

Use these links to rapidly review the document

[TABLE OF CONTENTS](#)

[Index to Consolidated Financial Statements](#)

[Table of Contents](#)

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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, 2012**

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)

<b>Delaware</b>	<b>51-0619477</b>
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer 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:

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

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate 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  No

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

The aggregate market value of 17,621,276 shares of voting stock held by non-affiliates of the registrant, based upon the closing sale price of the common stock on June 30, 2012, the last business day of the registrant's most recently completed second fiscal quarter, of \$16.04 per share as reported on Nasdaq was \$282,645,267. Shares of common stock held by each director and executive officer 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 25, 2013, 32,656,356 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 2013 annual meeting of stockholders to be filed no later than 120 days after the end of the registrant's fiscal year ended December 31, 2012.

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**Table of contents**

	<b><u>Page No.</u></b>
<a href="#">PART I</a>	<a href="#">4</a>
<a href="#">Item 1. <u>Business</u></a>	<a href="#">4</a>
<a href="#">Item 1A. <u>Risk Factors</u></a>	<a href="#">33</a>
<a href="#">Item 1B. <u>Unresolved Staff Comments</u></a>	<a href="#">64</a>
<a href="#">Item 2. <u>Properties</u></a>	<a href="#">64</a>
<a href="#">Item 3. <u>Legal Proceedings</u></a>	<a href="#">65</a>
<a href="#">Item 4. <u>Mine Safety Disclosures</u></a>	<a href="#">65</a>
<a href="#">PART II</a>	<a href="#">65</a>
<a href="#">Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u></a>	<a href="#">65</a>
<a href="#">Item 6. <u>Selected Financial Data</u></a>	<a href="#">65</a>
<a href="#">Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u></a>	<a href="#">66</a>
<a href="#">Item 7A. <u>Quantitative and Qualitative Disclosures about Market Risk</u></a>	<a href="#">84</a>
<a href="#">Item 8. <u>Financial Statements and Supplementary Data</u></a>	<a href="#">84</a>
<a href="#">Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u></a>	<a href="#">84</a>
<a href="#">Item 9A. <u>Controls and Procedures</u></a>	<a href="#">84</a>
<a href="#">Item 9B. <u>Other Information</u></a>	<a href="#">87</a>
<a href="#">PART III</a>	<a href="#">87</a>
<a href="#">Item 10. <u>Directors, Executive Officers and Corporate Governance</u></a>	<a href="#">87</a>
<a href="#">Item 11. <u>Executive Compensation</u></a>	<a href="#">87</a>
<a href="#">Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u></a>	<a href="#">87</a>
<a href="#">Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u></a>	<a href="#">87</a>
<a href="#">Item 14. <u>Principal Accounting Fees and Services</u></a>	<a href="#">87</a>
<a href="#">PART IV</a>	<a href="#">87</a>
<a href="#">Item 15. <u>Exhibits and Financial Statement Schedules</u></a>	<a href="#">87</a>



## 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 DepoCyt(e) when discussed in the context of Europe.

## Explanatory Note

Under SEC rules and regulations, because the aggregate worldwide market value of our common stock held by non-affiliates was more than \$75 million, but less than \$700 million, as of June 30, 2012, the last business day of our most recently completed second fiscal quarter, we are considered to be an "accelerated filer" for fiscal year 2013. We were considered to be a "smaller reporting company" for fiscal year 2012. SEC rules and regulations provide that a smaller reporting company transitioning to the larger reporting system, as we are doing this year, may finish reporting as a smaller reporting company for the rest of the fiscal year, including in its annual report on Form 10-K. Accordingly, the Company has elected to comply with the disclosure requirements for a smaller reporting company in connection with the preparation of this Annual Report on Form 10-K.

## 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 to include nerve block; 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

#### Overview

We are an emerging specialty pharmaceutical company focused on the development, commercialization and manufacture of proprietary pharmaceutical products, based on our proprietary DepoFoam extended release drug delivery technology, for use in hospitals and ambulatory surgery centers.

Our lead product, EXPAREL, which consists of bupivacaine encapsulated in DepoFoam, was approved by the United States Food and Drug Administration, or FDA, on October 28, 2011. We commercially launched EXPAREL in April 2012.

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 estimate there are approximately 40 million opportunities annually in the United States for EXPAREL to be used.

We have developed a sales force entirely dedicated to commercializing EXPAREL comprised of approximately 60 representatives. This sales force has been active in the marketplace since January 2012.

Our commercial team has identified product champions for EXPAREL at key institutions for pharmacy therapeutic committee reviews, to support formulary approvals and to establish the optimal clinical role for EXPAREL among our key customers. As of December 31, 2012, we had access to 75% of our top 100 target hospital accounts, and 53% of our top 500 target hospital accounts. Since launch through December 31, 2012, we added, on average, 22 new accounts per week, and we had a total of approximately 819 accounts. In addition, as of December 31, 2012, we had 191 total accounts that had reordered EXPAREL greater than or equal to 6 times, and 110 accounts that had ordered EXPAREL greater than or equal to 10 times.

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

<u>Product(s)/Product Candidate(s)</u>	<u>Primary Indication(s)</u>	<u>Status</u>	<u>Commercialization Rights</u>
<b>EXPAREL</b>	Postsurgical analgesia by infiltration	Marketed	Pacira (worldwide)
	Postsurgical analgesia-nerve block	Phase 2 (completed)	Pacira (worldwide)
<b>Bupivacaine Liposome Injectable Suspension</b>	Veterinary postsurgical analgesia	Filed INAD	Aratana Therapeutics, Inc. (worldwide)

## [Table of Contents](#)

<b>Product(s)/Product Candidate(s)</b>	<b>Primary Indication(s)</b>	<b>Status</b>	<b>Commercialization Rights</b>
<b>DepoCyt(e)</b>	Lymphomatous meningitis	Marketed in U.S.	Sigma-Tau Pharmaceuticals
		Marketed in E.U.	Mundipharma International
<b>DepoDur</b>	Post-operative pain	Withdrawn	Pacira (worldwide)
<b>DepoNSAID</b>	Acute pain	Preclinical	Pacira (worldwide)
<b>DepoMethotrexate</b>	Rheumatoid arthritis	Preclinical	Pacira (worldwide)
	Oncology	Preclinical	Pacira (worldwide)

## **Our Strategy**

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

- 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;
- in order to demonstrate the economic benefits of EXPAREL, working directly with managed care payers, quality improvement organizations, 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 by securing a commercial partner for Bupivacaine Liposome Injectable Suspension to serve the companion animal market;
- manufacturing all our DepoFoam-based products, including EXPAREL, in our current Good Manufacturing Practices, or cGMP, compliant facilities;
- 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.

## **Postsurgical Pain Market Overview**

According to Thomson Reuters, roughly 75 million inpatient and outpatient surgical procedures are performed annually in the United States. We estimate there are approximately 40 million



## [Table of Contents](#)

opportunities annually in the United States where EXPAREL could be used to improve patient outcomes and enhance hospital economics. Postsurgical pain is a response to tissue damage during surgery that stimulates peripheral nerves, which signal the brain to produce a sensory and psychological response. Numerous studies reveal that the incidence and severity of postsurgical pain is primarily determined by the type of surgery, duration of surgery and the pain treatment choice following surgery. Postsurgical pain is usually the most severe the first few days after the completion of a surgical procedure.

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

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

#### ***Local Anesthetics***

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

#### ***Opioids***

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

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

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

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

## [Table of Contents](#)

### **NSAIDs**

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

### **Our Solution—EXPAREL**

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

Our EXPAREL strategy has four principal elements:

- 1) *Replace the use of bupivacaine in postsurgical infiltration.* Based on our clinical data, EXPAREL:
  - extends postsurgical analgesia for up to 72 hours, from approximately eight hours or less;
  - utilizes existing postsurgical infiltration administration techniques;
  - dilutes easily with saline to reach desired volume;
  - is a ready-to-use formulation; and
  - facilitates treatment of both small and large surgical sites.
  
- 2) *Become the foundation of a postsurgical pain management regimen in order to reduce and delay opioid usage.* Based on the clinical data from our Phase 3 hemorrhoidectomy trial as well as our retrospective health outcomes studies data, EXPAREL:
  - significantly delays and reduces opioid usage while improving postsurgical pain management;
  - 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.* We believe EXPAREL:
  - provides effective pain control without the need for expensive and difficult to use delivery technologies which 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 with an NSAID and acetaminophen and morphine rescue;
  - reduces the need for patients to be constrained by elastomeric bags and PCA systems, which are clumsy, difficult to use and may

introduce catheter-related issues, including infection;

- promotes maintenance of early postsurgical pain management, thereby reducing the time spent in the intensive care unit; and

## [Table of Contents](#)

- promotes early ambulation, which potentially reduces the risk of life-threatening blood clots, and allows quicker return of bowel function, thereby leading to a faster switch to oral nutrition and medicine, and thus a faster discharge from the hospital.
- 4) *Develop and seek approval of EXPAREL for nerve block administration.* We believe this additional indication for EXPAREL:
- presents a low-risk, low-cost opportunity for clinical development; and
  - enables us to fully leverage our manufacturing and sales infrastructure.

### **EXPAREL Development Program**

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

The safety of EXPAREL has been demonstrated in 21 clinical trials consisting of nine Phase 1 trials, seven Phase 2 trials and five Phase 3 trials. EXPAREL was administered to over 1,300 human patients at doses ranging from 10 mg to 750 mg administered by local infiltration into the surgical site, and by subcutaneous, perineural, epidural and intraarticular administration. In all 21 clinical trials, EXPAREL was well tolerated. The most common treatment emergent adverse events in the EXPAREL and placebo groups were nausea and vomiting and occurred with similar frequency across the EXPAREL and placebo groups. No signal of any of the central nervous system or cardiovascular system adverse events typically observed with high doses of bupivacaine has been observed with EXPAREL. We conducted two thorough QTc studies that demonstrated that EXPAREL did not cause significant QTc prolongation (a measure of cardiac safety mandated by the FDA for all new products) even at the highest dose evaluated. No events of destruction of articular cartilage, or chondrolysis, have been reported in any of the EXPAREL trials. EXPAREL did not require dose adjustment in patients with mild to moderate liver impairment.

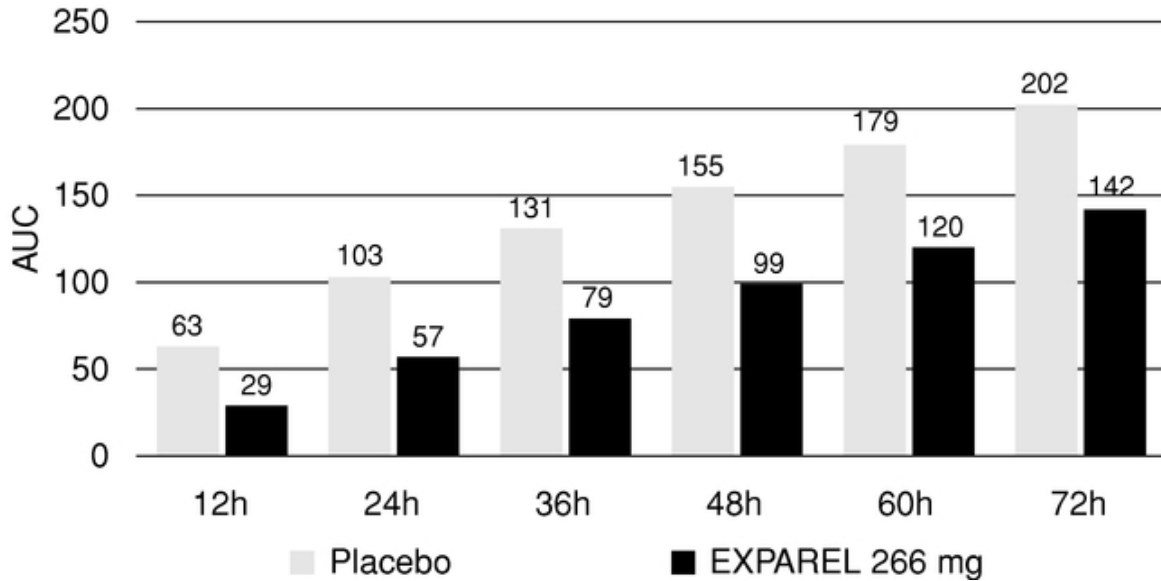
#### ***Pivotal Phase 3 Clinical Trials***

*Hemorrhoidectomy.* Our pivotal Phase 3 hemorrhoidectomy clinical trial was a multicenter, randomized, double-blind, placebo-controlled trial conducted in 189 patients at 14 sites in Europe. The study enrolled patients 18 years of age or older undergoing a two or three column excisional hemorrhoidectomy under general anesthesia using the Milligan-Morgan technique, a commonly used method for surgically removing hemorrhoids. We studied a 266 mg dose of EXPAREL with a primary endpoint of pain control for up to 72 hours with morphine rescue medication available to both trial groups. Additional endpoints included the proportion of pain-free patients, proportion of patients requiring opioid rescue medication, total opioid usage, time to first use of opioid rescue medication and patient satisfaction.

The 266 mg dose of EXPAREL provided a statistically significant 30% reduction in pain ( $p < 0.0001$ ), as measured by the area under the curve, or AUC, of the NRS-R pain scores at 72 hours and all additional time points measured up to 72 hours. The numeric rating scale at rest score, or the NRS-R, is a commonly used patient reported measurement of pain. Under the NRS-R, severity of pain

is measured on a scale from 0 to 10, with 10 representing the worst possible pain. The AUC of the NRS-R pain score represents a sum of the patient's pain measured at several time points using the NRS-R, from time of surgery to the specified endpoint. A lower number indicates less cumulative pain. The p-value is a measure of probability that the difference between the placebo group and the EXPAREL group is due to chance (e.g.,  $p = 0.01$  means that there is a 1% ( $0.01 = 1.0\%$ ) chance that the difference between the placebo group and EXPAREL group is the result of random chance as opposed to the EXPAREL treatment). A p-value less than or equal to 0.05 ( $0.05 = 5\%$ ) is commonly used as a criterion for statistical significance.

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



In referencing our pivotal Phase 3 hemorrhoidectomy clinical trial, the FDA-approved label EXPAREL noted there was a significant treatment effect for EXPAREL compared to placebo treatment over the first 72 hour period. In addition, the FDA noted that EXPAREL demonstrated a significant reduction in pain intensity compared to placebo for the first 24 hours. While the FDA concluded that between 24 and 72 hours after the drug administration there was minimal to no difference between EXPAREL and the placebo treatment group on mean pain intensity, there was an attendant decrease in opioid consumption.

In secondary endpoints, EXPAREL demonstrated efficacy in reducing the use of opioid rescue medication, which was available to both the EXPAREL treatment group and the placebo treatment group. Approximately three times the number of patients in the EXPAREL treatment group avoided opioid rescue medication altogether, and patients in the EXPAREL treatment group showed 45% less opioid usage compared to the placebo treatment group at 72 hours. Opioid-related secondary endpoints included:

- *Total avoidance of opioid rescue medication.* 28% of patients treated with EXPAREL received no postsurgical opioid rescue pain medication through 72 hours post-dose. By contrast only 10% of placebo treated patients avoided all opioid rescue medication through 72 hours, and this difference was statistically significant ( $p=0.0007$ );

## [Table of Contents](#)

- *Reduced total consumption of opioid rescue medication.* The adjusted mean total postsurgical consumption of supplemental opioid pain medication was 45% lower in patients treated with EXPAREL compared to the placebo treatment group through 72 hours ( $p=0.0006$ ) post-dose; and
- *Delayed use of opioid rescue medication.* EXPAREL delayed the median time to first opioid use from approximately one hour in the placebo treatment group to approximately 14 hours in the EXPAREL treatment group and this difference was statistically significant ( $p<0.0001$ ). At 14 hours post-surgery compared to one hour post-surgery, patients substantially recovered from the effects of surgical anesthesia and were able to tolerate oral opioids and required less intensive monitoring.

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

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

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

*Bunionectomy.* Our pivotal Phase 3 bunionectomy clinical trial was a multicenter, randomized, double-blind, placebo-controlled trial conducted in 193 patients at four sites in the United States. The study enrolled patients 18 years of age or older undergoing a bunionectomy. We studied a 106 mg dose of EXPAREL with a primary endpoint of pain control at 24 hours, the critical period for postsurgical pain management in bunionectomy, with opioid rescue medication available to both trial groups. EXPAREL provided a statistically significant reduction in pain, as measured by the AUC of the NRS-R pain scores at 24 hours ( $p=0.0005$ ). This reduction was also statistically significant at 36 hours.

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

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

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

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

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

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

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

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

In addition to being efficacious and safe, we believe that EXPAREL provides health economic benefits that play an important role in formulary decision making and these health economic benefits are an often over-looked factor in planning for the commercial success of a pharmaceutical product. Several members of our management team have extensive experience applying health economic outcomes research to support the launch of successful commercial products. Our strategy is to work directly with our hospital 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.

EXPAREL is designed as a single postsurgical injection intended to replace the current use of clumsy and expensive PCA systems and elastomeric bag systems, reduce the consumption of opioids, and their related side effects, and reduce the length of stay in the hospital, all factors that negatively impact patient outcomes and hospital economics.

In our Phase 2 hemorrhoidectomy trial which was performed in a multimodal design where patients were randomized to bupivacaine or EXPAREL with all patients receiving ketorolac, acetaminophen and opioid rescue the EXPAREL patients experienced:

- a 47% reduction in pain;
- 66% less opioid usage at 72 hours post-surgery compared to bupivacaine; and

## [Table of Contents](#)

- delayed first opioid usage to approximately 19 hours post-surgery, compared to approximately eight hours or less for bupivacaine ( $p < 0.0049$ ).

In our Retrospective Health Outcomes programs being conducted by our hospital customer groups utilizing their own data, they have found that the use of opioids for postsurgical pain control is a significant driver of hospital resource consumption including length of stay, or LOS.

We intend to expand upon the results of this Phase 2 hemorrhoidectomy trial with commercial Phase 4 retrospective and prospective studies designed to confirm that the administration of EXPAREL in the surgical setting improves patient outcomes while consuming fewer resources. We have conducted several retrospective studies working with our hospital customers, integrated health networks and group purchasing organizations which demonstrate that the use of opioid postsurgical pain control is a significant driver of inappropriate resource utilization, including extending LOS. We have developed and will continue to develop publications, abstracts, clinical pharmacology newsletters and meeting presentations that demonstrate the value of EXPAREL as the foundation for effective multimodal postsurgical pain management. We have completed a series of prospective trials with our hospital customers to demonstrate how the use of EXPAREL as the foundation of a multimodal regimen replaces morphine (opioid) PCA, improves the quality of care by reducing the burden of opioids and enhances hospital economics by reducing inappropriate resource consumption including length of stay.

In November 2012, we announced that results from the first completed IMPROVE study of our prospective Phase 4 clinical program were published in the online version of the *Journal of Pain Research*. The IMPROVE studies compare the difference in opioid use, total hospital cost and length of stay (LOS) between patients receiving EXPAREL as the foundation of an opioid-sparing multimodal regimen versus a standard opioid-based postsurgical pain management regimen.

Compared to patients undergoing open colectomy in the standard opioid-based treatment arm, patients undergoing the same procedure and receiving an EXPAREL-based multimodal regimen had:

- A 2.9-day reduction in median LOS (4.9 days in the hospital vs 2.0 days in the hospital, respectively;  $p=0.004$ )
- A \$3,084 reduction in mean total hospital cost (\$11,850 vs \$8,766, respectively;  $p=0.027$ )
- A 58 mg reduction in mean opioid consumption (115 mg vs 57 mg, respectively;  $p=0.025$ )

In addition, we plan to develop new treatment protocols for postsurgical pain management overall and in specific patient populations who are known to be most problematic with the use of opioids for postsurgical pain control. By providing models which are predictive for patients likely to be resource consumption and length of stay outliers, we can work with our hospital customers to improve patient care and enhance hospital economics.

Reimbursement for surgical procedures is typically capitated, or fixed by third-party payers based on the specific surgical procedure performed regardless of the cost or amount of treatments provided. However, many patients, including those who are elderly, obese, suffer from sleep apnea or are opioid tolerant, are likely to have a high incidence of opioid-related adverse events, increasing the length of stay and the cost relative to the capitated reimbursement. Furthermore, the use of EXPAREL to reduce opioid consumption may also present the opportunity to move selected hospital procedures to the ambulatory setting.

### ***EXPAREL Regulatory Plan***

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.



## [Table of Contents](#)

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 DepoDur.

The FDA, as a condition of the 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 - 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 NDA, or sNDA, for nerve block administration. We believe that this additional indication for EXPAREL presents a low-risk, 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.

We have completed one Phase 2 clinical trial in which 38 patients received EXPAREL for nerve block. EXPAREL demonstrated effectiveness and was safe and well tolerated in this clinical trial. In 2012 we began two pivotal nerve block studies, an intercostal block study in posterolateral thoracotomy patients and a femoral nerve block in total knee arthroplasty (TKA) patients. We expect the studies to be completed in 2013, and we expect to file an sNDA in 2014.

### **Sales and Marketing**

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

The members of our management team who are leading the commercialization of EXPAREL have successfully launched multiple products in the hospital market, including Rocephin, Versed, Zantac IV and Angiomax. We have developed our commercialization strategy with the input of KOLs in the field of postsurgical pain management as well as healthcare practitioner and quality improvement organizations.

Our commercial team executed on a full range of prelaunch activities for EXPAREL, including:

- preparing publications and abstracts for the EXPAREL clinical program efficacy and safety, health outcomes program and review articles on pain management;

## [Table of Contents](#)

- conducting 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;
- participating in KOL development programs and advisory boards to address topics of best practice techniques, guidelines and protocols for the use of EXPAREL, educational needs of our physician, pharmacist and registered nurse customers, nerve block clinical studies and additional indications for the future development of EXPAREL; and
- undertaking education initiatives such as center of excellence programs, preceptorship programs, pain protocols and predictive models for enhanced patient care, web-based training and virtual launch programs.

We believe that all of these programs and personal interactions with our hospital customers helped position Pacira and EXPAREL for a successful launch in April of 2012. We focused on the following for our launch strategy:

- Plastic Surgery—we focused on abdominoplasty, or tummy tuck and mommy make over, procedures since these procedures are predominately performed outside of the hospital environment and do not require formulary approval, are typically a cash market and the plastic surgeons have been most interested in providing long term non-opioid pain control. We recently completed a prospective study, EXCLAIM, with patient reported outcomes in this ambulatory patient setting. In addition, these surgeons often perform reconstructive procedures in the hospital setting which is an important focus of our outcomes research.
- Replacing Elastomeric Bags—these bags are typically filled with bupivacaine and the drug is dripped through a catheter which is inserted directly into the surgical site. In addition to being clumsy and difficult to use there have been a number of safety issues associated with the use of these bags. We have support from the pharmacy community to replace these bags with a single postsurgical injection of EXPAREL based on safety, patient compliance, ease of use and cost.

Abdominal, genitourinary and peri-anal soft tissue surgery such as cholecystectomy, colectomy, hysterectomy, herniorraphy, hemorrhoidectomy, prostatectomy and ileostomy reversal. This strategy allows our sales force to focus on colorectal surgeons, general surgeons, urologists and OBGYNs. Our focus will be to replace the current use of elastomeric bags and opioid PCA to improve patient outcomes and enhance hospital economics.

Initially, through our relationship with Quintiles, we outsourced our dedicated commercial sales force, consisting of approximately 60 representatives. 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. In order to increase the speed with which we address market segments, or to increase our access to market segments 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 target audience for EXPAREL is healthcare practitioners who influence pain management decisions, including surgeons, anesthesiologists, pharmacists and nurses. Our commercial sales force focuses on reaching the top 500 U.S. hospitals performing surgical procedures (based on Thomson Reuters benchmark obstetrician and gynecological, general and orthopedic surgical procedures performed within these hospitals), which represent greater than 50% of U.S. surgeries with a soft tissue focus. If we obtain regulatory approvals for additional indications for EXPAREL and our product candidates, our targeted audience may change to reflect new market opportunities.

## DepoFoam—Our Proprietary Drug Delivery Technology

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

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

- *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, DepoCyt(e) and DepoDur, have been approved in the United States and Europe, making regulatory authorities familiar with our DepoFoam technology;
- *Extensive safety history.* Our DepoFoam products have over ten years of safety data as DepoCyt(e) has been sold in the United States since 1999;
- *Proven manufacturing capabilities.* We make the DepoFoam-based product, 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 \$6.0 million from our commercial partners in 2012.

## 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

## [Table of Contents](#)

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 2013.

### ***DepoMethotrexate***

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

### **Commercial Partners and Agreements**

#### ***SkyePharma***

In connection with the stock purchase agreement related to the Acquisition, we agreed to pay SkyePharma Holdings, Inc., or SPHI, specified contingent milestone payments related to EXPAREL sales. Additionally, we agreed to pay to SPHI a 3% percentage of our sales of EXPAREL 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

We have the right to cease paying the 3% percentage payments in the event that SPHI breaches certain covenants not to compete contained in the stock purchase agreement. In the event that we cease to sell EXPAREL and begin marketing a similar replacement product for EXPAREL, we would no longer be obligated to make percentage payments, but we may be required to make certain milestone payments upon reaching certain sales milestones.

#### ***Research Development Foundation***

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

#### ***Sigma-Tau Pharmaceuticals***

In December 2002, we entered into a supply and distribution agreement with Enzon Pharmaceuticals Inc. regarding the sale of DepoCyt. Pursuant to the agreement, Enzon was appointed the exclusive distributor of DepoCyt in the United States and Canada for a ten year term. In January 2010, Sigma-Tau Pharmaceuticals, Inc., or Sigma-Tau, acquired the rights to sell DepoCyt from Enzon Pharmaceuticals for the United States and Canada. Under the supply and distribution agreement, we

## [Table of Contents](#)

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

Under the agreement, as amended, and a separate supply agreement, we receive a fixed payment for manufacturing the vials of DepoCyt, 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 DepoCyt in any three countries in the territory covered in the agreement by a final non-appealable judgment in respect of infringement by DepoCyt of any third party intellectual property rights.

### ***EKR Therapeutics Inc.***

In August 2007, we entered into a licensing, distribution and marketing agreement with EKR Therapeutics, Inc., or EKR, granting them exclusive distribution rights to DepoDur in North America, South America and Central America. Under this agreement, as amended, we received nonrefundable license fees of \$5.0 million upon execution of the agreement in August 2007, \$5.0 million in 2008, and \$5.0 million in 2009. At the time we entered into the agreement we had the right to receive aggregate milestone payments of up to \$20.0 million, but we do not expect any additional milestone payments under the agreement.

On January 3, 2012, EKR exercised its right to terminate the agreement and delivered a notice of termination. Pursuant to the terms of the agreement, the termination of the licensing, distribution and marketing agreement was effective 180 days from the date of the notice or July 1, 2012. Pursuant to the terms of the agreement the associated supply agreement also terminated concurrently with the termination of the licensing agreement. In connection with the termination of the agreement, EKR transferred the New Drug Application for DepoDur back to us, per the terms of the agreement, and the NDA has since been withdrawn.

[Table of Contents](#)

***Flynn Pharma Limited***

In September 2007, we entered into a marketing agreement with Flynn Pharma Limited, or Flynn, granting them exclusive distribution rights to DepoDur in the European Union, certain other European countries, South Africa and the Middle East.

We had the right to terminate the agreement if Flynn failed to make its first commercial sale of DepoDur in specified countries covered by the agreement by one year from the later of Flynn's receipt of marketing authorization or pricing approval for DepoDur, or if first commercial sale had not been made within 18 months of Flynn's receipt of marketing authorization or pricing approval for DepoDur. Because Flynn failed to make its first commercial sale, per the terms noted above, we terminated this agreement effective immediately on October 29, 2012.

***Novo Nordisk***

In January 2011, we entered into an agreement with Novo Nordisk A/S, or Novo, pursuant to which we granted non-exclusive rights to Novo under certain of our patents and know-how to develop, manufacture and commercialize formulations of a Novo proprietary drug using our DepoFoam drug delivery technology. Under this agreement, we agreed to undertake specified development and technology transfer activities and to manufacture pre-clinical and certain clinical supplies of such DepoFoam formulated Novo product until the completion of such technology transfer activities. In connection with the Novo agreement, we received a one-time upfront payment of \$1.5 million in January 2011 and a milestone payment of \$2.0 million in November 2011. On June 29, 2012, Pacira received from Novo a notice of termination of this agreement due to Novo's decision to discontinue development of the proprietary drug subject to the agreement. Pursuant to the terms of the agreement, the termination of the agreement was effective August 28, 2012.

***Paul Capital***

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

***Aratana Therapeutics***

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.

## [Table of Contents](#)

In connection with our entry into the agreement, we received a one-time payment of \$1 million and are eligible to receive up to an additional aggregate \$42.5 million upon the achievement of development and commercial milestones. Once the product has been approved by the 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.

### ***Feasibility Agreements with Third Parties***

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

### **Manufacturing**

We manufacture EXPAREL and DepoCyt(e) in two manufacturing facilities that we refer to as our 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

## [Table of Contents](#)

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 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. We are working on expanding our manufacturing capacity to meet future demand of EXPAREL.

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, 2012, 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 regard to patents providing protection for EXPAREL, issued patents in the United States relating to the composition of the product candidate and methods for modifying the rate of drug release of the product candidate expire in November 2013 and September 2018, respectively. Pending U.S. applications relating to the composition of the product candidate and the process for making the product candidate, if granted, would expire in September 2018 and November 2018, respectively. In Europe, granted patents related to the composition of the product candidate expire in November 2014



## [Table of Contents](#)

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 entities that receive our confidential data or materials.

### **Competition**

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

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

## [Table of Contents](#)

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 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 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

## [Table of Contents](#)

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

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

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

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

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

## [Table of Contents](#)

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 (NME) 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 NME 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

[Table of Contents](#)

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

## [Table of Contents](#)

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

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

therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

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

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

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

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

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

The commercial success of our 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

## [Table of Contents](#)

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



## [Table of Contents](#)

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

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

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

[Table of Contents](#)

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 for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. In addition, the 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. Additional safe harbor provisions providing similar protections have been published intermittently since 1991. Although full compliance with these provisions ensures against prosecution under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued. However, conduct and business arrangements that do not fully satisfy 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.

## [Table of Contents](#)

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 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.

## [Table of Contents](#)

### ***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, 2012, we employed 156 employees, of which 154 were full-time employees. 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**

We file reports and other information with the SEC as required by the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act. You can find, copy and inspect information we file at the SEC's public reference room, which is located at 100 F Street, N.E., Room 1580, Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the SEC's public reference room. You can review our electronically filed reports and other information that we file with the SEC on the SEC's web site at <http://www.sec.gov>. In addition, 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.

## 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), DepoDur®, 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.

### Item 1A. Risk Factors

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

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

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

We have invested a significant portion of our efforts and financial resources in the development of EXPAREL. Our success depends on our ability to effectively commercialize EXPAREL, which was approved by the FDA on October 28, 2011, for administration into the surgical site to produce postsurgical analgesia.

We commercially launched EXPAREL in April of 2012, but our ability to effectively generate revenues from EXPAREL will depend on our ability to:

- create market demand for EXPAREL through our marketing and sales activities, and any other arrangements to promote this product we may later establish;
- 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;
- ensure that our entire supply chain for EXPAREL 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.

[Table of Contents](#)

*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.*

As EXPAREL is a newly marketed drug, none of the members of the EXPAREL sales force have ever promoted EXPAREL. As a result, we expend significant time and resources to train the sales force to be credible and persuasive in convincing physicians and hospital 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 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 convenience and ease of administration of EXPAREL;
- the prevalence and severity of adverse events associated with EXPAREL;
- cost of treatment versus economic and clinical benefit in relation to alternative treatments;
- the availability of adequate coverage or reimbursement by third parties, such as insurance companies and other healthcare payers, and by government healthcare programs, including Medicare and Medicaid;
- the extent and strength of our marketing and distribution of EXPAREL;

## [Table of Contents](#)

- 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 generally and technology. As a result, these companies may obtain regulatory approval more rapidly than we are able to and may be more effective in selling and marketing their products. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis technologies and drug products that are more effective or less costly than EXPAREL or any 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 limit our ability to develop other indications for, or commercialize, EXPAREL. Our competitors may also develop drugs that are more effective, useful or less costly than ours and may be more successful than us in manufacturing and marketing their products.

EXPAREL 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

[Table of Contents](#)

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 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 commercialize EXPAREL, 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. We may also seek to commercialize EXPAREL outside the United States, although we currently plan to do so with a marketing and sales collaborator and not with our own sales force.

The establishment, 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.

***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.



## [Table of Contents](#)

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, 2012, we had 156 employees. We will 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;
- ensure that our consultants and other service providers successfully carry out their contractual obligations, provide high quality results, and meet expected deadlines;
- continue to carry out our own contractual obligations to our licensors and other third parties; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

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

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

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

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the development and manufacturing expertise for our DepoFoam delivery technology and the commercialization expertise of certain members of our senior management. In particular, we are highly dependent on the skills and leadership of our management team, including David Stack, our president and chief executive officer. If we lose one or more of these key employees, our ability to successfully implement our business strategy could be seriously harmed.

Replacing key

[Table of Contents](#)

employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate additional key personnel.

Mr. Stack, our chief executive officer, is also a managing director at MPM Capital and a managing partner of Stack Pharmaceuticals, Inc. Although Mr. Stack has devoted substantially all of his 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.

***The Medicines and Healthcare products Regulatory Agency issued an inspection report noting certain critical deficiencies in our manufacturing of DepoCyt(e) and remediation of these deficiencies could result in significant costs or delays in the production and sale of DepoCyt(e).***

In July 2012, the Medicines and Healthcare products Regulatory Agency, or MHRA, conducted its standard inspection of our DepoCyt(e) manufacturing facility, which is located in a separate building from our EXPAREL manufacturing facility. Following its inspection, 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. We temporarily ceased manufacturing DepoCyt(e) in order to implement a remediation plan and address the failures noted in the MHRA inspection report. In connection with the inspection report, the European Medicines Agency issued an assessment report which recommended the use of alternative treatments in countries where DepoCyt(e) is not deemed to be an essential medical product. 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." The assessment report did not recommend a recall for member countries where DepoCyt(e) is considered to have "essential medicinal product" status.

EU member states give "essential medicinal product" status to a product if there are no alternative treatments in such countries and each country made a determination of whether DepoCyt(e) was an "essential medicinal product" on a country by country basis. The extent of the recall's impact on our sales of DepoCyt(e) is difficult to predict because a number of countries that determined DepoCyt(e) was not an "essential medicinal product" also determined that it could still be used in exceptional circumstances or upon special request. The recall contributed to a reduction in product sales of DepoCyt(e) for the three and twelve months ended December 31, 2012, respectively.

We have completed the implementation of our remediation plan. In December 2012, the MHRA re-inspected our DepoCyt(e) manufacturing facility to review progress in the implementation of our remediation commitments arising from the July 2012 inspection. We received notice in January 2013 from the MHRA that our remediation efforts were successful and that we could resume production of DepoCyt(e) for sale in Europe. The temporary cessation of the manufacturing of DepoCyt(e) for sales in the EU could result in additional costs or delays in the production and sale of DepoCyt(e), which could have a material adverse effect on our business, financial position and results of operations.

We advised the FDA of the MHRA's inspectional findings after we received the July inspection report, and the FDA indicated it had no issue with continued distribution of DepoCyt(e) in the U.S. market pending our remediation efforts. We plan to resume production of DepoCyt(e) for sales in the United States in the first quarter of 2013.

[Table of Contents](#)

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

The use of DepoCyt(e), DepoDur, 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 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 current Good Manufacturing Practices, or 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, imposition of a consent decree, or withdrawal of product approval, and would limit the availability of

[Table of Contents](#)

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.

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

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.***

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.

If we are unable to achieve and maintain satisfactory production yields and quality as we expand our manufacturing capabilities, our relationships with potential customers and overall reputation may be harmed, and our revenues could decrease.

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

We are the sole manufacturer of DepoCyt(e). We develop and manufacture DepoCyt(e) at our facility in San Diego, California, which is the only FDA approved site for manufacturing DepoCyt(e) in the world. In connection with our response to the MHRA regarding their inspectional observations, we temporarily ceased manufacturing DepoCyt(e) in order to implement our remediation plan and address the failures noted in the MHRA inspection report. In December 2012, the MHRA conducted a further inspection of our DepoCyt(e) manufacturing facility to review progress in the implementation of our remediation commitments arising from the MHRA's July 2012 inspection. In January 2013, the MHRA cleared us to recommence manufacturing of DepoCyt(e) for Europe. We advised the FDA of the MHRA's inspectional findings after we received the July inspection report, and the FDA indicated it

[Table of Contents](#)

had no issue with continued distribution of DepoCyt(e) in the U.S. market pending our remediation efforts. We plan to resume production of DepoCyt(e) for sales in the United States in the first quarter of 2013. The temporary cessation of the manufacturing of DepoCyt(e) for sales in the EU could result in additional costs or delays in the production and sale of DepoCyt(e), which could have a material adverse effect on our business, financial position and results of operations.

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 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 DepoCyt(e) at our facility in San Diego, California could result in a disruption in the supply of DepoCyt(e) to our partners and breach of our contractual obligations.

***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.***

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

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

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

- difficulty or inability to secure financing to fund development activities for such development, acquisition or in-licensed products or technologies;
- incurrence of substantial debt or dilutive issuances of securities to pay for development, acquisition or in-licensing of new products;
- disruption of our business and diversion of our management's time and attention;

## [Table of Contents](#)

- higher than expected development, acquisition or in-license and integration costs;
- exposure to unknown liabilities;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- inability to retain key employees of any acquired businesses;
- difficulty in managing multiple product development programs; and
- inability to successfully develop new products or clinical failure.

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

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

Our manufacturing activities involve the controlled storage, use and disposal of hazardous materials, including the components of our products, product candidates and other hazardous compounds. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling, release and disposal of, and exposure to, these hazardous materials. Violation of these laws and regulations could lead to substantial fines and penalties. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials 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, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed clinical trials for EXPAREL could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of our product candidates may be delayed.

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

Our business model is to commercialize our product candidates in the United States and generally to seek collaboration arrangements with pharmaceutical or biotechnology companies for the

## [Table of Contents](#)

development or commercialization of our product candidates in the rest of the world. Accordingly, we may enter into collaboration arrangements in the future on a selective basis. Any future collaboration arrangements that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaboration arrangements.

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

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

### **Regulatory Risks**

***We may not receive regulatory approval for 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, denial, suspension or withdrawal of regulatory approval by the FDA or other regulatory authorities for any or

## [Table of Contents](#)

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 undesirable side effects caused by 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 or change the labeling of the product;
- we may be subject to product liability claims and litigation; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of EXPAREL or any of our 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



[Table of Contents](#)

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.

***EXPAREL and any other products we may market, including DepoCyt(e), will remain subject to substantial regulatory scrutiny.***

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

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

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

For example, 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 the inspectional observations 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 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

## [Table of Contents](#)

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

## [Table of Contents](#)

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

[Table of Contents](#)

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, 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 our contract manufacturers 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;
- fines and other monetary penalties;
- criminal prosecutions; and
- unanticipated expenditures.

***If the government or third-party payers fail to provide coverage and adequate coverage and payment rates for EXPAREL, DepoCyt(e) or any future products 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

## [Table of Contents](#)

considered cost-effective. Adequate third-party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

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

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

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

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

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

## [Table of Contents](#)

- 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. 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.

Recently, the President signed into law the Food and Drug Administration Safety and Innovation Act, or FDASIA. The new law and related agreements make 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;

## [Table of Contents](#)

- 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;
- creates 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 FDA to issue a report on, among other things, ensuring the safety of prescription drugs that have the potential for abuse;
- requires FDA to hold a public meeting regarding the potential rescheduling of drug products containing hydrocodone, which was held in October 2012; and
- requires electronic submission of certain marketing applications following the issuance of final FDA regulations.

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

## [Table of Contents](#)

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 are more reliant on trade secrets to protect against generic competition.

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

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.

## [Table of Contents](#)

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 an emerging 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 \$52.3 million, \$43.3 million and \$27.1 million, for the years ended December 31, 2012, 2011 and 2010, respectively. As of December 31, 2012, we had an accumulated deficit of \$232.5 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 during 2010, 2011 and 2012 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

## [Table of Contents](#)

- 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, in 2010, 2011 and 2012 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;

## [Table of Contents](#)

- 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;

## [Table of Contents](#)

- our execution of other collaborative, licensing or similar arrangements and the timing of payments we may make or receive under these arrangements;
- variations in the level of expenses related to our future development programs;
- any product liability or intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting EXPAREL or the product candidates of our competitors; and
- 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.

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

As a public company, we incur significant legal, accounting, insurance and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We also have incurred and will incur costs associated with complying with the requirements of the Sarbanes-Oxley Act of 2002 and related rules implemented by the Securities and Exchange Commission and The NASDAQ Global Select Market. The expenses incurred by public companies generally for reporting and corporate governance purposes have been increasing. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any degree of certainty. These laws and regulations could also make it more difficult or costly for us to obtain or maintain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as our executive officers. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions and other regulatory action and potentially civil litigation.

[Table of Contents](#)

***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 carryforward indefinitely. Additionally, our ability to use any net operating loss and credit carryforwards to offset taxable income or tax, respectively, in the future will be limited under Internal Revenue Code Sections 382 and 383 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.

## [Table of Contents](#)

***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 25, 2013, the trading prices of our stock have ranged from \$6.16 to \$21.17 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

[Table of Contents](#)

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.

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

As of December 31, 2012, our executive officers, directors and 5% stockholders and their affiliates beneficially own approximately 60% of our outstanding voting stock. As a result, these stockholders have significant influence and may be able to determine matters requiring stockholder approval. For example, these stockholders may be able to materially affect elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transactions. This concentration of ownership could delay or prevent any acquisition of our company on terms that other stockholders may desire.

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 existing stockholders may sell a substantial number of shares in the public market. Furthermore, a substantial number of shares of our common stock is reserved for issuance upon the exercise of stock options and upon conversion of the Notes. 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, 2012, the average per day trading volume of our common stock was 275,771 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.

***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 the "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 continue to 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.

As of December 31, 2012, our total consolidated indebtedness was \$27.5 million, all of which was secured indebtedness, and our subsidiaries had no indebtedness (in each case, excluding trade payables, intercompany liabilities and income tax-related liabilities).

[Table of Contents](#)

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 net proceeds from the offering were approximately \$115.3 million, after deducting the initial purchasers' discounts and commissions and the estimated offering expenses payable by the Company. 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.

The Company used \$30.1 million of the net proceeds from the offering of the Notes to repay in full the \$27.5 million credit facility with Oxford Finance LLC. In connection with such termination, the Company paid the remaining principal amount of \$27.5 million as well as accrued interest, certain prepayment fees and an end of term charge in the aggregate amount of \$2.6 million.

***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, may adversely affect our financial condition and operating results.***

In the event the conditional conversion feature of the Notes is triggered, holders of the Notes will be 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

[Table of Contents](#)

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 could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

***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.

[Table of Contents](#)

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

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

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

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

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

We have never declared or paid cash dividends on our common stock. In addition, we must comply with the covenants in our credit facilities if we want to pay cash dividends. 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 current or future financing instruments and such other factors as our board of directors deems relevant.

**Item 1B. Unresolved Staff Comments**

Not applicable.

**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 July 2015. We use these facilities for research and development, manufacturing and general and administrative purposes. 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 are sufficient for our current needs. We intend to add new facilities or expand existing facilities as we add employees or expand our geographic markets, and

[Table of Contents](#)

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:

<u>Year Ended 2012</u>	<u>High</u>	<u>Low</u>
Fourth Quarter	\$ 19.09	\$ 15.07
Third Quarter	19.31	14.00
Second Quarter	16.93	9.60
First Quarter	12.01	7.38

<u>Year Ended 2011</u>	<u>High</u>	<u>Low</u>
Fourth Quarter	\$ 12.10	\$ 6.51
Third Quarter	12.41	7.06
Second Quarter	15.34	6.80
First Quarter (beginning February 3, 2011)	7.60	6.16

On February 25, 2013, the closing price of our common stock as reported on The NASDAQ Global Select Market was \$20.54 per share and we had approximately 32 holders of record of our common stock.

**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.

**Issuer Purchases of Equity Securities**

We did not purchase any of our equity securities during the period covered by this Annual Report on Form 10-K.

**Item 6. Selected Financial Data**

Not applicable

## 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 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 an emerging specialty pharmaceutical company focused on the development, commercialization and manufacture of proprietary pharmaceutical products, based on our proprietary DepoFoam drug delivery technology, for use in hospitals and ambulatory surgery centers. Our commercial stage products include 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 United States Food and Drug Administration, or FDA, in October 2011. It is marketed by our sales force entirely dedicated to commercializing EXPAREL. We commercially launched EXPAREL in April 2012. As a result of our first commercial sale of EXPAREL, we triggered a \$10.0 million payment obligation to Skyepharma Holding, Inc., or Skyepharma, in connection with the acquisition of our California operating subsidiary, which we refer to as the Acquisition.
- DepoCyt(e) is a sustained release liposomal formulation of the chemotherapeutic agent cytarabine and is indicated for the intrathecal treatment of lymphomatous meningitis. DepoCyt(e) was granted accelerated approval by the FDA in 1999 and full approval in 2007. We sell DepoCyt(e) to our commercial partners located in the U.S. and Europe.

Initially, through our relationship with Quintiles, we outsourced our dedicated EXPAREL field sales force, consisting of approximately 60 representatives. On January 28, 2013, this field force transitioned from Quintiles to Pacira. 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.

In July 2012, we received an inspection letter from the MHRA noting certain critical and major deficiencies in the DepoCyt(e) manufacturing line, which is located in a separate building from the EXPAREL manufacturing site. As a result of the findings, the European Medicines Agency issued an assessment report which recommended that, until corrective actions were taken allowing new supply to enter the market, alternative medicines be used in European Union member countries where there are suitable alternatives. The assessment report also recommended a selective recall of DepoCyt(e) in European Union member countries where DepoCyt(e) was not considered to be an "essential medicinal product." We temporarily ceased manufacturing DepoCyt(e) in order to implement a remediation plan and address the failures noted in the MHRA inspection report. We completed the implementation of our remediation plan and, in December 2012, the MHRA re-inspected our DepoCyt(e) manufacturing facility to review progress in the implementation of our remediation commitments arising from the July 2012 inspection. We received notice in January 2013 from the MHRA that our remediation efforts were successful and that we could resume production of DepoCyt(e) for sale in Europe. We advised the FDA of the MHRA's inspectional findings after we received the July inspection report, and the FDA indicated it had no issue with continued distribution of DepoCyt(e) in the U.S. market pending our remediation efforts. We plan to resume production of DepoCyt(e) for sales in Europe and the United States in the first quarter of 2013.

## [Table of Contents](#)

The selective recall contributed to a reduction in product sales and royalty revenue of DepoCyt(e) in the second half of 2012. Though we do not expect new DepoCyt(e) product to be available to the European market until the second quarter of 2013, we do not currently expect an out of stock situation in either the United States or Europe as a result of the interruption in manufacturing of DepoCyt(e).

We also partner with other companies who desire access to our proprietary DepoFoam extended release drug delivery technology to conduct research, feasibility and formulation work with their products.

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 its 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. 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.

On June 29, 2012, we received a notice of termination from Novo Nordisk AS, or Novo, of a Development and License Agreement, dated January 14, 2011. Pursuant to the terms of the agreement, the termination of the agreement is effective 60 days from the date of the notice, or August 28, 2012. Under the agreement, we granted exclusive rights to Novo under certain of our patents and know-how to develop, manufacture and commercialize formulations of a Novo proprietary drug using our DepoFoam drug delivery technology. The agreement was terminated due to Novo's decision to discontinue development of the proprietary drug subject to the agreement. As a result, our future collaborative licensing and development revenue may be negatively impacted.

On January 3, 2012, EKR Therapeutics, Inc., or EKR, delivered a notice to us to terminate the licensing, distribution and marketing agreement relating to DepoDur. Pursuant to the terms of the agreement, the termination of the agreement was effective 180 days from the date of the notice, or July 1, 2012. The associated supply agreement also terminated concurrently with the termination of the licensing, distribution and marketing agreement. Both parties agreed to terminate the agreements effective June 8, 2012. As a result of the termination, we recognized any unamortized deferred revenue relating to the agreement on a straight-line basis through the termination date in June 2012. The NDA for DepoDur was also withdrawn and we do not expect any future DepoDur sales.

Since inception, we have incurred significant operating losses. We expect to continue to incur significant expenses as we commercialize EXPAREL and advance the development of product candidates, seek FDA approval for our product candidates that successfully complete clinical trials and develop our sales force and marketing capabilities to prepare for their commercial launch. We also expect to incur additional expenses to add operational, financial and management information systems and personnel, including personnel to support our product development efforts and our obligations as a public reporting company. For us to become and remain profitable, we believe that we must succeed in commercializing EXPAREL or other product candidates with significant market potential.



## Recent Developments

### *Convertible Notes*

On January 23, 2013, we completed a private offering of \$120.0 million in aggregate principal amount of 3.25% convertible senior notes due 2019, or Notes, and entered into an indenture with Wells Fargo Bank, National Association, a national banking association, as trustee, governing the 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, are approximately \$115.3 million, after deducting the initial purchasers' discounts and commissions and the estimated offering expenses payable by us. The Notes accrue interest at 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.

We used \$30.1 million of the net proceeds from the offering of the Notes to repay in full our \$27.5 million credit facility with Oxford Finance LLC. In connection with such termination, we paid the remaining principal amount of \$27.5 million as well as accrued interest, certain prepayment fees and an end of term charge in the aggregate amount of \$2.6 million.

## Financial Operations Overview

### *Revenue*

Our net product sales are derived of 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 and have no product held by wholesalers. We reported EXPAREL product sales of \$14.6 million for the year ended December 31, 2012, which is net of allowances for sales returns, prompt pay discounts, volume rebates and distribution service fees payable to wholesalers. DepoCyt(e) net product sales of \$3.5 million for the year ended December 31, 2012 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, 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 cGMP manufacturing facilities, including allocated rent, utilities, insurance, depreciation and salaries and related costs of personnel 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

## [Table of Contents](#)

- 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, 2012, we incurred research and development expenses of \$123.6 million, of which \$119.5 million is related to the development of EXPAREL. We expect to incur additional research and development expenses as we accelerate the development of EXPAREL in additional indications. In 2012 we began two pivotal nerve block studies, an intercostal block study in posterolateral thoracotomy patients and a femoral nerve block in total knee arthroplasty (TKA) patients. We expect the studies to be completed in 2013, and we expect to file an sNDA in 2014. 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 is comprised of approximately 60 representatives, which we transitioned as our employees on January 28, 2013. We also ran 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 marketing 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 expanded EXPAREL Suite C manufacturing line. During 2010 and 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.

### ***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 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 DepoCyt(e) and DepoDur and a significant estimation, performed quarterly, of certain of our future cash flows related to these products during the remaining term of the Amended and Restated Royalty Interests Assignment Agreement which terminates on December 31, 2014. The effect of the change in the estimates is reflected in our consolidated statements of operations as royalty interest obligation. In addition, such cash flows are subject to foreign exchange movements related to sales of DepoCyt(e) and DepoDur denominated in currencies other than U.S. dollars.

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

We have based our management's discussion and analysis of our financial condition and results of operations on our financial statements that have been prepared in accordance with generally accepted

## [Table of Contents](#)

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***

#### *Net Product Sales*

We sell EXPAREL to wholesalers based on orders of the product from hospitals and other end user customers such as ambulatory surgery centers and doctors. 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. Sales to wholesalers provide for selling prices that are fixed on the date of sale. 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. Prior to the shipment of the manufactured products, we conduct initial product release and stability testing in accordance with our current Good Manufacturing Practices or 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 Pay 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 contracted specified timeframes if the products do not meet the applicable inspection tests. We estimate our return reserves based on our experience with historical return rates. Historically, our product returns have not been material.

## [Table of Contents](#)

### *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.

### *Allowance for Doubtful Accounts*

We evaluate accounts receivable to determine if a provision for an allowance for doubtful accounts is appropriate. Our sales are mostly to established customers.

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

We recognize revenues from non-refundable up-front 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. 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,		
	2012	2011	2010
Expected dividend yield	None	None	None
Risk free interest rate	0.84 - 1.70%	1.1 - 2.7%	1.6 - 3.4%
Expected volatility	74.0%	76.8%	80.8%
Expected life of options	6.76 years	6.73 years	6.25 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 utilize our available historic volatility data combined with the publicly traded peer's 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, 2012, 2011 and 2010***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,			2012 versus	2011 versus
	2012	2011	2010	2011	2010
				% Increase / (Decrease)	
Net product sales:					
EXPAREL	\$ 14,591	\$ —	\$ —	N/A	N/A
DepoCyt(e)	3,537	6,812	6,843	(48)%	(0)%
DepoDur	63	83	797	(24)%	(90)%
Total net product sales	18,191	6,895	7,640	164%	(10)%
Collaborative licensing and development revenue	18,390	5,074	3,217	262%	58%
Royalty revenue	2,503	3,720	3,705	(33)%	0%
Total revenues	\$ 39,084	\$ 15,689	\$ 14,562	149%	8%

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. We report product sales net of allowances for sales returns, prompt pay discounts, volume rebates and distribution service fees payable to wholesalers. We ship products directly to the end user based on orders placed to wholesalers or directly to us and have no product held by wholesalers. The increase in EXPAREL product sales was partially offset by a \$3.3 million decrease in DepoCyt(e) product sales primarily driven by a selective recall of DepoCyt(e) recommended by the European Medicines Agency for European Union member countries where DepoCyt(e) is not considered to be an "essential medicinal product."

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 Nordisk and (iii) \$1.5 million for Flynn Pharma. 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.

Total revenues increased \$1.1 million, or 8%, in the year ended December 31, 2011 as compared to 2010. This increase was attributable to a \$1.9 million increase in collaborative licensing and development revenue primarily due to activities performed under the Novo Agreement, which was signed in January 2011. During 2011, we received an up-front one-time payment of \$1.5 million and a milestone payment of \$2.0 million from Novo, which were both deferred and recognized on a straight line basis over the expected contract period. This increase was partially offset by a \$0.7 million decrease in net product sales due to the lower number of DepoDur lots sold to our commercial partners.

[Table of Contents](#)*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):

	<u>Year Ended December 31,</u>			<u>2012 versus</u>	<u>2011 versus</u>
	<u>2012</u>	<u>2011</u>	<u>2010</u>	<u>2011</u>	<u>2010</u>
				<u>% Increase / (Decrease)</u>	
Cost of goods sold	\$ 31,744	\$ 15,310	\$ 11,374	107%	35%
Cost of collaborative licensing and development revenue	395	1,429	902	(72)%	58%
Total cost of revenues	\$ 32,139	\$ 16,739	\$ 12,276	92%	36%

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 by the European Medicines Agency and (iv) EXPAREL production costs, which were 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 Novo agreement for which we received a notice of termination in June 2012.

Total cost of revenues increased \$4.5 million, or 36% in the year ended December 31, 2011 as compared to 2010. The increase was primarily driven by excess capacity relating to running two cGMP facilities that have a substantial level of infrastructure cost, including the EXPAREL production line which went into service during the fourth quarter of 2011 with all operating costs expensed as incurred due to commercial manufacturing challenges. Additionally, the total cost of collaborative licensing and development increased \$0.5 million due to activities performed under the Novo agreement.

*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):

	<u>Year Ended December 31,</u>			<u>2012 versus</u>	<u>2011 versus</u>
	<u>2012</u>	<u>2011</u>	<u>2010</u>	<u>2011</u>	<u>2010</u>
				<u>% Increase / (Decrease)</u>	
Research and development	\$ 9,937	\$ 14,873	\$ 18,628	(33)%	(20)%

Research and development expenses decreased by \$4.9 million, or 33%, for the year ended December 31, 2012 as compared to 2011, due to the 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 on clinical development 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



[Table of Contents](#)

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, which is in pre-clinical stage.

Research and development expenses decreased by \$3.8 million, or 20%, for the year ended December 31, 2011 as compared to 2010 primarily due to a \$5.1 million decrease in third party clinical trials and regulatory costs. This decrease is related to the close out of our pivotal Phase 3 placebo controlled studies in EXPAREL and NDA preparation costs in 2010. Additional cost reductions resulted from the shift in expenses from research and development to cost of revenues upon the approval of EXPAREL in the fourth quarter of 2011. This reduction was partially offset by a \$1.8 million increase in compensation costs, including stock-based compensation and bonus accrual, which were not present in 2010, and an increase in EXPAREL pre-commercial manufacturing-related costs.

In the years ended December 31, 2012, 2011 and 2010, research and development expenses attributable to EXPAREL were \$9.9 million, or 100% \$14.4 million, or 97%, and \$18.4 million, or 99% of total research and development expenses, respectively. The research and development expenses not attributable to EXPAREL relate to our product candidate initiatives, including DepoNSAID and DepoMethotrexate.

*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,			2012 versus	2011 versus
	2012	2011	2010	2011	2010
				% Increase / (Decrease)	
General and administrative	\$ 15,974	\$ 10,036	\$ 5,975	59%	68%
Sales and marketing	30,332	10,123	392	200%	2,482%
Total selling, general and administrative expenses	\$ 46,306	\$ 20,159	\$ 6,367	130%	217%

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 for the year ended December 31, 2011, due to a \$12.4 million increase in our sales force entirely dedicated to commercializing EXPAREL, which was comprised of approximately 60 hospital specialists, seven regional directors and a national sales director, 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 for the year ended December 31, 2011 due to increases of \$3.1 million in salaries and benefits associated with our increased headcount, \$2.0 million in consulting costs primarily to support our information technology structure and recruiting efforts.

[Table of Contents](#)

Selling, general and administrative expenses increased by \$13.8 million, or 217%, in the year ended December 31, 2011, as compared to 2010, primarily due to the following:

- selling and marketing expenses increased by \$9.7 million to \$10.1 million in the year ended December 31, 2011, as compared to \$0.4 million for the year ended December 31, 2010, due to the hiring of commercial personnel and activities supporting the commercialization of EXPAREL, including costs incurred for our retrospective and prospective health outcome studies and promotional/educational material; and
- general and administrative expenses increased by \$4.0 million to \$10.0 million in the year ended December 31, 2011, as compared to \$6.0 million for the year ended December 31, 2010, primarily due to additional compensation related expenses of \$2.5 million, including bonus, stock-based compensation and severance costs, and other expenses associated with being a public company.

*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 Ended December 31,			2012 versus	2011 versus
	2012	2011	2010	2011	2010
				% Increase / (Decrease)	
Impairment of long-lived assets	\$ —	\$ 3,019	\$ —	(100)%	N/A

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 production line to expand EXPAREL capacity resulting in certain software and equipment that are 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,			2012 versus	2011 versus
	2012	2011	2010	2011	2010
				% Increase / (Decrease)	
Interest income	\$ 275	\$ 255	\$ 146	8%	75%
Interest expense	(1,807)	(4,780)	(3,959)	(62)%	21%
Loss on early extinguishment of debt	(1,062)	—	(184)	N/A	(100)%
Royalty interest obligation	(278)	227	(930)	(222)%	(124)%
Other, net	(111)	71	487	(256)%	(85)%
Total other expense, net	\$ (2,983)	\$ (4,227)	\$ (4,440)	(29)%	(5)%

## [Table of Contents](#)

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 mostly 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 the first quarter of 2011.

Additionally, the decrease in interest expense was offset by a \$1.1 million loss on the extinguishment of our Hercules Credit Facility in May 2012. We 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.

Total other expense, net decreased by \$0.2 million, or 5%, to \$4.2 million in the year ended December 31, 2011 as compared to 2010. Interest expense, net increased \$0.8 million, or 21%, in the year ended December 31, 2011 as compared to 2010 primarily due to \$1.1 million of amortization of the remaining value of the warrants and beneficial conversion feature associated with the convertible notes we issued in 2010 due to the conversion of these notes into shares of our common stock upon the closing of our initial public offering in February 2011. This was partially offset by interest capitalized for the construction of our manufacturing site for EXPAREL.

Royalty interest obligation decreased \$1.2 million, or 124%, in the year ended December 31, 2011 as compared to 2010 due primarily to changes in forecasted sales projections based on plateauing sales trends for DepoCyt(e) and the weakening Euro exchange rate. Additionally, the royalty interest obligation was further reduced due to the expected decrease in DepoDur sales as a result of the termination of the EKR license agreement.

We recorded a \$0.2 million loss on extinguishment of debt during the year ended December 31, 2010 related to the repayment of a \$11.3 million credit facility, established with GE Capital Corporation in April 2010. Although the facility was established originally for a period of 3 years, we elected to repay the debt in full in November 2010, from proceeds of a new term loan, established with Hercules Technology Growth Capital, Inc. in November 2010. The amount represented the final payment fees and the balance of deferred financing cost which were written off when the debt was paid off.

## **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 the development of 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, product sales, collaborative licensing and development revenue and royalty revenue.

In April 2012, we sold 6,900,000 shares of common stock at a price of \$9.75 per share in a registered public offering, which includes the underwriter's exercise of the overallotment option. We raised approximately \$62.9 million in net proceeds after deducting underwriting discounts and offering expenses.

[Table of Contents](#)

We have generated limited revenue, and we are highly dependent on the commercial success of EXPAREL, which we commercially launched in April 2012. We have incurred losses and generated negative cash flows from operations since inception. As of December 31, 2012, we had an accumulated deficit of \$232.5 million, cash and cash equivalents, restricted cash and short-term investments of \$42.6 million and working capital of \$46.8 million.

The following table summarizes our cash flows from operating, investing and financing activities for the years ended December 31, 2012, 2011, and 2010 (in thousands):

	Year Ended December 31,		
	2012	2011	2010
<b>Consolidated Statement of Cash Flows Data:</b>			
Net cash provided by (used in):			
Operating activities	\$ (70,130)	\$ (31,000)	\$ (24,880)
Investing activities	(29,522)	(36,123)	(6,769)
Financing activities	63,610	87,158	50,705
Net (decrease) increase in cash and cash equivalents	\$ (36,042)	\$ 20,035	\$ 19,056

### *Operating Activities*

For the years ended December 31, 2012, 2011 and 2010, our net cash used in operating activities was \$70.1 million, \$31.0 million and \$24.9 million, respectively. 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 trial in total knee arthroplasty and our Phase 3 nerve block trial in thoracotomy.

The \$6.1 million increase in net cash used in operations in 2011 as compared to 2010 was primarily driven by (i) higher operating expenses, including the increase in headcount from 83 employees at December 31, 2010 to 133 at December 31, 2011, as we were preparing to manufacture and commercially launch EXPAREL and (ii) \$2.4 million increase in cash paid for interest on the Hercules Note as compared to interest paid in the form of equity on the convertible and secured notes. This increase was partially offset by \$3.5 million of total up-front and milestone payments received in 2011 from our development partner Novo pursuant to the agreement signed in January 2011.

### *Investing Activities*

For the years ended December 31, 2012, 2011 and 2010, our net cash used in investing activities was \$29.5 million, \$36.1 million and \$6.8 million, respectively. The \$6.6 million decrease in net cash used in investing activities in 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 (i) \$10 million contingent milestone payment made in April 2012 to Skyepharma in connection with the first commercial sale of EXPAREL, and (ii) \$12.1 million increase in the purchase of fixed assets relating to the construction of our Suite C manufacturing line for EXPAREL, which we recommenced following approval from the United States Food and Drug Administration in October 2011.

The net cash used in investing activities in 2011 was primarily for the investment of the proceeds from the initial public offering and follow-on public offering in short-term investments of \$30.0 million and the purchase of fixed assets of \$6.2 million primarily relating to the continued construction of our

[Table of Contents](#)

manufacturing sites. In 2010, net cash used in investing activities was primarily for the purchases of fixed assets of \$6.8 million relating to our manufacturing sites.

***Financing Activities***

For the years ended December 31, 2012, 2011 and 2010, our net cash provided by financing activities was \$63.6 million, \$87.2 million and \$50.7 million, respectively. 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 to repay the remaining principal on the Hercules Credit Facility of \$24.2 million, early prepayment penalty of \$0.3 million and the end of term fee of \$0.6 million.

The net cash provided by financing activities in 2011 was from the net proceeds of \$37.1 million from the issuance of common stock in connection with our initial public offering completed in February 2011 (after deducting \$0.9 million of offering expenses paid for in 2010) and net proceeds of \$49.0 million from the issuance of common stock in the follow-on offering completed in November 2011. The net cash provided by financing activities in 2010 was primarily due to borrowings under the Hercules Credit Facility for net proceeds of \$25.8 million, sale and issuance of secured notes for net proceeds of \$18.6 million, and sale and issuance of convertible notes to certain of our existing investors for net proceeds of \$7.5 million.

***Equity Financings***

From inception through December 31, 2012, we raised approximately \$149 million of net proceeds from the sale of common stock and we have received net proceeds of approximately \$85 million from the sale of our Series A convertible preferred stock.

***Series A Convertible Preferred Stock***

In March 2007, we entered into a Series A Preferred Stock Purchase Agreement pursuant to which we issued and sold an aggregate of 6,322,640 shares of Series A convertible preferred stock in four separate closings held in March 2007, February 2008, July 2008 and October 2008, at a purchase price of \$13.44 per share. The aggregate consideration for the shares of Series A convertible preferred stock was \$85.0 million in cash. Upon the closing of the initial public offering, all outstanding shares of Series A convertible preferred stock and the principal and accrued interest balance on the convertible promissory notes sold in January 2009, the secured notes sold in June 2009, the secured notes sold in March 2010, the convertible promissory notes sold in December 2010, and the secured notes sold to entities affiliated with HBM BioVentures in April 2010 were converted into an aggregate of 10,647,549 shares of common stock.

***Common Stock***

In February 2011, we completed an initial public offering of 6,000,000 shares of common stock at \$7.00 per share. As a result of our initial public offering, we raised approximately \$37.1 million in net proceeds after deducting underwriting discounts and commissions and offering expenses.

In November 2011, we completed a follow-on registered public offering of common stock. An aggregate of 8,050,000 shares of common stock, including the over-allotment option exercised by our underwriters, were sold at a price of \$6.50 per share. We raised approximately \$49.0 million in net proceeds after deducting underwriting discounts and offering expenses.

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, 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, are approximately \$115.3 million, after deducting the initial purchasers' discounts and commissions and the estimated 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.

We used \$30.1 million of the net proceeds from the offering of the Notes to repay in full our \$27.5 million credit facility with Oxford Finance LLC, or the Lender. In connection with such termination, we paid the remaining principal amount of \$27.5 million as well as accrued interest, certain prepayment fees and an end of term charge in the aggregate amount of \$2.6 million.

*Oxford Loan Agreement*

On May 2, 2012, we entered into a definitive loan and security agreement, or the Loan Agreement, with the Lender, and borrowed the principal amount of \$27.5 million, or the Loan Facility, at a fixed rate of 9.75%, with the first principal payment due December 1, 2013. Payments under the Loan Agreement were interest-only in arrears through November 30, 2013, followed by 30 equal monthly payments of principal and interest. In addition, a payment equal to 6.00% of the Loan Facility was due on the final payment date, or such earlier date as specified in the Loan Agreement. The \$1.65 million end of term fee was recorded as a debt discount and amortized to interest expense over the term of the loan. The proceeds from the Loan Agreement were used to repay the entire \$24.2 million outstanding balance plus accrued interest, \$0.6 million end of term fee and \$0.3 million early prepayment penalty on our credit facility with Hercules Technology Growth Capital, Inc. and Hercules Technology II, L.P., as lenders, or Hercules Credit Facility. We recorded a loss on extinguishment of debt of \$1.1 million comprised of the remaining unamortized debt issuance costs, warrants and end of term fee, as well as the early prepayment penalty on the note issued under the Hercules Credit Facility.

As of December 31, 2012, we had \$27.5 million of indebtedness with Oxford Finance LLC. On January 23, 2013, we completed a private offering of \$120.0 million in aggregate principal amount of 3.25% convertible senior notes due 2019, or the Notes. We used \$30.1 million of the net proceeds from the offering of the Notes to repay in full our \$27.5 million credit facility with Oxford Finance LLC. In connection with such termination, we paid the remaining principal amount of approximately \$27.5 million as well as accrued interest, certain prepayment fees and an end of term charge in the aggregate amount of \$2.6 million.

*Hercules Credit Facility*

On November 24, 2010, we entered into a \$26.3 million credit facility with Hercules Technology Growth Capital, Inc. and Hercules Technology III, L.P., as lenders. At the closing of the Hercules Credit Facility, we entered into a term loan in the aggregate principal amount of \$26.3 million, which was the full amount available under the Hercules Credit Facility. The term loan under the Hercules Credit Facility was comprised of two tranches, Tranche A and Tranche B. The Tranche A portion of the term loan was comprised of \$11.3 million in principal and carried a floating per annum interest rate equal to 11.00% plus the amount, if any, by which the prime rate exceeded 4.00%. The Tranche B portion of the term loan was comprised of \$15.0 million in principal and carried a floating per annum interest rate equal to 12.65% plus the amount, if any, by which the prime rate exceeded 4.00%. The proceeds of the term loan under the Hercules Credit Facility were used to repay the GECC Credit Facility in full and the remainder was used for other general corporate purposes.

## [Table of Contents](#)

As further consideration to the lenders to provide the term loan to us under the Hercules Credit Facility, we issued to the lenders a warrant to purchase 178,986 shares of our common stock.

We used the proceeds from the Oxford Loan to repay the term loan under the Hercules Credit Facility in May 2012.

### ***Royalty Interests Assignment Agreement***

On March 23, 2007, we entered into the Amended and Restated Royalty Interests Assignment Agreement with Paul Capital, pursuant to which we assigned to Paul Capital the right to receive up to approximately 20% of our royalty payments from DepoCyt(e) and DepoDur. The original agreement was entered into prior to the Acquisition by the Predecessor in order to monetize certain royalty payments from DepoCyt(e) and DepoDur. In connection with the Acquisition, the original agreement with Paul Capital was amended and restated and the responsibility to pay the royalty interest in product sales of DepoCyt(e) and DepoDur was transferred to us and we were required to make payments to Paul Capital upon the occurrence of certain events. To secure our obligations to Paul Capital, we granted Paul Capital a security interest in collateral which includes the royalty payments we are entitled to receive with respect to sales of DepoCyt(e) and DepoDur, as well as to bank accounts to which such payments are deposited. Under our arrangement with Paul Capital, upon the occurrence of certain events, including if we experience a change of control, undergo certain bankruptcy events of us or our subsidiary, transfer any or substantially all of our rights in DepoCyt(e) and/or DepoDur, transfer all or substantially all of our assets, breach certain of the covenants, representations or warranties under the Amended and Restated Royalty Interests Assignment Agreement, or sales of DepoCyt(e) and/or DepoDur are suspended due to an injunction or if we elect to suspend sales of DepoCyt(e) and/or DepoDur as a result of a lawsuit filed by certain third parties, Paul Capital may require us to repurchase the rights we assigned to it at a cash price equal to (a) 50% of all cumulative payments made by us to Paul Capital under the Amended and Restated Royalty Interests Assignment Agreement during the preceding 24 months, multiplied by (b) the number of days from the date of Paul Capital's exercise of such option until December 31, 2014, divided by 365. Under the terms of the Amended and Restated Royalty Interests Assignment Agreement, 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, including the proceeds from the issuance of \$120.0 million of convertible notes in January 2013, will be sufficient to enable us to fund our operating expenses, capital expenditure requirements and service our indebtedness for at least the next 12 months. However, no assurance can be given that this will be the case, and we may require additional debt or equity financing to meet our working capital requirements. Our need for additional external sources of funds will depend significantly on the level and timing of our sales of EXPAREL. Moreover, changing circumstances may cause us to expend cash significantly faster than we currently anticipate, and we may need to spend more cash than currently expected because of circumstances beyond our control. Our expectations regarding future cash requirements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we make in the future. We have no current understandings, agreements or commitments for any material acquisitions or licenses of any products, businesses or technologies. We may need to raise substantial additional capital in order to engage in any of these types of transactions. We expect to continue to incur substantial additional operating losses as we commercialize EXPAREL and develop and seek regulatory approval for our other product candidates. We will incur significant sales and marketing and manufacturing expenses due to the commercialization of 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. We also

## [Table of Contents](#)

expect to incur significant costs to comply with corporate governance, internal controls and similar requirements applicable to us as a public company.

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;
- the 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 two Phase 2/3 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 review of our other product candidates;
- the extent to which we acquire or invest in products, businesses and technologies;
- the extent to which we choose to establish collaboration, co-promotion, distribution or other similar agreements for our product candidates; and
- the costs of preparing, submitting and prosecuting patent applications and maintaining, enforcing and defending intellectual property claims.

To the extent that our capital resources are insufficient to meet our future operating and capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives. The covenants under the 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.

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

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

### **Recent Accounting Pronouncements**

See Note 2 to the Notes to Consolidated Financial Statements in Item 8 below for discussion of recent accounting pronouncements.



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

Not applicable.

**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-36 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 Rule 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 and Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, but not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure control and procedure also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on their evaluation as of December 31, 2012, our President and Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective.

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

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 and Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2012, based on the criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). 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.

Management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the results of our evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2012.

[Table of Contents](#)

The effectiveness of our internal control over financial reporting as of December 31, 2012 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, 2012.

**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, 2012, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Inherent Limitations on Effectiveness of Controls**

Our management, including our President and Chief Executive Officer and Chief Financial Officer, do not expect that our disclosure controls or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, but not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within Pacira have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited Pacira Pharmaceuticals, Inc.'s and Subsidiaries' ("Pacira") internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Pacira'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'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 has maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012 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 as of December 31, 2012 and 2011, and for each of the three years in the period ended December 31, 2012 and our report dated March 6, 2013, expressed an unqualified opinion thereon.

/s/ CohnReznick LLP

Roseland, New Jersey  
March 6, 2013

**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 2013 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 2013 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 2013 annual stockholders' meeting and is incorporated by reference into this report, with the exception of the items listed below.

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

Information required by this item will be included in the proxy statement for our 2013 annual stockholders' meeting and is incorporated by reference into this report.

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

Information required by this item will be included in the proxy statement for our 2013 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

Not applicable.

(3) Exhibits

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



**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.

Date: March 7, 2013

By:   /s/ DAVID STACK

David Stack  
*President and Chief Executive Officer*

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>  /s/ DAVID STACK</u> David Stack	Director, President and Chief Executive Officer (Principal Executive Officer)	March 7, 2013
<u>  /s/ JAMES SCIBETTA</u> James Scibetta	Chief Financial Officer (Principal Financial Officer)	March 7, 2013
<u>  /s/ LAUREN RIKER</u> Lauren Riker	Executive Director, Accounting and Reporting (Principal Accounting Officer)	March 7, 2013
<u>  /s/ FRED MIDDLETON</u> Fred Middleton	Chairman	March 7, 2013
<u>  /s/ LUKE EVNIN</u> Luke Evnin	Director	March 7, 2013
<u>  /s/ LAURA BREGE</u> Laura Brege	Director	March 7, 2013
<u>  /s/ JOHN LONGENECKER</u> John Longenecker	Director	March 7, 2013
<u>  /s/ GARY PACE</u> Gary Pace	Director	March 7, 2013
<u>  /s/ ANDREAS WICKI</u> Andreas Wicki	Director	March 7, 2013
<u>  /s/ PAUL HASTINGS</u> Paul Hastings	Director	March 7, 2013

**Pacira Pharmaceuticals, Inc.**

**Index to Consolidated Financial Statements**

<a href="#">Report of Independent Registered Public Accounting Firm</a>	<a href="#">F-2</a>
<a href="#">Consolidated Balance Sheets as of December 31, 2012 and 2011</a>	<a href="#">F-3</a>
<a href="#">Consolidated Statements of Operations for the years ended December 31, 2012, 2011, and 2010</a>	<a href="#">F-4</a>
<a href="#">Consolidated Statements of Comprehensive Loss for the years ended December 31, 2012, 2011, and 2010</a>	<a href="#">F-5</a>
<a href="#">Consolidated Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2012, 2011, and 2010</a>	<a href="#">F-6</a>
<a href="#">Consolidated Statements of Cash Flows for the years ended December 31, 2012, 2011, and 2010</a>	<a href="#">F-7</a>
<a href="#">Notes to Consolidated Financial Statements</a>	<a href="#">F-8</a>

## **Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders  
Pacira Pharmaceuticals, Inc.

We have audited the consolidated balance sheets of Pacira Pharmaceuticals, Inc. and Subsidiaries as of December 31, 2012 and 2011, 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, 2012. 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, 2012 and 2011, and their results of operations and cash flows for each of the three years in the period ended December 31, 2012, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Pacira Pharmaceuticals, Inc. and Subsidiaries' internal control over financial reporting as of December 31, 2012 based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 6, 2013, expressed an unqualified opinion thereon.

/s/ CohnReznick LLP

Roseland, New Jersey  
March 6, 2013



**Pacira Pharmaceuticals, Inc.**

**Consolidated Balance Sheets**

(In thousands, except share and per share amounts)

	<b>December 31,</b>	
	<b>2012</b>	<b>2011</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 10,126	\$ 46,168
Restricted cash	1,523	1,299
Short-term investments	30,924	29,985
Accounts receivable, net	4,352	2,113
Inventories	12,077	1,245
Prepaid expenses and other current assets	1,920	1,839
Total current assets	<u>60,922</u>	<u>82,649</u>
Fixed assets, net	39,116	25,103
Goodwill	8,297	—
Intangibles, net	3,208	5,259
Other assets	511	479
Total assets	<u>\$ 112,054</u>	<u>\$ 113,490</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 2,569	\$ 3,440
Accrued expenses	9,792	7,159
Current portion of royalty interest obligation	823	1,219
Current portion of deferred revenue	972	13,054
Current portion of long-term debt	—	7,039
Total current liabilities	<u>14,156</u>	<u>31,911</u>
Long-term debt	25,191	18,537
Royalty interest obligation	857	1,537
Deferred revenue	3,720	8,416
Contingent purchase liability	—	2,042
Other liabilities	2,275	2,778
Total liabilities	<u>46,199</u>	<u>65,221</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value \$0.001; 5,000,000 shares authorized, none issued and outstanding at December 31, 2012 and 2011	—	—
Common stock, par value \$0.001 and 250,000,000 shares authorized; 32,624,049 shares issued and 32,622,984 shares outstanding at December 31, 2012; 25,340,103 shares issued and 25,339,038 shares outstanding at December 31, 2011	33	25
Additional paid-in capital	298,317	228,470
Accumulated deficit	(232,520)	(180,239)
Accumulated other comprehensive income	27	15
Treasury stock at cost, 1,065 shares	(2)	(2)
Total stockholders' equity	<u>65,855</u>	<u>48,269</u>
Total liabilities and stockholders' equity	<u>\$ 112,054</u>	<u>\$ 113,490</u>

See accompanying notes to consolidated financial statements

**Pacira Pharmaceuticals, Inc.****Consolidated Statements of Operations****(In thousands, except share and per share amounts)**

	Year Ended December 31,		
	2012	2011	2010
<b>Revenues:</b>			
Net product sales	\$ 18,191	\$ 6,895	\$ 7,640
Collaborative licensing and development revenue	18,390	5,074	3,217
Royalty revenue	2,503	3,720	3,705
Total revenues	39,084	15,689	14,562
<b>Operating expenses:</b>			
Cost of revenues	32,139	16,739	12,276
Research and development	9,937	14,873	18,628
Selling, general and administrative	46,306	20,159	6,367
Impairment of long-lived assets	—	3,019	—
Total operating expenses	88,382	54,790	37,271
Loss from operations	(49,298)	(39,101)	(22,709)
<b>Other (expense) income:</b>			
Interest income	275	255	146
Interest expense	(1,807)	(4,780)	(3,959)
Loss on early extinguishment of debt	(1,062)	—	(184)
Royalty interest obligation	(278)	227	(930)
Other, net	(111)	71	487
Total other expense, net	(2,983)	(4,227)	(4,440)
Net loss	\$ (52,281)	\$ (43,328)	\$ (27,149)
<b>Net loss per share:</b>			
Basic and diluted net loss per common share	\$ (1.72)	\$ (2.64)	\$ (47.29)
<b>Weighted average common shares outstanding:</b>			
Basic and diluted	30,331,965	16,437,464	574,072

See accompanying notes to consolidated financial statements

**Pacira Pharmaceuticals, Inc.**

**Consolidated Statements of Comprehensive Loss**

(In thousands)

	Year Ended December 31,		
	2012	2011	2010
Net loss	\$ (52,281)	\$ (43,328)	\$ (27,149)
Other comprehensive income:			
Net unrealized gain on investments	12	15	—
Total other comprehensive income	12	15	—
Comprehensive loss	\$ (52,269)	\$ (43,313)	\$ (27,149)

See accompanying notes to consolidated financial statements

Pacira Pharmaceuticals, Inc.

Consolidated Statements of Stockholders' Equity (Deficit)

Years Ended December 31, 2012, 2011 and 2010

(In thousands)

	Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Treasury Stock	Accumulated Other Comprehensive Income	Total
	Shares	Amount	Shares	Amount					
<b>Balances at December 31, 2009</b>	6,322	6	574	1	86,806	(109,762)	—	—	\$ (22,949)
Exercise of stock options	—	—	1	—	2	—	—	—	2
Share-based compensation	—	—	—	—	23	—	—	—	23
Purchase of treasury stock	—	—	—	—	—	—	(2)	—	(2)
Debt discount from beneficial conversion features and issuance of warrants with convertible notes	—	—	—	—	1,692	—	—	—	1,692
Net loss	—	—	—	—	—	(27,149)	—	—	(27,149)
<b>Balances at December 31, 2010</b>	6,322	6	575	1	88,523	(136,911)	(2)	—	(48,383)
Exercise of stock options	—	—	67	—	135	—	—	—	135
Share-based compensation	—	—	—	—	2,493	—	—	—	2,493
Initial public offering, net of issuance costs	—	—	6,000	6	37,103	—	—	—	37,109
Follow-on public offering, net of issuance costs	—	—	8,050	8	48,998	—	—	—	49,006
Conversion of preferred stock	(6,322)	(6)	6,322	6	—	—	—	—	—
Conversion of 2009 Convertible 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 Notes and accrued interest	—	—	1,157	1	15,548	—	—	—	15,549
Conversion of 2010 Convertible Notes and accrued interest	—	—	1,071	1	7,499	—	—	—	7,500
Conversion of HBM Secured Notes and accrued interest and early prepayment penalty	—	—	297	—	3,981	—	—	—	3,981
Unrealized gain on short-term investments	—	—	—	—	—	—	—	15	15
Net loss	—	—	—	—	—	(43,328)	—	—	(43,328)
<b>Balances at December 31, 2011</b>	—	—	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 investments	—	—	—	—	—	—	—	12	12
Follow-on public offering, net of issuance costs	—	—	6,900	7	62,848	—	—	—	62,855
Debt discount on issuance of warrants	—	—	—	—	1,354	—	—	—	1,354
Net loss	—	—	—	—	—	(52,281)	—	—	(52,281)
<b>Balances at December 31, 2012</b>	—	\$ —	32,623	\$ 33	\$ 298,317	\$ (232,520)	\$ (2)	\$ 27	\$ 65,855

See accompanying notes to consolidated financial statements

**Pacira Pharmaceuticals, Inc.**

**Consolidated Statements of Cash Flows**

(In thousands)

	<u>Year Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
<b>Operating activities:</b>			
Net loss	\$(52,281)	\$(43,328)	\$(27,149)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	5,648	4,314	4,071
Amortization of unfavorable lease obligation and deferred financing costs	(239)	(85)	(149)
Amortization of end of term fee and warrants	831	1,644	146
Loss on disposal of fixed assets	1	273	11
Loss on early extinguishment of debt	1,062	—	184
Impairment of long-lived assets	—	3,019	—
Stock-based compensation	4,776	2,493	23
Changes in operating assets and liabilities:			
Restricted cash	(224)	14	(98)
Accounts receivable, net	(2,239)	(922)	264
Inventories	(10,832)	360	124
Prepaid expenses and other assets	(59)	(608)	32
Accounts payable and accrued expenses	1,386	2,549	(1,118)
Royalty interest obligation	(1,076)	(1,815)	(675)
Other liabilities	(106)	27	1,782
Deferred revenue	(16,778)	1,065	(2,328)
Net cash used in operating activities	<u>(70,130)</u>	<u>(31,000)</u>	<u>(24,880)</u>
<b>Investing activities:</b>			
Purchase of fixed assets	(18,257)	(6,167)	(6,770)
Proceeds from sales of fixed assets	1	14	1
Purchases of short-term investments	(54,047)	(52,619)	—
Sale of short-term investments	53,120	22,649	—
Payment of contingent consideration	(10,339)	—	—
Net cash used in investing activities	<u>(29,522)</u>	<u>(36,123)</u>	<u>(6,769)</u>
<b>Financing activities:</b>			
Proceeds from exercise of stock options and warrants	870	136	2
Proceeds from borrowings on long-term debt	27,500	—	—
Proceeds from initial public offering, net	—	38,016	—
Proceeds from public offering, net	62,855	49,006	—
Purchase of treasury stock	—	—	(2)
Proceeds from convertible notes	—	—	7,500
Proceeds from secured promissory notes and credit facility	—	—	56,250
Repayment of debt	(26,250)	—	(11,250)
Payment of debt issuance and financing costs	(1,365)	—	(1,795)
Net cash provided by financing activities	<u>63,610</u>	<u>87,158</u>	<u>50,705</u>
Net (decrease) increase in cash and cash equivalents	(36,042)	20,035	19,056
Cash and cash equivalents, beginning of year	46,168	26,133	7,077
Cash and cash equivalents, end of year	<u>\$ 10,126</u>	<u>\$ 46,168</u>	<u>\$ 26,133</u>
<b>Supplemental cash flow information</b>			
Cash paid for interest, including royalty interest obligation	\$ 4,229	\$ 4,739	\$ 2,371

Initial public offering costs paid in 2010	\$	—	\$	907	\$	—
<b>Non cash investing and financing activities:</b>						
Value of warrants issued with debt	\$	1,354	\$	—	\$	—
Value of warrants issued with debt and beneficial conversion feature	\$	—	\$	—	\$	1,692
Accrued financing cost	\$	—	\$	—	\$	500
Conversion of notes to common stock	\$	—	\$	51,222	\$	—
Conversion of preferred stock to common stock	\$	—	\$	6	\$	—

See accompanying notes to consolidated financial statements

**Pacira Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements**

**NOTE 1—BUSINESS**

Pacira Pharmaceuticals, Inc. and its subsidiaries (collectively, the "Company" or "Pacira") is an emerging specialty pharmaceutical company focused on the development, commercialization and manufacture of proprietary pharmaceutical products, based on its proprietary DepoFoam extended release drug delivery technology, for use in hospitals and ambulatory surgery centers. The Company's lead product EXPAREL, which consists of bupivacaine encapsulated in DepoFoam, was approved by the FDA on October 28, 2011 and launched commercially in April 2012. DepoFoam is also the basis for the Company's other FDA-approved product, DepoCyt(e), which the Company manufactures for commercial partners, and DepoDur, which the Company is no longer marketing.

Pacira Pharmaceuticals, Inc. is the holding company for its California operating subsidiary of the same name, also referred to as PPI-California, which was acquired from SkyePharma Holding, Inc., or Skyepharma, in March 2007, or the Acquisition.

***Risks and Uncertainties***

The Company is subject to risks common to companies in similar industries and stages of development, including, but not limited to, competition from larger companies, reliance on revenue from few customers and products, reliance on single manufacturing sites, new technological innovations, dependence on key personnel, reliance on third-party service providers and sole source suppliers, protection of proprietary technology and compliance with government regulations.

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

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

The consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America, or GAAP, and in accordance with the rules and regulations of the Securities and Exchange Commission, or SEC. The accounts of wholly owned subsidiaries are included in the consolidated financial statements. All intercompany balances and transactions have been eliminated in consolidation. Certain reclassifications were made to conform to the current presentation. Specifically, the Company reclassified DepoCyt(e) and DepoDur supply sales for the years ended December 31, 2011 and 2010 to net product sales to conform to the current presentation. This reclassification had no impact on net loss or stockholders' equity as previously reported.

***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities, including disclosure of contingent assets and contingent liabilities, at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates are used for, among other things, the valuation of assets acquired, impairment of long-lived assets, goodwill, stock-based compensation and valuation of deferred tax assets. The Company's critical accounting policies are those that are both most important to the Company's consolidated financial condition and results of operations and require the most difficult, subjective or complex judgments on the part of management in their application, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Because of the uncertainty of factors surrounding the estimates or judgments used



**Pacira Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

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

in the preparation of the consolidated financial statements, actual results could differ from these estimates.

***Liquidity***

Management believes that the Company's existing cash and cash equivalents, short-term investments, including the proceeds from its private offering of \$120.0 million in convertible senior notes completed in January 2013, and revenue from product sales will be sufficient to enable the Company to meet its planned operating expenses, capital expenditure requirements and service its indebtedness at least through December 31, 2013. However, changing circumstances may cause the Company to expend cash significantly faster than currently anticipated, and the Company may need to spend more cash than currently expected because of circumstances beyond its control. The Company expects to continue to incur substantial additional operating losses as it commercializes EXPAREL and develops and seeks regulatory approval for its product candidates.

***Revenue Recognition***

***Product Sales***

The Company sells EXPAREL primarily to wholesalers based on orders of the product from hospitals and other end user customers such as ambulatory surgery centers and doctors. The Company recognizes revenue when there is persuasive evidence that an arrangement exists, title has passed, collection is reasonably assured and the price is fixed or determinable. Sales to wholesalers provide for selling prices that are fixed on the date of sale. EXPAREL is delivered directly to the end user with the wholesaler never taking physical possession of the product. The Company records revenue at the time the product is delivered to the end user. The Company also recognizes revenue from products manufactured and supplied to commercial partners. Prior to the shipment of the manufactured products such as DepoCyt(e), the Company conducts initial product release and stability testing in accordance with current Good Manufacturing Practices, or cGMP.

At the time the Company recognizes revenue, it also records 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 the sales reserves, the actual amount of volume rebates, chargebacks and returns may be different from estimates, at which time the Company would adjust the reserves accordingly.

***Prompt Pay Reserve***

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

***Return Reserves***

The Company allows customers to return product that is damaged or received in error. In addition, the Company allows for EXPAREL product to be returned beginning six months prior to, and twelve months following product expiration. As EXPAREL is a new commercially available product, the

**Pacira Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

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

Company is estimating its sales return reserve based on return history from other hospital-based products with similar distribution models, which management believes is the best estimate of the anticipated product to be returned. The returns reserve is recorded at the time of sale as a reduction to sales and an increase in returns liability.

Commercial partners can return the products within contracted specified timeframes if the products do not meet the applicable inspection tests. Historically, returns from commercial partners have not been material.

*Volume Rebates and Chargeback Reserve*

Volume rebates and chargeback reserve are based upon contracted discounts and promotional offers the Company provides to certain end users, including hospitals and ambulatory surgery centers 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*

The Company's customers include major and regional wholesalers with whom the Company has 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.

*Allowance for Doubtful Accounts*

The Company evaluates its accounts receivable to determine if a provision for an allowance for doubtful accounts is appropriate. The Company's sales to date are primarily to established customers. As of December 31, 2012 and 2011, the accounts receivable was considered collectible and no allowance for doubtful accounts was recorded.

*Royalty Revenue*

The Company recognizes revenue from royalties based on sales of its products by commercial partners. Royalties are recognized as earned in accordance with contract terms when they can be estimated based on historical product sales, royalty receipts and other relevant information and collectability is reasonably assured.

*Collaborative Licensing and Development Revenue*

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

The Company recognizes revenues from non-refundable up-front license fees received ratably over the performance period using the estimated development period in development agreements and the contract period or longest patent life in supply and distribution agreements. If the estimated

**Pacira Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****NOTE 2—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

performance period is subsequently modified, the Company will modify the period over which the up-front license fee is recognized accordingly on a prospective basis. Upon notification of a termination of a collaboration agreement, any remaining non-refundable license fees received by the Company, which had been deferred, are recognized over the remaining contractual term. If the termination is immediate and no additional services are to be performed, the deferred revenue is generally recognized in full. All such recognized revenues are included in collaborative licensing and development revenue in the Company's consolidated statements of operations.

The Company recognizes revenue from milestone payments received under collaboration agreements when earned, provided that the milestone event is substantive, its achievability was not reasonably assured at the inception of the agreement, the Company has no further performance obligations relating to the event, and collectability is reasonably assured. If these criteria are not met, the Company recognizes milestone payments ratably over the remaining period of the Company's performance obligations under the collaboration agreement. All such recognized revenues are included in collaborative licensing and development revenue in the Company's consolidated statements of operations.

***Concentration of Major Customers***

The Company's customers are its major and regional wholesalers and commercial and collaborative and licensing partners. The Company is dependent on its commercial partners to market and sell DepoCyt(e). The table below includes the percentage of revenue comprised by the three largest customers in each year presented.

	Year Ended		
	December 31, 2012	December 31, 2011	December 31, 2010
Largest customer	30%	43%	49%
Second largest customer	14%	23%	21%
Third largest customer	11%	19%	13%
	<u>55%</u>	<u>85%</u>	<u>83%</u>

Sales to customers outside the U.S. accounted for 23%, 64% and 52% of the Company's revenue for the years ended December 31, 2012, 2011 and 2010, respectively.

***Research and Development Expenses***

Research and development expenses consist of costs associated with products being developed internally, and include related personnel expenses, laboratory supplies, active pharmaceutical ingredients, manufacturing supplies, facilities costs, preclinical and clinical trial costs, and other outside service fees. The Company expenses research and development costs as incurred. A significant portion of the Company's development activities are outsourced to third parties, including contract research organizations. In such cases, the Company may be required to estimate related service fees to be accrued.

**Pacira Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

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

***Cash and Cash Equivalents***

All highly-liquid investments with maturities of 90 days or less when purchased are considered cash equivalents.

***Restricted Cash***

As further discussed in Note 9, *Debt*, the Company has entered into a financing agreement with Royalty Securitization Trust I ("RST") for the sale of a royalty interest in its DepoCyt(e) and DepoDur product revenue and royalties. As part of this financing agreement, the Company and RST maintain a lockbox, where all DepoCyt(e) and DepoDur product revenue and royalties are received. The Company has no minimum payment obligations under this agreement. Commencing on April 1 of every year, the first \$2.5 million received in the lockbox is restricted and is used to make quarterly payments due to RST, if any, under the agreement during the subsequent 12 month period. On March 31 of the subsequent year, the balance of cash in the lockbox, if any, is remitted to the Company. The RST agreement terminates on December 31, 2014. The royalty interest agreement pertains only to DepoCyt(e) and DepoDur, and does not include revenue related to EXPAREL or any other product candidates.

***Short-Term Investments***

The Company determines the appropriate classification of its investments at the time of purchase and reevaluates such determination at each balance sheet date. The Company's investment policy sets minimum credit quality criteria and maximum maturity limits on its investments to provide for preservation of capital, liquidity and a reasonable rate of return. Available-for-sale securities are recorded at fair value, based on current market valuations. Unrealized holding gains and losses on available-for-sale securities are excluded from net loss and are reported as a separate component of other comprehensive income (loss) until realized. Realized gains and losses are included in non-operating other income (expense) on the consolidated statement of operations and are derived using the specific identification method for determining the cost of the securities sold.

***Inventories***

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

***Fixed Assets***

Fixed assets are recorded at cost, net of accumulated depreciation and amortization. The Company reviews its property, plant and equipment assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

**Pacira Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****NOTE 2—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

Depreciation of fixed assets is provided over their estimated useful lives on a straight-line basis. Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or the related lease terms. Useful lives by asset category are as follows:

<u>Asset Category</u>	<u>Years</u>
Manufacturing and laboratory equipment	5 to 10 years
Computer equipment and software	1 to 3 years
Office furniture and equipment	5 years

***Goodwill and Intangible Assets***

Intangible assets are recorded at cost, net of accumulated amortization. Amortization of intangible assets is provided over their estimated useful lives on a straight-line basis. The Company evaluates the recoverability of intangible assets periodically and takes into account events and circumstances which indicate that impairment exists. Goodwill represents the excess of purchase price over fair value acquired in a business combination and is not amortized, but subject to impairment at least annually or when a triggering event occurs that could indicate a potential impairment.

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

Management reviews long-lived assets, including fixed assets, for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the assets exceeds the fair value of the assets.

***Foreign Currencies***

The Company receives payment from certain of its commercial partners relating to royalties on DepoCyte in Euros. Realized gains and losses from foreign currency transactions are reflected in the consolidated statements of operations and were not significant in any period. All foreign currency receivables and payables are measured at the applicable exchange rate at the end of the reporting period.

***Income Taxes***

The Company uses the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. As of December 31, 2012 and 2011, all deferred tax assets were fully offset by a valuation allowance.

**Pacira Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

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

The Company accrues interest and penalties, if any, on underpayment of income taxes related to unrecognized tax benefits as a component of income tax expense in its consolidated statements of operations.

***Per Share Data***

Basic net loss per share is computed by dividing net loss available (attributable) to common stockholders by the weighted average number of shares of common stock outstanding during the period. Because the holders of the Series A convertible preferred stock were not contractually required to share in the Company's losses, in applying the two-class method to compute basic net loss per common share no allocation to preferred stock was made for the years ended December 31, 2011 and 2010. At December 31, 2012, there were no Series A convertible preferred stock outstanding as a result of the initial public offering on February 8, 2011 when all convertible preferred stock was converted into common stock.

Diluted net income (loss) per share is calculated by dividing net income available (attributable) to common stockholders as adjusted for the effect of dilutive securities, if any, by the weighted average number of common stock and dilutive common stock outstanding during the period. Potential common shares include the shares of common stock issuable upon the exercise of outstanding stock options and warrants (using the treasury stock method). Potential common shares in the diluted net loss per share computation are excluded to the extent that they would be anti-dilutive. No potentially dilutive securities are included in the computation of any diluted per share amounts as the Company reported a net loss for all periods presented.

***Stock-Based Compensation***

The Company's stock-based compensation programs include grants of stock options to employees, consultants and non-employee directors. The expense associated with these programs is recognized in the Company's consolidated statements of operations based on their fair values as they are earned under the applicable vesting terms.

The valuation of stock options is an inherently subjective process, since market values are generally not available for long-term, non-transferable stock options. Accordingly, the Company uses an option pricing model to derive an estimated fair value. In calculating the estimated fair value of stock options granted, the Company uses the Black-Scholes option pricing model which requires the consideration of the following variables for purposes of estimating fair value:

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

**Pacira Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

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

Because the Company's common stock was not publicly held prior to February 2011, the expected volatility was based on the historic volatility for publicly traded industry peers for shares granted prior to the initial public offering. Since its initial public offering, the Company utilizes its available historic volatility data combined with the publicly traded peer's historic volatility to determine expected volatility over the expected option term. The Company's limited historical stock option exercise experience does not provide a reasonable basis upon which to estimate expected term. Accordingly, the Company uses a term based on a simplified method, pursuant to SEC Staff Accounting Bulletin No. 107, Share-based Payment, for "plain vanilla" options. The risk-free interest rate is based on the implied yield on U.S. Department of the Treasury zero coupon bonds for periods commensurate with the expected term of the options. The dividend yield on the Company's common stock is estimated to be zero as the Company has not paid any dividends since inception. The Company estimates the level of award forfeitures expected to occur, and records compensation cost only for those awards that are ultimately expected to vest.

***Segment Reporting***

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

**NOTE 3—RECENT ACCOUNTING PRONOUNCEMENTS**

In February 2013, the Financial Accounting Standards Board, or FASB, issued amendments to the accounting guidance for presentation of comprehensive income to improve the reporting of reclassifications out of accumulated other comprehensive income. The amendments do not change the current requirements for reporting net income or other comprehensive income, but do require an entity to provide information about the amounts reclassified out of accumulated other comprehensive income by component. In addition, an entity is required to present, either on the face of the statement where the net income is presented or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income but only if the amount reclassified is required under GAAP to be reclassified to net income in its entirety in the same reporting period. For other amounts that are not required under GAAP to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures required under GAAP that provide additional detail about these amounts. These amendments are effective prospectively for reporting periods beginning after December 15, 2012. The Company does not believe the adoption of this guidance will have a material impact on the consolidated financial statements.

Other pronouncements issued by the FASB or other authoritative accounting standards groups with future effective dates are either not applicable or not significant to the consolidated financial statements of the Company.

**NOTE 4—FINANCIAL INSTRUMENTS**

***Fair Value Measurements***

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in the principal or most advantageous market in an orderly transaction. To increase consistency and comparability in fair value measurements, FASB established a three-level hierarchy, which requires

**Pacira Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**NOTE 4—FINANCIAL INSTRUMENTS (Continued)**

an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The three levels are:

- *Level 1:* Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.
- *Level 2:* Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.
- *Level 3:* Unobservable inputs that are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

The fair value of the long-term debt at December 31, 2012 is calculated using a discounted cash flow analysis factoring in current market borrowing rates for similar types of borrowing arrangements under a similar credit profile. The carrying amount and fair value of the Company's long-term debt is for disclosure purposes only (in thousands):

<u>Financial Liabilities Carried at Historical Cost</u>	<u>Carrying Value</u>	<u>Fair Value Measurements Using</u>		
		<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
<b>December 31, 2012</b>				
Long term debt—current and long-term	\$ 27,500	\$ —	\$ 28,497	\$ —

Short-term investments consist of U.S. Treasury securities, investment grade commercial paper, asset-backed securities collateralized by credit card receivables and corporate bonds with initial maturities of greater than three months at the date of purchase but less than one year. The net unrealized gains (losses) from the Company's short-term investments are captured in other comprehensive income (loss). At December 31, 2012, all of the Company's short-term investments are classified as available for sale investments and determined to be Level 2 instruments, which are measured at fair value using standard industry models with observable inputs. At December 31, 2012, the Company had \$30.9 million invested in short-term investments which were rated A or better by Standard & Poor's and had maturities ranging from 210 to 356 days from date of purchase.

The following summarizes the Company's short-term investments at December 31, 2012 and 2011 (in thousands):

<u>December 31, 2012</u>	<u>Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value (Level 2)</u>
Debt securities:				
Commercial Paper	\$ 15,974	\$ 23	\$ —	\$ 15,997
Corporate Bonds	8,874	1	(1)	8,874
Asset-backed Securities	6,049	4	—	6,053
<b>Total</b>	<b>\$ 30,897</b>	<b>\$ 28</b>	<b>\$ (1)</b>	<b>\$ 30,924</b>



**Pacira Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****NOTE 4—FINANCIAL INSTRUMENTS (Continued)**

<u>December 31, 2011</u>	<u>Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value (Level 2)</u>
Debt securities:				
US Treasury Securities	\$ 1,000	\$ —	\$ —	\$ 1,000
Commercial Paper	11,476	23	—	11,499
Corporate Bonds	17,494	2	(10)	17,486
Total	<u>\$ 29,970</u>	<u>\$ 25</u>	<u>\$ (10)</u>	<u>\$ 29,985</u>

Certain assets and liabilities are measured at fair value on a nonrecurring basis including assets and liabilities acquired in a business combination, equity-method investments and long-lived assets, which would be recognized at fair value if deemed to be impaired or if reclassified as assets held for sale. The fair value in these instances would be determined using Level 3 inputs.

*Credit Risk*

Financial instruments which potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents, short-term investments and accounts receivable. The Company maintains its cash and cash equivalents and short-term investments with high-credit quality financial institutions. At times, such amounts may exceed Federally insured limits. The Company performs ongoing credit evaluations of its customers, as warranted, and generally does not require collateral. As of December 31, 2012, four customers accounted for over 10% of the Company's accounts receivable; 31%, 27%, 16% and 15%. At December 31, 2011, two customers accounted for 56% and 41% of the Company's accounts receivable. Revenues are primarily derived from major wholesalers and pharmaceutical companies that generally have significant cash resources. Allowances for doubtful accounts receivable are maintained based on historical payment patterns, aging of accounts receivable and actual write-off history. As of December 31, 2012 and 2011, no allowances for doubtful accounts were deemed necessary by the Company on its accounts receivable.

**NOTE 5—INVENTORIES**

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

	<u>December 31,</u>	
	<u>2012</u>	<u>2011</u>
Raw materials	\$ 4,081	\$ 862
Work-in-process	5,979	96
Finished goods	2,017	287
Total	<u>\$ 12,077</u>	<u>\$ 1,245</u>

For the year ended December 31, 2012, the Company recorded a \$0.3 million write down of DepoCyt(e) finished inventory related to the amount of excess product that may not be marketable under the remediation plan committed to the Medicines and Healthcare products Regulatory Agency, or MHRA. See Note 18, *Commitments and Contingencies*, for further discussion. For the year ended December 31, 2011, the Company recorded a \$0.2 million write down of DepoDur inventory.

**Pacira Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****NOTE 6—FIXED ASSETS**

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

	<u>December 31,</u>	
	<u>2012</u>	<u>2011</u>
Machinery and laboratory equipment	\$ 12,414	\$ 12,188
Computer equipment and software	1,579	1,133
Office furniture and equipment	437	352
Leasehold improvements	6,217	6,056
Construction in progress	30,072	13,656
Total	50,719	33,385
Less accumulated depreciation	(11,603)	(8,282)
Fixed assets, net	<u>\$ 39,116</u>	<u>\$ 25,103</u>

Depreciation expense for the years ended December 31, 2012, 2011 and 2010 was \$3.6 million, \$2.0 million and \$1.8 million, respectively. During the years ended December 31, 2012 and 2011, the Company capitalized interest of \$2.0 million and \$0.8 million, respectively, on the construction of its manufacturing site. Capitalized interest was not material and, therefore, not capitalized for the year ended December 31, 2010, due to non-routine delays in the construction of the manufacturing site.

During the year ended December 31, 2011, an impairment loss of \$1.3 million was recognized due to a decision made during the fourth quarter of 2011 to change the automation technology process in the Company's production line to expand EXPAREL capacity resulting in certain software and equipment previously capitalized as construction in progress that were no longer utilizable. Also during 2011, the Company impaired \$0.3 million of DepoDur-related equipment. Refer to Note 7, *Goodwill and Intangible Assets*, for discussion on the impairment. These impairment losses are reflected in impairment of long-lived assets in the Company's consolidated statements of operations.

**NOTE 7—GOODWILL AND INTANGIBLE ASSETS**

The Company's goodwill arose from the triggering in April 2012 of a contingent milestone payment to Skyepharma in connection with the Acquisition. The Acquisition was accounted for under Statement of Financial Accounting Standards 141, *Accounting for Business Combinations*, which was the effective GAAP at the Acquisition date. In connection with the Acquisition, the Company agreed to certain earn-out payments based on a percentage of net sales of EXPAREL collected and certain other yet-to-be-developed products, as well as milestone payments for EXPAREL as follows:

- (a) \$10.0 million upon first commercial sale in the United States;
- (b) \$4.0 million upon first commercial sale in a major EU country (United Kingdom, France, Germany, Italy and Spain);
- (c) \$8.0 million when annual net sales collected reach \$100.0 million;
- (d) \$8.0 million when annual net sales collected reach \$250.0 million; and
- (e) \$32.0 million when annual net sales collected reach \$500.0 million.

**Pacira Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****NOTE 7—GOODWILL AND INTANGIBLE ASSETS (Continued)**

The first contingency was resolved in April 2012 resulting in a \$10.0 million payment to Skyepharma. The Company recorded this payment net of the \$2.0 million contingent consideration liability recognized at the time of the Acquisition resulting in \$8.0 million recorded as goodwill. Additionally, as of December 31, 2012, the Company also recorded \$0.3 million as goodwill for the percentage payments on net sales of EXPAREL collected. Any remaining earn-out payments will also be treated as additional cost of the Acquisition and, therefore, recorded as goodwill if and when each contingency is resolved.

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

	Year Ended		Estimated Useful Life
	December 31,		
	2012	2011	
<b>Core Technology</b>			
Gross amount	\$ 2,900	\$ 2,900	9 years
Accumulated amortization	(1,853)	(1,530)	
Net	1,047	1,370	
<b>Developed Technology</b>			
Gross amount	11,700	11,700	7 years
Accumulated amortization	(9,610)	(7,939)	
Net	2,090	3,761	
<b>Trademarks and trade names</b>			
Gross amount	400	400	7 years
Accumulated amortization	(329)	(272)	
Net	71	128	
<b>Intangible assets, net</b>	<b>\$ 3,208</b>	<b>\$ 5,259</b>	

Annual amortization expense for intangibles for the years ended December 31, 2012, 2011 and 2010 was \$2.1 million, \$2.3 million and \$2.3 million, respectively.

In December 2011, the Company was notified of the intent of its commercial partner, EKR Therapeutics, Inc., or EKR, to exit the DepoDur market. As a result, the Company recorded an impairment loss of \$1.4 million representing the entire net intangible value of the DepoDur rights. In making the determination to impair the intangible asset, the Company also considered its inability to re-sublicense the product due to minimal supply revenue for the product both in the U.S. and in Europe as well as DepoDur's complex manufacturing process. Such impairment losses are reflected in impairment of long-lived assets in the Company's consolidated statements of operations.

**Pacira Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**NOTE 7—GOODWILL AND INTANGIBLE ASSETS (Continued)**

The approximate amortization expense for intangibles subject to amortization is as follows (in thousands):

	Core Technology	Developed Technology	Trademarks and Tradenames	Total
2013	\$ 322	\$ 1,671	\$ 57	\$ 2,050
2014	322	419	14	755
2015	322	—	—	322
2016	81	—	—	81
Total	<u>\$ 1,047</u>	<u>\$ 2,090</u>	<u>\$ 71</u>	<u>\$ 3,208</u>

**NOTE 8—ACCRUED EXPENSES**

Accrued expenses consist of the following (in thousands):

	<u>December 31,</u>	
	<u>2012</u>	<u>2011</u>
Compensation and benefits	\$ 1,635	\$ 2,824
Accrued operating expenses	5,924	3,090
Accrued royalties	360	345
Accrued interest and end of term fee	1,873	900
Total	<u>\$ 9,792</u>	<u>\$ 7,159</u>

**NOTE 9—DEBT**

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

	<u>December 31,</u>	
	<u>2012</u>	<u>2011</u>
<b>Debt:</b>		
Current portion of long-term debt	\$ —	\$ 7,039
Long-term debt	27,500	19,211
Discount on debt	(2,309)	(674)
Total debt, net of discount	<u>25,191</u>	<u>25,576</u>
<b>Royalty interest obligation:</b>		
Current portion of royalty interest obligation	823	1,219
Long-term portion of royalty interest obligation	857	1,537
Total royalty interest obligation	<u>1,680</u>	<u>2,756</u>
Total debt and financing obligations	<u>\$ 26,871</u>	<u>\$ 28,332</u>

**Pacira Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**NOTE 9—DEBT (Continued)**

*Oxford Loan Facility*

On May 2, 2012, the Company entered into a definitive loan and security agreement, or the Loan Agreement, with Oxford Finance LLC, or the Lender, and borrowed the principal amount of \$27.5 million, or the Loan Facility, at a fixed rate of 9.75%, with the first principal payment due December 1, 2013. Payments under the Loan Agreement were interest-only in arrears through November 30, 2013, followed by 30 equal monthly payments of principal and interest. In addition, a payment equal to 6% of the Loan Facility was due on the final payment date, or such earlier date as specified in the Loan Agreement. The \$1.65 million end of term fee was recorded as a debt discount and amortized to interest expense over the term of the loan. The proceeds from the Loan Agreement were used by the Company to repay the entire \$24.2 million outstanding balance plus accrued interest, \$0.6 million end of term fee and \$0.3 million early prepayment penalty on its credit facility with Hercules Technology Growth Capital, Inc. and Hercules Technology II, L.P., as lenders, or Hercules Credit Facility. The Company recorded a loss on extinguishment of debt of \$1.1 million comprised of the remaining unamortized debt issuance costs, warrants and end of term fee, as well as the early prepayment penalty on the note issued under the Hercules Credit Facility.

The Company's obligations under the Loan Agreement were secured by a first priority security interest in substantially all of its assets, other than its intellectual property. The Company agreed not to pledge or otherwise encumber its intellectual property assets, except for permitted liens or to the extent the intellectual property constitutes royalty collateral, as such terms are defined in the Loan Agreement and except as otherwise provided in the Loan Agreement.

If the Company repaid all or a portion of the Loan Facility prior to maturity, it would pay the Lender a prepayment fee based on a percentage of the then outstanding principal balance equal to: 3.00% if the prepayment occurred prior to or on the first anniversary of the funding date, 2.00% if the prepayment occurs after the first anniversary of the funding date but prior to or on the second anniversary of the funding date, or 1.00% if the prepayment occurs after the second anniversary of the funding date.

The Loan Agreement includes customary affirmative and restrictive covenants for transactions of this type and customary events of default, including the following events of default: payment defaults, breaches of covenants, judgment defaults, cross defaults to certain other contracts, the occurrence of certain events under the Company's royalty agreements, certain events with respect to governmental approvals if such events could cause a material adverse change, a material impairment in the perfection or priority of the Lender's security interest or in the value of the collateral, a material adverse change in the business, operations or condition of the Company or any of its subsidiaries and a material impairment of the prospect of repayment of the loans. Upon the occurrence of an event of default, a default increase in the interest rate of an additional 5.00% could be applied to the outstanding loan balance and the Lender could declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement.

**Pacira Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**NOTE 9—DEBT (Continued)**

In connection with the Loan Agreement, the Company issued to the Lender warrants that are exercisable for an aggregate of 162,885 shares of its common stock at a per share exercise price of \$10.97. Each warrant may be exercised on a cashless basis in whole or in part. The value of the warrants was recorded as a debt discount and amortized over the term of the loan to interest expense. The fair value of the warrants was determined using Black-Scholes option model (using a discount rate of 1.96%, volatility of 69.69%, a dividend yield of 0%, and a contractual term of 10 years). The relative fair value of the warrants totaled \$1.4 million.

The Company's principal payments were due under the Loan Agreement as follows: \$0.8 million in 2013, \$10.3 million in 2014, \$11.3 million in 2015 and \$5.1 million in 2016. See Note 19, *Subsequent Events*, for further discussion.

*Hercules Credit Facility*

On November 24, 2010, the Company entered into the \$26.3 million Hercules Credit Facility. At the closing of the Hercules Credit Facility, the Company entered into a term loan in the aggregate principal amount of \$26.3 million, which was the full amount available under the facility. The term loan under the Hercules Credit Facility was comprised of two tranches, Tranche A and Tranche B. The Tranche A portion of the term loan was comprised of \$11.3 million in principal and carried a floating per annum interest rate equal to 10.25% plus the amount, if any, by which the prime rate exceeds 4.00%. Upon the release of the investors' guaranty in November 2011, the interest rate on the Tranche A portion of the term loan was increased to a floating per annum interest rate equal to 11.00% plus the amount, if any, by which the prime rate exceeds 4.00%. The Tranche B portion of the term loan was comprised of \$15.0 million in principal and carried a floating per annum interest rate equal to 12.65% plus the amount, if any, by which the prime rate exceeds 4.00%. As of December 31, 2011, the blended interest rate was 11.94%.

As further consideration to the lenders to provide the term loan to the Company under the Hercules Credit Facility, the Company issued a warrant to purchase 178,986 shares of the Company's stock.

The term loan under the Hercules Credit Facility was terminated in May 2012.

*Sale of Royalty Interests*

In 2000, PPI-California and SkyePharma PLC entered into a Royalty Interests Assignment Agreement ("PLC Royalty Agreement") with an affiliate of Paul Capital Advisors, LLC ("Paul Capital") to raise \$30.0 million. Under the PLC Royalty Agreement, Paul Capital had the right to receive a royalty interest in four of SkyePharma's product sales including product sales of, and other payments related to DepoCyt(e) and DepoDur. Payments began for product sales realized on or after January 1, 2003 and continue through December 31, 2014.

In connection with the Acquisition, the PLC Royalty Agreement was amended ("Amended and Restated Royalty Interests Assignment Agreement"). As part of this amendment the responsibility to pay the royalty interest in product sales of DepoCyt(e) and DepoDur were transferred to the Company and the payment to Paul Capital in a "Purchase Option Event" of the Company, as described below, was defined. The net present value of royalties expected to be repaid to Paul Capital (the "royalty interest obligation") was valued at \$13.0 million.

**Pacira Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**NOTE 9—DEBT (Continued)**

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

The PLC Royalty Agreement also includes a provision for a "Purchase Option Event." The events include: (1) any change of control, a direct or indirect consequence of which is a material abatement of efforts to develop, market or sell any of the products or reformulated products; or (2) the transfer by the parent of all or substantially all of the parent's consolidated assets; or (3) the transfer by the Company of all or any part of their respective interests in the products or reformulated products, or (4) bankruptcy or other breach or default under the agreement. In the event a Purchase Option Event occurs, Paul Capital shall have the right, but not the obligation, exercisable within 90 days, to require the Company to repurchase from Paul Capital the Royalty Interests Assignment, for a repurchase price equal to 50% of the cumulative amount of all payments made during the preceding 24 months (calculated from the date of the Purchaser's receipt of the notice from the Company of the Purchase Option Event) multiplied by the number of days from the date of Paul Capital's exercise of such option until December 31, 2014, divided by 365.

The Company has no minimum payment obligations under the PLC Royalty Agreement. However, the repayment of the Paul Capital liability is supported through a jointly controlled lockbox, where all DepoCyt(e) and DepoDur supply revenue and royalties are received as discussed in Note 2, *Summary of Significant Accounting Policies*.

**NOTE 10—STOCKHOLDERS' EQUITY**

*Common Stock*

On February 8, 2011, the Company completed an initial public offering of common stock for an aggregate of 6,000,000 shares and raised \$37.1 million in net proceeds after deducting underwriting discounts and offering expenses. In November 2011, the Company raised an additional \$49.0 million in net proceeds after deducting underwriting discounts and offering expenses in a registered public offering of common stock for an aggregate of 8,050,000 shares.

In April 2012, the Company sold 6,900,000 shares of common stock at a price of \$9.75 per share in a registered public offering, which includes the underwriter's exercise of the overallotment option. The Company raised approximately \$62.9 million in net proceeds after deducting discounts and offering expenses.

*Convertible Preferred Stock*

Upon the closing of the initial public offering in February 2011, all outstanding shares of Series A convertible preferred stock and the principal and accrued interest balance totaling \$51.2 million on the

**Pacira Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****NOTE 10—STOCKHOLDERS' EQUITY (Continued)**

convertible promissory notes sold in January 2009, the secured notes sold in June 2009, the secured notes sold in March 2010, the convertible promissory notes sold in December 2010, and the secured notes sold in April 2010 were converted into an aggregate of 10,647,549 shares of common stock, as shown in the table below.

	<u>Conversion Shares</u>
Series A Convertible Preferred Stock	6,322,640
2009 Convertible Notes	871,635
2009 Secured Notes	927,881
2010 Secured Notes	1,156,606
HBM Secured Notes	297,359
2010 Convertible Notes	1,071,428

*Warrants*

On May 2, 2012, the Company issued warrants to the Lender in connection with the Loan Agreement that are exercisable for an aggregate of 162,885 shares of its common stock at a per share exercise price of \$10.97. On October 5, 2012, the Lender exercised the warrants on a cashless basis and received 67,279 shares of common stock. At December 31, 2012 and 2011, the Company had 490,464 and 527,656 warrants outstanding at a weighted average exercise price of \$10.79 and \$10.22, respectively.

*Accumulated Other Comprehensive Income*

	<u>Net Unrealized Gains (Losses) From Marketable Securities</u>	<u>Total Accumulated Other Comprehensive Income (Loss)</u>
Balances at December 31, 2010	\$ —	\$ —
Period Change	15	15
Balances at December 31, 2011	\$15	\$15
Period Change	12	12
Balances at December 31, 2012	<u>\$27</u>	<u>\$27</u>

**NOTE 11—STOCK PLANS**

The Company's 2007 stock incentive plan, or 2007 Plan, provides 1,729,498 shares for issuance. The Company's 2011 stock incentive plan, or 2011 Plan, which became effective immediately prior to the completion of the Company's initial public offering in February 2011, was adopted by its board of directors and approved by its stockholders in December 2010. The 2011 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards and other stock-based awards. The remaining shares available for issuance under the 2007 Plan at the time of the completion of the Company's initial public offering were reallocated to the 2011 Plan. The 2011 Plan also increased the shares reserved for issuance from 1,729,498 to 2,546,657 shares. The 2011 Plan contained an "evergreen" provision, which allowed for an annual increase of up to 557,880 shares available for issuance under the 2011 Plan on the first day of each calendar year from 2012 through 2015. On



**Pacira Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****NOTE 11—STOCK PLANS (Continued)**

January 1, 2012, the evergreen provision increased the number of shares of common stock authorized for issuance under the 2011 stock plan by 557,880 shares. On June 5, 2012, the 2011 Plan was amended, to, among other things: (i) increase the number of shares of common stock authorized for issuance under the 2011 Plan by 2,100,000, (ii) remove the evergreen provision and (iii) require stockholder approval prior to any repricing of awards granted under the 2011 Plan.

The following table contains information about the Company's plans at December 31, 2012:

<u>Plan</u>	<u>Awards Reserved for Issuance</u>	<u>Awards Issued</u>	<u>Awards Available for Grant</u>
2011 Plan	3,138,519	2,393,214	745,305
2007 Plan	2,066,018	2,066,018	—
	<u>5,204,537</u>	<u>4,459,232</u>	<u>745,305</u>

*Stock-Based Compensation*

The Company recognized stock-based compensation in its consolidated statements of operations for the years ended December 31, 2012, 2011 and 2010 as follows (in thousands):

	<u>Year Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
Cost of revenues	\$ 563	\$ 218	\$ 12
Research and development	1,155	804	10
Selling, general and administrative	3,058	1,471	1
Total	<u>\$ 4,776</u>	<u>\$ 2,493</u>	<u>\$ 23</u>

**Pacira Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**NOTE 11—STOCK PLANS (Continued)**

The following table summarizes the Company's stock option activity and related information for the period from January 1, 2010 to December 31, 2012 (in thousands except share and per share amounts):

	Number of shares	Weighted average exercise price	Weighted Average remaining contractual term (years)	Aggregate intrinsic value (in thousands)
Outstanding at January 1, 2010	52,430	1.79	8.06	\$ 47
Granted	2,028,158	2.71		
Exercised	(1,177)	1.89		\$ 1
Forfeited	(3,337)	1.89		
Expired	(2,374)	1.75		
Outstanding at December 31, 2010	2,073,700	2.69	9.70	\$ 6
Granted	395,234	10.21		
Exercised	(67,456)	2.01		\$ 420
Forfeited	(62,776)	5.05		
Expired	(1,685)	2.69		
Outstanding at December 31, 2011	2,337,017	3.92	8.80	\$ 11,829
Granted	2,120,250	11.55		
Exercised	(279,476)	2.75		\$ 3,005
Forfeited	(174,610)	7.94		
Expired	(15)	7.07		
Outstanding at December 31, 2012	4,003,166	\$ 7.86	8.66	\$ 38,485
Exercisable at December 31, 2012	1,269,921	\$ 3.76	7.80	\$ 17,415
Vested and expected to vest at December 31, 2012	3,889,392	\$ 7.78	8.64	\$ 37,686

As of December 31, 2012, \$17.7 million of total unrecognized compensation cost related to non-vested stock options is expected to be recognized over the respective vesting terms of each award. The weighted average contractual term of the unrecognized stock-based compensation is approximately 3 years.

The weighted average fair value of stock options granted for the years ended December 31, 2012, 2011 and 2010 was \$8.52, \$7.06 and \$5.61 per share, respectively. The fair values of stock options granted were estimated using the Black-Scholes option pricing model with the following weighted average assumptions:

	Year Ended December 31,		
	2012	2011	2010
Expected dividend yield	None	None	None
Risk free interest rate	0.84 - 1.70%	1.1 - 2.7%	1.6 - 3.4%
Expected volatility	74.0%	76.8%	80.8%
Expected life of options	6.76 years	6.73 years	6.25 years

**Pacira Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****NOTE 12—EARNINGS PER SHARE**

Basic earnings per share is calculated by dividing the net loss attributable by the weighted average number of shares outstanding during the period, without consideration for common stock equivalents. Diluted earnings per share is calculated by dividing the net loss attributable by the weighted average number of shares outstanding plus common stock equivalents computed using the treasury stock method. For purposes of this calculation, convertible preferred stock, stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive. The following table sets forth the computation of basic and diluted loss per share for the years ended December 31, 2012, 2011 and 2010 (in thousands except per share amounts):

	Year Ended		
	December 31, 2012	December 31, 2011	December 31, 2010
<b>Numerator:</b>			
Net loss	\$ (52,281)	\$ (43,328)	\$ (27,149)
<b>Denominator:</b>			
Weighted average shares of common stock outstanding	30,332	16,437	574
<b>Net loss per share</b>			
Basic and diluted net loss per share of common stock	\$ (1.72)	\$ (2.64)	\$ (47.29)

The preferred stock, convertible debt, stock options and warrants are excluded from the calculation of diluted loss per share because the net loss for the years ended December 31, 2012, 2011 and 2010, causes such securities to be anti-dilutive. The potential dilutive effect of these securities is shown in the chart below (in thousands):

	Year Ended		
	December 31, 2012	December 31, 2011	December 31, 2010
Convertible series A preferred stock	—	—	6,323
Stock options	1,276	1,177	1,058
Convertible debt	—	—	1,425
Warrants	161	110	80
<b>Total</b>	<b>1,437</b>	<b>1,287</b>	<b>8,886</b>

**NOTE 13—COST OF REVENUES**

Cost of revenues consists of the following (in thousands):

	Year Ended December 31,		
	2012	2011	2010
Cost of goods sold	\$ 31,744	\$ 15,310	\$ 11,374
Cost of collaborative licensing and development	395	1,429	902
<b>Total cost of revenues</b>	<b>\$ 32,139</b>	<b>\$ 16,739</b>	<b>\$ 12,276</b>

**Pacira Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**NOTE 13—COST OF REVENUES (Continued)**

Cost of goods sold consists of the manufacturing and allocated overhead costs related to the Company's products. Cost of collaborative licensing and development consists of the Company's expenses related to feasibility studies and development work for third parties who desire to utilize the Company's DepoFoam extended release drug delivery technology for their products. Cost of goods sold and cost of collaborative licensing and development both include royalties due to Research Development Foundation ("RDF") for the use of DepoFoam technology.

**NOTE 14—INCOME TAXES**

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

	<u>Year Ended December 31,</u>		
	<u>2012</u>	<u>2011</u>	<u>2010</u>
Benefit at U.S. Federal statutory rate	35.00%	35.00%	35.00%
State taxes—deferred	6.73%	3.98%	7.75%
Increase in valuation allowance	(39.62)%	(38.27)%	(44.77)%
Tax credits	0.00%	0.13%	0.18%
Other	(2.11)%	(0.84)%	1.84%
Provision for income taxes	<u>0.00%</u>	<u>0.00%</u>	<u>0.00%</u>

Significant components of the Company's deferred tax assets are as follows (in thousands):

	<u>December 31,</u>	
	<u>2012</u>	<u>2011</u>
Deferred tax assets:		
Federal and state net operating loss carry-forwards	\$ 89,150	\$ 62,231
Federal and state research credits	3,631	3,395
Depreciation and amortization	3,891	4,867
Accruals and reserves	3,388	2,685
Deferred revenue	1,897	8,745
Other	1,997	1,325
Total gross deferred tax assets	<u>103,954</u>	<u>83,248</u>
Less valuation allowance for deferred tax assets	<u>(103,954)</u>	<u>(83,248)</u>
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

The Company has significant federal and state net operating loss carryforwards and federal and state research and development tax credit carryforwards. As of December 31, 2012, federal and state net operating losses totaled \$219.2 million and \$216.1 million, respectively. The Company also had federal and state research and development tax credit carry-forwards of approximately \$2.6 million and \$1.6 million, respectively. The net operating loss carryforwards will begin expiring in 2026 for federal purposes and 2015 for state purposes if the Company has not used them prior to that time, and the federal tax credits will begin expiring in 2028 unless previously used. The state tax credits carry forward indefinitely. There is significant doubt regarding the Company's ability to utilize its net deferred tax

**Pacira Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**NOTE 14—INCOME TAXES (Continued)**

assets and, therefore, the Company has recorded a full valuation allowance. The valuation allowance for deferred tax assets increased by approximately \$20.7 million, \$16.6 million and \$12.2 million during the years ended December 31, 2012, 2011 and 2010, respectively.

Additionally, the Company's 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 since the Company had a cumulative change in ownership of more than 50% within the three-year period. Such an ownership change was triggered by the cumulative ownership changes arising as a result of the completion of the initial public offering and other financing transactions. Because of the ownership change, the Company will be limited regarding the amount of net operating loss carryforwards and research tax credits that it can utilize annually in the future to offset taxable income or tax, respectively. The annual limitation may significantly reduce the utilization of the net operating loss carryforwards and research tax credits before they expire. In addition, California and certain states have suspended use of net operating loss carryforwards for certain taxable years, and other states are considering similar measures. As a result, the Company may incur higher state income tax expense in the future.

The Acquisition was treated as a stock acquisition for tax purposes and, therefore, the acquired intangibles for book purposes are not deductible for income tax purposes. The Company also recorded goodwill relating to contingent payments due under the Acquisition during the year ended December 31, 2012, which is not deductible for income tax purposes.

In connection with the adoption of stock-based compensation guidance in 2006, the Company elected to follow the with-and-without approach to determine the sequence in which deductions and net operating loss carryforwards are utilized. Accordingly, no tax benefit related to stock options was recognized in the current year. At December 31, 2012, the Company has approximately \$2.2 million of net operating loss carryforwards that relate to stock-based compensation for which future tax benefits will be credited to equity.

The Company evaluates its uncertain tax positions in a two-step process. The Company first determines whether it is more-likely-than-not that a tax position will be sustained upon examination. If a tax position meets the more-likely-than-not recognition threshold it is then measured to determine the amount of benefit to be recognized in the financial statements. The tax position is measured as the largest amount of benefit that has a greater than 50% likelihood of being realized upon ultimate settlement.

The Company did not have a liability related to unrecognized tax benefits as of December 31, 2012 and 2011 due to operating losses but has reduced its deferred tax assets by \$0.4 million at December 31, 2012 and 2011. Further, because the Company has recorded a full valuation allowance on its net deferred assets, the effect of implementing ASC 740 has been a reduction of the allowance

**Pacira Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****NOTE 14—INCOME TAXES (Continued)**

by the amount above. A reconciliation of the beginning and ending amount of gross unrecognized tax benefit is as follows:

	Year Ended	
	December 31,	
	2012	2011
Balance at beginning of year	\$ 420	\$ 420
Increases related to tax positions taken during the current year	—	—
Increases related to tax positions taken during a prior period	—	—
Balance at end of year	<u>\$ 420</u>	<u>\$ 420</u>

No interest or penalties were accrued for 2012, 2011 or 2010. The Company is currently open for audit by the United States Internal Revenue Service and state tax jurisdictions for 2006 through 2012. The American Tax Relief Act of 2012, enacted on January 2, 2013, retroactively reinstated the research and development tax credit for 2012. The Company will report credits of approximately \$0.2 million for federal income tax purposes in the first quarter of 2013.

**NOTE 15—OTHER EMPLOYEE BENEFITS**

The Company sponsors a 401(k) savings plan. Under the plan, employees may make contributions to the plan, which are eligible for a discretionary percentage match as defined in the plan and determined by the board of directors. The Company recognized \$0.3 million, \$0.2 million and \$0.0 million of related compensation expense for the years ended December 31, 2012, 2011 and 2010, respectively.

**NOTE 16—COMMERCIAL PARTNERS AND OTHER AGREEMENTS*****Commercial Partners******Aratana Therapeutics, Inc.***

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

**Pacira Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**NOTE 16—COMMERCIAL PARTNERS AND OTHER AGREEMENTS (Continued)**

*Mundipharma International Holdings Limited*

In June 2003, the Company entered into an agreement granting Mundipharma International Holdings Limited, or Mundipharma, exclusive marketing and distribution rights to DepoCyt in the European Union and certain other European countries. Under the agreement, as amended, and a separate supply agreement, the Company receives a fixed payment for manufacturing the vials of DepoCyt and a double-digit royalty, net of supply price, on sales in the applicable territories.

*Sigma -Tau*

In December 2002, the Company entered into a supply and distribution agreement with Enzon Pharmaceuticals Inc., subsequently acquired by Sigma-Tau Pharmaceuticals, Inc., or Sigma-Tau, regarding the sale of DepoCyt. Pursuant to the agreement, Sigma-Tau was appointed the exclusive distributor of DepoCyt in the United States and Canada. Under the supply and distribution agreement, the Company supplies unlabeled DepoCyt vials to Sigma-Tau for finished packaging by Sigma-Tau. Under these agreements, the Company receives a fixed payment for manufacturing the vials of DepoCyt and a double-digit royalty on sales, net of supply price, in the United States and Canada.

*EKR Therapeutics, Inc.*

On January 3, 2012, EKR Therapeutics, Inc., or EKR, delivered a notice to the Company to terminate the licensing, distribution and marketing agreement relating to DepoDur. Pursuant to the terms of the agreement, the termination of the agreement was effective on July 1, 2012. The associated supply agreement also terminated concurrently with the termination of the licensing, distribution and marketing agreement. Both parties agreed to terminate the agreements effective June 8, 2012. As a result of the termination, the Company recognized any unamortized deferred revenue relating to the agreement on a straight-line basis through the termination date in June 2012.

*Flynn Pharmaceuticals Limited*

On October 29, 2012, the Company terminated the marketing agreement with Flynn Pharma Limited, or Flynn, which had granted exclusive distribution rights to DepoDur in the European Union, certain other European countries, South Africa and the Middle East. The supply agreement terminated concurrently with the marketing agreement. The termination was effective immediately. As a result of the termination, the Company recognized any unamortized deferred revenue relating to the agreement upon termination.

***Other Agreements***

In the ordinary course of its business activities, the Company enters into agreements with third parties who desire access to its proprietary DepoFoam extended release drug delivery technology to conduct research, feasibility and formulation work. Under these agreements, the Company is compensated to perform feasibility testing on a third party product to determine the likelihood of developing a successful formulation of that product using its proprietary DepoFoam extended release drug delivery technology. If successful in the feasibility stage, these programs can advance to a full development contract.

**Pacira Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**NOTE 16—COMMERCIAL PARTNERS AND OTHER AGREEMENTS (Continued)**

*Novo Nordisk*

On June 29, 2012, the Company received a notice of termination from Novo Nordisk AS, or Novo, of the Development and License Agreement, dated January 14, 2011, which had granted non-exclusive rights to Novo under certain of its patents and know-how to develop, manufacture and commercialize formulations of a Novo proprietary drug using the Company's DepoFoam drug delivery technology. The Company received a one-time upfront payment of \$1.5 million in January 2011 and a milestone payment of \$2.0 million in November 2011, both of which had been deferred and was being recognized on a straight-line basis over the estimated contract period to collaborative licensing and development revenue in the consolidated statements of operations. Pursuant to the terms of the agreement, the termination of the agreement was effective on August 28, 2012. The agreement was terminated due to Novo's decision to discontinue development of the proprietary drug subject to the agreement. As a result of the termination, the Company recognized any unamortized deferred revenue relating to the agreement on a straight-line basis through the termination date in August 2012.

*Amylin Pharmaceuticals, Inc.*

In March 2008, the Company entered into a development and licensing agreement with Amylin Pharmaceuticals, Inc., or Amylin. Under the development and licensing agreement, the Company provides Amylin with access to its proprietary DepoFoam drug delivery technology to conduct research, feasibility and formulation work, and for the manufacturing of pre-clinical and clinical material for various Amylin products. The Company is entitled to payments from Amylin for its work on the formulation and development of compounds with the DepoFoam technology, its achievement of certain clinical development milestones, its achievement of certain worldwide sales and a tiered royalty based upon sales. The development and licensing agreement with Amylin remains effective, however, neither party is currently performing any activities under the agreement.

**NOTE 17—RELATED PARTY TRANSACTIONS**

MPM Asset Management, or MPM, an investor in the Company, holds a seat on the Company's board of directors. MPM provides clinical management consulting services to the Company through Gary Patou, or Consultant, the Company's Chief Medical Officer. In October 2010, the Company entered into an agreement with MPM to provide services at a monthly rate of approximately \$26,000 in 2010 and 2011 in exchange for 80% of Consultant's business time devoted to the Company, \$16,000 in 2012 in exchange for 50% of Consultant's business time and \$6,000 in 2013 and 2014 in exchange for 20% of Consultant's business time. The original services agreement has been amended twice. The first amendment to this agreement was entered into in December 2011 and declared that Consultant will continue to earn a monthly consulting fee of approximately \$26,000 in exchange for 80% of its business time through September 30, 2012. In November 2012, the Company entered into a second amendment to the services agreement with MPM. Pursuant to the terms of the amended services agreement, the monthly services fee will remain at approximately \$16,000, through December 31, 2013, in exchange for 50% of Consultant's business time. The Company incurred expenses of \$0.4 million, \$0.5 million and \$0.7 million for the years ended December 31, 2012, 2011 and 2010, respectively. As of December 31, 2012 and 2011, \$0.1 million and \$0.2 million, respectively, was payable to MPM.



**Pacira Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**NOTE 17—RELATED PARTY TRANSACTIONS (Continued)**

In December 2012, the Company entered into a worldwide license, development and commercialization agreement with Aratana as discussed in Note 16, *Commercial Partners and Other Agreements*. MPM and its affiliates are holders of capital stock of Aratana.

In April 2010, the Company signed a statement of work for a feasibility study with Rhythm Pharmaceuticals, Inc., or Rhythm. During the year ended December 31, 2010, the Company earned \$0.3 million contract revenue from this statement of work. MPM and its affiliates are holders of capital stock of Rhythm and a managing director of MPM is a member of the board of directors of Rhythm.

In June 2011, the Company entered into an agreement with Gary Pace, a member of its board of directors, to provide consulting services for manufacturing-related activities at a monthly fee of \$5,000, not to exceed \$60,000 annually. In connection with these services, Dr. Pace received an option to purchase 10,000 shares of common stock at an exercise price of \$11.02 per share. In April 2012, the Company entered into an amended and restated consulting agreement with Gary Pace, whereby Dr. Pace will provide consulting services at the rate of \$10,000 per month and received an option to purchase 20,000 shares of common stock at an exercise price of \$11.02 per share pursuant to the amended and restated consulting agreement. The amendment also removed the stipulation that Dr. Pace's total yearly consulting fees could not exceed \$60,000. In August 2012, the Company further amended and restated the consulting agreement with Gary Pace, whereby Dr. Pace will provide consulting services at the rate of \$15,000 per month and received an option to purchase 70,000 shares of common stock at an exercise price of \$16.67 per share pursuant to the amended and restated consulting agreement. Under this amendment, Dr. Pace will be eligible to receive a bonus up to \$0.2 million, contingent upon the date of FDA approval of the Company's Suite C manufacturing facility for EXPAREL. The Company recorded expenses under the consulting arrangement for the years ended December 31, 2012 and 2011 of \$0.2 million and less than \$0.1 million, respectively.

In November 2011, the Company terminated its services agreement with Stack Pharmaceuticals Inc., or SPI, an entity controlled by David Stack, the Company's chief executive officer. SPI had provided the Company with the use of SPI's office facilities and certain consulting services. In November 2011, the Company also purchased \$0.02 million of office furniture and equipment from SPI. The Company incurred expenses under the SPI agreement of \$0.2 million and \$0.3 million for the years ended December 31, 2011 and 2010, respectively. As of December 31, 2012 and 2011, the Company had no outstanding balance payable to SPI.

**NOTE 18—COMMITMENTS AND CONTINGENCIES**

*Leases*

In August 2011, the Company entered into a new lease contract for its corporate headquarters in Parsippany, New Jersey. The lease, which occupies approximately 13,000 square feet, expires in June 2017. Under the lease, the Company is required to pay certain maintenance expenses in addition to rent.

In addition, the Company leases research and development and manufacturing facilities in San Diego, California, in two facilities occupying approximately 106,000 square feet, referred to as the Science Center campus. The leases expire in July 2015. Under these leases, the Company is required to pay certain maintenance expenses in addition to the monthly rent. In connection with the Acquisition, the Company determined that its lease rates associated with the Science Center campus were in excess

**Pacira Pharmaceuticals, Inc.****Notes to Consolidated Financial Statements (Continued)****NOTE 18—COMMITMENTS AND CONTINGENCIES (Continued)**

of market rates resulting in a \$3.3 million unfavorable lease accrual as of the Acquisition date. The unfavorable lease accrual, which is recorded in other long-term liabilities in the Company's consolidated balance sheets, is amortized over the remaining terms of the leases. The annual amortization of the unfavorable lease accrual for each of the years ended December 31, 2012, 2011 and 2010 was \$0.4 million. In December 2012, the Company signed a letter of intent to negotiate an extension of the leases for the Science Center campus through August 31, 2020.

As of December 31, 2012, annual minimum payments due under the Company's lease obligations are as follows (in thousands):

<u>Year</u>	
2013	\$ 5,284
2014	5,463
2015	3,464
2016	405
2017	201
Total	<u>\$ 14,817</u>

Total rent expense, net of unfavorable lease obligation amortization, under all operating leases for years ended December 31, 2012, 2011 and 2010 was \$4.8 million, \$4.7 million and \$4.5 million, respectively. Deferred rent at December 31, 2012 and 2011 was \$1.3 million and \$1.4 million, respectively.

*Litigation*

The Company periodically becomes subject to legal proceedings and claims arising in connection with its business. The ultimate legal and financial liability of the Company in respect to all claims, lawsuits and proceedings cannot be estimated with any certainty. Any outcome, either individually or in the aggregate, is not expected to be material to the Company's consolidated financial position, results of operations, or cash flows.

*Other Contingencies and Commitments*

In July 2012, the Company received an inspection letter from the MHRA noting certain critical and major failures to comply with the Principles and Guidelines of Good Manufacturing Practices in the DepoCyt(e) manufacturing line, which is located in a separate building from the EXPAREL manufacturing site. As a result of the findings, the European Medicines Agency issued an assessment report which recommended that, until corrective actions are taken allowing new supply to enter the market, alternative medicines be used in European Union member countries where there are suitable alternatives. The assessment report also recommended a selective recall of DepoCyt(e) in European Union member countries where DepoCyt(e) is not considered to be an "essential medicinal product." In European Union member countries where the product is classified as an "essential medicinal product," DepoCyt(e) can be used with specific recommendations to monitor patients' safety. No regulatory action has been taken by the FDA in the United States as a result of these inspection findings.

**Pacira Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**NOTE 18—COMMITMENTS AND CONTINGENCIES (Continued)**

During the year ended December 31, 2012, the Company recorded a charge of \$1.3 million, in cost of revenues associated with the implementation of a remediation plan and estimated costs to replace the product once new product is available in Europe, which is expected in mid-2013. While the corrective actions and upgrades to the facilities were taking place, the Company stopped manufacturing DepoCyt(e). In December 2012, the MHRA re-inspected the DepoCyt(e) manufacturing facility to review progress in the implementation of the remediation commitments arising from the July 2012 inspection. The Company received notice in January 2013 from the MHRA that the Company's remediation efforts were successful and it plans to resume production of DepoCyt(e) for the European market in the first quarter of 2013. The temporary cessation of the manufacturing of DepoCyt(e) could result in additional costs or delays in production and sale of DepoCyt(e).

In May 2012, the Company entered into a construction management agreement with DPR Construction, a general partnership, or DPR. Under the terms of the agreement, DPR is responsible for the management of the renovation of the Company's existing manufacturing facility in San Diego, California. The manufacturing facility is being renovated to allow the Company to expand the current manufacturing capacity and meet anticipated future market demand for EXPAREL. Pursuant to the agreement, the contract sum (the cost of the work plus the contractor fee) will not exceed approximately \$7.7 million, provided that such amount is subject to change based on agreed-upon changes to the scope of work.

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

In addition to the initial \$19.6 million purchase price for the Acquisition, the Company entered into an earn-out agreement with SkyePharma which was based on the Company reaching certain revenue milestones following the Acquisition. According to this agreement, the Company would pay SkyePharma percentage payments based on the net revenues of EXPAREL and certain other products from the future yet-to-be-developed biologics product line and milestone payments of up to an aggregate of \$62.0 million upon the occurrence of the following events: (a) first commercial sale in the United States; (b) first commercial sale in a major EU country (UK, France, Germany, Italy, or Spain); (c) annual net sales reaching \$100 million; (d) annual net sales reaching \$250 million and (e) annual net sales reaching \$500 million. Additionally, the Company agreed to pay to SkyePharma a 3% percentage payment on collections of EXPAREL sales in the United States, Japan, the United Kingdom, France, Germany, Italy and Spain. Refer to Note 7, *Goodwill and Intangible Assets*, for further discussion.

**NOTE 19—SUBSEQUENT EVENTS**

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 ("Notes") and entered into an indenture with Wells Fargo Bank, National Association, a national banking association, as trustee, governing the Notes. The net proceeds from the offering are approximately \$115.3 million, after deducting the initial purchasers' discounts and commissions and the estimated offering expenses payable by the Company. The Notes accrue interest at 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.

**Pacira Pharmaceuticals, Inc.**

**Notes to Consolidated Financial Statements (Continued)**

**NOTE 19—SUBSEQUENT EVENTS (Continued)**

The Company used \$30.1 million of the net proceeds from the offering of the Notes to repay in full the \$27.5 million credit facility with Oxford Finance LLC. In connection with such termination, the Company paid the remaining principal amount of \$27.5 million as well as accrued interest, certain prepayment fees and an end of term charge in the aggregate amount of \$2.6 million.

## EXHIBIT INDEX

<u>Exhibit number</u>	<u>Description</u>
3.1	Amended and Restated Certificate of Incorporation of the Registrant.(1)
3.3	Amended and Restated Bylaws of the Registrant.(1)
4.1	Specimen Certificate evidencing shares of common stock.(2)
10.1	Second Amended and Restated 2007 Stock Option/Stock Issuance Plan.(2)
10.2	Form of Stock Option Agreement under the Second Amended and Restated 2007 Stock Option/Stock Issuance Plan.(2)
10.3	Investors' Rights Agreement, dated March 23, 2007, among the Registrant and the parties named therein.(2)
10.4	Assignment Agreement, dated February 9, 1994, amended April 15, 2004, between the Registrant and Research Development Foundation.(2)
10.5	Stock Purchase Agreement, dated January 8, 2007, between SkyePharma, Inc. and the Registrant.(2)
10.6	Amended and Restated Royalty Interests Assignment Agreement, dated March 23, 2007, as amended, between SkyePharma, Inc. and Royalty Securitization Trust I.(2)
10.7	Amended and Restated Security Agreement (SKPI), dated March 23, 2007, between SkyePharma, Inc. and Royalty Securitization Trust I.(2)
10.8	Supply Agreement, dated June 30, 2003, between SkyePharma, Inc. and Mundipharma Medical Company.(2)
10.9	Distribution Agreement, dated June 30, 2003, between SkyePharma, Inc. and Mundipharma International Holdings Limited.(2)
10.10	Distribution Agreement, dated July 27, 2005, between SkyePharma, Inc. and Mundipharma International Holdings Limited.(2)
10.11	Co-development, Collaboration and License Agreement, dated January 2, 2003, among Enzon Pharmaceuticals, Inc., Jagotec, AG, SkyePharma, Inc. and SkyePharma PLC.(2)
10.12	DepoCyt Supply and Distribution Agreement, dated December 31, 2002, between SkyePharma, Inc. and Enzon Pharmaceuticals, Inc.(2)
10.13	Amended and Restated Strategic Licensing, Distribution and Marketing Agreement, dated October 15, 2009, between the Registrant and EKR Therapeutics, Inc.(2)
10.14	Amended and Restated Supply Agreement, dated October 15, 2009, between the Registrant and EKR Therapeutics, Inc.(2)
10.15	Strategic Marketing Agreement, dated September 25, 2007, between the Registrant and Flynn Pharma Limited.(2)

- 10.16 Supply Agreement, dated December 5, 2007, between the Registrant and Flynn Pharma Limited.(2)
- 10.17 Lease Agreement, dated August 17, 1993, amended July 2, 2009, between Pacira Pharmaceuticals, Inc. and HCP TPSP, LLC.(2)
- 10.18 Lease Agreement, dated December 8, 1994, amended July 2, 2009, between Pacira Pharmaceuticals, Inc. and LASDK Limited Partnership.(2)
- 10.19 Services Agreement, dated October 28, 2010, between the Registrant, MPM Asset Management LLC and Gary Patou.(2)
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[Table of Contents](#)

<u>Exhibit number</u>	<u>Description</u>
10.20	Amendment to Services Agreement, dated October 28, 2010, between the Registrant, MPM Asset Management LLC and Gary Patou.(4)
10.21	Services Agreement, dated September 15, 2010, between Pacira Pharmaceuticals, Inc. and Stack Pharmaceuticals, Inc.(2)
10.22	Employment Agreement between the Registrant and David Stack.(2)
10.23	Employment Agreement between the Registrant and James Scibetta.(2)
10.24	Employment Agreement between the Registrant and Mark Walters.(2)
10.25	Employment Agreement between the Registrant and William Lambert.(2)
10.26	Loan and Security Agreement, dated November 24, 2010, among the Registrant, Pacira Pharmaceuticals, Inc. (California), Hercules Technology Growth Capital, Inc. and Hercules Technology II, L.P.(2)
10.27	Guaranty Agreement, dated November 24, 2010, between the Registrant, Hercules Technology Growth Capital, Inc., Hercules Technology II, L.P. and the parties named therein.(2)
10.28	Warrant to purchase preferred stock of the Registrant, dated November 24, 2010.(2)
10.29	Form of Warrant to purchase Series A convertible preferred stock of the Registrant, dated July 2, 2009.(2)
10.30	Form of Warrant to purchase common stock of the Registrant, dated January 22, 2009.(2)
10.31	Form of Warrant to purchase common stock of the Registrant, dated December 29, 2010.(2)
10.32	2011 Stock Incentive Plan.(2)
10.33	Form of Indemnification Agreement between the Registrant and its directors and officers.(2)
10.34	Development and License Agreement, dated January 14, 2011, between the Registrant and Novo Nordisk A/S.(2)
10.35	Commercial Outsourcing Services Agreement entered into as of August 25, 2011 by the Registrant and Integrated Commercialization Solutions, Inc.(3)
10.36	Master Services Agreement effective as of August 30, 2011, between the Registrant and Quintiles Commercial US, Inc.(3)
10.37	Amended and Restated Consulting Agreement, dated April 3, 2012, between the Registrant and Gary Pace(5)
10.38	Executive employment Agreement, dated November 1, 2010, between the Registrant and Tania Markvicka(5)
10.39	Executive employment Agreement, dated November 18, 2011, between the Registrant and John Pratt(5)

10.40 Employment Agreement, dated April 19, 2012, between the Registrant and Lauren Riker(5)

10.41 Amended and Restated 2011 Stock Option Plan(6)

10.42 Construction Managenet Agreement between the Registrant and DPR, dated May 17, 2012(7)

10.43 Loan and Security Agreement between the Registrant and Oxford Finance LLC, dated May 2, 1012(7)

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[Table of Contents](#)

<u>Exhibit number</u>	<u>Description</u>
10.44	Warrant to Purchase Stock No 1, 2, 3 and 4, issued by the Registrant to Oxford Finance LLC, dated May 2, 2012(7)
10.45	Second Amended and Restated Consulting Agreement, dated August 17, 2012, between the Registrant and Gary Pace(8)
10.46	Amendment #2 to Services Agreement, between Registrant and MPM, dated November 29, 2012(9)
10.47†	License, Development and Commercialization Agreement, dated December 5, 2012 between the Registrant and Aratana Therapeutics, Inc.*
10.48†	Supply Agreement, dated December 5, 2012 between the Registrant and Aratana Therapeutics, Inc.*
21.1	Subsidiaries of Registrant.*
23.1	Consent of CohnReznick LLP.*
31.1	Certification of President and Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a)*
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a)*
32.1	Certification of President and Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**
101.INS*	XBRL Instance Document.
101.CAL*	XBRL Taxonomy Calculation Linkbase Document.
101.LAB*	XBRL Taxonomy Label Linkbase Document.
101.PRE*	XBRL Taxonomy Presentation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.

- (1) Incorporated by reference to the registrant's Current Report on Form 8-K, filed on February 11, 2011.
- (2) Incorporated by reference to the exhibits to the registrant's Registration Statement on Form S-1 (SEC File 333-170245).
- (3) Incorporated by reference to the exhibits to the registrant's Quarterly Report on Form 10-Q, filed on October 31, 2011.
- (4) Incorporated by reference to the exhibits to the registrant's Current Report on Form 8-K, filed on December 9, 2011.
- (5) Incorporated by reference to the exhibits to the registrant's Quarterly Report on Form 10-Q, filed on May 9, 2012.
- (6) Incorporated by reference to the exhibits to the registrant's Current Report on Form 8-K, filed on June 7, 2012.

(7) Incorporated by reference to the exhibits to the registrant's Quarterly Report on Form 10-Q, filed on August 9, 2012.

(8) Incorporated by reference to the exhibits to the registrant's Quarterly Report on Form 10-Q, filed on November 1, 2012

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[Table of Contents](#)

- (9) Incorporated by reference to the exhibits to the registrant's Current Report on Form 8-K, filed on December 4, 2012.
- \* Filed herewith.
- \*\* Furnished herewith.
- † Confidential treatment requested as to certain portions, which portions were omitted and filed separately with the Securities and Exchange Commission pursuant to a Confidential Treatment Request.

Attached as Exhibit 101 to this report are the following formatted in XBRL (Extensible Business Reporting Language): (i) Consolidated Balance Sheets at December 31, 2012 and 2011, (ii) Consolidated Statements of Operations for the years ended December 31, 2012, 2011 and 2010, (iii) Consolidated Statements of Comprehensive Loss for the years ended December 31, 2012, 2011 and 2010, (iv) Consolidated Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2012, 2011 and 2010, (v) Consolidated Statements of Cash Flows for the years ended December 31, 2012, 2011 and 2010 and (vi) Notes to Consolidated Financial Statements.

In accordance with Rule 406T of Regulation S-T, the XBRL related information in Exhibit 101 to this Annual Report on Form 10-K is deemed not filed or part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Act, is deemed not filed for purposes of section 18 of the Exchange Act, and otherwise is not subject to liability under these sections.

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

### EXCLUSIVE LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

This Exclusive License, Development and Commercialization Agreement (this “**Agreement**”) is made effective as of December 5, 2012 (the “**Effective Date**”) by and between Pacira Pharmaceuticals, Inc., a California corporation with a principal place of business at 5 Sylvan Way, Parsippany, New Jersey U.S. 07054 (“**Pacira**”) and Aratana Therapeutics, Inc., a Delaware corporation with a place of business at 1901 Olathe Blvd, Kansas City, Kansas 66103 (“**Aratana**”). Pacira and Aratana are each hereafter referred to individually as a “**Party**” and together as the “**Parties**.”

WHEREAS, Pacira owns the global rights to develop and commercialize the Licensed Product (as hereinafter defined);

WHEREAS, Aratana has significant expertise in developing and commercializing pharmaceutical products in the Field (as hereinafter defined); and

WHEREAS, Aratana wishes to acquire and Pacira wishes to grant to Aratana an exclusive license to Develop (as herein after defined), market, sell and distribute the Licensed Product in the Field subject to the terms and conditions of this Agreement.

NOW THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties hereby agree as follows.

#### 1. DEFINITIONS

1.1 “**Affiliate**” shall mean with respect to any entity, any other entity that, directly or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, such entity. For purposes of this Section 1.1, “**control**” means ownership, directly or indirectly through one or more Affiliates, of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or fifty percent (50%) or more of the equity interests in the case of any other type of legal entity, status as a general partner in any partnership, or any other arrangement whereby a Party controls or has the right to control the Board of Directors or equivalent governing body of a corporation or other entity.

1.2 “**Additional Supply Agreement**” shall have the meaning set forth in Section 2.3.2.

1.3 “**Administrative NADA**” is a new animal drug application that is submitted after all of the technical sections that fulfill the requirements for the approval of the new animal drug application under 21 CFR 514.1 have been reviewed by CVM and CVM has issued a technical section complete letter for each of those technical sections.

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1.4 “**Adverse Event**” shall mean any unexpected, unusual, or untoward medical occurrence during the Development or Commercialization of the Licensed Product whether or not considered related to the Licensed Product, including, without limitation, any undesirable sign (including abnormal laboratory findings of clinical concern), symptom or disease temporally associated with the use of such Licensed Product.

1.5 “**Alternative Vial Size**” shall have the meaning set forth in Section 2.3.2.

1.6 “**Aratana Indemnitees**” shall have the meaning set forth in Section 9.1.2.

1.7 “**Chairperson**” shall have the meaning set forth in Section 3.1.1.

1.8 “**Client-owned Animal Subject**” shall mean any animal (pet) owned by a Third Party (and not a laboratory or test animal purchased by or on behalf of Aratana for experimental purposes).

1.9 “**Clinical Data**” shall have the meaning set forth in Section 3.2(a).

1.10 “**Commercialize**” or “**Commercialization**” shall mean any and all activities, excluding Development or manufacturing, necessary or desirable to realize and maximize commercial sales of the Licensed Product in accordance with applicable law, including distributing, importing, transporting, customs clearance, export, warehousing, packing, handling and delivering to customers, as well as offering for sale and sales, marketing, promoting and reimbursement related activities, including booking sales. When used as a verb “**Commercialize**” means to engage in Commercialization.

1.11 “**Commercially Reasonable Efforts**” shall mean the use of commercially reasonable efforts and the dedication of commercially reasonable resources. With respect to the Licensed Product, Commercially Reasonable Efforts means efforts and diligence in, as applicable, Development or Commercialization of Licensed Product that is in accordance with the efforts and resources a reasonably comparable animal health company (in the case of Aratana) or specialty pharmaceutical company (in the case of Pacira) would use for a product owned by it and to which it has exclusive rights which is of similar market potential and at a similar stage of its product life as the Licensed Product, taking into account the establishment of the Licensed Product in the marketplace, the proprietary position of the Licensed Product, the regulatory and reimbursement structure involved and the profitability of the Licensed Product. Commercially Reasonable Efforts shall be determined on a jurisdiction by jurisdiction basis within the Territory for the Licensed Product.

1.12 “**Confidential Information**” shall mean with respect to a Party (the “**Receiving Party**”), all information which is disclosed by the other Party (the “**Disclosing Party**”) to the Receiving Party hereunder or to any of its employees, consultants, Affiliates, licensee or Sublicensees, except to the extent that the Receiving Party can demonstrate by written record or other suitable physical evidence that such information, (a) as of the date of disclosure is demonstrably known to the Receiving Party or its Affiliates other than by virtue of a prior confidential disclosure to such Party or its Affiliates; (b) as of the date of disclosure is in, or subsequently enters, the public domain, through no fault or omission of the Receiving Party; (c) is obtained from a Third Party having a lawful right to make such disclosure free from any

obligation of confidentiality to the Disclosing Party; or (d) is independently developed by or for the Receiving Party without reference to or reliance upon any Confidential Information of the Disclosing Party. Confidential Information shall include all information disclosed to or accessible by Aratana or Pacira, as the case may be, relating to the subject matter of this Agreement prior to the Effective Date.

1.13 “**Control**” or “**Controlled**” shall mean with respect to Pacira the possession by ownership or contract by Pacira, as the result of its pending or issued intellectual property rights, of the right to exclude Third Parties from Developing and commercializing a given compound, product, or process.

1.14 “**CVM**” shall mean the Center for Veterinary Medicine (and any successor authority) of the FDA.

1.15 “**Delivery**” means Pacira making available at the loading docks of the manufacturing facilities the bulk vials of the Licensed Product for collection by Aratana or its nominated carrier.

1.16 “**Development**” and “**Develop**” shall mean all activities relating to research and development in connection with seeking, obtaining and/or maintaining any Regulatory Approval of the Licensed Product throughout the Territory in the Field, including all development activities, all animal clinical studies and all other activities relating to seeking, obtaining and/or maintaining any Regulatory Approvals from any Regulatory Authority, but excluding any manufacturing activities.

1.17 “**Development Plan**” shall have the meaning set forth in [Section 3.1](#).

1.18 “**Drug Approval Application**” shall mean any application for Regulatory Approval including, without limitation, (a) any application filed with the FDA and (b) any equivalent application filed with any Foreign Regulatory Authority for Regulatory Approval required prior to any sale or use or any Commercialization of a Licensed Product in any country or jurisdiction in the Territory.

1.19 “**European Union**” shall mean the member states of the European Union, as may exist from time to time, which as of the date hereof include Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and United Kingdom, and all other countries which accede to the European Union during the Term.

1.20 “**EXPAREL®**” shall mean Bupivacaine Liposome Injectable Suspension — NDA #022496.

1.21 “**Ex-U.S.**” shall mean any jurisdiction in the Territory residing outside the United States of America.

1.22 “**Ex-U.S. Development Costs**” shall have the meaning set forth in [Section 5.4.1](#).

1.23 “**Ex-U.S. Sublicense**” shall have the meaning set forth in Section 2.2.1.

1.24 “**Ex-U.S. Sublicensee**” shall have the meaning set forth in Section 2.2.1.

1.25 “**FDA**” shall mean the U.S. Food and Drug Administration and any successor agency or authority thereto.

1.26 “**First Commercial Sale**” shall mean with respect to the Licensed Product, on a jurisdiction-by-jurisdiction basis in the Territory, the date when Aratana or any Affiliate or any Sublicensee first sells or otherwise commercially disposes of such Licensed Product for use or consumption in the Field after receipt of the relevant Regulatory Approval in such jurisdiction.

1.27 “**Field**” shall mean all prophylactic or therapeutic uses of the Licensed Product for veterinary use. For the avoidance of doubt, the Field shall not include use of the Licensed Product in humans.

1.28 “**Foreign Regulatory Authorities**” shall mean any applicable supranational, national, federal, provincial, state or local regulatory agency, department, bureau or other Governmental Authority of any country or jurisdiction in the Territory (other than the United States of America), having responsibility in such country or jurisdiction for any Regulatory Approvals of any kind in such country or jurisdiction, and any successor agency or authority thereto.

1.29 “**Generic Intrusion**” shall mean, on a jurisdiction-by-jurisdiction basis, the launch in such jurisdiction in the Territory in the Field of an extended release injectible bupivacaine referencing any Drug Approval Application which is deemed bioequivalent or directly substitutable to the Licensed Product by a Regulatory Authority in the respective jurisdiction of the Territory.

1.30 “**Governmental Authority**” shall mean any governmental or quasi-governmental department, commission, board, bureau, agency, court or other instrumentality of any country or jurisdiction in the Territory or any political subdivision thereof.

1.31 “**Initial Supply Agreement**” shall have the meaning set forth in Section 2.3.2.

1.32 “**JCCC**” shall have the meaning set forth in Section 3.1.

1.33 “**Know-How**” shall mean all information, data, knowledge, discoveries and trade secrets whether or not reduced to writing pertinent to the Licensed Product or to the manufacture, use or sale of the Licensed Product now or hereafter Controlled by Pacira.

1.34 “**Law**” shall mean all laws, treaties, statutes, ordinances, judgments, decrees, rules, codes, injunctions, writs, regulations, binding arbitration rulings, orders, and judicial or administrative interpretations or promulgations of any Governmental Authority having jurisdiction over the transactions contemplated hereunder.



1.35 **“Licensed Patent Rights”** shall mean any patents and patent applications, having claims directed to or providing exclusivity to the Licensed Product, or to the acquisition, manufacture, use, method of use, performance, sale, offer for sale, importation or other disposition of the Licensed Product that is owned or Controlled by Pacira, including but not limited to those patents and patent applications described in Schedule 1.35 attached hereto, and any divisional, continuation, continuation-in-part, reissue, reexamination, confirmation, revalidation, registration, patent of addition, renewal, extension, substitute or foreign counterparts thereof, or any patent issuing therefrom or any supplementary protection certificates related thereto.

1.36 **“Licensed Product”** shall mean DepoBupivacaine™ Extended Release Liposome Injection for use in the Field.

1.37 **“Licensed Product Infringement Claim”** shall mean a claim or action alleging infringement of any claim of any patent or other proprietary right of a Third Party in the Territory by the manufacture, use or sale of the Licensed Product by Aratana, its Affiliates, or Sublicensees but which claim or action does not also allege any infringement of such claim of any patent or other proprietary right of a Third Party by the manufacture, use or sale of EXPAREL® in the human field.

1.38 **“Minimum Annual Revenue”** shall have the meaning set forth in Section 10.2.5.

1.39 **“Net Sales”** shall mean the total gross sales of all Licensed Product invoiced and actually collected by Aratana, its Affiliates or any Sublicensees (or a further sublicensee of a Sublicensee) to Third Parties throughout the Territory, less the following amounts actually deducted or allowed during the applicable reference period (regardless of the period in which such related sales were made):

- (a) transport, freight and insurance costs;
- (b) sales and excise taxes and duties;
- (c) normal and customary trade, quantity and cash discounts and rebates;
- (d) refunds and chargebacks;
- (e) actual rebates and credits or allowances allowed to customers in respect thereof; and
- (f) amounts repaid or credited for actually returned or recalled Licensed Product.

Notwithstanding anything else contained in this Section 1.39, the supply or other disposition of Licensed Product at no cost or charge to the recipient (x) as reasonable quantities of samples consistent with industry practice (y) for use in non-clinical or clinical studies or (z) for use in any tests or studies reasonably necessary to comply with any law, regulation or request by any Regulatory Authority shall not be included in the calculation of Net Sales.

- 1.40 “**OctoPlus**” means OctoPlus Sciences B.V.
- 1.41 “**OctoPlus Agreement**” means that certain Non-Exclusive License Agreement, dated September 9, 2010, between Pacira and OctoPlus, as amended, supplemented or modified from time to time.
- 1.42 “**Other Jurisdictions**” shall have the meaning set forth in [Section 10.2.3](#).
- 1.43 “**Pacira Indemnitees**” shall have the meaning set forth in [Section 9.1.1](#).
- 1.44 “**Pacira Intellectual Property**” shall have the meaning set forth in [Section 2.4](#).
- 1.45 “**Primary Territory**” shall mean the United States, its territories and possessions, the SP Royalty Territory and the other countries of the European Union.
- 1.46 “**RDF**” shall mean Research Development Foundation.
- 1.47 “**RDF Agreement**” shall mean that certain Assignment Agreement between Pacira (as successor to SkyePharma, Inc.) and RDF dated February 9, 1994, as amended, supplemented or modified from time to time.
- 1.48 “**Regulatory Approval**” shall mean any and all approvals or authorizations of any kind of any Regulatory Authority necessary required prior to any commercial marketing, sale or use of the Licensed Product (or any component thereof) for use in the Field in any country or jurisdiction in the Territory for a particular indication in the Field. For clarity, Regulatory Approval: (i) in the United States shall consist of approval by the FDA of the Administrative NADA; and (ii) shall not include any approvals, licenses, registrations or authorizations necessary for the manufacture or supply of the Licensed Product, or any component thereof, by Pacira to Aratana or its Affiliates or Sublicensees.
- 1.49 “**Regulatory Authority**” shall mean the FDA or any Foreign Regulatory.
- 1.50 “**Renewal Term**” shall have the meaning set forth in [Section 10.1](#).
- 1.51 “**Royalty Rate**” shall have the meaning set forth in [Section 5.3.1](#).
- 1.52 “**Shared Infringement Claim**” shall mean a claim or action alleging infringement of any claim of any patent or other proprietary right of a Third Party in the Territory by the manufacture, use or sale of the Licensed Product by Aratana, its Affiliates, or Sublicensees and which claim or action also alleges infringement of such claim of any patent or other proprietary right of a Third Party by the manufacture, use or sale of EXPAREL® in the human field.
- 1.53 “**SkyePharma**” shall mean SkyePharma Holding, Inc.

1.54 “**SkyePharma Agreement**” shall mean that certain Stock Purchase Agreement among Pacira (as successor to Blue Acquisition Corp.), SkyePharma and SkyePharma, Inc. dated January 8, 2007.

1.55 “**Sublicensee**” shall mean any Affiliate or Third Party to whom Aratana grants, in accordance with the terms of this Agreement, a sublicense of some or all of the rights granted to Aratana under this Agreement.

1.56 “**Supply Agreement**” shall have the meaning set forth in Section 2.3.

1.57 “**SP Royalty**” shall mean [\*\*]% of Net Sales payable to SkyePharma per the SkyePharma Agreement.

1.58 “**SP Royalty Territory**” shall mean the United Kingdom, Italy, France, Germany, Spain and Japan.

1.59 “**Term**” shall have the meaning set forth in Section 10.1.

1.60 “**Territory**” shall mean worldwide.

1.61 “**Third Party**” shall mean any person or entity other than Aratana, Pacira and their respective Affiliates or Sublicensees.

1.62 “**Trademark(s)**” shall mean (i) EXPAREL® and (ii) any other trademark or trademarks including logo mark and/or trade dress selected by, registered or owned by Pacira, its Affiliates or sublicensees in connection with the promotion and marketing of EXPAREL in the Territory.

1.63 “**Upfront Payment Amount**” shall have the meaning set forth in Section 5.1.

1.64 “**U.S. Development Costs**” shall have the meaning set forth in Section 5.4.3.

1.65 “**U.S. Sublicense**” shall have the meaning set forth in Section 2.2.2.

1.66 “**U.S. Sublicensee**” shall have the meaning set forth in Section 2.2.2.

In this Agreement, unless the context requires otherwise:

- (a) the headings are included for convenience only and shall not affect the construction of this Agreement;
- (b) words denoting the singular shall include the plural and vice versa;
- (c) words denoting one gender shall include each gender and all genders;
- (d) the words “include” or “including” shall mean “include, without limitation” or “including, without limitation,” as the case may be, and the language following “include” or “including” shall not be deemed to set forth an exhaustive list; and

(e) any reference to an enactment or statutory provision is a reference to it as it may have been, or may from time to time be amended, modified, consolidated or reenacted.

The Schedules to this Agreement comprise part of and shall be construed in accordance with the terms of this Agreement.

## 2. GRANT OF RIGHTS

2.1 Grant of License. Pacira hereby grants to Aratana an exclusive (even as to Pacira) royalty-bearing license, including the limited right to grant sublicenses (as provided herein), to the Licensed Patent Rights and Pacira's Know-How to Develop, register, use, have used, distribute, have distributed, sell, offer for sale, have sold, import, have imported and Commercialize, the Licensed Product in the Territory, solely for any and all uses within the Field. The license granted hereunder shall specifically not include the right of Aratana or any Affiliate or Sublicensee of Aratana to manufacture the Licensed Product or to utilize the Trademarks in connection with the Development or Commercialization of the Licensed Product.

### 2.2 Right to Sublicense.

2.2.1 Sublicenses Outside the United States. Aratana shall have the limited right to grant sublicenses under the license set forth in Section 2.1 to Develop and Commercialize the Licensed Product outside the United States (an "**Ex-U.S. Sublicense**"), solely for any and all uses within the Field; provided, however, that (i) Aratana shall provide Pacira periodic updates of its ex-US sublicensing activities at each meeting of the JCCC (as hereinafter defined); (ii) Pacira shall be notified of the proposed grant of an Ex-U.S. Sublicense to any and all potential Sublicensees outside the United States (an "**Ex-U.S. Sublicensee**"), for approval by Pacira which approval shall not be unreasonably withheld together with a copy of the proposed Ex-U.S. Sublicense, such approval to be determined within [\*\*] calendar days of receipt of the notice and copy of the proposed sublicense; (iii) any and all Ex-U.S. Sublicenses shall be consistent with all the terms and conditions of this Agreement and shall require the Ex-U.S. Sublicensee to comply fully with the obligations imposed by this Agreement; and (iv) following execution of such Ex-U.S. Sublicense, Aratana shall provide Pacira with a copy of each such Ex-U.S. Sublicense and any supplements, amendments or modifications within [\*\*] calendar days of execution. Aratana will be fully responsible under this Agreement for the actions and omissions of such Ex-U.S. Sublicensees as if such actions or omissions were its own. Aratana will not grant an Ex-U.S. Sublicense other than as permitted in this Section 2.2.1. Notwithstanding the foregoing, any Ex-U.S. Sublicense shall not provide the Ex-U.S. Sublicensee with the right to grant further sublicenses under such Ex-U.S. Sublicense unless such further sublicense is expressly conditioned upon the prior written consent of Pacira, which consent may be withheld by Pacira in its absolute discretion.

2.2.2 Sublicenses Within United States. In the event Aratana determines to sublicense all or any portion of the rights granted in the United States in the Field hereunder to an Affiliate or Third Party (a "**U.S. Sublicense**"), the Parties will work together to find the appropriate partner. Any such U.S. Sublicense, including any supplement, amendment or modification thereto, will require the written consent of Pacira, which consent will be considered in the good-faith business judgment of Pacira but may be withheld by Pacira in its sole discretion. Any and all U.S. Sublicenses shall be consistent with all the terms and conditions of

this Agreement and shall require each Sublicensee under a U.S. Sublicense (a “ **U.S. Sublicensee**”) to comply fully with the obligations imposed by this Agreement and, following execution of such U.S. Sublicense, Aratana shall provide Pacira with a copy of each such U.S. Sublicense within [\*\*] calendar days of execution. Aratana will be fully responsible under this Agreement for the actions and omissions of each U.S. Sublicensee as if such actions or omissions were its own. Aratana will not grant a U.S. Sublicense other than as permitted in this Section 2.2.2. Notwithstanding the foregoing, any U.S. Sublicense shall not provide the U.S. Sublicensee with the right to grant further sublicenses under such U.S. Sublicense unless such further sublicense is expressly conditioned upon the prior written consent of Pacira, which consent may be withheld by Pacira in its absolute discretion.

2.3 Manufacturing.

2.3.1 Exclusive Supplier. During the Term, Pacira shall be the exclusive supplier of the Licensed Product to Aratana. Neither Aratana nor any Affiliate or Sublicensee shall have the right to make or have made the Licensed Product in the Territory.

2.3.2 Supply Agreements. Concurrently herewith, the Parties are entering into a supply agreement in substantially the form attached hereto as Exhibit A (the “**Initial Supply Agreement**”), pursuant to which Pacira is agreeing to supply unlabeled vials of the Licensed Product to Aratana in the sizes and at the prices contemplated thereby. Thereafter, during the Term, in the event that Pacira manufactures the Licensed Product for its human health program in any vial size not contemplated by the Initial Supply Agreement (an “ **Alternative Vial Size**”), or in the event that Aratana requires the Licensed Product in any Alternative Vial Size and agrees to pay for all reasonable costs incurred by Pacira in connection with developing the process to manufacture the Licensed Product in such Alternative Vial Size, the Parties agree that they will negotiate in good faith to enter into an additional supply agreement (the “**Additional Supply Agreement**” and, together with the Initial Supply Agreement, the “**Supply Agreements**”) on substantially similar terms as the Initial Supply Agreement with appropriate, negotiated economic adjustments based on the differences between the Alternative Vial Size and the vial sizes contemplated by the Initial Supply Agreement.

2.4 Ownership. Aratana shall own all right, title and interest in any Drug Approval Application during the Term and all trade names, trademarks and trade dress utilized in the Commercialization of the Licensed Product. Pacira shall own all right, title and interest in and to the Licensed Patent Rights, Know How and Trademarks (collectively “**Pacira Intellectual Property**”). To the extent any rights, title or interest in or to any Pacira Intellectual Property would otherwise vest in Aratana, any of its Affiliates or any of their respective personnel or contractors, Aratana hereby assigns (and shall cause Aratana’s Affiliates and the respective personnel and contractors of Aratana or Aratana’s Affiliates to assign) all such rights, title and interest to Pacira.

**3. DEVELOPMENT/COMMERCIALIZATION OF LICENSED PRODUCTS**

3.1 Joint Clinical and Commercial Committee. Within [\*\*] calendar days after the Effective Date, the Parties shall establish a Joint Clinical and Commercial Committee (“**JCCC**”) to direct Development and Commercialization of the Licensed Product, including but

not limited to the sharing by both parties of information on Development of the Licensed Product, sublicensing and other business development activities of Aratana related to the Licensed Product, intellectual property management and Commercialization, and ensuring any plans for Development or Commercialization of the Licensed Product will not be adverse to, materially conflict with, or interfere with any regulatory approval, manufacture, marketing authorization or marketing efforts for EXPAREL® outside of the Field. The JCCC will consist of an equal number of, and not less than [\*\*], representatives of each Party, as determined by the CEO of each Party. Any decisions made by the JCCC shall be unanimous with each Party's representatives collectively having one vote. The JCCC shall have the following powers and duties:

- Oversee the Development of the Licensed Product in the Field, including but not limited to the clinical development program, which shall be reviewed and subject to the approval of the JCCC (the “**Development Plan**”);
- Review, coordination and approval of any scientific publications relating to the Licensed Product;
- Review and approval of any Commercialization plans for the Licensed Product in the Territory;
- Review of any sublicensing or business development activities related to the Licensed Product in the Field; and
- Such other powers and duties as agreed to by the Parties.

3.1.1 Chairmanship. One JCCC representative from a Party shall chair the JCCC (the “**Chairperson**”) on a rotating annual calendar year basis, alternating between a representative from Aratana and a representative from Pacira, with the initial Chairperson to be from [\*\*]. The Chairperson shall send notices and agendas for all JCCC meetings to all JCCC members and ensure review and approval of the minutes of each JCCC meeting within [\*\*] calendar days of adjournment of a JCCC meeting.

3.1.2 Meetings. The JCCC will meet as needed upon request from at least one of the Parties to the then-current Chairperson, but not less than [\*\*]. At each meeting, the Parties shall provide updates on the status of their respective responsibilities. Meetings may be held by teleconference, videoconference or in person, as mutually agreed upon by the Parties. At each meeting, a secretary shall be appointed by the Chairperson to record meeting minutes. Within [\*\*] calendar days after a meeting, the Chairperson shall circulate draft minutes to the Parties for review, comment and distribution, in order to finalize the minutes within [\*\*] calendar days of such meeting.

3.1.3 Dispute Resolution. If a dispute arises in connection with the Development Plan, Commercialization of the Licensed Product or any other issue addressed by the JCCC, the JCCC shall confer immediately and use commercially reasonable efforts to resolve the dispute or issue within [\*\*] calendar days of their initial conference. No such dispute or

issue shall be considered resolved until the JCCC has unanimously agreed to the resolution; provided, however, that if the JCCC does not reach consensus, within a [\*\*] calendar day period, the resolution of the dispute or issue shall be made by the JCCC representatives of Aratana unless such resolution in the opinion of any member of the JCCC would be reasonably expected to be adverse to, materially conflict with, or interfere with the regulatory approval, manufacture, marketing authorization or marketing efforts for EXPAREL® outside of the Field, in which case such dispute will be handled in accordance with Section 11 of this Agreement.

3.2 Responsibilities of Pacira. Under the supervision of the JCCC, Pacira shall:

- (a) make available to Aratana copies of any and all documentation in possession of Pacira related to the Licensed Product including but not limited to research data and reports, regulatory materials and correspondence (including INDs and NDAs in U.S.), clinical and preclinical data (including all raw data), chemistry, manufacturing and controls (CMC) data, relevant to conducting animal clinical studies and obtaining Regulatory Approval in the Field in the Territory (collectively, the “**Clinical Data**”) and Aratana shall have the right to use the Clinical Data solely in connection with, and as necessary for, the Development and Commercialization of the Licensed Product;
- (b) provide to Aratana without charge (EXW Incoterms 2010 Pacira's or its designee's manufacturing facility) such reasonable quantities of Licensed Product in unlabeled [\*\*] vials (or [\*\*] vials at all such times when such vials are otherwise being manufactured for commercial sale in Pacira's human health program for EXPAREL®) necessary for Aratana to conduct such studies in the Field in the Territory as necessary to seek Regulatory Approvals in accordance with the Development Plan;
- (c) supply unlabeled vials (without commercial packaging) of bulk Licensed Product to Aratana (EXW Incoterms 2010 Pacira's manufacturing facility), at the transfer prices and otherwise pursuant to the terms and conditions set forth in the Supply Agreements; and
- (d) keep the JCCC reasonably informed of any activities concerning the manufacture of the Licensed Product, including those related to a Change in Process (as defined in the Supply Agreement).

3.3 Responsibilities of Aratana. Under the supervision of the JCCC, Aratana shall:

- (a) at its sole cost and expense and using Commercially Reasonable Efforts, be responsible for Development of

Licensed Product in the Territory in accordance with the Development Plan approved by the JCCC;

(b) use Commercially Reasonable Efforts to conduct or cause to be conducted such clinical studies necessary to achieve Regulatory Milestone C described in Section 5.2.1 below;

(c) be responsible for the preparation and filing at its sole cost and expense of any Drug Approval Applications in the Territory, including an Administrative NADA, which Drug Approval Applications shall be filed no later than [\*\*] days following receipt of the requisite technical section complete letters for each of the technical sections that fulfill the requirements for the approval of the Administrative NADA;

(d) be responsible for the performance of all activities and undertakings as may be required by any Regulatory Authorities to obtain approval of the Drug Approval Applications;

(e) at its sole cost and expense, be responsible for the Commercialization of the Licensed Product, including all sales and marketing activities, in the Field in the Territory;

(f) following Delivery by Pacira be responsible for the labeling, packaging and shipping of bulk vials of the Licensed Product for commercial sale, utilizing such branding, trade names and trade dress selected by Aratana and approved by the JCCC;

(g) following receipt of Regulatory Approval, be responsible at its sole cost and expense for (i) the maintenance and updating of all Regulatory Approvals as may be required by any Regulatory Authorities, including any post approval studies required by any Regulatory Authorities and pharmacovigilance and (ii) any user fees relating to the manufacturing of the Licensed Product for Aratana that are required by the FDA; and

(h) such other activities requested by the JCCC.

3.4 Adverse Events. The Parties agree to provide each other with Adverse Event information and product complaint information relating to Licensed Product as compiled and prepared by the Parties in the normal course of business in connection with the Development, Commercialization or sale of the Licensed Product, within time frames consistent with reporting obligations under applicable Law. All reports, updates, Adverse Events, product complaint and other information provided by one Party to the other Party under this Agreement (including under this Section 3.4), shall be considered Confidential Information of the disclosing Party, subject to the terms of Section 6 hereof it being understood that the FDA may publish information relating to Adverse Events on its website.

3.5 Commercialization in the U.S. In the event that Aratana proposes to exercise its rights pursuant to Section 2.2.2 to pursue a U.S. Sublicense or a co-promotion partner for the Commercialization of the Licensed Product in the U.S., Aratana shall, prior to entering into negotiations with any Third Party relating to such U.S. Sublicense, co-promotion agreement or similar arrangement, negotiate in good faith with Pacira for a period of [\*\*] days regarding shared Commercialization rights between Aratana and Pacira in the Field in the U.S.; provided, however, that each Party's decision to accept or reject such shared Commercialization rights on the terms offered by the other Party shall be made in its absolute discretion.



#### 4. ADDITIONAL OBLIGATIONS OF ARATANA

4.1 Compliance. Aratana shall be solely responsible for compliance with all applicable Law in the Territory relating to the storage (following the delivery of the Licensed Product by Pacira), Development, Commercialization, and all other activities concerning the Licensed Product.

4.2 Permits and Licenses. Aratana shall throughout the Term, at its expense, obtain and maintain any and all licenses, permits, orders, authorizations and consents required by any Regulatory Authorities in the Territory to perform its obligations under this Agreement.

4.3 Sale of Licensed Product. Aratana shall use its Commercially Reasonable Efforts to market and sell the Licensed Product, either directly or through a Sublicensee, in the Territory in compliance with all applicable laws using techniques and methods which are customary in the pharmaceutical industry for veterinary products.

4.4 Exclusive Supplier. During the Term, Aratana agrees to purchase all of its requirements for Licensed Product exclusively from Pacira, and Pacira agrees to supply the Licensed Product on the terms and conditions to be set forth in the Supply Agreements.

4.5 No Competing Products. During the Term, neither Aratana nor any of its Affiliates shall Develop or Commercialize either directly or indirectly (including, but not limited to, by providing any assistance or license to any Third Party to do any of the foregoing), any injectible long-acting analgesic product for veterinary use other than the Licensed Product. Aratana shall not grant any Third Party (other than Pacira) a right of reference to any Drug Approval Application.

4.6 Use of Confidential Information. Aratana shall only use Confidential Information for the purposes of this Agreement and shall not modify, copy or reverse engineer any aspect or component of the Licensed Product or Know-How nor shall Aratana authorize or permit any Third Party to modify, copy or reverse engineer any aspect or component of the Licensed Product or Know How.

#### 5. PAYMENTS AND ROYALTIES

5.1 Upfront Payment. In consideration of the grant of the licenses and rights hereunder, Aratana shall pay to Pacira the non-refundable sum of U.S. \$1,000,000 (the “**Upfront Payment Amount**”) upon execution of this Agreement.

##### 5.2 Milestone Payments

5.2.1 Milestone Payments: In further consideration of the grant of the license and rights by Pacira hereunder, and subject to the other terms of this Agreement (including the remainder of this Section 5), Aratana shall pay to Pacira the following milestone payments within [\*\*] calendar days of achievement of the designated milestones:

Regulatory Milestone	Milestone Amount
A. [**]	U.S. \$ [**]
B. [**]	U.S. \$ [**]
C. [**]	U.S. \$ [**]
D. [**]	U.S. \$ [**]
E. [**]	U.S. \$ [**]
Total Potential Regulatory Milestones	U.S. \$ [**]
Commercial Milestones	
A. Upon achievement of annual Net Sales of Licensed Product of U.S. \$[**] in the Territory:	U.S. \$ [**]
B. Upon achievement of annual Net Sales of Licensed Product of U.S. \$[**] in the Territory:	U.S. \$ [**]
C. Upon achievement of annual Net Sales of Licensed Product of U.S. \$[**] in the Territory:	U.S. \$ [**]
Total Potential Commercial Milestones	U.S. \$ [**]

5.2.2 Milestones Achieved Only Once: Each Regulatory and Commercial Milestone can only be achieved once. After the Licensed Product achieves a regulatory or commercial milestone, payment shall not come due upon the achievement of the same milestone.

5.2.3 Notice of Achievement of Milestones. Aratana shall provide Pacira with notice of achievement of any Regulatory or Commercial Milestones within [\*\*] calendar days of achievement of such Milestone.

5.3 Payment of Royalties; Royalty Rates

5.3.1 Royalty Payments. Commencing on the Effective Date and continuing for the Term in the Territory, Aratana shall pay to Pacira royalty payments based on annual Net Sales by Aratana or its Affiliates as follows:

<u>Territory</u>	<u>Annual Net Sales</u>	<u>Royalty Rate</u>
U.S.	\$ [**]	[**]%
	>\$ [**]	[**]%
Ex-U.S.	\$ [**]	[**]%
	>\$ [**]	[**]%

(collectively, the “**Royalty Rate**”). All calculations for this Section 5.3.1 shall be done in U.S. dollars. Royalties on sales by any Ex-U.S. Sublicensees and U.S. Sublicensees shall be paid in accordance with Sections 5.4.1 and 5.4.2 below.

5.3.2 Third-Party Royalty Payments. Should Aratana be required to pay royalties to a Third Party (excluding any SP Royalty (which, except as provided in Section 5.4.3, shall be the responsibility of Pacira) and any royalties due RDF under the RDF Agreement and not including any royalties that may be due Sublicensees for the sale of Licensed Product) in order to settle or avoid any Licensed Product Infringement Claim or Shared Product Infringement Claim in the Territory, the royalty paid to Pacira shall be reduced by [\*\*] percent ([\*\*]%) of the royalty paid to such Third Party, but in no event shall the royalty paid to Pacira for Net Sales in the Territory be reduced by more than [\*\*] percent ([\*\*]%).

5.3.3 Reduction of Royalty Rate. In the event of Generic Intrusion in any jurisdiction of the Territory, the Royalty Rate shall be reduced by [\*\*]% in such jurisdiction.

5.3.4 Royalty Floor. Notwithstanding any reduction in Royalty Rate payable to Pacira as contemplated in Sections 5.3.2 and 5.3.3 above, at no time shall the Royalty Rate paid to Pacira on Net Sales by Aratana in any jurisdiction in the Territory be reduced below [\*\*] percent ([\*\*]%).

5.3.5 Payment of Royalties. Aratana shall make royalty payments owed to Pacira pursuant to Section 5.3 hereunder quarterly in arrears, within [\*\*] calendar days from the end of each calendar quarter. For purposes of determining when a sale of any Licensed Product occurs under this Agreement, the sale shall be deemed to occur on the earlier of (a) the date the Licensed Product (in final form) is shipped by Aratana or its Affiliates or Sublicensees for sale to a Third Party or (b) on the date of payment on the invoice to the purchaser of the Licensed Product. Each royalty payment shall be accompanied by a report for each jurisdiction in the Territory in which sales of Licensed Products occurred in the calendar quarter covered by such statement, specifying: (i) the total gross sales and Net Sales (including an itemization of the deductions applied to gross sales to derive such Net Sales) in each jurisdiction’s currency; (ii) the number of units of Licensed Product sold (less damaged, rejected, returned or recalled Licensed Product) during the relevant Calendar Quarter; (iii) the applicable royalty rate under this Agreement; (iv) the royalties payable in each jurisdiction’s currency; (v) the applicable exchange rate to convert from each jurisdiction’s currency to U.S. dollars under Section 5.5 and (vi) the royalties payable in U.S. dollars.

5.4 Sublicense Payments.

5.4.1 Payments for Ex-U.S. Sublicenses. Subject to any adjustments to royalty payments set forth in Section 5.4.2, Aratana shall pay to Pacira fifty percent (50%) of all (a) sublicense fees, milestones and royalty payments received by Aratana pursuant to any Ex-U.S. Sublicenses and (b) any profits, including any amounts by which resale/transfer price exceeds Product Price, derived by Aratana in connection with any transfer or resale of Bulk Product (as defined in the Supply Agreement) or Licensed Product to any Ex-U.S. Sublicensees as contemplated by the Supply Agreement; provided, however, that prior to making any such payments to Pacira, Aratana shall first be entitled to recoup from any upfront fees or milestone payments (but not from any royalty payments or supply revenue) received by Aratana from any Ex-U.S. Sublicensee its out-of-pocket Third Party direct, documented fees and expenses associated with any Drug Approval Applications for the Licensed Product in jurisdictions in the Territory outside the United States, including any fees and expenses associated with any Ex-U.S. clinical program used for submission with any such Drug Approval Application (“**Ex-U.S. Development Costs**”). For the avoidance of doubt, Aratana may not recoup identified and specified Ex-U.S. Development Costs against payments received pursuant to any Ex-U.S. Sublicense more than once. Ex-U.S. Development Costs shall not include the Upfront Payment Amount or any milestone or royalty payments due or payable to Pacira hereunder and Aratana may not recoup any Ex-U.S. Development Costs against any payments due or payable to Pacira hereunder. Aratana’s right to recoup expenses pursuant to this Section 5.4.1 shall also not supersede its payment obligations pursuant to Section 5.4.2 below.

5.4.2 SP Royalty Payments on Sales by Sublicensees in SP Royalty Territory. In addition to Aratana’s obligation to pay to Pacira 50% of any sublicense fees, milestones and royalty payments received pursuant to Section 5.4.1 above, for as long as Pacira has an obligation to pay the SP Royalty, the Parties shall share in the responsibility for the SP Royalty in the SP Royalty Territory as follows:

(a) If the royalty received from a Sublicensee is less than [\*\*]% of Net Sales in the Third Party Royalty Territory, Pacira shall be responsible for [\*\*]% and Aratana shall be responsible for [\*\*]% of the SP Royalty such that Aratana shall pay to Pacira [\*\*]% of any royalties on Net Sales received from a Sublicensee in the SP Royalty Territory;

(b) If the royalty received from a Sublicensee is greater than or equal to [\*\*]% but less than [\*\*]% of Net Sales in the SP Royalty Territory, Pacira shall be responsible for [\*\*]% and Aratana shall be responsible for [\*\*]% of the SP Royalty such that Aratana shall pay to Pacira [\*\*]% of any royalties on Net Sales received from a Sublicensee in the SP Royalty Territory;

(c) If the royalty received from a Sublicensee is greater than or equal to [\*\*]% of Net Sales in the SP Royalty Territory, Pacira shall be responsible for [\*\*]% and Aratana shall be responsible for [\*\*]% of the SP Royalty such that Aratana shall pay to Pacira [\*\*]% of any royalties received on Net Sales from a Sublicensee in the SP Royalty Territory; and

(d) For as long as Pacira has the obligation, Pacira shall pay the SP Royalties to SkyePharma in accordance with the terms of the SkyePharma Agreement. Pacira shall also be responsible for payment to RDF of any amounts due under the RDF Agreement.

5.4.3 Payments for U.S. Sublicenses. Aratana and Pacira shall equally share fifty percent (50%) of all (a) sublicense fees, milestones and royalty payments received by Aratana from any U.S. Sublicensees (b) any profits, including any amounts by which resale/transfer price exceeds Product Price, derived by Aratana in connection with any transfer or resale of Bulk Product (as defined in the Supply Agreement) or Licensed Product to any U.S. Sublicensees as contemplated by the Supply Agreement until Aratana recoups its out-of-pocket Third Party direct, documented fees and expenses associated with any Drug Approval Application in the United States for the Licensed Product, including any fees and expenses associated with the Development of the Licensed Product in the U.S. (“**U.S. Development Costs**”), and any milestones (other than the Upfront Payment Amount) paid to Pacira hereunder. Any sharing of royalty payments under this Section 5.4.3 shall be updated to reflect any sharing of SP Royalty as provided in Section 5.4.2. Following Aratana’s recoupment of its U.S. Development Costs, except as provided below, the license granted to Aratana for the United States shall terminate and Aratana shall no longer be entitled to receive any royalties or other payments due under the U.S. Sublicense with all rights thereunder reverting to Pacira, and upon such event Aratana shall comply with Section 10.3.5 below; provided, however, if Aratana enters into a U.S. Sublicense and is nevertheless able to continue to meet its financial obligations and royalty payments to Pacira as outlined in Sections 5.2 and 5.3.1, Aratana will be entitled to retain its rights to the Licensed Product and can retain all amounts in excess of the amounts due Pacira hereunder.

5.4.4 Payment of Sublicense Payments, etc. Aratana shall pay to Pacira within [\*\*] calendar days of receipt of its share of any payments received by Aratana pursuant to any Ex-U.S. Sublicense or U.S. Sublicense. Each sublicense payment shall be accompanied by a report specifying (i) the sublicense fees, milestones and royalty payments received in each jurisdiction’s currency; (ii) an account of deductions taken for any U.S. Development Costs or Ex-U.S. Development Costs (as the case may be); (iii) the applicable exchange rate to convert from each jurisdiction’s currency to U.S. dollars under Section 5.5; (iv) a breakdown of any SP Royalty amounts; (v) the amount payable in United States Dollars; and (vi) any other information requested by Pacira.

5.5 Accounting. All payments hereunder shall be made in U.S. dollars. Conversion of foreign currency to United States dollars shall be made at the conversion rate existing in the United States (as reported in The Wall Street Journal, East Coast edition) on the immediately preceding business day. If The Wall Street Journal ceases to be published, then the rate of exchange to be used shall be that reported in such other business publication of national circulation in the United States as the Parties reasonably agree.

5.6 Taxes; Withholding; Restrictions on Payment. Each Party shall pay the applicable taxes levied on all payments made to it under this Agreement. If provision is made in Law or regulation of any jurisdiction for withholding of taxes of any type, levies or other charges with respect to any amounts payable under this Agreement to the other Party, the paying Party

shall promptly pay such tax, levy or charge for and on behalf of the other Party to the proper governmental authority, and shall promptly furnish the other Party with receipt of such payment. The paying Party shall have the right to deduct any such tax, levy or charge actually paid from payment due to the other Party or be promptly reimbursed by the other Party. Each Party agrees to assist the other Party in claiming exemption from such deductions or withholdings under double taxation or similar agreement or treaty from time to time in force and in minimizing the amount required to be so withheld or deducted and shall use all reasonable and legal efforts to reduce tax withholding on payments made hereunder. If by law, regulations or fiscal policy of a particular jurisdiction in the Territory, remittance of royalties in U.S. dollars is restricted or forbidden, written notice thereof shall promptly be given to Pacira, and payment of the royalty shall be made by the deposit thereof in local currency to the credit of Pacira in a recognized banking institution reasonably designated by Pacira by written notice to Aratana.

5.7 Reports. Following the date of First Commercial Sale of the first Licensed Product hereunder, Aratana shall, and shall require each of its Sublicensees to, provide monthly reports to Pacira no later than the [\*\*] calendar day after the end of each such calendar month setting forth (i) the gross sales and Net Sales of Licensed Product in each jurisdiction of the Territory; (ii) the number of units of Licensed Product sold in each jurisdiction of the Territory; and (iii) such other information reasonably requested by Pacira. Aratana also agrees to provide such information to, and reasonably cooperate with, Pacira as may be reasonably requested by Pacira in order to comply with its reporting obligations to SkypePharma and RDF.

5.8 Records Retention; Review.

5.8.1 Royalties. Commencing as of the date of First Commercial Sale of the first Licensed Product hereunder, Aratana and its Affiliates and Sublicensees shall keep for at least [\*\*] years from the end of the calendar year to which they pertain complete and accurate records of sales by Aratana or its Affiliates and Sublicensees, as the case may be, of each Licensed Product, in sufficient detail to allow the accuracy of the payments hereunder to be confirmed.

5.8.2 Review. Subject to the other terms of this Section 5.8.2, at the request of Pacira, which shall not be made, without cause, more frequently than [\*\*] per calendar year during the Term, upon at least [\*\*] calendar days' prior written notice from Pacira, and at the expense of Pacira (except as otherwise provided herein), Aratana shall permit an independent certified public accountant reasonably selected by Pacira and reasonably acceptable to Aratana to inspect (during regular business hours) the relevant records required to be maintained by Aratana under this Section 5.8 for any period within the preceding [\*\*] calendar years. In every case the accountant must have previously entered into a confidentiality agreement with both Parties substantially similar to the provisions of Section 6 and limiting the disclosure and use of such information by such accountant to authorized representatives of the Parties and the purposes germane to this Section 5.8. Results of any such review shall be binding on both Parties absent manifest error. Each Party agrees to treat the results of any such accountant's review of the other Party's records under this Section 5.8 as Confidential Information of the other Party subject to the terms of Section 6. If any review reveals either (i) a deficiency in the calculation and/or payment of royalties, milestones or other amounts due Pacira hereunder by Aratana or (ii) an overpayment of royalties, milestones or other payments due Pacira hereunder, then: (a) Aratana

shall promptly pay Pacira the amount remaining to be paid for an underpayment or take a credit towards payment of royalties for the next calendar quarter for an overpayment, and (b) if there is an underpayment exceeding [\*\*] percent ([\*\*]%) of any such payment, Aratana shall pay all reasonable costs and expenses incurred by Pacira in connection with the review.

5.8.3 Other Parties. Aratana shall include in any agreement with its Affiliates or Sublicensees terms requiring such party to retain records as required in this Section 5.6 and to permit Pacira to inspect such records as required by this Section 5.8.3.

## 6. TREATMENT OF CONFIDENTIAL INFORMATION

6.1 Confidential Obligations. Pacira and Aratana each recognize that the other Party's Confidential Information constitutes highly valuable and proprietary confidential information. Pacira and Aratana each agree that during the Term and for [\*\*] years thereafter, it will keep confidential, and will cause its employees, consultants, Affiliates and Sublicensees to keep confidential, all Confidential Information of the other Party; provided, however that Aratana's and its employees', consultants', Affiliates' and Sublicensees' obligation to keep confidential with respect to Pacira's Know How and trade secrets related to the Licensed Product and know how related to its proprietary manufacturing drug delivery systems shall continue in perpetuity. Neither Pacira nor Aratana nor any of their respective employees, consultants, Affiliates or Sublicensees shall use Confidential Information of the other Party for any purpose whatsoever other than exercising any rights granted to it or reserved by it hereunder. Without limiting the foregoing, each Party may disclose information to the extent such disclosure is reasonably necessary to (a) file and prosecute patent applications and/or maintain patents which are filed or prosecuted in accordance with the provisions of this Agreement, or (b) file, prosecute or defend litigation in accordance with the provisions of this Agreement or (c) comply with applicable laws, regulations or court orders; provided, however, that if a Party is required to make any such disclosure of the other Party's Confidential Information in connection with any of the foregoing, it will give reasonable advance notice to the other Party of such disclosure requirement and will use reasonable efforts to assist such other Party in efforts to secure confidential treatment of such information required to be disclosed.

6.2 Limited Disclosure and Use. Pacira and Aratana each agree that any disclosure of the other Party's Confidential Information to any officer, employee, consultant or agent of the other Party or any of its Affiliates or Sublicensees shall be made only if and to the extent necessary to carry out its rights and responsibilities under this Agreement, shall be limited to the maximum extent possible consistent with such rights and responsibilities and shall only be made to the extent any such persons are bound by written confidentiality obligations to maintain the confidentiality thereof and not to use such Confidential Information except as expressly permitted by this Agreement. Pacira and Aratana each further agree not to disclose or transfer the other Party's Confidential Information to any Third Parties under any circumstance without the prior written approval from the other Party (such approval not to be unreasonably withheld), except as otherwise required by applicable Law, and except as otherwise expressly permitted by this Agreement. Each Party shall take such action, and shall cause its Affiliates or Sublicensees to take such action, to preserve the confidentiality of each other's Confidential Information as it would customarily take to preserve the confidentiality of its own Confidential Information, using, in all such circumstances, not less than prudent and reasonable care. Each Party, upon the

request of the other Party, will return all the Confidential Information disclosed or transferred to it by the other Party pursuant to this Agreement, including all copies and extracts of documents and all manifestations in whatever form, within [\*\*] calendar days of such request or, if earlier, the termination or expiration of this Agreement; provided however, that a Party may retain (a) any Confidential Information of the other Party relating to any license which expressly survives such termination and (b) one (1) copy of all other Confidential Information in inactive archives solely for the purpose of establishing the contents thereof.

6.3 Public and Private Disclosure. Neither Party may publicly disclose the existence or terms or any other matter of fact regarding this Agreement and any ancillary agreements without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed; provided, however, that either Party may make such a disclosure and provide a copy of this Agreement and any ancillary agreements (a) to the extent required by applicable Law or by the requirements of any nationally recognized securities exchange, quotation system or over-the-counter market on which such Party has its securities listed or traded or (b) in the form of the press release attached hereto as Exhibit B. In the event that such disclosure is required as aforesaid, the disclosing Party shall make reasonable efforts to provide the other Party with notice beforehand and to coordinate with the other Party with respect to the wording and timing of any such disclosure. The Parties, upon the execution of this Agreement, will mutually agree to a press release with respect to this transaction for publication. Once such press release or any other written statement is approved for disclosure by both Parties, either Party may make subsequent public disclosure of the contents of such statement without the further approval of the other Party. Notwithstanding the foregoing, either Party may disclose to a Third Party the existence or terms or any other matter of fact regarding this Agreement and any ancillary agreements and provide a copy of this Agreement and any ancillary agreements without the prior written consent of the other Party: (i) pursuant to, and in accordance with, any existing contractual obligations with such party or (b) if such Third Party is an investor or a prospective investor, purchaser, partner, lender or other potential financing source (or a representative of any of the foregoing) who is obligated in writing to keep such information confidential.

6.4 Use of Name. Neither Party shall employ or use the name of the other Party in any promotional materials or advertising without the prior express written permission of the other party.

## **7. PROVISIONS CONCERNING THE OWNERSHIP, FILING, PROSECUTION AND MAINTENANCE OF INTELLECTUAL PROPERTY**

7.1 Third Party Licensors. The Parties agree and acknowledge that each of Pacira, RDF and OctoPlus have certain respective rights and obligations under the RDF Agreement and the OctoPlus Agreement. The Parties agree that this Section 7 shall be subject in all respects to the applicable terms and conditions of the RDF Agreement and the OctoPlus Agreement and, in the event of any conflict between the terms of the RDF Agreement or the OctoPlus Agreement, on the one hand, and this Agreement, on the other hand, the terms of the RDF Agreement or the OctoPlus Agreement, as applicable, shall govern.

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7.2 Patent Filing, Prosecution and Maintenance. Subject to the other terms of this Section 7, Pacira shall be responsible for preparing, filing, prosecuting, obtaining and maintaining, at its sole cost and expense, all Licensed Patent Rights in the Territory.

7.3 Notice of Infringement. If, during the Term, either Party learns of any actual, alleged or threatened infringement by a Third Party of any Licensed Patent Rights under this Agreement, such Party shall promptly (but no later than [\*\*] business days) notify the other Party and shall provide such other Party with available evidence of such infringement.

### 7.4 Infringement of Patent Rights.

7.4.1 By Pacira. Pacira shall have the first right (but not the obligation), at its own expense, to bring suit (or take other appropriate legal action) against any actual, alleged or, based on the reasonable belief of Pacira, threatened infringement or misappropriation of the Licensed Patent Rights in the Territory in the Field, or to defend an action seeking declaratory judgment filed against Pacira with respect to the Licensed Patent Rights in the Territory in the Field. Pacira shall have sole control over the prosecution and settlement of such claims. Aratana shall have the right, at its own expense, to be represented in any such action by Pacira by counsel of Aratana's own choice subject to approval by Pacira.

7.4.2 Infringement Suits Requested by Aratana. Aratana shall have the right to require Pacira to sue for infringement one alleged infringer under the Licensed Patent Rights in one country of the Territory. Pacira will choose such country at its sole discretion. Pacira will be under no obligation to bring any other suit in any other country in the Territory with regard to the requested infringer nor will it be obligated to bring a lawsuit against any other alleged infringer in the Territory requested by Aratana during the pendency of the first lawsuit brought by Pacira at Aratana's request under this Section 7.4.2. Pacira shall have sole control over the initiation, conduct and settlement of such lawsuit. Aratana shall have the right, at its own expense, to be represented in any such action by Pacira by counsel of Aratana's own choice subject to approval by Pacira.

7.4.3 Allocation of Recovery. Any damages, monetary awards or other amounts recovered (net of any amounts due to RDF or OctoPlus), whether by judgment or settlement, pursuant to any suit, proceeding or other legal action taken under this Section 7.4, shall be applied as follows:

(a) First, to reimburse the Parties on a pro rata basis for their respective costs and expenses (including reasonable attorneys' fees and costs) incurred in prosecuting such enforcement action; and

(b) Second, [\*\*] percent ([\*\*]%) to Aratana and [\*\*] percent ([\*\*]%) to Pacira.

7.4.4 Cooperation. If either Party brings any such action or proceeding contemplated by this Section 7.4, the other Party agrees to be joined as party plaintiff if necessary to prosecute such action or proceeding, and to give the Party bringing such action or proceeding reasonable assistance



including prompt access to witnesses and documents within such other Party's control and authority to file and prosecute the suit; provided, however, that

neither Party shall be required to transfer any right, title or interest in or to any property to the other Party or any Third Party to confer standing on a Party hereunder.

#### 7.5 Defense of Claims.

7.5.1 Pacira shall have the first right (but not the obligation) to defend any Licensed Product Infringement Claim. If Pacira determines to defend such Licensed Product Infringement Claim, Pacira shall have sole control over the defense and settlement of such Licensed Product Infringement Claims; provided, however, that Aratana shall be entitled in each instance to participate in an advisory capacity through counsel of its selection at its own expense. Aratana agrees to give Pacira reasonable assistance and authority to defend the suit. If Pacira declines to defend such Licensed Product Infringement Claim, Aratana may defend such claim; provided, however, Aratana may not settle any Licensed Product Infringement Claim without the consent of Pacira. Any damages and costs (but exclusive of any related royalty payments which are the subject of Section 5.3.2) generated in the defense of such Licensed Product Infringement Claims by Pacira (other than costs and expenses incurred by Aratana from its participation in such claim pursuant to this Section 7.5.1, which shall be borne solely by Aratana) shall be borne **[\*\*]**% by Aratana and **[\*\*]**% by Pacira.

7.5.2 Pacira shall have the first right (but not the obligation) to defend any Shared Infringement Claim. If Pacira determines to defend such Shared Product Infringement Claim, Pacira shall have sole control over the defense and settlement of such Shared Infringement Claims; provided, however, that Aratana shall be entitled in each instance to participate in an advisory capacity through counsel of its selection at its own expense. Aratana agrees to give Pacira reasonable assistance and authority to defend the suit. Any damages and costs (but exclusive of any related royalty payments which are the subject of Section 5.3.2) generated in the defense of such Shared Infringement Claims (other than costs and expenses incurred by Aratana from its participation in such claim pursuant to this Section 7.5.2, which shall be borne solely by Aratana) shall be borne by Aratana and Pacira on a *pro rata* basis based on the aggregate net sales of the Licensed Product and EXPAREL® in the applicable jurisdiction of the Territory for the twelve-month period ending on the date of filing of the Shared Infringement Claim.

### 8. REPRESENTATIONS, WARRANTIES AND COVENANTS

8.1 Representations, Warranties and Covenants. Each Party hereby represents, warrants and covenants to the other Party as of the Effective Date, as follows:

8.1.1 Such Party (i) has the power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder, and (ii) has taken all necessary action on its part required to authorize the execution and delivery of this Agreement. This Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party and is in accordance with its terms subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity.

8.1.2 Such Party is not aware of any pending or threatened litigation (and has not received any communication) that alleges that such Party's activities related to this Agreement have violated, or that by conducting the activities as contemplated in this Agreement such Party would violate, any of the intellectual property rights of any Person (after giving effect to the license grants in this Agreement).

8.1.3 All necessary consents, approvals and authorizations of all regulatory and governmental authorities and other Persons required to be obtained by such Party in connection with the execution and delivery of this Agreement and the performance of its obligations under this Agreement have been obtained (other than such consents, approvals and authorizations that the Parties will obtain in the course of performing their obligations under this Agreement).

8.1.4 The execution and delivery of this Agreement the performance of such Party's obligations hereunder (i) do not conflict with or violate in any material way any requirement of applicable Law, (ii) do not conflict with or violate any provision of the articles of incorporation, bylaws, limited partnership agreement or any similar instrument of such Party, and (iii) do not conflict with, violate, or breach or constitute a default or require any consent under, any contractual obligation or court or administrative order by which such Party is bound.

8.2 Additional Representations, Warranties and Covenants of Aratana. Aratana represents, warrants and covenants to Pacira, as of the Effective Date, that:

8.2.1 Aratana (i) is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware, and (ii) has full power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement.

8.2.2 Neither Aratana nor any of its Affiliates has been debarred or is subject to debarment and neither Aratana nor any of its Affiliates shall use in any capacity, in connection with the services to be performed under this Agreement, any Person who has been debarred pursuant to Section 306 of the U.S. Act (21 U.S.C 335a), or who is the subject of a conviction described in such section. Aratana agrees to inform Pacira in writing immediately if it or any Person who is performing services on behalf of Aratana under this Agreement is debarred or is the subject of a conviction described in Section 306 of the U.S. Act, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the knowledge of Aratana, is threatened, relating to the debarment or conviction of Aratana or any Person performing services on behalf of Aratana under this Agreement.

8.2.3 Aratana will use Commercially Reasonable Efforts to Develop and Commercialize the Product for the Field in the Territory.

8.2.4 Aratana and its Affiliates shall launch the Licensed Product within [\*\*] months of Regulatory Approval in the Primary Territory.

8.2.5 Aratana has, or will have, the necessary financial resources available to it to consummate the transactions contemplated hereby and satisfy its obligations hereunder, in each case when and as contemplated by this Agreement.

8.3 Additional Representations, Warranties and Covenants of Pacira. Pacira represents, warrants and covenants to Aratana, as of the Effective Date, that:

8.3.1 Pacira (i) is a corporation duly organized, validly existing and in good standing under the laws of the State of California, and (ii) has full power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement.

8.3.2 Neither Pacira nor any of its Affiliates has been debarred or is subject to debarment and neither Pacira nor any of its Affiliates shall use in any capacity, in connection with the services to be performed under this Agreement, any Person who has been debarred pursuant to Section 306 of the U.S. Act, or who is the subject of a conviction described in such section. Pacira agrees to inform Aratana in writing immediately if it or any Person who is performing services on behalf of Pacira under this Agreement is debarred or is the subject of a conviction described in Section 306 of the U.S. Act, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the knowledge of Aratana, is threatened, relating to the debarment or conviction of Pacira or any Person performing services on behalf of Pacira under this Agreement.

8.3.3 Pacira shall pay when due any SP Royalties to SkyePharma and maintain the SkyePharma Agreement in effect as necessary to enable Aratana to exercise the rights being granted hereunder.

8.3.4 Pacira owns or Controls, and has the right, power, and authority to license, the Licensed Patent Rights and Know-How to Aratana under this Agreement.

8.3.5 Pacira has not granted or will grant during the term of this Agreement any license, or right of any similar nature with respect to any Licensed Patent Rights or Know-How which would conflict with the license granted to Aratana under this Agreement.

8.3.6 To the knowledge of Pacira, all of the Licensed Patent Rights that have issued are valid and enforceable, and no proceeding is pending or, to the knowledge of Pacira, threatened, nor to the knowledge of Pacira has any claim been made, which challenges or challenged the legality, validity, or enforceability of any Licensed Patent Right.

8.3.7 All maintenance fees, annuity payments, and similar payments relating to the Licensed Patent Rights to be made by Pacira prior to the date hereof have been made and all such payments to be made by Pacira on or after the date hereof, solely to the extent Pacira determines, in its sole discretion, that its continued payment of any such fee is warranted or desired, will be made in a timely manner during the Term; provided, however, that notwithstanding the foregoing, if Pacira exercises its right under this Section 8.3.7 to cease payment of any maintenance fees, annuity payments, or similar payments relating to the Licensed Patent Rights, Pacira will, not less than [\*\*] calendar days prior to such non-payment, inform Aratana of such decision and upon receipt of such notice, Aratana shall have [\*\*] calendar days to notify Pacira of its election to make such payment or to direct Pacira to make such payment and promptly reimburse Pacira for doing so (Aratana's failure to deliver such

notice to Pacira within the [\*\*]-day period shall constitute a waiver of Aratana's rights under this [Section 8.3.7](#)).

8.3.8 To the knowledge of Pacira, Aratana's exercise of its license rights in accordance with the terms of this Agreement will not infringe any patent or other intellectual property rights of any Third Party.

8.4 [Disclaimer](#). EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, EACH PARTY (AND THEIR RESPECTIVE AFFILIATES) HEREBY DISCLAIMS ANY AND ALL WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING WITH RESPECT TO ANY TECHNOLOGY LICENSED UNDER THIS AGREEMENT, INCLUDING ANY WARRANTY OF QUALITY, PERFORMANCE, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE. FOR THE AVOIDANCE OF DOUBT, NOTHING CONTAINED IN THIS [SECTION 8.4](#) SHALL OPERATE TO LIMIT OR INVALIDATE ANY EXPRESS WARRANTY CONTAINED HEREIN.

## 9. INDEMNIFICATION

### 9.1 [Indemnification](#).

9.1.1 [Aratana Indemnity](#). Subject to [Section 9.1.2](#) below, Aratana shall indemnify, defend and hold harmless Pacira, its Affiliates and their respective directors, officers, employees, stockholders and agents and their respective successors, heirs and assigns (the "**Pacira Indemnitees**") from and against any liability, damage, loss or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon such Pacira Indemnitees, or any of them, in connection with any Third Party claims, suits, actions, demands or judgments, including, without limitation, personal injury and product liability matters, to the extent arising out of (a) the Development or Commercialization of the Licensed Product by any person or in connection with Licensed Product in the Territory sold by Aratana or any Affiliate or Sublicensee under this Agreement, (b) any material breach of this Agreement by Aratana, or (c) the gross negligence, willful misconduct or violation of applicable Law on the part of Aratana or any Affiliate or Sublicensee, in any such case under this [Section 9.1.1](#), except to the extent of Pacira's responsibility therefor under [Section 9.1.2](#) below.

9.1.2 [Pacira Indemnity](#). Subject to [Section 9.1.1](#) above, Pacira shall indemnify, defend and hold harmless Aratana, its Affiliates and Sublicensees and their respective directors, officers, employees, and agents, and their respective successors, heirs and assigns (the "**Aratana Indemnitees**"), from and against any liability, damage, loss or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon such Aratana Indemnitees, or any of them, in connection with any Third Party claims, suits, actions, demands or judgments, including, without limitation, personal injury and product liability matters (but excluding any patent infringement matters, which are governed by [Section 7](#) above), to the extent arising out of (a) any material breach of this Agreement by Pacira or (b) the gross negligence, willful misconduct or violation of applicable Law on the part of Pacira, in any such case under this [Section 9.1.2](#), except to the extent of Aratana's or any Affiliate's or Sublicensee's responsibility therefor under [Section 9.1.1](#) above.

9.2 **Indemnification Procedures.** In the event that any Indemnitee is seeking indemnification under Section 9.1 above from a Party (the “**Indemnifying Party**”), the other Party shall notify the Indemnifying Party of such claim with respect to such Indemnitee as soon as reasonably practicable after the Indemnitee receives notice of the claim, and the Party (on behalf of itself and such Indemnitee) shall permit the Indemnifying Party to assume direction and sole control of the defense of the claim (including the right to settle the claim solely for monetary consideration) and shall cooperate as requested (at the expense of the Indemnifying Party) in the defense of the claim. The indemnification obligations under Section 9 shall not apply to any harm suffered as a direct result of any delay in notice to the Indemnifying Party hereunder or to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the consent of the Indemnifying Party, which consent shall not be withheld or delayed unreasonably. The Indemnitee, its employees and agents, shall reasonably cooperate with the Indemnifying Party and its legal representatives in the investigation of any claim, demand, action or other proceeding covered by Section 9.1.

9.3 **Insurance.**

9.3.1 **Pacira Insurance.** In the event Aratana obtains insurance pursuant to Section 9.3.2 below, Pacira shall thereafter, during the remainder of the Term and for a period of [\*\*] years after the expiration date of the last unit of Licensed Product sold by Aratana, maintain a policy of product liability insurance for the Product insuring against personal injury, death and damage to property. The said policy shall have a liability limit of not less than [\*\*] U.S. dollars (\$[\*\*]) per occurrence and in the aggregate, and shall be maintained with a financially sound and reputable insurer. If the above required insurance policy is written on a claims made basis, such policy must include a provision for an extended reporting period of not less than [\*\*] months. Pacira will provide [\*\*] calendar days written notice to Aratana prior to any cancellation. Pacira shall, within [\*\*] calendar days from the date of obtaining insurance coverage, furnish to Aratana a certificate of insurance evidencing the foregoing coverage.

9.3.2 **Aratana Insurance.** Aratana shall to the extent available, during the Term and for a period of [\*\*] years after the expiration date of the last unit of Licensed Product sold by Aratana, maintain a policy of product liability insurance for the Licensed Product insuring against personal injury, death and damage to property. The said policy shall have a liability limit of not less than [\*\*] U.S. dollars (\$[\*\*]) per occurrence and in the aggregate, and shall be maintained with a financially sound and reputable insurer. If the above required insurance policy is written on a claims made basis, such policy must include a provision for an extended reporting period of not less than [\*\*] months. Aratana shall provide [\*\*] calendar days’ written notice to Pacira prior to any cancellation. Aratana shall, within [\*\*] calendar days from the date of obtaining insurance coverage furnish to Pacira a certificate of insurance evidencing the foregoing coverage.

9.4 **Survival.** The indemnification obligations set forth in this Section 9 shall survive the termination of this Agreement and remain in full force and effect for an indefinite period after termination in relation to any claim based on events which occur during the Term.

9.5 **Limitation of Liability.** Except in the event of a Party’s fraud, gross negligence or willful misconduct or a breach by Aratana (or any of its Affiliates or Sublicensees)

of any exclusivity or confidentiality obligations under this Agreement, in no event shall either Party be liable to compensate the other Party for any indirect, incidental, punitive, special or consequential damages, including, without limitation, loss of anticipated profits, loss of time, or loss of opportunity, in connection with this Agreement or any breach thereof, and whether any such loss or damage may be based upon principles of contract, warranty, negligence or other tort, the failure of any limited or exclusive remedy to achieve its essential purpose, or for any other reason whatsoever.

## 10. TERM AND TERMINATION

10.1 Term. This Agreement shall commence on the Effective Date and unless terminated earlier in accordance with the provisions hereof shall continue for a period of fifteen (15) years (“**Initial Term**”). Upon expiration, provided that Aratana is not in any material breach of its obligations or any condition, representation, warranty or covenant under this Agreement or the Supply Agreement, Aratana shall have the option to renew this Agreement (subject to the provisions of Section 10.2.6) for a single five (5) year term (the “**Renewal Term**”) upon written notice to Pacira no later than six (6) months prior to the end of the Initial Term. The Initial Term and the Renewal Term, if applicable, are referred to herein as the “**Term**.”

### 10.2 Termination Rights.

10.2.1 Termination for Breach. Subject to the other terms of this Agreement, this Agreement and the rights and options granted herein may be terminated by either Party upon any material breach by the other Party of any material obligation or condition, representation, warranty or covenant effective [\*\*] calendar days after giving written notice to the breaching Party which notice shall describe such breach in reasonable detail. The foregoing notwithstanding, if such default or breach is cured or remedied or shown to be non-existent within the aforesaid [\*\*] day period the notice shall be automatically withdrawn and of no effect. If the Parties agree in writing, the [\*\*] day period may be extended. However, prior to giving any notice of termination for breach, the Parties shall first attempt to resolve any disputes as to the existence of any breach as set forth in Section 11.

10.2.2 Termination for Non-Payment. Pacira may terminate this Agreement on thirty (30) calendar days’ written notice to Aratana upon the failure of Aratana to pay any amounts due hereunder.

10.2.3 Termination upon Termination of the Supply Agreement. This Agreement shall automatically terminate upon Pacira’s termination of the Supply Agreement in accordance with the terms thereof.

10.2.4 Termination for Failure to Receive Regulatory Approval. Pacira may terminate this Agreement (i) with respect to the United States and each country in the European Union, on a country-by-country basis on thirty (30) calendar days’ written notice in the event Aratana does not obtain Regulatory Approval for the Licensed Product in such country within [\*\*] years of the Effective Date, or (ii) with respect to jurisdictions other than the United States and European Union (the “**Other Jurisdictions**”) on a country by country basis on thirty (30)

calendar days' written notice; if Aratana has not commenced Development and dosed its first patient/subject in support of obtaining Regulatory Approval for the Licensed Product in the Other Jurisdictions within [\*\*] years of the Effective Date.

10.2.5 Termination for Failure to Achieve the First Commercial Sale Within Six (6) Months of Regulatory Approval. Pacira may terminate this Agreement on sixty (60) calendar days' written notice to Aratana with respect to any jurisdiction in the Territory on a country by country basis in the event Aratana or its Sublicensee fails to achieve the First Commercial Sale of the Licensed Product within [\*\*] months of receipt of Regulatory Approval in such jurisdiction.

10.2.6 Termination for Failure to Achieve Minimum Annual Revenue. Either Party may terminate this Agreement on thirty (30) calendar days' written notice to the other Party in the event that Aratana and/or its Sublicensees fail to achieve sufficient Net Sales to provide to Pacira annual revenue of not less than U.S. \$[\*\*] (the "**Minimum Annual Revenue**") under this Agreement by the [\*\*] year following First Commercial Sale of the Licensed Product and each year thereafter, provided, however, that should Pacira exercise its right to terminate under this Section 10.2.6, Aratana shall have the option to pay Pacira an additional "**make-whole**" payment to satisfy the Minimum Annual Revenue within [\*\*] calendar days of its receipt of Pacira's notice of termination, in which case such payment shall negate Pacira's ability to terminate the Agreement under this Section 10.2.6 solely with respect to the failure to achieve the Minimum Annual Revenue for such year. Should Aratana exercise its right to extend the Term, the Parties shall work in good faith to renegotiate the Minimum Annual Revenue taking into consideration the global sales of the Licensed Product. The revised Minimum Annual Revenue amount shall be agreed upon within [\*\*] calendar days prior to the commencement of the Renewal Term.

10.2.7 Termination for Bankruptcy. In the event that either Party files for protection under bankruptcy laws, makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it which is not discharged within sixty (60) calendar days of the filing thereof, then the other Party may terminate this Agreement effective immediately upon written notice to such Party.

10.2.8 Termination by Right. Following Generic Intrusion in the Territory by a Third Party, Aratana may terminate this Agreement on a country by country basis, as the intrusion in such country occurs, with ninety (90) calendar days' written notice to Pacira.

10.2.9 Termination by Mutual Consent. This Agreement may be terminated upon mutual consent of the Parties.

10.2.10 Voluntary Termination by Aratana. Aratana may terminate this Agreement or any of the licenses granted under this Agreement, on a country-by-country basis within the Territory, at any time and without specifying a reason therefor, in each case on thirty (30) calendar days' written notice to Pacira; provided, however, that the foregoing termination right shall not apply to the United States or any country in the European Union.



10.3 Effects of Termination. Upon any termination of this Agreement pursuant to Section 10.2, on a jurisdiction-by-jurisdiction basis, as of the effective date of such termination, all licenses granted to Aratana hereunder in such jurisdiction shall terminate and all rights to the Licensed Product and the Licensed Patent Rights and Know-How in such jurisdiction (in each case to the extent not applicable to ongoing licenses in non-terminated jurisdictions) shall be returned to Pacira, provided, however, that:

10.3.1 Aratana shall retain, for a period of [\*\*] calendar days from the effective date of expiration or termination, a nonexclusive license to the Licensed Patent Rights and Know-How as necessary to sell off any Licensed Product in inventory or on order as of the effective date of such termination or expiration (and Aratana shall pay Pacira any Royalty Payments due with respect to such sales);

10.3.2 Neither Party shall be under any further obligation to the other in relation to the Licensed Product in the Territory provided, however that Pacira shall fulfill, and Aratana shall pay for, any Purchase Order placed by Aratana under the Supply Agreement and accepted by Pacira prior to the effective date of termination of this Agreement;

10.3.3 Aratana shall forthwith make all payments due to Pacira (including any Royalty Payments with respect to the period prior to the effective date of termination and the period during which Aratana's sell-off rights under Section 10.3.1 above ends);

10.3.4 Neither Party shall have any rights in relation to the Confidential Information of the other Party. Each Party shall return to the other Party all of the other Party's Confidential Information and copies thereof (whatever the format) except for copies that must be retained in order to comply with applicable Laws, which information may be retained, but only for so long as required and subject to the confidentiality obligations herein; and

10.3.5 Aratana shall (and shall cause its Affiliates and Sublicensees to): (i) assign or re-assign, as applicable, to vest in Pacira all right, title and interest in all Regulatory Approvals and Drug Approval Applications for the Licensed Product in all respects (upon which Aratana shall have no further rights of any nature with respect to such Regulatory Approvals and Drug Approval Applications); (ii) assign (or, if a non-owned asset or right, exclusively license) to Pacira all rights to any intellectual property or know-how Controlled by Aratana or its Affiliates or Sublicensees with respect to the Licensed Product; (iii) deliver to Pacira all files and documents relating to any of the foregoing and/or containing any product information including any clinical data, protocols and other documents related to the Development or Commercialization of the Licensed Product; and (iv) reasonably cooperate with Pacira to ensure the smooth transition of the marketing, distribution and sale of the Licensed Product in the Territory to Pacira or its designee.

10.4 Remedies. Except as otherwise expressly set forth in this Agreement, the termination provisions of this Section 10 are in addition to any other relief and remedies available to either Party at law.

10.5 Surviving Provisions. Other than Section 10.2 herein, notwithstanding any provision herein to the contrary, the rights and obligations of the Parties set forth in Sections 6, 7

and 9 as well as any rights or obligations otherwise accrued hereunder (including any accrued payment obligations), shall survive the expiration or termination of the Term. Without limiting the generality of the foregoing, Aratana shall have no obligation to make any milestone or royalty payment to Pacira that has not accrued prior to the effective date of any termination of this Agreement, but shall remain liable for all such payment obligations accruing prior to the effective date of such termination and any milestone payment which becomes due as a result of the sell-off period provided under Section 10.3.1 above.

## 11. DISPUTES

11.1 Negotiation. The Parties recognize that a bona fide dispute as to certain matters may from time to time arise during the Term that relates to either Party's rights and/or obligations hereunder. In the event of the occurrence of such a dispute (other than a claim for non-payment under Section 10.2.2), either Party may, by written notice to the other Party, have such dispute referred to their respective senior officials designated below or their successors, for attempted resolution by good faith negotiations within [\*\*] calendar days after such notice is received. Said designated senior officials are as follows:

For Aratana: Chief Executive Officer, or its designee

For Pacira: Chief Executive Officer, or its designee

In the event the designated senior officials are not able to resolve such dispute within the [\*\*] day period, either Party may invoke the provisions of Section 11.2. Failure to invoke Section 11.2 may cause the Agreement to be subject to an assertion of termination.

11.2 Arbitration. Subject to Section 11.1, any dispute, controversy or claim initiated by either Party arising out of, resulting from or relating to this Agreement, or the performance by either Party of its obligations under this Agreement (other than bona fide Third Party actions or proceedings filed or instituted in an action or proceeding by a Third Party against a Party), whether before or after termination of this Agreement, shall be finally resolved by binding arbitration. Whenever a Party shall decide to institute arbitration proceedings, it shall give written notice to that effect to the other Party. Any such arbitration shall be conducted under the Commercial Arbitration Rules of the American Arbitration Association by a panel of three arbitrators appointed in accordance with such rules with the arbitration taking place in New Jersey. The method and manner of discovery in any such arbitration proceeding shall be governed by the laws of the State of New Jersey. The arbitrators shall have the authority to grant injunctions and/or specific performance and to allocate between the parties the costs of arbitration in such equitable manner as they determine. Judgment upon the award so rendered may be entered in any court having jurisdiction or application may be made to such court for judicial acceptance of any award and an order of enforcement, as the case may be. In no event shall a demand for arbitration be made after the date when institution of a legal or equitable proceeding based upon such claim, dispute or other matter in question would be barred by the applicable statute of limitations. Notwithstanding the foregoing, either Party shall have the right, without waiving any right or remedy available to such Party under this Agreement or otherwise, to seek and obtain from any court of competent jurisdiction any interim or provisional relief that is necessary or desirable to protect the rights or property of such Party, pending the selection of

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the arbitrators hereunder or pending the arbitrators' determination of any dispute, controversy or claim hereunder.

## 12. MISCELLANEOUS

12.1 Notification. All notices, requests and other communications hereunder shall be in writing, shall be addressed to the receiving party's address set forth below or to such other address as a party may designate by notice hereunder, and shall be either (i) delivered by hand, (ii) made by facsimile transmission (to be followed with written confirmation by overnight courier providing evidence of receipt), (iii) sent by overnight courier providing evidence of receipt, or (iv) sent by registered or certified mail, return receipt requested, postage prepaid. The addresses and other contact information for the parties are as follows:

If to Pacira: Pacira Pharmaceuticals, Inc.  
5 Sylvan Way  
Parsippany, NJ 07054  
Attn: David Stack, CEO  
Facsimile No.: [\*\*]  
Telephone No.: [\*\*]  
Email: [\*\*]

With a copy to: Pacira Pharmaceuticals, Inc.  
5 Sylvan Way  
Parsippany, NJ 07054  
Attn: Corporate Counsel  
Facsimile No.: (973) 267-0050  
Email: Contracts@Pacira.com

If to Aratana: Aratana Therapeutics, Inc.  
901 Olathe Blvd  
Kansas City, KS 66103  
ATTN: Steven St. Peter

Facsimile No. (913) 904-9641:  
Telephone No.: (913) 951-2133  
Email: sstpeter@aratanarx.com

All notices, requests and other communications hereunder shall be deemed to have been delivered upon receipt.

12.2 Language. This Agreement has been prepared in the English language and the English language shall control its interpretation.

12.3 Governing Law. This Agreement will be construed, interpreted and applied in accordance with the laws of the State of New Jersey, excluding its conflict of law rules.

12.4 Limitations. Except as expressly set forth in this Agreement, neither Party grants to the other Party any right or license to any of its intellectual property.

12.5 Entire Agreement. This is the entire Agreement between the Parties with respect to the subject matter hereof and supersedes all prior representations, understandings and agreements between the Parties with respect to the subject matter hereof. No modification shall be effective unless in writing with specific reference to this Agreement and signed by the Parties.

12.6 Waiver. The terms or conditions of this Agreement may be waived only by a written instrument executed by the Party waiving compliance. The failure of either Party at any time or times to require performance of any provision hereof shall in no manner affect its rights at a later time to enforce the same. No waiver by either Party of any condition or term shall be deemed as a continuing waiver of such condition or term or of another condition or term.

12.7 Headings. Section and subsection headings are inserted for convenience of reference only and do not form part of this Agreement.

12.8 Assignment. Neither this Agreement nor any right or obligation hereunder may be assigned, delegated or otherwise transferred, in whole or part, by Aratana without the prior express written consent of Pacira, except with respect to a transfer to Affiliate or pursuant to a sale of substantially all of the assets of Aratana. The terms and conditions of this Agreement shall be binding upon and inure to the benefit of the permitted successors and assigns of the parties. Any transfer by Aratana other than in accordance with the terms hereof shall be void and shall entitle Pacira to immediately terminate this Agreement.

12.9 Force Majeure. Neither Party shall be liable for failure of or delay in performing obligations set forth in this Agreement, and neither shall be deemed in breach of its obligations, if such failure or delay is due to natural disasters or any causes beyond the reasonable control of such Party. In event of such force majeure, the Party affected thereby shall use reasonable efforts to cure or overcome the same and resume performance of its obligations hereunder.

12.10 Construction. The Parties hereto acknowledge and agree that: (i) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (ii) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (iii) the terms and provisions of this Agreement shall be construed fairly as to all Parties hereto and not in favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.

12.11 Severability. If any provision(s) of this Agreement are or become invalid, are ruled illegal by any court of competent jurisdiction or are deemed unenforceable under then current applicable Law from time to time in effect during the License Term, it is the intention of the Parties that the remainder of this Agreement shall not be affected thereby provided that a Party's rights under this Agreement are not materially affected. The Parties hereto covenant and agree to renegotiate any such term, covenant or application thereof in good faith in order to provide a reasonably acceptable alternative to the term, covenant or condition of this Agreement

or the application thereof that is invalid, illegal or unenforceable, it being the intent of the Parties that the basic purposes of this Agreement are to be effectuated.

12.12 Status. Nothing in this Agreement is intended or shall be deemed to constitute a partner, agency, employer-employee, or joint venture relationship between the Parties.

12.13 Section 365(n). All licenses granted under this Agreement are deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to “**intellectual property**” as defined in Section 101 of such Code. The Parties agree that Aratana may fully exercise all of its rights and elections under the U.S. Bankruptcy Code, regardless of whether either Party files for bankruptcy in the United States or other jurisdiction. The Parties further agree that, in the event Aratana elects to retain its rights as a licensee under such Code, Aratana shall be entitled to complete access to any technology licensed to it hereunder and all embodiments of such technology. Such embodiments of the technology shall be delivered to Aratana not later than: (a) the commencement of bankruptcy proceedings against Pacira, upon written request, unless Pacira elects to perform its obligations under the Agreement, or (b) if not delivered under clause (a) of this Section 12.13, upon the rejection of this Agreement by or on behalf of Aratana, upon written request.

12.14 Export Compliance. Aratana and its Affiliates and Sublicensees shall comply with all United States laws and regulations controlling the export of certain commodities and technical data, including without limitation all Export Administration Regulations of the United States Department of Commerce. Among other things, these laws and regulations prohibit or require a license for the export of certain types of commodities and technical data to specified countries. Aratana hereby gives written assurance that it will comply with, and will cause its Affiliates and Sublicensees to comply with, all United States export control laws and regulations, that it bears sole responsibility for any violation of such laws and regulations by itself or its Affiliates or Sublicensees, and that it will indemnify, defend, and hold Aratana harmless (in accordance with Section 9) for the consequences of any such violation.

12.15 Further Assurances. Each Party agrees to execute, acknowledge and deliver such further instructions, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

12.16 Counterparts. This Agreement may be executed simultaneously in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, each of the Parties have caused this Exclusive License, Development and Commercialization Agreement to be executed by its duly authorized representative as of the Effective Date.

PACIRA PHARMACEUTICALS, INC.:

ARATANA THERAPEUTICS, INC.:

By: /s/ David Stack

By: /s/ Steven St. Peter

Name: David Stack

Name: Steven St. Peter

Title: President, CEO

Title: President

Date: December 5, 2012

Date: 12/5/2012

SCHEDULE 1.35  
LICENSED PATENTS

See attached

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Country	Patent or Publication Number
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

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SCHEDULE 1.36

LICENSED PRODUCT

DepoBupivacaine™ Extended Release Liposome Injection

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EXHIBIT A

Form of Initial Supply Agreement

Incorporated by reference to Exhibit 10.48 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2012.

EXHIBIT B

Form of Press Release

FOR IMMEDIATE RELEASE

**Pacira Pharmaceuticals, Inc. and Aratana Therapeutics Inc. Enter into Global Licensing Agreement for Development and Commercialization of Bupivacaine Liposome Injectable Suspension for Animal Health Indications**

**PARSIPPANY, N.J. and KANSAS CITY, Kan., December 6, 2012** — Pacira Pharmaceuticals, Inc. (NASDAQ: PCRX) and Aratana Therapeutics Inc. today announced a global licensing agreement for the development and commercialization of bupivacaine liposome injectable suspension for animal health indications. Under the agreement, Aratana will develop and seek approval for the use of the product in veterinary surgery to manage postsurgical pain, focusing initially on developing the product for cats, dogs and other companion animals.

Bupivacaine liposome injectable suspension is approved for human use in the United States for the management of postsurgical pain and is currently marketed by Pacira under the name EXPAREL®. EXPAREL is a non-opioid local anesthetic, which was approved by the U.S. Food and Drug Administration (FDA) in October 2011 for administration into the surgical site to produce postsurgical analgesia. EXPAREL utilizes DepoFoam®, a proprietary delivery technology utilized in several Pacira products approved for human use. Veterinary development of the product may address the estimated 33 million surgical procedures performed each year on companion animals in the U.S.(1)

Steven St. Peter, M.D., chief executive officer of Aratana Therapeutics, stated, “Given the rapid and widespread implementation of EXPAREL by surgeons performing human procedures, we are confident that adoption of this innovative product by veterinary surgeons will be equally impressive. The global companion animal health market remains significantly underserved despite the more than 150 million companion animals in the U.S.(2) — many of whom will undergo surgical procedures. We believe this product fits nicely into our growing portfolio of companion animal therapeutics and will be welcomed by veterinarians committed to providing their patients with the best care available.”

“The management of postsurgical pain in animal health settings represents a large and growing market for our EXPAREL product,” said David Stack, president and chief executive officer of Pacira. “We continue to see EXPAREL adoption in a wide range of surgical settings, the generation of positive Phase 4 data and considerable sales growth during our launch year. We also have recently completed the installation of our expanded manufacturing suite — these milestones all strongly position the program for a strategic partnership. Given the Aratana team’s combined decades of veterinary drug development experience, we believe Aratana is the ideal partner for maximizing the product’s value in the companion animal health market.”

Under the agreement, Aratana made a one-time payment to Pacira of \$1 million and will pay additional development and commercial milestones totaling up to \$42.5 million. In addition, upon approval of the product by the FDA, Aratana will pay Pacira a double-digit royalty on net sales of

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the product. Should Aratana sublicense the product to a third party, Aratana and Pacira will share the proceeds by a predetermined formula (after Aratana has recovered certain direct development costs). Pacira will be responsible for all product manufacturing, and Pacira and Aratana will form a joint committee to oversee commercialization and development activities.

#### **About Pacira**

Pacira Pharmaceuticals, Inc. (NASDAQ: PCRX) is an emerging specialty pharmaceutical company focused on the clinical and commercial development of new products that meet the needs of acute care practitioners and their patients. The company's current emphasis is the development of non-opioid products for postsurgical pain control, and its lead product, EXPAREL® (bupivacaine liposome injectable suspension), was commercially launched in the United States in April 2012. EXPAREL and two other products have utilized the Pacira proprietary product delivery technology DepoFoam®, a unique platform that encapsulates drugs without altering their molecular structure and then releases them over a desired period of time. Additional information about Pacira is available at <http://www.pacira.com>.

#### **About Aratana Therapeutics**

Aratana Therapeutics is a biopharmaceutical company positioned to deliver high quality new medicines that address significant therapeutic needs for cats and dogs (companion animals). Aratana licenses and develops proprietary, patent-protected compounds acquired from human pharmaceutical and biotechnology companies and then maximizes the value of the programs for the animal health market. For more information, please visit [www.aratanatherapeutics.com](http://www.aratanatherapeutics.com).

#### **Forward Looking Statements**

Any statements in this press release about our future expectations, plans and prospects, including statements about our plans to develop and commercialize a bupivacaine liposome injectable suspension product for animal health indications, the size of the market for such a product and the level and rate of adoption for such a product and other statements containing the words "believes," "anticipates," "plans," "expects," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including risks relating to: the attainment of all necessary regulatory approvals for the marketing of any product developed under the Aratana license agreement; 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; our commercialization and marketing capabilities; and other factors discussed in the "Risk Factors" of our most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2011, our most recent Quarterly Report on Form 10-Q for the quarter ended September 30, 2012, and in other filings that we periodically make with the SEC. In addition, the forward-looking statements included in this press release represent our views as of the date of this press release. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

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(1) Small Animal and Equine Veterinary Surveys Regarding Surgical Procedures and Local Anesthetic Use (2008). Brakke Consulting, Inc., Dallas, TX. Prepared for Pacira Pharmaceuticals, Inc.

(2) American Veterinary Medical Association (2011). [www.avma.org](http://www.avma.org)

\*EXPAREL is a registered trademark of Pacira Pharmaceuticals, Inc.

**For Pacira Pharmaceuticals, Inc.**

James S. Scibetta, 973-254-3570

or

Media Contact:

Pure Communications, Inc.

Susan Heins, 864-286-9597

**For Aratana Therapeutics Inc.**

**Investors & Media:**

Joshua Drumm, Ph.D. / Andrew Mielach

Tiberend Strategic Advisors, Inc.

(212) 827-0020

[jdrumm@tiberend.com](mailto:jdrumm@tiberend.com)

[amielach@tiberend.com](mailto:amielach@tiberend.com)

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

**PACIRA PHARMACEUTICALS, INC.**

**and**

**ARATANA THERAPEUTICS, INC.**

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**SUPPLY AGREEMENT**

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**DATED AS OF DECEMBER 5, 2012**

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**THIS SUPPLY AGREEMENT** (this “**Agreement**”) is made effective as of December 5, 2012 (the “**Effective Date**”) by and between **Pacira Pharmaceuticals, Inc.**, a California corporation with a principal place of business at 5 Sylvan Way, Parsippany, New Jersey 07054 (“**Pacira**”) and **Aratana Therapeutics, Inc.**, a Delaware corporation with a place of business at 1901 Olathe Blvd, Kansas City, Kansas 66103 (“**Aratana**”). Pacira and Aratana are each hereafter referred to individually as a “**Party**” and together as the “**Parties**.” Capitalized terms used herein and not otherwise defined herein shall have the meanings set forth in Section 1.

**WHEREAS**, Pacira and Aratana have entered into that certain Exclusive License, Development and Commercialization Agreement, dated as of December 5, 2012 (the “**License Agreement**”), under which Aratana will develop, market, sell and distribute the Licensed Product in the Field in the Territory pursuant to the terms and conditions thereof;

**WHEREAS**, Pacira and Aratana have agreed that Pacira shall be the exclusive supplier of the Licensed Product to Aratana pursuant to the terms of this Agreement; and

**WHEREAS**, this Agreement constitutes the “Initial Supply Agreement” as contemplated by the License Agreement.

**NOW THEREFORE**, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties hereby agree as follows.

## **1. DEFINITIONS**

1.1. “[\*\*] **Vial**” shall mean a [\*\*] vial (without commercial labeling and packaging) containing the Licensed Product.

1.2. “**20ml Vial**” shall mean a 20ml vial (without commercial labeling and packaging) containing the Licensed Product.

1.3. “**Administrative NADA**” is a new animal drug application that is submitted after all of the technical sections that fulfill the requirements for the approval of the NADA under 21 CFR 514.1 have been reviewed by CVM and CVM has issued a technical section complete letter for each of those technical sections.

1.4. “**Affiliate**” shall mean with respect to any entity, any other entity that, directly or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, such entity and for purposes of this definition, “control” shall mean ownership, directly or indirectly through one or more Affiliates, of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or fifty percent (50%) or more of the equity interests in the case of any other type of legal entity, status as a general partner in any partnership, or any other arrangement whereby a Party controls or has the right to control the board of directors or equivalent governing body of a corporation or other entity.

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1.5. **“Approved Facilities”** shall mean the facilities of Pacira located at 10450 Science Center Drive, San Diego, CA 92121 (or the approved facility of a Third Party Manufacturer), in each case as may be changed by Pacira from time to time, comprising buildings and equipment where Pacira shall Manufacture and store or have Manufactured and stored the Bulk Product.

1.6. **“Bulk Product”** shall mean Licensed Product presented in [\*\*] Vials or 20ml Vials, as applicable, without commercial label and packaging.

1.7. **“Business Day”** shall mean any day other than a Saturday, a Sunday or a day on which banks in New York City, New York are authorized or obligated by Law to not open or remain closed.

1.8. **“Certificate of Analysis”** shall mean a document setting out the results of analysis of a Lot of Bulk Product together with the Specification and methods by which, the tests were performed.

1.9. **“Certificate of Compliance”** shall mean a document certifying that the Approved Facility is in compliance with cGMP and all other applicable Law.

1.10. **“cGMP”** shall mean current Good Manufacturing Practice as set out in the United States 21 CFR 210 and 211, as amended from time to time, together with, as applicable, any analogous regulations, codes or guidelines having effect in any jurisdiction in the countries in which the Licensed Product is to be Manufactured and/or distributed.

1.11. **“Commercialize” or “Commercialization”** shall mean any and all activities, excluding Development or manufacturing, necessary or desirable to realize commercial sales of the Licensed Product in accordance with applicable Law, including distributing, importing, transporting, customs clearance, export, warehousing, packing, handling and delivering to customers, as well as offering for sale and sales, marketing, promoting and reimbursement related activities, including booking sales. When used as a verb “Commercialize” means to engage in Commercialization.

1.12. **“Confidential Information”** shall mean with respect to a Party (the **“Receiving Party”**), all information which is disclosed by the other Party (the **“Disclosing Party”**) to the Receiving Party hereunder or to any of its employees, consultants, Affiliates, licensee or Sublicensees, except to the extent that the Receiving Party can demonstrate by written record or other suitable physical evidence that such information, (a) as of the date of disclosure is demonstrably known to the Receiving Party or its Affiliates other than by virtue of a prior confidential disclosure to such Party or its Affiliates; (b) as of the date of disclosure is in, or subsequently enters, the public domain, through no fault or omission of the Receiving Party; (c) is obtained from a Third Party having a lawful right to make such disclosure free from any obligation of confidentiality to the Disclosing Party; or (d) is independently developed by or for the Receiving Party without reference to or reliance upon any Confidential Information of the Disclosing Party. Confidential Information shall include all information disclosed to or accessible by Aratana or Pacira, as the case may be, relating to the subject matter of the License Agreement or this Agreement prior to the Effective Date.

- 1.13. **“Contract Quarter”** shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 or December 31, for so long as this Agreement is in effect.
- 1.14. **“CVM”** shall mean the Center for Veterinary Medicine (and any successor authority) of the FDA.
- 1.15. **“Delivery”** shall mean Pacira making available at the loading docks of the Approved Facilities the Bulk Product for collection by Aratana or its nominated carrier.
- 1.16. **“Drug Approval Application”** shall mean any application for Regulatory Approval, including, without limitation, (a) any application filed with the FDA and (b) any equivalent application filed with any Foreign Regulatory Authority for Regulatory Approval required prior to any sale or use or any Commercialization of a Licensed Product in any country or jurisdiction in the Territory.
- 1.17. **“Equipment”** shall mean the equipment used in the Manufacture, assembly, analysis and testing of the Product.
- 1.18. **“EXPAREL®”** shall mean Bupivacaine Liposome Injectable Suspension — NDA #022496 dated October 28, 2011.
- 1.19. **“FDA”** shall mean the U.S. Food and Drug Administration and any successor agency or authority thereto.
- 1.20. **“Field”** shall mean all prophylactic or therapeutic uses of finished Licensed Product for veterinary use only. For the avoidance of doubt, the Field shall not include use of the Licensed Product in humans.
- 1.21. **“Force Majeure”** shall have the meaning set forth in [Section 13.1](#).
- 1.22. **“Foreign Regulatory Authority”** shall mean any applicable supranational, national, federal, state or local regulatory agency, department, bureau or other Government Authority of any country or jurisdiction in the Territory (other than the United States of America), having responsibility in such country or jurisdiction for any Regulatory Approvals of any kind in such country or jurisdiction, and any successor agency or authority thereto.
- 1.23. **“Governmental Authority”** shall mean any governmental or quasi-governmental department, commission, board, bureau, agency, court or other instrumentality of any country or jurisdiction in the Territory or any political subdivision thereof.
- 1.24. **“JCCC”** shall have the meaning ascribed to such term in Section 3.1 of the License Agreement.
- 1.25. **“Labeling”** shall have the meaning set forth in [Section 7.3\(b\)](#).
- 1.26. **“Laboratory”** shall have the meaning set forth in [Section 4.3\(c\)](#).

- 1.27. **“Law”** shall mean all laws, treaties, statutes, ordinances, judgments, decrees, rules, codes, injunctions, writs, regulations, binding arbitration rulings, orders, and judicial or administrative interpretations or promulgations of any Governmental Authority having jurisdiction over the transactions contemplated hereunder.
- 1.28. **“License Agreement”** shall have the meaning set forth in the recitals to this Agreement.
- 1.29. **“Licensed Product”** shall mean shall mean DepoBupivacaine™ Extended Release Liposome Injection for use in the Field.
- 1.30. **“Lot”** shall have the meaning set forth in [Section 3.2\(c\)](#).
- 1.31. **“Manufacturing Approval”** shall mean all necessary or appropriate approvals, licenses, permits, registrations and authorizations in respect of the manufacture and Quality Control of the Licensed Product.
- 1.32. **“Manufacturing License”** shall mean any license as granted by the Regulatory Authority to Pacira or the Third Party Manufacturer in the applicable territory to manufacture the Licensed Product.
- 1.33. **“NADA”** shall mean any new animal drug application or Administrative NADA and all amendments and supplements.
- 1.34. **“Person”** shall include both corporate and real persons and institutions, partnerships and associations or entities of all kinds.
- 1.35. **“Product Delivery Date”** shall mean that date upon which the Bulk Product is available for collection from the Approved Facilities.
- 1.36. **“Product Price”** shall mean either (a) [\*\*] Dollars (\$[\*\*]) per 20ml Vial of Bulk Product or (b) [\*\*] Dollars (\$[\*\*]) per [\*\*] Vial of Bulk Product, in each case, as each may adjusted from time to time pursuant to [Section 5.1](#).
- 1.37. **“Quality Agreement”** shall mean an agreement to be entered into pursuant to [Section 6.1](#), which provides the responsibilities of the Parties related to the quality and regulatory requirements of the Bulk Product manufactured under this Agreement.
- 1.38. **“Quality Control”** shall mean the sampling, laboratory testing and inspection at the Approved Facilities of:
- (a) raw materials, in-process materials and Bulk Product; and
  - (b) the Bulk Product as necessary for Release.
- 1.39. **“Regulatory Approval”** shall mean any and all approvals or authorizations of any kind of any Regulatory Authority required prior to any commercial marketing, sale, or use of the Licensed Product in any country or jurisdiction in the Territory for a particular indication

within the Field. For clarity, Regulatory Approval: (i) in the United States shall consist of the approval by the FDA of the Administrative NADA; and (ii) shall not include any approvals, licenses, registrations or authorizations necessary for the manufacture or supply of the Licensed Product, or any component thereof, by Pacira to Aratana or its Affiliates or Sublicensees.

1.40. **“Regulatory Authority”** shall mean the FDA or any Foreign Regulatory.

1.41. **“Release”** shall mean release of the Bulk Product from the Approved Facilities to Aratana for labeling and packaging by Aratana.

1.42. **“Specification”** shall mean the specification of the Licensed Product as set out on Appendix I hereto.

1.43. **“Sublicensee”** shall mean any Third Party to whom Aratana grants a sublicense of some or all of the rights granted to Aratana under, and in accordance with, the License Agreement.

1.44. **“Term”** shall mean the term of this Agreement as set out in Section 10.

1.45. **“Territory”** shall mean worldwide.

1.46. **“Third Party”** shall mean any person or entity other than Aratana, Pacira and their respective Affiliates.

1.47. **“Third Party Manufacturer”** shall mean a Third Party appointed by Pacira to manufacture the Licensed Product on its behalf.

In this Agreement, unless the context requires otherwise:

(a) the headings are included for convenience only and shall not affect the construction of this Agreement;

(b) words denoting the singular shall include the plural and vice versa;

(c) words denoting one gender shall include each gender and all genders;

(d) the words “include” or “including” shall mean “include, without limitation” or “including, without limitation,” as the case may be, and the language following “include” or “including” shall not be deemed to set forth an exhaustive list; and

(e) any reference to an enactment or statutory provision is a reference to it as it may have been, or may from time to time be amended, modified, consolidated or re enacted.

The Appendices comprise part of and shall be construed in accordance with the terms of this Agreement.

## 2. SUPPLY OF BULK PRODUCT

2.1. Subject to the terms and conditions of this Agreement, during the Term, Pacira shall manufacture and supply, or shall cause to be manufactured and supplied, to Aratana Bulk Product for labeling, packaging and sale by Aratana, and, in consideration of the manufacture of Bulk Product by Pacira or by its Third Party Manufacturer, during the Term, Aratana shall purchase exclusively from Pacira all of its requirements of Bulk Product.

2.2. Pacira shall supply Bulk Product under this Agreement, in (a) 20ml Vials or (b) solely at such times as when [\*\*] Vials are being manufactured for commercial sale in Pacira's human health program for EXPAREL®, [\*\*] Vials. Each of which 20ml Vials and [\*\*] Vials shall thereafter be labeled, packaged or otherwise prepared for commercial sale by Aratana. Aratana shall be solely responsible, at its sole cost and expense, for all labeling, packaging and shipping of Bulk Product in accordance with applicable Law and utilizing such branding, trade names and trade dress selected by Aratana and approved by the JCCC. Aratana shall not materially alter any Bulk Product as supplied to Aratana by Pacira (other than to label, package and otherwise prepare the Bulk Product for commercial sale as set forth above) and shall only resell such Bulk Product in accordance with this Agreement, the License Agreement and applicable Law.

2.3. Pacira shall give Aratana reasonable notice of any proposal to appoint a Third Party Manufacturer and shall satisfy all legal and regulatory requirements relating to any variation of the Administrative NADA or any other Regulatory Approval relating to such appointment at its own cost and shall procure reasonable inspection and audit rights for Aratana in respect of the Third Party Manufacturer's site.

2.4. The terms and conditions of this Agreement shall control the manufacture and supply of Bulk Product by Pacira to Aratana, and no terms or conditions contained in any purchase order, acknowledgment, invoice, bill of lading, acceptance or other preprinted form issued by any Party shall have any force or effect to the extent they are inconsistent with or purport to modify the terms and conditions of this Agreement including those set forth in this Section 2.

2.5. Aratana shall be permitted to transfer or resell Bulk Product purchased in accordance with the terms of this Agreement to an Affiliate or Sublicensee and any such transfer or resale shall not be considered a commercial sale of Licensed Product under the License Agreement; provided, however, that any mark-up or increase in transfer price or any other revenue derived by Aratana from such transfer or resale shall be subject to Pacira's rights under the License Agreement. In no event shall Aratana or any of its Affiliate or any Sublicensee be permitted to transfer or resell Bulk Product other than as expressly contemplated by this Agreement or as expressly agreed to by Pacira in advance of any such purported resale or transfer. The transfer or sale of Bulk Product by Aratana to an Affiliate or Sublicensee shall in no way relieve Aratana of any of its obligations or liabilities hereunder.

## 3. FORECASTING AND ORDERING

3.1. *Forecasts.* Not less than [\*\*]days prior to the anticipated initial launch date of the Licensed Product, and on the [\*\*] day prior to the first Business Day of each Contract Quarter

occurring during the Term thereafter (each, a “**Forecast Delivery Date**”), Aratana shall provide to Pacira a rolling forecast in the format attached hereto as Appendix II, as such format may be reasonably modified from time to time by Pacira (a “**Rolling Forecast**”), of estimated quantities and anticipated Product Delivery Dates of units of Bulk Product in each case, for each month of the [\*\*] successive Contract Quarters following such Forecast Delivery Date (without regard to potential expiration or termination of this Agreement). Absent earlier expiration or termination of this Agreement, the forecast for the first [\*\*] months in each Rolling Forecast shall constitute a binding commitment by Aratana to place additional Purchase Orders pursuant to Section 3.2 that, when taken together with any Purchase Orders submitted up to such date by Aratana with respect to such period, shall be consistent with such Rolling Forecast, but in no event represent less than [\*\*] percent ([\*\*]%) of the amount of Bulk Product specified in such Rolling Forecast. Unless otherwise agreed by Pacira, the forecast with respect to any Contract Quarter in the Rolling Forecast shall not exceed [\*\*] percent ([\*\*]%) of the forecast for the immediately preceding Contract Quarter in such Rolling Forecast and Pacira agrees to supply to Aratana at least the following quantities of Bulk Product specified in the binding portion of such Rolling Forecast as provided in Sections 3.2(b) and 4.1:

Applicable Quarter after initial launch of the Licensed Product by Aratana	Committed Quantity of Bulk Product to be supplied by Pacira
1st Contract Quarter	[**]%
2nd Contract Quarter	[**]%
3rd Contract Quarter	[**]%
4th Contract Quarter	[**]%
5th Contract Quarter	[**]%
6th Contract Quarter	[**]%
7th Contract Quarter and thereafter	[**]%

Notwithstanding the foregoing, Pacira shall only be entitled to supply less than [\*\*]% of the amount of Bulk Product specified in the binding portion of a Rolling Forecast (or such lesser amount as may be specified in the applicable Purchase Order for such period in accordance with this Section 3.1) pursuant to the table above in the event that it determines in good faith that it is no longer commercially reasonable to supply in excess of the reduced amounts set forth in such table in light of its own supply demands for Bulk Product for its human health program for EXPAREL®.

3.2. *Purchase Orders.*

(a) Not less than [\*\*] days prior to the anticipated initial launch date of the Licensed Product, Aratana shall place with Pacira an irrevocable order (the “**Initial Purchase**”

**Order**) for Bulk Product sufficient to meet Aratana's projected requirements of Licensed Product in the first Contract Quarter of the Rolling Forecast. The Initial Purchase Order shall separately specify desired delivery dates for the first Contract Quarter Bulk Product. Thereafter, in accordance with the terms hereunder, Aratana shall place irrevocable orders (each, including the Initial Purchase Order, a "**Purchase Order**") for Bulk Product with Pacira in writing. Each Purchase Order shall be in a format requested by Pacira, specifying the quantities thereof desired and applicable Product Delivery Dates, said Product Delivery Dates to be no earlier than [\*\*] calendar days after delivery of such Purchase Order. All Purchase Orders shall be sent by Aratana to the following address, which may be updated from time to time by Pacira upon notice to Aratana:

Pacira Pharmaceuticals, Inc.  
10450 Science Center Drive  
San Diego, CA 92121  
Attention: Purchasing Manager  
Telephone: [To be provided]  
E-mail: [To be provided]

(b) Pacira will supply quantities of Bulk Product, in each case as set forth in the applicable Purchase Order in accordance with the delivery schedule set forth therein and, to the extent that such estimated amounts do not meet Aratana's actual requirements, Pacira will use commercially reasonable efforts to supply Aratana with its requirements beyond the amounts specified in the applicable Rolling Forecast as stated in Section 3.2(a), it being understood that Pacira shall have no obligation to supply Bulk Product in amounts exceeding the amounts specified in the applicable Rolling Forecast. Aratana agrees to purchase, in accordance with any Purchase Order, the terms and conditions of this Agreement, the Specification and applicable Law, such quantities of Bulk Product supplied by Pacira.

(c) Aratana shall purchase Bulk Product from Pacira in full lot quantities, consistent with Pacira's standard minimum batch sizes, currently estimated to be not more than [\*\*] 20ml Vials or [\*\*] Vials (each such lot quantity, a "**Lot**") or such other quantities as may be permitted by Pacira.

#### 4. DELIVERY, TITLE AND ACCEPTANCE

4.1. *Delivery.* Pacira shall supply all Bulk Product Ex Works (as defined in Incoterms 2010) the Approved Facilities. Pacira shall use its commercially reasonable efforts to Deliver to Aratana each of Aratana's orders for Bulk Product on the applicable Delivery Date specified in each Purchase Order. If Pacira becomes aware that for any reason it will be unable to Deliver ordered Bulk Product on the specified Delivery Date, Pacira shall promptly advise Aratana of that fact, the reason for the delay and (if appropriate) give its reasonable, good faith estimate of the likely delayed Delivery Date. Pacira shall use its commercially reasonable efforts to minimize the delay. Pacira shall submit to Aratana with each Lot of Bulk Product Delivered by Pacira a Certificate of Analysis setting out the results of the analysis of that Lot of Bulk Product and confirming that the Lot is manufactured in conformity with the Specification and cGMP. With the initial shipment of Bulk Product and annually thereafter, Pacira shall provide Aratana with a Certificate of Compliance. On Delivery, Bulk Product shall have a remaining shelf-life of

8

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at least [\*\*] months; provided, that, in the event Pacira proposes to deliver to Aratana Bulk Product with a remaining expiry of less than [\*\*] months, Pacira shall notify Aratana, and the Parties shall discuss in good faith such reasonable steps as may be implemented by Aratana to accommodate Aratana's distribution of such Bulk Product (in finished form) so as not to render such Bulk Product non-saleable, it being understood that Aratana shall not be obligated to accept delivery of Bulk Product with a remaining expiry of less than [\*\*] months.

4.2. *Title.* Legal title shall pass to, and all risk in and responsibility for Bulk Product shall be with, Aratana from and after Delivery. Aratana shall be responsible for all tariff, customs, clearance and other similar charges and will bear all risk of loss, delay, or damage in transit, as well as cost of freight and insurance.

4.3. *Receipt of Product; Acceptance.*

(a) Promptly after each Delivery Date, and prior to the labeling and packaging of such Bulk Product, Aratana shall conduct (i) a visual inspection of the Bulk Product for defects or damages and (ii) an inspection of all associated quality assurance documents, including, without limitation, the Certificate of Analysis delivered in accordance with Section 4.1. Aratana shall be entitled to reject and return any portion or all of any shipment of Bulk Product that does not conform to the Specification or otherwise fails to comply with the warranty set forth in Section 7.2(b) (unless such nonconformity or noncompliance is attributable to an act or omission of Aratana after the time such Bulk Product was Delivered by Pacira); provided, that Aratana provides notice of non-conformance discovered by Aratana based on such visual inspection and inspection of the associated quality assurance document or any other non-conformance to the warranties provided in Section 7.2(b) within [\*\*] calendar days after Delivery of such Bulk Product. If no notice is provided by Aratana within such time period, then Aratana shall be deemed to have accepted the shipment and all such Bulk Product Delivered to Aratana shall be deemed to materially conform with the Specification. Any notice of rejection by Aratana shall specify the shipment and Purchase Order number and shall be accompanied by a reasonably detailed statement of Aratana's exact reasons for rejection along with reasonable evidence of the alleged nonconformity or noncompliance (including a sample of the Bulk Product from the shipment tested) and, if applicable, a report of any pertinent analysis performed by Aratana on the allegedly nonconforming or noncomplying Bulk Product, together with the methods and procedures used to determine such non-conformity. Pacira shall notify Aratana in writing as promptly as practicable, but in any event within [\*\*] Business Days after receipt of such notice of rejection, whether Pacira accepts Aratana's assertions of nonconformity or noncompliance.

(b) Whether or not Pacira accepts Aratana's assertion of nonconformity or noncompliance, promptly upon receipt of a notice of rejection, Pacira shall use commercially reasonable efforts to provide replacement Bulk Product for the quantity of Bulk Product rejected by Aratana in the

original shipment as soon as reasonably possible but no later than [\*\*] days after the date of receipt of the notice of rejection. Aratana shall remain responsible for the purchase price for the allegedly nonconforming or noncomplying Bulk Product; provided, however, if the Bulk Product rejected by Aratana from such original shipment ultimately is found to be nonconforming or noncomplying (whether pursuant to Section 4.3(a) or if Aratana acknowledges such in writing), Pacira shall bear all costs and expenses of such replacement Bulk



Product (including the purchase price thereof and/or disposal charges for such nonconforming or noncomplying Bulk Product). If it is determined subsequently that such Bulk Product was in fact conforming (whether pursuant to Section 4.3(a) or if Aratana acknowledges such in writing), then Aratana shall be responsible for the purchase price for the allegedly nonconforming Bulk Product, as well as, upon receipt and acceptance by Aratana in accordance with the procedures set forth herein, the replacement Bulk Product, which shall be purchased at the then-effective purchase price for such Bulk Product. Replacement shipments shall also be subject to the procedures contained in this Section 4.3(b). Pacira shall be under no obligation to accept a return of Bulk Product except as provided for in this Section 4.3.

(c) If Pacira disagrees with any alleged nonconformity or noncompliance, then the Parties shall have [\*\*] days from the date of Pacira's receipt of Aratana's notification pursuant to Section 4.2(a) to resolve any such dispute. If such dispute is not resolved in the [\*\*] day period then an independent cGMP-certified laboratory (or other expert or consultant) of recognized repute (the "**Laboratory**"), selected by Pacira and reasonably acceptable to Aratana, shall analyze an aliquot sample or such other portions of a shipment, furnished by Aratana from the shipment received and rejected by Aratana, as may be necessary to substantiate whether the shipment rejected by Aratana conformed in all material respects to the Specification at the time of Delivery to, which analysis shall be performed in compliance with applicable FDA regulations for re-testing of pharmaceutical products. The Parties agree to cooperate with the Laboratory's reasonable requests for assistance in connection with its analysis hereunder. The Parties shall be bound by the Laboratory's results of analysis, which, absent manifest error, shall be deemed final as to any dispute over compliance of the Bulk Product in all material respects with the Specification at the time of Delivery. The fees and expenses of the Laboratory making such determination shall be by the Party against which the determination is made, or if the Laboratory cannot place the fault noticed and complained about, then the Parties shall share equally such costs.

(d) If Pacira accepts rejection of any shipment due to nonconformity or noncompliance (or if not, then following the decision of the Laboratory that the shipment was nonconforming), Pacira shall promptly (and in any case within [\*\*] Business Days thereafter) make arrangements for the return, reworking or disposal, at Pacira's option, of any nonconforming or noncomplying Bulk Product. If Pacira requests that Aratana dispose of such nonconforming or noncomplying Bulk Product, Pacira shall give Aratana written instructions as to how Aratana or its agent should dispose of such nonconforming or noncomplying Bulk Product, and Aratana shall provide Pacira with written certification of such destruction. Pacira shall pay (or reimburse Aratana) for any reasonable return shipping charges or out-of-pocket costs or expenses incurred by Aratana for such return shipment or lawful disposal of such nonconforming or noncomplying Bulk Product.

## 5. PRICING AND PAYMENT

5.1. *Pricing.* During the Term, the purchase price for the supply of Bulk Product sold to Aratana shall be the applicable Product Price then in effect. As of the Effective Date, the Product Price shall be either (a) [\*\*] Dollars (\$[\*\*]) per 20ml Vial of Bulk Product or (b) [\*\*] Dollars (\$[\*\*]) per [\*\*] Vial of Bulk Product, as applicable. Pacira shall review the Product Price annually and may increase the Product Price based upon inflation and any increases in the

cost of manufacture (including the cost of raw materials) of the Licensed Product; provided, however, that notwithstanding the foregoing, in no event shall any annual increase to the Product Price due solely to inflation exceed the percentage change in the Producer Price Index (Commodities) for Chemicals and Allied Products—Drugs and Pharmaceuticals (as published by the Bureau of Labor Statistics) over the preceding one (1) year period. Notice of any price increases shall be provided to Aratana [\*\*] days prior to the end of each calendar year during the Term with such increases becoming effective as of the first day the next calendar year.

5.2. *Invoices and Payments.* Payments to Pacira from Aratana pursuant to this Agreement shall be made by Aratana within [\*\*] days of receipt of the relevant invoice from Pacira, which invoice shall be delivered at the time of Delivery of Bulk Product under a Purchase Order. Aratana shall make all payments required under this Agreement by wire transfer to a bank account designated by Pacira in United States dollars.

5.3. *Taxes.* Any and all transfer, sales, use, registration and other taxes imposed upon or with respect to or measured by the sale or delivery by Pacira to Aratana of any Bulk Product hereunder shall be identified by Pacira and assessed to Pacira and Aratana, as applicable, as mutually agreed upon from time to time. To the extent any such taxes are applicable to Aratana, such amounts shall be included on Pacira's invoices to Aratana for such Bulk Product, to the extent that Aratana has not provided Pacira with an appropriate exemption certificate.

5.4. *Payments.* All payments by Aratana hereunder shall be payable in full when due, shall be absolute and non-refundable and shall not be subject to rights of set off, counterclaim, decrease, reduction or deduction whatsoever.

5.5. *Currency.* All amounts payable and calculations hereunder shall be in United States dollars.

## 6. MANUFACTURE

6.1. *Manufacture.* During the Term, and subject to the provisions of this Section 6, Pacira shall manufacture and supply Bulk Product in accordance with: (a) this Agreement; (b) the applicable Specification; (c) the applicable NADA; (d) cGMP requirements; (e) the Quality Agreement; and (f) all other applicable Law. The Parties will negotiate in good faith and enter into a Quality Agreement as soon as reasonably practicable and no later than [\*\*] days after the Effective Date. Notwithstanding the foregoing or any other provision of this Agreement, nothing set forth in this Agreement shall prohibit Pacira from: (i) effecting any change, modification or alteration to the manufacturing processes related to the manufacture of the Licensed Product (a “ **Change to Process**”); (ii) relocating or shutting down the then current Approved Facilities; (iii) manufacturing other pharmaceutical products or prioritizing its activities at the Approved Facilities; or (iv) prioritizing its business needs generally if and when such activities or needs conflict with its obligations to Aratana hereunder; provided; that (A) Pacira will notify Aratana as promptly as practicable after taking affirmative action in furtherance of any of the foregoing actions and (B) Pacira's right to engage in any of the foregoing actions does not excuse Pacira from its obligation to supply the Bulk Product to Aratana as required under Sections 3 and 4, subject to Section 6.3(b). Notwithstanding the foregoing, Pacira will notify Aratana through the JCCC of any Change to Process or any other

actions described above in this Section 6.1, in each case which would reasonably be expected to require Aratana to submit any new or supplemental filing with any Regulatory Authority or to engage in any new or supplemental clinical study.

6.2. *Compliance with Law.* While the Licensed Product is in the possession or under the control of Pacira, Pacira shall comply with all applicable Law regarding the manufacture, handling and storage of such Licensed Product.

6.3. *Changes Affecting Manufacture.*

(a) In the event that a Regulatory Authority imposes any change affecting the NADA, the Manufacturing Approval or the manufacture of the Bulk Product, each Party shall notify the other Party and the Parties shall discuss in good faith with a view to reaching agreement on the actions and timing required to effect such change, any regulatory approval required, and including any pricing implications.

(b) In the event that Pacira effects any Change to Process, the Parties shall discuss in good faith with a view to reaching agreement on the actions and timing required to continue supply of Bulk Product to Aratana, which may include, by way of example only, incorporation of the Change to Process within the Specification via a modification to the NADA mutually agreed to by Pacira and Aratana (the submission of which, including all incidental regulatory filings and requirements, shall be the sole responsibility of Aratana), the transfer of technology from Pacira to Aratana in order to allow Aratana to manufacture the Licensed Product in accordance with the applicable Specification, and regulatory approval required and including any pricing implications; provided, however, in no event shall Pacira be obligated to supply Bulk Product under this Agreement or enter into any alternate supply arrangements if Pacira determines, in its sole discretion, that it is no longer commercially reasonable to supply Bulk Product in accordance with the then-current Specification in light of the Change to Process. In furtherance, and not in limitation, of the foregoing, Pacira shall keep Aratana informed of any proposed Change to Process.

## 7. **WARRANTIES**

7.1. *Organization, Good Standing, Power.* Each of Pacira and Aratana represents and warrants to the other Party that:

- (a) it is duly organized, validly existing and in good standing under the Law of the jurisdiction in which it is incorporated or formed;
- (b) it has the requisite corporate or other power and authority to execute and deliver this Agreement and to consummate the transactions contemplated hereby;
- (c) the execution and delivery of this Agreement and the consummation by it of the transactions contemplated hereby have been duly authorized by all necessary corporate or similar action on its part and no other or further corporate or similar proceedings will be necessary for the execution and delivery of this Agreement by such Party, the performance of such Party's obligations hereunder, and the consummation by such Parties of the transactions contemplated hereby; and

(d) this Agreement has been duly executed and delivered by it and constitutes a legal, valid and binding obligation of such Party enforceable against such Party in accordance with its terms, except as the same may be limited by bankruptcy, insolvency, moratorium, reorganization or other Laws of general applicability relating to or affecting the enforcement of creditors' rights and general principles of equity.

7.2. *Representations and Warranties of Pacira.* Pacira represents and warrants that:

(a) *Approved Facilities.* The Approved Facilities (i) comply in all material respects with all relevant and applicable Law and standards and have all relevant regulatory permits and approvals including valid Manufacturing Licenses and Manufacturing Approvals; and (ii) currently have, and Pacira shall use commercially reasonable efforts to maintain, the necessary Equipment and personnel required for the manufacture of the Licensed Product in compliance with the NADA.

(b) *Conformance of Bulk Product.* Each Lot of Bulk Product supplied to Aratana under this Agreement shall: (i) meet the Specification; (ii) be manufactured in compliance with the applicable NADA or other applicable Regulatory Approval and cGMP; and (iii) be sold free from any lien or encumbrance. THE FOREGOING WARRANTY IS EXCLUSIVE, AND IS IN LIEU OF ALL OTHER WARRANTIES (WHETHER WRITTEN, ORAL OR IMPLIED) INCLUDING A WARRANTY OF MERCHANTABILITY IN OTHER RESPECTS THAN EXPRESSLY SET FORTH ABOVE AND A WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE.

PACIRA MAKES NO WARRANTIES, EXPRESS OR IMPLIED, OTHER THAN THOSE EXPRESSLY MADE HEREIN WITH RESPECT TO THE LICENSED PRODUCT. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY, SATISFACTORY QUALITY AND FITNESS FOR A PARTICULAR PURPOSE ARE HEREBY DISCLAIMED BY PACIRA.

7.3. *Representations and Warranties of Aratana.* Aratana represents and warrants that:

(a) *Regulatory Compliance.* (i) Aratana has obtained or will obtain, and at all times during the term of this Agreement as shall be required under applicable Law shall maintain, any and all Regulatory Approvals necessary for Aratana to Commercialize the Licensed Product under the License Agreement and (ii) all Labeling (as defined below) copy and artwork approved, designated or utilized by or on behalf of Aratana will be in compliance with applicable Law.

(b) *Non-Infringement.* None of the (i) labels and any other written, printed or graphic matter upon any Licensed Product or any container, wrapper or other packaging utilized with the Bulk Product, (ii) any package inserts and other written material accompanying the Licensed Product or (iii) other Licensed Product-related materials or information provided by or on behalf of Aratana (collectively, "**Labeling**"), nor the use of any Labeling in connection with the Commercialization of the Licensed Product, will infringe, misappropriate or otherwise

violate any patent, copyright, trade secret, trademark laws or other intellectual property right of any Third Party.

## **8. APPROVALS, AUDITS AND INSPECTIONS**

8.1. Aratana (or its representatives) shall be entitled, but in any event no more than [\*\*] in any twelve (12) month period during the Term, to access records related solely to the manufacture of the Bulk Product and those portions, and only those portions, of the Approved Facilities where the Bulk Product is manufactured, in the company of a representative of Pacira as is reasonably necessary to review and audit such records and portions of the Approved Facilities or the manufacture of the Bulk Product. Such inspection shall be conducted upon reasonable prior notice by Aratana, but not less than [\*\*] days prior to the proposed inspection, during normal business hours and at the specific time and date mutually agreed to by the Parties. Any information, data, technology or other materials accessed by or provided to Aratana or any of its representatives in connection with any such inspection shall be deemed Know-How (as defined in the License Agreement) of Pacira in which Pacira retains all right, title and interest, subject to the obligations contained in, and any use, as may be permitted under the License Agreement with respect thereto.

8.2. Pacira shall use all commercially reasonable efforts to obtain and maintain in force all the Manufacturing Licenses in relation to the manufacture of the Licensed Product, as may be required in the country of manufacture of the Licensed Product.

## **9. PROJECT MANAGEMENT**

9.1. Each Party shall from time to time by notice to the other nominate a Project Manager to co-ordinate relationships between the Parties. The Project Manager shall be the first point of contact between the Parties in relation to the placement of Bulk Product orders, confirmation of Delivery Dates, issues relating to manufacturing and Manufacturing Approvals. The Project Managers shall form a project team comprising relevant staff from both Pacira and Aratana for the co-ordination of the supply of the Bulk Product to Aratana.

9.2. Pacira and Aratana shall diligently carry out the tasks assigned to them hereunder, and as subsequently agreed in writing during the Term. Each Party shall co-operate with the other in good faith particularly with respect to problems or contingencies that arise during the Term and shall perform its obligations in good faith and in a commercially reasonable, diligent and workmanlike manner.

## **10. TERM AND TERMINATION**

10.1. *Term.* This Agreement shall come into effect on signature and, subject to earlier termination pursuant to this Section 10, shall continue for as long as the License Agreement continues in force.

10.2. *Termination by Pacira.* Pacira may terminate this Agreement, except as limited hereinafter, immediately upon written notice, in the event:

- (a) Aratana fails to make any undisputed payment (or undisputed portion of any payment) due and owing within [\*\*] days after notice thereof from Pacira that such payment has not been timely made by Aratana;
- (b) Aratana commits a breach of any material provision of this Agreement which is not cured within [\*\*] days of notice thereof from Pacira;
- (c) in the event that Pacira effects any Change to Process and the Parties are not able to reach agreement to continue supply of Bulk Product to Aratana after complying with Section 6.3(b); or
- (d) Pacira (including any successor or assignee thereof and any Third Party Manufacturer) ceases manufacture, for any reason, of EXPAREL®.

10.3. *Consequences of Termination.*

- (a) Termination or expiration of this Agreement shall not relieve the Parties of any obligation accruing prior to such termination or expiration, including, but not limited, to the regulatory and quality/technical responsibility provisions herein and the obligation to pay money, and shall be without prejudice to the rights and remedies of either Party with respect to the antecedent breach of any of the provisions of this Agreement.
- (b) Upon the termination of this Agreement by Pacira pursuant to Section 10.2(c) or 10.2(d), if requested by Aratana, Pacira will fulfill any and all Purchase Order(s) previously submitted and accepted by Pacira.
- (c) Upon the expiration or termination of this Agreement by Pacira pursuant to Section 10.2(a) or 10.2(b), Pacira may cancel, in whole or in part, any Purchase Order previously submitted.
- (d) Upon the expiration or termination of this Agreement by Pacira pursuant to Section 10.2(c) or 10.2(d), if requested by Aratana, Pacira will sell to Aratana all inventory of finished Bulk Product in the possession or control of Pacira that has been designated for future sale to Aratana (and not intended for sale or use in Pacira's human health program for EXPAREL®) and within the relevant expiry for such Bulk Product as of the effective date of termination, at the cost for such Bulk Product as of the effective date of termination. Payment for the finished inventory and materials shall be due within [\*\*] days of receipt of Pacira's invoice.
- (e) After the expiration or termination of this Agreement, Aratana shall be responsible, at its own expense, for manufacturing its requirements of Bulk Product.

10.4. *Survival.* Upon expiry or termination for any reason the provisions of Sections 4.3, 6, 7.2(b), 7.3, 10.3, 11, 12, 13, 14, 15 and 16 shall continue in full force and effect in accordance with their respective terms and Pacira shall retain pharmaceutical records and samples in accordance with cGMP.

## 11. ASSIGNMENT AND SUB-CONTRACTING

Neither this Agreement nor any right or obligation hereunder may be assigned, delegated or otherwise transferred, in whole or part, by Aratana without the prior express written consent of Pacira, except with respect to a transfer to Affiliate or pursuant to a sale of substantially all of the assets of Aratana. The terms and conditions of this Agreement shall be binding upon and inure to the benefit of the permitted successors and assigns of the Parties. Any transfer by Aratana other than in accordance with the terms hereof shall be void and shall entitle Pacira to immediately terminate this Agreement.

## 12. CONFIDENTIALITY

12.1. Pacira and Aratana undertake to each other to keep confidential, and to procure that their respective Affiliates, employees, directors, officers, contractors, lawyers and accountants (including those of their Affiliates) keep confidential, Confidential Information disclosed to it by or belonging to the other Party, until it ceases to be Confidential Information.

12.2. Any Confidential Information received from the other Party shall not be disclosed to any third party or used for any purpose other than as provided or specifically envisaged by this Agreement, unless it ceases to be Confidential Information.

12.3. The confidentiality and non-use obligations contained in this Agreement shall survive the termination of this Agreement and remain in full force and effect for an indefinite period after termination in relation to any claim based on events which occur during the Term.

## 13. FORCE MAJEURE

13.1. Neither Party shall be entitled to terminate this Agreement or shall be liable to the other under this Agreement for loss or damages attributable to acts of God, war or other hostility, civil disorder, the elements, fire, explosion, flood, or any other similar reason where failure to perform is beyond the control and not caused by the negligence of the non-performing Party (“**Force Majeure**”), provided the Party affected shall give prompt notice thereof to the other Party. Subject to Section 13.2, the Party giving such notice shall be excused from all affected obligations hereunder for so long as it continues to be affected by Force Majeure.

13.2. If such Force Majeure continues unabated for a period of at least ninety (90) days, the Parties will meet to discuss in good faith what actions to take or what modifications should be made to this Agreement as a consequence of such Force Majeure in order to alleviate its consequences on the affected Party.

## 14. DISPUTES

14.1. Negotiation. The Parties recognize that a bona fide dispute as to certain matters may from time to time arise during the term of this Agreement that relates to either Party’s rights and/or obligations hereunder. In the event of the occurrence of such a dispute, either Party may, by written notice to the other Party, have such dispute referred to their respective senior officials designated below or their successors, for attempted resolution by good faith negotiations within [\*\*] calendar days after such notice is received. Said designated senior officials are as follows:

For Aratana: Chief Executive Officer, or its designee

For Pacira: Chief Executive Officer, or its designee

In the event the designated senior officials are not able to resolve such dispute within the [\*\*] day period, either Party may invoke the provisions of Section 14.2. Failure to invoke Section 14.2 may cause the Agreement to be subject to an assertion of termination.

14.2. Arbitration. Subject to Section 14.1, any dispute, controversy or claim initiated by either Party arising out of, resulting from or relating to this Agreement, or the performance by either Party of its obligations under this Agreement (other than bona fide Third Party actions or proceedings filed or instituted in an action or proceeding by a Third Party against a Party), whether before or after termination of this Agreement, shall be finally resolved by binding arbitration. Whenever a Party shall decide to institute arbitration proceedings, it shall give written notice to that effect to the other Party. Any such arbitration shall be conducted under the Commercial Arbitration Rules of the American Arbitration Association by a panel of three arbitrators appointed in accordance with such rules with the arbitration taking place in New Jersey. The method and manner of discovery in any such arbitration proceeding shall be governed by the laws of the State of New Jersey. The arbitrators shall have the authority to grant injunctions and/or specific performance and to allocate between the parties the costs of arbitration in such equitable manner as they determine. Judgment upon the award so rendered may be entered in any court having jurisdiction or application may be made to such court for judicial acceptance of any award and an order of enforcement, as the case may be. In no event shall a demand for arbitration be made after the date when institution of a legal or equitable proceeding based upon such claim, dispute or other matter in question would be barred by the applicable statute of limitations. Notwithstanding the foregoing, either Party shall have the right, without waiving any right or remedy available to such Party under this Agreement or otherwise, to seek and obtain from any court of competent jurisdiction any interim or provisional relief that is necessary or desirable to protect the rights or property of such Party, pending the selection of the arbitrators hereunder or pending the arbitrators' determination of any dispute, controversy or claim hereunder.

## 15. INDEMNIFICATION.

15.1. Aratana Indemnity. Aratana shall indemnify, defend and hold harmless Pacira, its Affiliates and their respective directors, officers, employees, stockholders and agents and their respective successors, heirs and assigns (the “**Pacira Indemnitees**”) from and against any liability, damage, loss or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon such Pacira Indemnitees, or any of them, in connection with any third party claims, suits, actions, demands or judgments, including, without limitation, personal injury and product liability matters, to the extent arising out of any material breach of this Agreement by Aratana, up to the amount of Aratana's available insurance coverage provided for in the License Agreement.

15.2. Pacira Indemnity. Pacira shall indemnify, defend and hold harmless Aratana and its Affiliates and their respective directors, officers, employees, and agents, and their respective successors, heirs and assigns (the “**Aratana Indemnitees**”), from and against any liability,



damage, loss or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon such Aratana Indemnitees, or any of them, in connection with any Third Party claims, suits, actions, demands or judgments, including, without limitation, personal injury and product liability matters to the extent arising out of any material breach of this Agreement by Pacira, up to the amount of Pacira's available insurance coverage provided for in the License Agreement.

15.3. Indemnification Procedures. In the event that any of the Pacira Indemnitees or the Aratana Indemnitees (each, an "Indemnitee") is seeking indemnification under this Section 15 from a Party (the "Indemnifying Party"), the other Party shall notify the Indemnifying Party of such claim with respect to such Indemnitee as soon as reasonably practicable after the Indemnitee receives notice of the claim, and the Party (on behalf of itself and such Indemnitee) shall permit the Indemnifying Party to assume direction and sole control of the defense of the claim (including the right to settle the claim solely for monetary consideration) and shall cooperate as requested (at the expense of the Indemnifying Party) in the defense of the claim. The indemnification obligations under this Section 15 shall not apply to any harm suffered as a direct result of any delay in notice to the Indemnifying Party hereunder or to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the consent of the Indemnifying Party, which consent shall not be withheld or delayed unreasonably. The Indemnitee, its employees and agents, shall reasonably cooperate with the Indemnifying Party and its legal representatives in the investigation of any claim, demand, action or other proceeding covered by this Section 15.

15.4. Limitation of Liability. Any damage, loss or expense payable by an Indemnifying Party shall be reduced by the amount of any insurance proceeds actually received by an Indemnitee against such damage, loss or expense and by the amount of any other indemnity, contribution or other similar payments actually recovered by the Indemnitee from an unrelated person with respect to such damage, loss or expense, provided that the Indemnitee has no obligation to seek recovery of any such damage, loss, or expense from its insurance provider or such unrelated person.

## 16. RECALLS.

In the event (i) any Regulatory Authority issues a request, directive or order that Licensed Product be recalled, or (ii) a court of competent jurisdiction orders such a recall, or (iii) Pacira reasonably determines after consultation with Aratana that the Licensed Product should be recalled because the Licensed Product does not conform to the applicable Specification at the time of shipment by Pacira, the Parties will take all appropriate corrective actions reasonably requested by the other Party hereto or by any Regulatory Authority. In the event that such recall (a) results from the breach of Pacira's warranties under Section 7.2 of this Agreement, Pacira will be responsible for all of the costs and expenses of the recall or (b) results from the breach of Aratana's warranties or covenants under this Agreement, Aratana will be responsible for all of the costs and expenses of the recall. To the extent that such recall is not covered by either clause (a) or (b) of the immediately preceding sentence, then Pacira and Aratana shall share equally the costs and expenses of the recall. For the purposes of this Agreement, the expenses of the recall will be the expenses of notification and destruction or return of the recalled Licensed Product, as well as any reasonable out-of-pocket costs incurred by Pacira and/or Aratana in connection with

18

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any corrective action taken by Pacira and Aratana. Notwithstanding anything to the contrary, to the extent that a recall of the Licensed Product is caused by a Party's gross negligence or willful misconduct, all costs and expenses of the recall (regardless of the Party incurring such cost or expense) shall be borne by the responsible Party (and the responsible Party shall promptly reimburse the other Party for such Recall Expenses incurred in connection with such recall upon receipt of an invoice therefor).

## 17. GENERAL PROVISIONS

17.1. Notices. All notices, requests and other communications hereunder shall be in writing, shall be addressed to the receiving Party's address set forth below or to such other address as a Party may designate by notice hereunder, and shall be either (i) delivered by hand, (ii) made by facsimile transmission (to be followed with written confirmation by overnight courier providing evidence of receipt), (iii) sent by overnight courier providing evidence of receipt, or (iv) sent by registered or certified mail, return receipt requested, postage prepaid. The addresses and other contact information for the Parties are as follows:

If to Pacira: Pacira Pharmaceuticals, Inc,  
5 Sylvan Way  
Parsippany, NJ 07054  
Attention: David Stack, CEO  
Facsimile No.: [\*\*]  
Telephone No.: [\*\*]  
Email: [\*\*]

With a copy to: Pacira Pharmaceuticals, Inc.  
5 Sylvan Way  
Parsippany, NJ 07054  
Attention: Corporate Counsel  
Facsimile No.: (973) 267-0050  
Email: Contracts@Pacira.com

If to Aratana: Aratana Therapeutics, Inc.  
1901 Olathe Blvd  
Kansas City, KS 66103

Attention: Steven St. Peter  
Facsimile No.: (913) 904-9641  
Telephone No.: (913) 951-2133  
Email: sstpeter@aratanarx.com

All notices, requests and other communications hereunder shall be deemed to have been delivered upon receipt.

17.2. Further Assurances. Each of the Parties shall do execute and perform and shall procure to be done executed and performed all such further acts, deeds, documents and things as the other Party may reasonably require from time to time to give full effect to the terms of this Agreement.

17.3. Governing Law. This Agreement will be construed, interpreted and applied in accordance with the laws of the state of New Jersey, excluding its conflict of law rules.

17.4. Status. Nothing in this Agreement is deemed to constitute a partnership between the Parties nor constitute either Party the agent of the other Party for any purpose.

17.5. Costs and Expenses. Each Party shall pay its own costs, charges and expenses incurred in connection with the negotiation, preparation and completion of this Agreement.

17.6. Entire Agreement; Amendment. This is the entire Agreement between the Parties with respect to the subject matter hereof and supersedes all prior representations, understandings and agreements between the Parties with respect to the subject matter hereof. No modification shall be effective unless in writing with specific reference to this Agreement and signed by the Parties. It is agreed that:

(a) no Party has entered into this Agreement in reliance upon any representation, warranty or undertaking of the other Party which is not expressly set out in this Agreement;

(b) no Party shall have any remedy in respect of misrepresentation or untrue statement made by the other Party or for any breach of warranty which is not contained in this Agreement; and

(c) this Section 17.6 shall not exclude any liability for, or remedy in respect of, fraudulent misrepresentation.

17.7. Waiver. The terms or conditions of this Agreement may be waived only by a written instrument executed by the Party waiving compliance. The failure of either Party at any time or times to require performance of any provision hereof shall in no manner affect its rights at a later time to enforce the same. No waiver by either Party of any condition or term shall be deemed as a continuing waiver of such condition or term or of another condition or term.

17.8. Severability. If any provision(s) of this Agreement are or become invalid, are ruled illegal by any court of competent jurisdiction or are deemed unenforceable under then current applicable Law from time to time in effect during the License Term, it is the intention of the Parties that the remainder of this Agreement shall not be affected thereby provided that a Party's rights under this Agreement are not materially affected. The Parties hereto covenant and agree to renegotiate any such term, covenant or application thereof in good faith in order to provide a reasonably acceptable alternative to the term, covenant or condition of this Agreement or the application thereof that is invalid, illegal or unenforceable, it being the intent of the Parties that the basic purposes of this Agreement are to be effectuated.

17.9. Remedies. The rights and remedies of each of the Parties under or pursuant to this Agreement are cumulative, may be exercised as often as such Party considers appropriate and are in addition to its rights and remedies under general Law.

17.10. Construction. The Parties hereto acknowledge and agree that: (i) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have

contributed to its revision, (ii) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (iii) the terms and provisions of this Agreement shall be construed fairly as to all Parties hereto and not in favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.

17.11. Counterparts. This Agreement may be executed simultaneously in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

*[Remainder of Page Intentionally Left Blank; Signature Page Follows ]*

IN WITNESS WHEREOF, each of the Parties have caused this Supply Agreement to be executed by its duly authorized representative as of the Effective Date.

**PACIRA PHARMACEUTICALS, INC.:**

**ARATANA THERAPEUTICS, INC.:**

By: /s/ David Stack

By: /s/ Steven St. Peter

Name: David Stack

Name: Steven St. Peter

Title: President, CEO

Title: President

Date: December 5, 2012

Date: 12/5/2012

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**APPENDIX I**

**SPECIFICATION**

**Bupivacaine, Extended-Release Liposome Injection (20 ml Vials)**

The Specification for Bulk Product shall be the same as the specifications for EXPAREL®.\*

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\*The Specification shall be made available to Aratana as necessary for regulatory purposes.

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**APPENDIX II**

**FORM OF FORECAST**

[ARATANA LETTERHEAD]

[DATE]

Direct Telephone: [●]

E-mail: [●]

Pacira Pharmaceuticals  
10450 Science Center Drive  
San Diego, CA 92121  
Attention: [●]

Re: Aratana Item #[●] unlabeled DepoBupivacaine™ Extended Release Liposome Injection ®

Dear [●]:

The following is an updated forecast for unlabeled DepoBupivacaine™ Extended Release Liposome Injection (Bulk Product) purchased by Aratana Therapeutics, Inc.

**[\*THE FOLLOWING INFORMATION IS PROVIDED  
FOR ILLUSTRATIVE PURPOSES ONLY]**

<b>Quarter:</b>	<b>1Q13</b>	<b>2Q13</b>	<b>3Q13</b>	<b>4Q13</b>
<b>Quantity:</b>	[**]	[**]	[**]	[**]
<b>Delivery:</b>	[**]	[**]	[**]	[**]

Note: Purchased lot size is [\*\*] vials.

The forecast shown above is based on current best estimates of market demand and product approvals and is provided for Pacira's planning purposes. Actual purchase commitments will be made by formal purchase order(s). A [\*\*]-month rolling forecast will continue to be provided on a quarterly basis.

If you have any questions, please do not hesitate to contact me at your earliest convenience.

Sincerely,

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**SUBSIDIARIES OF THE REGISTRANT**

Pacira Pharmaceuticals, Inc., a California corporation

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

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**Exhibit 23.1**

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in Registration Statement No. 333-175101 on Form S-8, Registration Statement No. 333-181986 on Form S-8, and Registration Statement No. 333-180384 on Form S-3 of our reports dated March 6, 2013, relating to our audits of the consolidated financial statements of Pacira Pharmaceuticals, Inc. and Subsidiaries as of December 31, 2012 and 2011, and for each of the three years in the period ended December 31, 2012 and the effectiveness of internal control over financial reporting of Pacira Pharmaceuticals, Inc. and Subsidiaries as of December 31, 2012, included in this Annual Report on Form 10-K of Pacira Pharmaceuticals, Inc. for the year ended December 31, 2012.

/s/ CohnReznick LLP  
Roseland, New Jersey  
March 6, 2013

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QuickLinks

[Exhibit 23.1](#)

[Consent of Independent Registered Public Accounting Firm](#)

**CERTIFICATION**

I, David Stack, certify that:

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

Date: March 7, 2013

/s/ DAVID STACK

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David Stack  
*President and Chief Executive Officer*  
*(Principal Executive Officer)*

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QuickLinks

[Exhibit 31.1](#)

[CERTIFICATION](#)

**CERTIFICATION**

I, James Scibetta, certify that:

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

Date: March 7, 2013

/s/ JAMES SCIBETTA

James Scibetta  
*Chief Financial Officer*  
*(Principal Financial Officer)*

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QuickLinks

[Exhibit 31.2](#)

[CERTIFICATION](#)

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**Exhibit 32.1**

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

Pursuant to 18 U.S.C. §1350, the undersigned certifies that this Annual Report on Form 10-K of Pacira Pharmaceuticals, Inc. for the year ended December 31, 2012, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in this report fairly presents, in all material respects, the financial condition and results of operations of Pacira Pharmaceuticals, Inc.

Date: March 7, 2013

/s/ DAVID STACK

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David Stack  
*President and Chief Executive Officer*  
*(Principal Executive Officer)*

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QuickLinks

[Exhibit 32.1](#)

[STATEMENT PURSUANT TO 18 U.S.C. §1350](#)



[QuickLinks](#) -- Click here to rapidly navigate through this document

**Exhibit 32.2**

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

Pursuant to 18 U.S.C. §1350, the undersigned certifies that this Annual Report on Form 10-K of Pacira Pharmaceuticals, Inc. for the year ended December 31, 2012, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in this report fairly presents, in all material respects, the financial condition and results of operations of Pacira Pharmaceuticals, Inc.

Date: March 7, 2013

/s/ JAMES SCIBETTA

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James Scibetta  
*Chief Financial Officer*  
*(Principal Financial Officer)*

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QuickLinks

[Exhibit 32.2](#)

[STATEMENT PURSUANT TO 18 U.S.C. §1350](#)

