to incur substantial additional operating losses as we commercialize EXPAREL and develop and seek regulatory approval for our other product candidates. We may also need to invest significant funds to expand our manufacturing capacity for EXPAREL. In addition, we expect to incur additional expenses to add operational, financial and information systems and personnel, including personnel to support our planned product commercialization efforts.

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

our ability to successfully commercialize EXPAREL;

•he costs of our commercialization activities for EXPAREL;

the cost and timing of expanding our manufacturing facilities and purchasing manufacturing and other capital equipment for EXPAREL and our other product candidates;

the costs of performing additional clinical trials for EXPAREL, including the pediatric trials required by the FDA as a condition of approval and the pivotal nerve block trials;

the scope, progress, results and costs of development for additional indications for EXPAREL and for our other product candidates;

the cost, timing and outcome of regulatory reviews of our other product candidates;

the extent to which we acquire or invest in products, businesses and technologies; the extent to which we choose to establish collaboration, co-promotion, distribution or other similar agreements for our product candidates; and

the costs of preparing, submitting and prosecuting patent applications and maintaining, enforcing and defending intellectual property claims.

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

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

#### **Contractual Obligations**

The table below presents a summary of our contractual obligations as of December 31, 2013 (in thousands):

	Payments due b					
Contractual Obligations (1)	Total	Less than one	1-3 Years	3-5 Years	More than 5	
	Total	year	1-3 Tears	3-3 T Cars	years	
Senior convertible notes - principal (2)	\$120,000	<b>\$</b> —	<b>\$</b> —	<b>\$</b> —	\$120,000	
Senior convertible notes - interest	19,825	3,900	7,800	7,800	325	
Lease obligations (3)	33,679	4,765	10,108	10,089	8,717	
Total	\$173,504	\$8,665	\$17,908	\$17,889	\$129,042	

- (1) This table does not include potential future milestone payments to Skyepharma which could be up to an aggregate of \$52.0 million if certain milestones pertaining to net sales of EXPAREL are met. This contingency is described further in Note 6, Goodwill and Intangible Assets, of our consolidated financial statements included herein for additional details.
- (2) The amounts displayed in the table above represent management's best estimate of timing with respect to the future convertibility of these instruments. See Note 8, Debt, of our consolidated financial statements included herein for additional details. 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, 2013, it would result in an approximate premium of 2.8 million shares or \$158 million of cash.
- (3) The amounts consist of operating leases for our corporate headquarters in Parsippany, New Jersey and manufacturing, research and warehouse space in San Diego, California.

**Off-Balance Sheet Arrangements** 

We had no material off-balance sheet arrangements as of December 31, 2013.

**Recent Accounting Pronouncements** 

See Note 2 to the Notes to Consolidated Financial Statements in Item 15 below for discussion of recent accounting pronouncements.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

The primary objective of our cash investment activities is to preserve principal while at the same time maximizing the income that we receive from our investments without significantly increasing risk. Some of the securities that we invest in may be subject to market 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 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, 2013 by \$0.1 million. To minimize this risk, we maintain our portfolio of cash equivalents and marketable securities in a variety of securities, including commercial paper, government and non-government debt securities, and/or money market funds that invest in such securities. At December 31, 2013, all cash, cash equivalents and available for sale securities mature within one year.

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Most of our transactions are conducted in U.S. dollars. We do have certain agreements with commercial partners located outside the United States, which have transactions conducted in Euros. As of December 31, 2013, we had approximately \$1.2 million in receivables from customers denominated in Euros. A hypothetical 10% decrease in the value of the U.S. dollar relative to the Euro would have decreased our revenue by \$0.2 million for the quarter ended December 31, 2013.

Our Notes carry a fixed interest rate and, thus, we are not subject to interest rate risk with respect to the Notes.

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

Our consolidated financial statements required by this item, together with the report of our independent registered public accounting firm, appear on pages F-1 through F-30 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, that 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 President, Chief Executive Officer and Chairman and Senior Vice President and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Based on their evaluation as of December 31, 2013, our President, Chief Executive Officer and Chairman and Senior Vice President and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2013.

Management's Report on Internal Control over Financial Reporting

Based upon the results of the evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2013. 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 generally accepted accounting principles in the United States of America. 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 President, Chief Executive Officer and Chairman and Senior Vice President and Chief Financial Officer, management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2013, based on the criteria established in Internal Control—Integrated Framework (1992 framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

The effectiveness of our internal control over financial reporting as of December 31, 2013 was audited by CohnReznick LLP, our independent registered public accounting firm, as stated in their report appearing below, which expressed an unqualified opinion on the effectiveness of our internal control over financial reporting as of December 31, 2013.

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, 2013, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders Pacira Pharmaceuticals, Inc.

We have audited Pacira Pharmaceuticals, Inc. and Subsidiaries' internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control-Integrated Framework (1992) 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 effectiveness of 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, evaluating management's assessment, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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

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

In our opinion, Pacira Pharmaceuticals, Inc. has maintained, in all material respects, effective internal control over financial reporting as of December 31, 2013 based on the COSO criteria.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements of Pacira Pharmaceuticals, Inc. and Subsidiaries as of December 31, 2013 and 2012, and for each of the three years in the period ended December 31, 2013 and our report dated February 25, 2014, which included an explanatory paragraph with respect to the Company's convertible senior notes, expressed an unqualified opinion thereon.

/s/ CohnReznick LLP Roseland, New Jersey February 25, 2014

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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 2014 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 2014 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 2014 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 2014 annual stockholders' meeting and is incorporated by reference into this report.

ITEM 14. Principal Accountant Fees and Services

Information required by this item will be included in the proxy statement for our 2014 annual stockholders' meeting and is incorporated by reference into this report.

#### **PART IV**

Item 15. Exhibits and Financial Statement Schedules

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

#### (1) Financial Statements

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets

Consolidated Statements of Operations

Consolidated Statements of Comprehensive Loss

Consolidated Statements of Stockholders' Equity (Deficit)

Consolidated Statements of Cash Flows

Notes to Consolidated Financial Statements

#### (2) Schedules

All financial statement schedules have been omitted because they are not required, are not applicable or the information is included in the Financial Statements or Notes thereto.

(3) Exhibits

The Exhibits listed in the Exhibit Index are filed as a part of this Form 10-K.

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#### **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

PACIRA PHARMACEUTICALS, INC.

/s/ DAVID STACK

Date: February 25, 2014

By:

David Stack

Provident C

President, Chief Executive Officer and

Chairman

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature /s/ DAVID STACK David Stack	Title Director, President, Chief Executive Officer and Chairman (Principal Executive Officer)	Date February 25, 2014
/s/ JAMES SCIBETTA James Scibetta	Senior Vice President and Chief Financial Officer (Principal Financial Officer)	February 25, 2014
/s/ LAUREN RIKER Lauren Riker	Executive Director, Finance (Principal Accounting Officer)	February 25, 2014
/s/ LAURA BREGE Laura Brege	Director	February 25, 2014
/s/ JOHN LONGENECKER John Longenecker	Director	February 25, 2014
/s/ GARY PACE Gary Pace	Director	February 25, 2014
/s/ ANDREAS WICKI Andreas Wicki	Director	February 25, 2014
/s/ DENNIS WINGER Dennis Winger	Director	February 25, 2014
/s/ MARK KRONENFELD Mark Kronenfeld	Director	February 25, 2014
/s/ PAUL HASTINGS Paul Hastings	Lead Director	February 25, 2014

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Report of Independent Registered Public Accounting Firm	<u>F-2</u>				
Consolidated Balance Sheets as of December 31, 2013 and 2012	<u>F-3</u>				
Consolidated Statements of Operations for the years ended December 31, 2013, 2012, and 2011	<u>F-4</u>				
Consolidated Statements of Comprehensive Loss for the years ended December 31, 2013, 2012, and 2011					
Consolidated Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2013, 2012, and 2011	<u>F-6</u>				
Consolidated Statements of Cash Flows for the years ended December 31, 2013, 2012, and 2011	F-7				
Notes to Consolidated Financial Statements	<u>F-8</u>				
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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 sheets of Pacira Pharmaceuticals, Inc. and Subsidiaries as of December 31, 2013 and 2012, and the related consolidated statements of operations, comprehensive loss, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2013. 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, 2013 and 2012, and their results of operations and cash flows for each of the three years in the period ended December 31, 2013, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Notes 2 and 8 to the consolidated financial statements, based on certain conditions that were met during the three months ended December 31, 2013, holders of the Company's convertible senior notes can convert such notes at any time during the quarter ending March 31, 2014.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Pacira Pharmaceuticals, Inc. and Subsidiaries' internal control over financial reporting as of December 31, 2013 based on criteria established in Internal Control-Integrated Framework (1992) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated February 25, 2014, expressed an unqualified opinion thereon.

/s/ CohnReznick LLP Roseland, New Jersey February 25, 2014

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Pacira Pharmaceuticals, Inc.

Consolidated Balance Sheets

(In thousands, except share and per share amounts)

(in thousands, except share and per share amounts)			
	December 31,		
	2013	2012	
ASSETS			
Current assets:			
Cash and cash equivalents	\$12,515	\$10,126	
Restricted cash	1,633	1,523	
Short-term investments	59,637	30,924	
Accounts receivable, net	14,590	4,352	
Inventories	15,557	12,077	
Prepaid expenses and other current assets	2,819	1,920	
Total current assets	106,751	60,922	
Fixed assets, net	48,182	39,116	
Goodwill	10,328	8,297	
Intangibles, net	1,157	3,208	
Other assets	3,402	511	
Total assets	\$169,820	\$112,054	
LIABILITIES AND STOCKHOLDERS' EQUITY	,		
Current liabilities:			
Accounts payable	\$3,069	\$2,569	
Accrued expenses	17,885	9,792	
Convertible senior notes	98,961		
Current portion of royalty interest obligation	1,020	823	
Current portion of deferred revenue	1,008	972	
Total current liabilities	121,943	14,156	
Long-term debt	_	25,191	
Royalty interest obligation	226	857	
Deferred revenue	3,212	3,720	
Other liabilities	3,190	2,275	
Total liabilities	128,571	46,199	
Commitments and contingencies (Note 18)	120,571	10,177	
Stockholders' equity:			
Preferred stock, par value \$0.001; 5,000,000 shares authorized, none issued and			
outstanding at December 31, 2013 and 2012		_	
Common stock, par value \$0.001 and 250,000,000 shares authorized; 33,636,442			
shares issued and outstanding at December 31, 2013; 32,624,049 shares issued and	34	33	
32,622,984 shares outstanding at December 31, 2012	54	33	
Additional paid-in capital	337,639	298,317	
Accumulated deficit	•	(232,520	)
Accumulated other comprehensive income	5	27	,
Treasury stock at cost, none at December 31, 2013 and 1,065 shares at December 31,	3	21	
2012		(2	)
Total stockholders' equity	41,249	65,855	
Total liabilities and stockholders' equity	\$169,820	\$112,054	
See accompanying notes to consolidated financial statements	¥ 102,020	ψ11 <b>2,</b> 00 i	
see accompanying notes to consolidated illiancial statements			

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Pacira Pharmaceuticals, Inc.

Consolidated Statements of Operations

(In thousands, except share and per share amounts)

(in thousands, except share and per share amounts)	Year Ended December 31,						
	2013	2012	2011				
Revenues:							
Net product sales	\$81,956	\$18,191	\$6,895				
Collaborative licensing and development revenue	972	18,390	5,074				
Royalty revenue	2,623	2,503	3,720				
Total revenues	85,551	39,084	15,689				
Operating expenses:							
Cost of revenues	54,772	32,139	16,739				
Research and development	21,560	9,937	14,873				
Selling, general and administrative	62,508	46,306	20,159				
Impairment of long-lived assets		_	3,019				
Total operating expenses	138,840	88,382	54,790				
Loss from operations	(53,289	) (49,298	) (39,101	)			
Other (expense) income:							
Interest income	259	275	255				
Interest expense	(7,253	) (1,807	) (4,780	)			
Loss on early extinguishment of debt	(3,398	) (1,062	) —				
Royalty interest obligation	(623	) (278	) 227				
Other, net	(47	) (111	) 71				
Total other expense, net	(11,062	) (2,983	) (4,227	)			
Loss before income taxes	(64,351	) (52,281	) (43,328	)			
Income tax benefit	442	_					
Net loss	\$(63,909	) \$(52,281	) \$(43,328	)			
Net loss per share:							
Basic and diluted net loss per common share	\$(1.93	) \$(1.72	) \$(2.64	)			
Weighted average common shares outstanding:							
Basic and diluted	33,181,895	30,331,965	16,437,464				
See accompanying notes to consolidated financial statements							

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Pacira Pharmaceuticals, Inc. Consolidated Statements of Comprehensive Loss (In thousands)

	Year Ended December 31,						
	2013	2012	2011				
Net loss	\$(63,909	) \$(52,281	) \$(43,328	)			
Other comprehensive income:							
Net unrealized gain (loss) on investments	(22	) 12	15				
Total other comprehensive income (loss)	(22	) 12	15				
Comprehensive loss	\$(63,931	) \$(52,269	) \$(43,313	)			
See accompanying notes to consolidated financial statements							

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Pacira Pharmaceuticals, Inc. Consolidated Statements of Stockholders' Equity (Deficit) Year Ended December 31, 2013, 2012, and 2011 (In thousands)

(III tilousulus)	PreferredPreferredommonCommon  Stock Stock Stock Additional AccumulatedTreasur Paid-In Deficit Stock							Accumulated Other ry Comprehensive	
	Shares	Amou	n <b>S</b> hares	Amou	n <b>C</b> apital	Deficit	Stock	Income (Loss)	Total
Balances at December 31, 2010 Exercise of stock options	6,322	\$6 —	575 67	\$ 1 —	\$ 88,523 135	\$ (136,911)	\$(2 ) —	` ′	\$(48,383) 135
Share-based compensation Initial public offering, net of	_	_	_	_	2,493	_	_	_	2,493
issuance	_	_	6,000	6	37,103	_	_	_	37,109
costs Follow-on public offering, net									
of	_		8,050	8	48,998	_		_	49,006
issuance costs	(6.222.)	(6)	( 222						
Conversion of preferred stock Conversion of 2009 Convertible	(6,322)	(6)	6,322	6		_	_		_
Notes and accrued interest	_		872	1	11,717	_		_	11,718
Conversion of 2009 Secured Notes and accrued interest	_		928	1	12,473	_	_	_	12,474
Conversion of 2010 Secured	_	_	1,157	1	15,548	_	_	_	15,549
Notes and accrued interest Conversion of 2010 Convertible	a		1,137	1	13,540				13,547
Notes and accrued interest			1,071	1	7,499	_		—	7,500
Conversion of HBM Secured Notes and accrued interest			297		2 001				2.001
and early prepayment penalty	_	_	291	_	3,981	_	_	_	3,981
Unrealized gain on short-term		_	_	_		_	_	15	15
investments Net loss						(43,328 )		_	(43,328 )
Balances at December 31, 2011		_	25,339	25	228,470	(180,239)	(2)	15	48,269
Exercise of stock options			279	1	769				770
Exercise of warrants	_		105		100	_		_	100
Share-based compensation				_	4,776		_		4,776
Unrealized gain on short-term	_			_	_	_		12	12
investments Follow-on public offering, net									
of	_		6,900	7	62,848	_		_	62,855
issuance costs									
Debt discount on issuance of warrants		_	_	_	1,354	_	_		1,354
Net loss	_				_	(52,281)		_	(52,281)
Balances at December 31, 2012			32,623	33	298,317	(232,520 )	(2)	27	65,855
Exercise of stock options		_	741	1	3,855	_	_		3,856
Cashless exercise of warrants		_	271	_					
Share-based compensation				_	11,513		_		11,513

Unrealized loss on short-term investments	· _	_		_	_	 _	_	(22	) (22	)
Equity component of										
convertible					23,956	 _	_		23,956	
senior notes, net of issuance co	osts									
Issuance of common stock from	om		1		(2					
treasury	_		1		(2					