Pacira Pharmaceuticals, Inc.
Form 10-K
March 27, 2012
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended: December 31, 2011

Or

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

For the transition period from to

Commission file number: 001-35060

PACIRA PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**51-0619477**
(State or Other Jurisdiction of Incorporation or Organization)	(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:

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

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

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

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

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

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

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

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

Large accelerated filer o	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company x

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

The aggregate market value of 5,490,450 shares of voting stock held by non-affiliates of the registrant, based upon the closing sale price of the common stock on June 30, 2011, the last business day of the registrant s most recently completed second fiscal quarter, of $12.00 per share as reported on Nasdaq was $65,885,400. 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 March 23, 2012, 25,410,791 shares of the registrant s common stock, $0.001 par value per share, were outstanding.

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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 refers to Pacira Pharmaceuticals, Inc., and its subsidiaries. In addition, references in this Annual Report on Form 10-K to DepoCyt(e) mean DepoCyt when discussed in the context of the United States and Canada and DepoCyte when discussed in the context of Europe.

Forward-Looking Statements

This Annual Report on Form 10-K and certain other communications made by us contain forward-looking statements within the meaning of Section 21E of the Securities Exchange 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, will and similar expressions to help identify forward-looking statements. We cannot assure you that our assumptions and expectations will prove to have been correct. These forward-looking statements include, among others, statements about: the company s plans to develop, manufacture, and commercialize EXPAREL; the Company s plans to continue to manufacture and provide support services for its commercial partners who have licensed DepoCyt(e) and DepoDur; the timing of the Company s anticipated commercial launch of EXPAREL; the rate and degree of market acceptance of EXPAREL; the size and growth of the potential markets for EXPAREL and the Company s ability to serve those markets; the Company s plans to expand the indications of EXPAREL to include nerve block; and our manufacturing, 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. 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.

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 drug delivery technology, for use in hospitals and ambulatory surgery centers.

On October 28, 2011, the United States Food and Drug Administration, or FDA, approved our New Drug Application, or NDA, for our lead product candidate, EXPAREL, a liposome injection of bupivacaine, an amide local anesthetic, indicated for single-dose infiltration into the surgical site to produce postsurgical analgesia.

Our clinical data demonstrates that EXPAREL provides analgesia for up to 72 hours post-surgery, compared with approximately eight hours or less for bupivacaine. Bupivacaine and other shorter acting local anesthetics of the amide type such as mepivacaine and lidocaine are commonly used as the first line of treatment, pre- and post-operatively, of a multimodal postsurgical pain treatment regimen. Because bupivacaine, mepivacaine and lidocaine last eight hours or less, administration of these local anesthetics is commonly followed by the systemic administration of opioids, such as morphine. Together, these drugs form the foundation of the multimodal postsurgical pain treatment regimen for the treatment of extended duration pain. Opioids are associated with a variety of significant adverse events leading to unfavorable hospital economics and healthcare practioners seeking opioid-sparing strategies for their patients.

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 39 million opportunities annually in the United States for EXPAREL to be used.

EXPAREL is being launched by certain members of our management team who have successfully launched multiple products in the hospital market. Our commercial team has executed on a full range of pre-launch activities for EXPAREL including: (i) publications and abstracts for the EXPAREL clinical program efficacy and safety, health outcomes studies, and review articles on postsurgical pain management; (ii) 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

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management; (iii) key opinion leader, or 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 (iv) 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 have developed a sales force entirely dedicated to commercializing EXPAREL comprised of approximately 60 representatives, seven regional managers and a national sales manager. We have developed this sales force pursuant to a contract with Quintiles Commercial US, Inc., a division of Quintiles, Inc., or Quintiles, and under the terms of this contract we have the flexibility to hire all or a portion of the sales force dedicated to commercializing EXPAREL as full-time employees of Pacira, upon 60 day s notice to Quintiles. We expect to have successfully resolved the commercial manufacturing challenges for EXPAREL to allow product to be commercially available in April 2012, and we believe that our pre-launch activities including significant personal interactions with our hospital customers, position us for a successful launch of EXPAREL.

EXPAREL consists of bupivacaine encapsulated in DepoFoam, both of which are used in FDA-approved products. DepoFoam, our extended release drug delivery technology, is the basis for our two additional FDA-approved commercial products: DepoCyt(e) and DepoDur, which we manufacture for our commercial partners. DepoFoam-based products have been manufactured for over a decade and have an extensive safety record and regulatory approvals in the United States, European countries and other territories. Bupivacaine, a well-characterized, FDA-approved anesthetic/analgesic, has an established safety profile and over 20 years of use in the United States.

The FDA-approved label for EXPAREL includes a broad label for postsurgical analgesia by local administration into the surgical site, or infiltration, a procedure commonly employing bupivacaine. The approved indication states EXPAREL is a liposome injection of bupivacaine, an amide local anesthetic, indicated for single-dose infiltration into the surgical site to produce postsurgical analgesia . We also currently plan to expand the indications of EXPAREL to include nerve block administration, where bupivacaine is also used routinely.

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

Product(s)/ Product Candidate(s)	Primary Indication(s)	Status	Commercialization Rights
EXPAREL	Postsurgical analgesia by infiltration	Approved by FDA	Pacira (worldwide)
	Postsurgical analgesia -nerve block	Phase 2 (completed)	Pacira (worldwide)
DepoCyt(e)	Lymphomatous meningitis	Marketed	Sigma-Tau Pharmaceuticals Mundipharma International
DepoDur	Post-operative pain	Marketed	EKR Therapeutics (1) Flynn Pharmaceuticals
DepoNSAID	Acute pain	Preclinical	Pacira (worldwide)
DepoMethotrexate	Rheumatoid arthritis Oncology	Preclinical Preclinical	Pacira (worldwide) Pacira (worldwide)

(1) 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 will be effective 180 days from the date of the notice or July 1, 2012.

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:

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- 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;

- working directly with managed care payers, quality improvement organizations, KOLs in the field of postsurgical pain management and leading influence hospitals with Phase 4 retrospective and prospective trials to demonstrate the economic benefits of EXPAREL;

- securing commercial partnerships for EXPAREL in regions outside of the United States;

- obtaining FDA approval for nerve block indication for EXPAREL;

- 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 45 million surgical procedures were performed in the United States during the twelve months ending in October 2007. We estimate there are approximately 39 million opportunities annually in the United States 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,

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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.

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:

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.

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;

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- 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.

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

- promotes early ambulation, which potentially reduces the risk of life-threatening blood clots, and allows quicker return of bowel function, thereby leading to a faster switch to oral nutrition and medicine, and thus a faster discharge from the hospital.

Develop and seek approval of EXPAREL for nerve block 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-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.

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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 opiod 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);

- 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

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- 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

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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

- 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 are currently initiating a series of prospective trials with our hospital customers to demonstrate how the use of EXPAREL, to replace morphine (opioid) PCA, improves the quality of care by reducing morphine adverse events and enhances hospital economics by reducing inappropriate resource consumption including length of stay. 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.

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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.

EXPAREL consists of bupivacaine encapsulated in DepoFoam, both of which are used in FDA-approved products:

- Bupivacaine, a well-characterized generic anesthetic/analgesic, has an established safety profile and over 20 years of use in the United States.

- DepoFoam, modified to meet the requirements of each product, is used to extend the release of the active drug substances in the marketed products DepoCyt(e) and DepoDur.

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 two Phase 2 clinical trials in which 40 patients received EXPAREL for nerve block. EXPAREL demonstrated efficacy and was safe and well tolerated in these clinical trials. We expect to conduct additional clinical trials in this indication.

Sales and Marketing

We have hired a marketing team and, through our relationship with Quintiles, 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 has 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;

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- 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 will position Pacira and EXPAREL for a successful launch in April of 2012. We expect to have three key focuses for our launch strategy:

- Plastic Surgery - we will focus on breast augmentation and abdominoplasty, or tummy tuck, 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.

- 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 and peri-anal soft tissue surgery such as cholycystectomy, colectomy, hysterectomy, herniorophy, hemorrhoidectomy, prostatectomy and ileostomy reversal. This strategy allows our sales force to focus on colorectal surgeons, general surgeons 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.

We have, through our relationship with Quintiles, outsourced our national sales director and seven regional sales directors and have built our dedicated field sales force, consisting of approximately 60 representatives. With 70 dedicated directors and representatives we can cover approximately 81% of the markets of interest for the launch of EXPAREL. Within three years of launch we expect to have approximately 80 representatives, which we estimate can effectively cover our hospital and ambulatory surgery customers in the United States. We believe a typical sales representative focused on office-based healthcare practitioners can effectively reach five to seven healthcare practitioners per day; whereas, a typical hospital-focused sales representative can reach many more healthcare practitioners. Notably, a hospital-focused sales representative faces significantly less travel time between sales calls and less wait time in healthcare practitioner offices as a large number of prescribers can be found in a single location. Our sales force is supported by our current marketing team as well as teams of healthcare professionals who support our formulary approval and customer education initiatives.

The target audience for EXPAREL is healthcare practitioners who influence pain management decisions, including surgeons, anesthesiologists, pharmacists and nurses. Our commercial sales force will focus on reaching the top 1,000 U.S. hospitals performing surgical procedures (based on Thomson Reuters benchmark obstetrician and gynecological, general and orthopedic surgical procedures performed within these hospitals), which represent approximately 81% of the hospital market opportunity for EXPAREL. 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:

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- *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 DepoFoam products, DepoCyt(e) and DepoDur, have been approved in the United States and Europe, making regulatory authorities familiar with our DepoFoam technology;

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

- *Administration into privileged sites*. Our DepoFoam products are approved for epidural administration (DepoDur) and intrathecal injection (DepoCyt(e)) and in the future we may study them for potential use for intraocular and intratumoral administration;

- *Proven manufacturing capabilities*. We continue to make DepoFoam-based products in our cGMP facilities as we prepare for the launch of EXPAREL;

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

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

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

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

Other Products

Depocyt(e)

DepoCyt(e) is a sustained-release liposomal formulation of the chemotherapeutic agent cytarabine utilizing our DepoFoam technology. Depocyt(e) is indicated for the intrathecal treatment of lymphomatous meningitis, a life-threatening complication of lymphoma, a cancer of the immune system. Lymphomatous meningitis can be controlled with conventional cytarabine, but because of the drug s short half-life, a spinal injection is required twice per week, whereas DepoCyt(e) is dosed once every two weeks in an outpatient setting. DepoCyt(e) was granted accelerated approval by the FDA in 1999 and full approval in 2007. We received revenue from DepoCyt(e) of $10.4 million from our commercial partners in 2011.

DepoDur

DepoDur is an extended-release injectable formulation of morphine utilizing our DepoFoam technology. DepoDur is indicated for epidural administration for the treatment of pain following major surgery. DepoDur is designed to provide effective pain relief of up to 48 hours and has demonstrated improved patient mobility and freedom from indwelling catheters. DepoDur was approved by the FDA in 2004. We received revenue from DepoDur of $0.2 million from our commercial partners in 2011. We expect revenues from DepoDur to decrease in the future due to the upcoming termination of our licensing, distribution and marketing agreement with EKR in July 2012.

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Product Candidates

DepoNSAID

Our preclinical product candidates, extended release formulations of NSAIDs, are designed to provide the benefits of injectable NSAIDs with a prolonged duration of action in order to improve patient care and ease of use in the acute pain environment. Currently available injectable systemic products provide a four to six hour duration of action. We believe that there is an unmet medical need for a product which could provide a local infiltration since the mode of action for NSAIDs is by local activity. A product developed for local infiltration should provide pain relief with a much lower dose of NSAID and potentially avoid the side effects commonly associated with the systemic use of these agents. We have DepoFoam formulations for several NSAIDs, and we expect to select a lead product candidate in 2012.

DepoMethotrexate

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

Commercial Partners and Agreements

SkyePharma

In connection with the stock purchase agreement related to the Acquisition, we agreed to pay SkyePharma Holdings, Inc., or SPHI, specified contingent milestone payments related to EXPAREL sales. Additionally, we agreed to pay to SPHI a 3% royalty of our sales of EXPAREL in the United States, Japan, the United Kingdom, France, Germany, Italy and Spain. Such obligations to make contingent milestone payments and royalties will continue for the term in which such sales related to EXPAREL are covered by a valid claim in certain patent rights related to EXPAREL and other biologics products.

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

Research Development Foundation

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

Sigma-Tau Pharmaceuticals

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

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

Mundipharma International Holdings Limited

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

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

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

EKR Therapeutics Inc.

In August 2007, we entered into a licensing, distribution and marketing agreement with EKR Therapeutics, Inc., or EKR, granting them exclusive distribution rights to DepoDur in North America, South America and Central America. Under this agreement, as amended, we received nonrefundable license fees of $5.0 million upon execution of the agreement in August 2007, $5.0 million in 2008, and $5.0 million in 2009. At the time we entered into the agreement we had the right to receive aggregate milestone payments of up to $20 million, but we do not expect any additional milestone payments under the agreement.

Under this agreement, as amended, we receive a fixed payment for manufacturing the vials of DepoDur and a royalty comprised of a fixed amount per vial, a single-digit royalty on any incremental price increase implemented by EKR over the base price specified in the agreement and a fixed advanced royalty payment that was made within three days of the agreement date, which is offset against EKR s future payment obligations.

We and EKR have the right to terminate the agreement for an uncured material breach by the other party, an uncured material misrepresentation in any representation or warranty made in the agreement, in connection with the other party s bankruptcy or insolvency, in connection with the threat of or actual cessation of all or any material part of the other party s business, if the other Party is prevented from performing any of its material obligations by any law, governmental or other action for a period of 120 days, or if force majeure prevents other party from performing any of its material obligations for six months. We have the right to terminate the agreement if EKR fails to make its first commercial sale of DepoDur within a fixed period from the receipt of marketing authorization for any country in the territory covered by the agreement, or if we terminate the supply agreement upon written notice to EKR and all royalties paid by EKR to us in any one year period following the date of such termination are less than a certain amount, unless the difference between that amount and the actual royalties paid by EKR is paid to us within 30 days of notice of such termination. EKR has the right to terminate the agreement at any time without cause upon written notice to us within a specified timeframe. EKR has the right to terminate the agreement as to any country if DepoDur is withdrawn from the market in such country as a result of regulatory action by FDA or other governmental entities or there are significant adverse reactions from use of DepoDur.

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 will be effective 180 days from the date of the notice or July 1, 2012. Pursuant to the terms of the agreement the associated supply agreement will also terminate concurrently with the termination of the agreement. In connection with the termination of the agreement, we currently expect that EKR will transfer the New Drug Application for DepoDur back to us, per the terms of the agreement.

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Flynn Pharma Limited

In September 2007, we entered into a marketing agreement with Flynn Pharma Limited, or Flynn, granting them exclusive distribution rights to DepoDur in the European Union, certain other European countries, South Africa and the Middle East. This agreement continues in force for the longer of five years from first commercial sale of DepoDur in the territory covered by the agreement or until the expiration of the last valid claim in our patents covering DepoDur for a maximum term of 15 years from the date of first commercial sale in such territory.

Under this agreement and a separate supply agreement with Flynn, we provide DepoDur manufacturing supply of finished product for sale in the territories licensed by Flynn, and we receive a fixed payment for manufacturing the vials and if net sales of DepoDur in the territory covered by the agreement exceed a certain amount, an additional payment. We are also entitled to receive milestone payments from Flynn upon the achievement by Flynn of certain milestone events.

We and Flynn have the right to terminate the agreement for an uncured material breach by the other party, in connection with the other party s bankruptcy or insolvency or the repossession of all or any material part of the other party s business or assets, or if force majeure prevents other party from performing any of its material obligations for 180 days. We have the right to terminate the agreement if Flynn fails to make its first commercial sale of DepoDur in specified countries covered by the agreement by one year from the later of Flynn s receipt of marketing authorization or pricing approval for DepoDur, or if first commercial sale has not been made within 18 months of Flynn s receipt of marketing authorization or pricing approval for DepoDur.

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. Novo is obligated to pay for all costs incurred by us in conducting such development, manufacturing and technology transfer activities. We are also entitled to receive single-digit royalties on sales of such Novo product for up to twelve years following the first commercial sale of such Novo product. In addition, we are entitled to receive up to $24.0 million in milestone payments based on achievement of specified development events, and up to an additional $20.0 million in milestone payments based on sales of such Novo product exceeding specified amounts. 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. Each party has the right to terminate the agreement for an uncured material breach by the other party or in connection with the other party s bankruptcy or similar event. In addition, Novo has the right to terminate the agreement for convenience at any time upon sixty (60) days notice prior to commercialization of such Novo product and upon ninety (90) days notice thereafter, subject to Novo s payment of a specified termination fee if, after initiation of the technology transfer but prior to commercialization, Novo terminates the agreement other than for certain specified reasons. We also have the right to terminate the agreement if (1) Novo decides to discontinue or terminate the development or commercialization of such Novo product, (2) such Novo product no longer has regulatory approval in any market, or (3) Novo or any of its affiliates or sublicensees of such Novo product challenges the validity or enforceability of any of the licensed patents.

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.

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Feasibility Agreements with Third Parties

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

Manufacturing

We manufacture DepoCyt(e) and DepoDur for our various commercial partners. We also manufacture all of our clinical and commercial supplies of EXPAREL. We manufacture our products in two manufacturing facilities. These facilities are designated as Building 1 and Building 6 and are located within two miles of each other on two separate and distinct sites in San Diego, California. Both of our facilities are inspected regularly and approved for pharmaceutical manufacturing by the FDA, the European Medicines Agency, or the EMA, the Medicines and Healthcare Products Regulatory Agency, or the MHRA, the Drug Enforcement Administration, or the DEA, and the Environmental Protection Agency, or the EPA.

We purchase raw materials and components from third party suppliers in order to manufacture EXPAREL. In most instances, alternative sources of supply are available, although switching to an alternative source would, in some instances, take time and could lead to delays in manufacturing our drug candidates. We also purchase raw materials and equipment from third party suppliers, for the manufacture of DepoCyt(e) and DepoDur. 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.

We provide DepoCyt(e) and DepoDur to our commercial partners on a set cost basis as established by each specific licensing and supply contract. All manufacturing of products, initial product release and stability testing are conducted by us in accordance with cGMP.

Building 1 is an approximately 80,000 square foot concrete structure located on a five acre site. It was custom built as a pharmaceutical R&D and manufacturing facility in August 1995. Activities in this facility include the manufacture of EXPAREL bulk pharmaceutical product candidate in a dedicated production line and its fill/finish into vials, the manufacture of the DepoDur bulk commercial pharmaceutical product, microbiological and quality control testing, product storage, development of analytical methods, research and development, the coordination of clinical and regulatory functions, and general administrative functions. We are renovating the dedicated EXPAREL production line to expand its capacity. This production line is designed to meet forecasted market demands after the initial commercial launch of EXPAREL. We have current plans to further expand 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) and DepoDur into vials, a pilot plant suite for new product development and early stage clinical product production, a microbiology laboratory and miscellaneous support and maintenance areas.

Distribution of our DepoFoam products, including EXPAREL, requires cold-chain distribution, whereby a product must be maintained between specified temperatures. We have validated processes for continuous monitoring of temperature from manufacturing through delivery to the end-user. We and our partners have utilized similar cold-chain processes for DepoCyt(e) and DepoDur.

Due to commercial manufacturing challenges relating to EXPAREL, we previously revised our estimate for product availability from January 2012 to April 2012. We believe we have now addressed these commercial manufacturing challenges that affected our ability to commercially produce EXPAREL. As a result, we currently expect that we will have an appropriate commercial supply of EXPAREL to support anticipated demand for the product following our commercial launch scheduled for April 2012.

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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, 2011, there are over 15 families of patents and patent applications relating to various aspects of the DepoFoam delivery technology. Patents have been issued in numerous countries, with an emphasis on the North American, European and Japanese markets. These patents generally have a term of 20 years from the date of the nonprovisional filing unless referring to an earlier filed application. Some of our U.S. patents have a term from 17 years from the grant date. Our issued patents expire at various dates in the future, with the last currently issued patent expiring in 2019. All of these patent families are assigned solely to us, with the exception of one family relating to DepoFoam formulations of insulin-like growth factor I, which is jointly assigned to us and Novartis Vaccines and Diagnostics, Inc. (formerly Chiron Corporation). In addition, two patents have been filed within the last year relating to either DepoFoam-based products or processes for making DepoFoam.

In regard to patents providing protection for EXPAREL, issued patents in the United States relating to the composition of the product candidate and methods for modifying the rate of drug release of the product candidate expire in November 2013 and January 2017, respectively. Pending U.S. applications relating to the composition of the product candidate and the process for making the product candidate, if granted, would expire in September 2018 and November 2018, respectively. In Europe, granted patents related to the composition of the product candidate expire in November 2014 and September 2018. Pending applications in Europe relating to methods of modifying the rate of drug release of the product candidate and the process for making the product candidate, if granted, would expire in January 2018 and November 2018, respectively. 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.

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

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

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

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

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

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

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

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

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

timeframes. Under PDUFA, the FDA agrees to specific goals for NDA review time through a two-tiered classification system, Priority Review and Standard Review. A Priority Review designation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. For a Priority Review application, the FDA aims to complete the initial review cycle in six months. Standard Review applies to all applications that are not eligible for Priority Review. The FDA aims to complete Standard Review NDAs within a ten-month timeframe. These timeframes may change in October 2012 after the expected reauthorization of PDUFA. 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.

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

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

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

Section 505(b)(2) New Drug Applications

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

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

In the NDA submissions for our product candidates, we intend to follow the development and approval pathway permitted under the FDCA that we believe will maximize the commercial opportunities for these product candidates.

Post-Approval Requirements

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

If new safety issues are identified following approval, the FDA can require the NDA sponsor to revise the approved labeling to reflect the new safety information; conduct post-market studies or clinical trials to assess the new safety information; and implement a REMS program to mitigate newly-identified risks. The FDA may also require post-approval testing, including Phase 4 studies, and surveillance programs to monitor the effect of approved products which have been commercialized, and the

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FDA has the authority to prevent or limit further marketing of a product based on the results of these post-marketing programs. Drugs may be marketed only for approved indications and in accordance with the provisions of the approved label. Further, if we modify a drug, including any changes in indications, labeling or manufacturing processes or facilities, the FDA may require us to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional preclinical studies and clinical trials.

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

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

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

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

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

DEA Regulation

One of our marketed products, DepoDur, is regulated as a controlled substance as defined in the Controlled Substances Act of 1970, or CSA, which establishes registration, security, recordkeeping, reporting, storage, distribution and other requirements administered by the DEA. The DEA is concerned with the control of handlers of controlled substances, and with the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use, and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential abuse liability and Schedule V substances the lowest potential abuse liability, relative to other controlled substances. DepoDur, a sustained-release injectable

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morphine sulfate, is listed as a Schedule II controlled substance under the CSA. Consequently, its manufacture, shipment, storage, sale and use is subject to a high degree of regulation. For example, generally, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription.

Annual registration is required for any facility that manufactures, tests, distributes, dispenses, imports or exports any controlled substance. Except for certain defined co-incident activities, each registration is specific to the particular location, activity and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration must specify which schedules of controlled substances are authorized.

The DEA typically inspects a facility to review its security measures prior to issuing a registration and, thereafter, on a periodic basis. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Required security measures include background checks on employees and physical control of inventory through measures such as vaults, cages, surveillance cameras and inventory reconciliations. Records must be maintained for the handling of all controlled substances, and periodic reports made to the DEA, for example distribution reports for Schedule I and II controlled substances, Schedule III substances that are narcotics, and other designated substances. Reports must also be made for thefts or significant losses of any controlled substance, and to obtain authorization to destroy any controlled substance. In addition, special authorization, notification and permit requirements apply to imports and exports.

In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II. Distributions of any Schedule I or II controlled substance must also be accomplished using special order forms, with copies provided to the DEA. Because DepoDur, a sustained-release injectable morphine sulfate, is regulated as a Schedule II controlled substance, it is subject to the DEA s production and procurement quota scheme. The DEA establishes annually an aggregate quota for how much morphine may be produced in total in the United States based on the DEA s estimate of the quantity needed to meet legitimate scientific and medicinal needs. This limited aggregate amount of morphine that the DEA allows to be produced in the United States each year is allocated among individual companies, who must submit applications annually to the DEA for individual production and procurement quotas. We must receive an annual quota from the DEA in order to produce or procure any Schedule I or Schedule II substance, including morphine sulfate for use in manufacturing DepoDur. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. Our quota of an active ingredient may not be sufficient to meet commercial demand or complete the manufacture or purchase of material required for clinical trials. Any delay or refusal by the DEA in establishing our quota for controlled substances could delay or stop our clinical trials or product launches, or interrupt commercial sales of our products which could have a material adverse effect on our business, financial position and results of operations.

The DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in enforcement action that could have a material adverse effect on our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could eventuate in criminal proceedings.

Individual states also regulate controlled substances, and we are subject to such regulation by several states with respect to the manufacture and distribution of these products.

International Regulation

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

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- 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 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.

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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. A number of states have challenged the constitutionality of certain provisions of the Health Care Reform Law, and the Supreme Court is expected to rule on these issues. 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 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 reimbursment. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and to operate at a reasonable return on investment

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. There can be no assurance that our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third-party payers, that an adequate level or reimbursement will be available so that the third-party payers reimbursement policies will not adversely affect our ability to sell our products profitably.

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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 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 $5000 against any person who is determined to have presented or caused to be presented claims to a federal health care program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Moreover, the lack of uniform court interpretation of the Anti-Kickback Statute makes compliance with the law difficult.

Recognizing that the 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.

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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.

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.

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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, 2011, we employed 133 employees, of which 131 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.

Facilities

We maintain our headquarters, containing executive, commercial, business development and administrative activities, in Parsippany, New Jersey, where we occupy approximately 13,000 square feet under a lease expiring in July 2017. In addition, our research and development and manufacturing facilities are located in San Diego, California, where we occupy two facilities totaling approximately 102,000 square feet under leases expiring in July 2015.

We believe that our manufacturing facilities are sufficient for our current needs. We intend to add new facilities or expand existing facilities as we add employees or expand our geographic markets, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

Legal Proceedings

From time to time, we have been and may again become involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any material litigation and we are not aware of any pending or threatened litigation against us that could have a material adverse effect on our business, operating results, financial condition or cash flows.

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

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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 prospectus 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 plan to commercially launch EXPAREL in April of 2012, but our ability to effectively commercialize and 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 which will be developed on a contract basis with Quintiles;

- 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 or lack of success in its commercialization will have a material and adverse impact on our results of operations.

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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 will be a newly marketed drug, none of the members of the EXPAREL sales force have ever promoted EXPAREL. As a result, we are required to expend significant time and resources to train the sales force to be credible and persuasive in convincing physicians and hospitals to use EXPAREL. In addition, we also must train the sales force to ensure that a consistent and appropriate message about EXPAREL is delivered to our potential customers. If we are unable to effectively train the sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits and risks of EXPAREL and its proper administration, our efforts to successfully commercialize EXPAREL could be put in jeopardy, which could have a material adverse effect on our future revenues and profits.

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

Even if we obtain hospital formulary approval for EXPAREL, physicians must still prescribe EXPAREL for its commercialization to be successful. Because EXPAREL is a new drug with no 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 will also depend 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 could make following FDA approval;
- the relative convenience and ease of administration of EXPAREL;
- the prevalence and severity of adverse events associated with EXPAREL;
- cost of treatment versus economic and clinical benefit in relation to alternative treatments;
- the availability of adequate coverage or reimbursement by third parties, such as insurance companies and other healthcare payers, and by government healthcare programs, including Medicare and Medicaid;

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

- the safety, efficacy and other potential advantages over, and availability of, alternative treatments, including, in the case of EXPAREL, a number of products already used to treat pain in the hospital setting; and

- distribution and use restrictions imposed by the FDA or to which we agree as part of a mandatory risk evaluation and mitigation strategy or voluntary risk management plan.

Our ability to effectively promote and sell EXPAREL and any 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.

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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 will compete with well-established products with similar indications. Competing products available for postsurgical pain management include opioids such as morphine, fentanyl, meperidine and hydromorphone, each of which is available generically from several manufacturers, and several of which are available as proprietary products using novel delivery systems. Ketorolac, an injectable non-steroidal anti-inflammatory drug, or NSAID, is also available generically in the United States from several manufacturers, and Caldolor (ibuprofen for injection), an NSAID, has been approved by the FDA for pain management and fever in adults. In addition, EXPAREL will compete with non-opioid products such as bupivacaine, Marcaine, ropivacaine and other anesthetics/analgesics, all of which are also used in the treatment of postsurgical pain and are available as either oral tablets, injectable dosage forms or administered using novel delivery systems. Additional products may be developed for the treatment of acute pain, including new injectable NSAIDs, novel opioids, new formulations of currently available opioids and NSAIDS, long-acting local anesthetics and new chemical entities as well as alternative delivery forms of various opioids and NSAIDs.

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 currently building our commercial infrastructure for the marketing, sale and distribution of pharmaceutical products. In order to commercialize EXPAREL, we must build our marketing, sales and distribution capabilities. We have entered into an agreement with Quintiles for the outsourcing of our specialty sales force of approximately 60 representatives. 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 and can potentially delay the commercial launch of EXPAREL. 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.

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We rely on third parties to perform many essential services for EXPAREL and any other products that we commercialize, including services related to customer service support, warehousing and inventory program services, distribution services, contract administration and chargeback processing services, accounts receivable management and cash application services, and financial management and information technology services. If these third parties fail to perform as expected or to comply with legal and regulatory requirements, our ability to commercialize EXPAREL will be significantly impacted and we may be subject to regulatory sanctions.

We have entered into agreements with third-party service providers to perform a variety of functions related to the sale and distribution of EXPAREL, key aspects of which are out of our direct control. These service providers provide key services related to customer service support, warehousing and inventory program services, distribution services, contract administration and chargeback processing services, accounts receivable management and cash application services, and financial management and information technology services. In addition, most of our inventory is stored at a single warehouse maintained by one such service provider. We substantially rely on these providers as well as other third-party providers that perform services for us, including entrusting our inventories of products to their care and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter physical or natural damage at their facilities, our ability to deliver product to meet commercial demand would be significantly impaired. In addition, we may engage third parties to perform various other services for us relating to adverse event reporting, safety database management, fulfillment of requests for medical information regarding our product candidates and related services. If the quality or accuracy of the data maintained by these service providers is insufficient, we could be subject to regulatory sanctions.

Distribution of our DepoFoam-based products, including EXPAREL, requires cold-chain distribution provided by third parties, whereby the product must be maintained between specified temperatures. We and our partners have utilized similar cold-chain processes for DepoCyt(e) and DepoDur. If a problem occurs in our cold-chain distribution processes, whether through our failure to maintain our products or product candidates between specified temperatures or because of a failure of one of our distributors or partners to maintain the temperature of the products or product candidates, the product or product candidate could be adulterated and rendered unusable. We have obtained limited inventory and cargo insurance coverage for our products. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. This could have a material adverse effect on our business, financial condition, results of operations and reputation.

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

As of December 31, 2011, we had 133 employees. We will need to substantially expand our managerial, commercial, financial, manufacturing and other personnel resources in order to manage our operations and commercialize 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. We will also need to effectively manage our sales force that we outsource from Quintiles. Our need to effectively manage our operations, growth and various projects requires that we:

- continue the hiring, outsourcing in the case of our sales force, 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 are reliant on our contract with Quintiles for the marketing and sale of EXPAREL.

We have entered into an agreement with Quintiles for the outsourcing of a sales force to commercialize EXPAREL. The risks in outsourcing the sales function to any third party include the following:

- the third party may not apply the expected financial resources or required expertise to successfully market and sell EXPAREL;

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- the third party may not invest in the development of a sales and marketing force and the related infrastructure at levels that ensure that sales of EXPAREL reach their full potential;

- the third party may not comply with applicable legal requirements, including the requirement to promote drug products only for uses for which they have been approved;

- disputes may arise between us and the third party that may delay the commercialization of EXPAREL or adversely affect its sales or profitability; or

- the third party may enter into agreements with other parties that have products that could compete with EXPAREL.

We are substantially dependent on the success of Quintiles in performing its responsibilities and the continued cooperation of Quintiles, including Quintiles cooperation with our training of the sales and marketing force. Quintiles may not cooperate with us to perform its obligations under our agreement and we cannot control the amount and timing of Quintiles resources that will be devoted to the marketing and sale of EXPAREL. The occurrence of any of these events could adversely affect the commercialization of EXPAREL and materially harm our business and stock price by slowing the pace of growth of such sales, by reducing the profitability of EXPAREL or by adversely affecting the reputation of EXPAREL in the market.

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

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

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the development and manufacturing expertise for our DepoFoam delivery technology and the commercialization expertise of certain members of our senior management. In particular, we are highly dependent on the skills and leadership of our management team, including David Stack, our president and chief executive officer. If we lose one or more of these key employees, our ability to successfully implement our business strategy could be seriously harmed. Replacing key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate additional key personnel.

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

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

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for DepoCyt(e), 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.

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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 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 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. For example, due to commercial manufacturing challenges relating to EXPAREL, we revised our estimate for product availability from January 2012 to April 2012. Although we currently expect that we will have manufactured sufficient quantities of EXPAREL by April 2012 to meet customer demands at launch, we cannot guarantee that sufficient quantities of EXPAREL will be available by April 2012 or at all.

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.

Any 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.

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In addition, the procurement time for the equipment we use to manufacture EXPAREL require 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) and DepoDur and we only have two FDA approved manufacturing facilities. Our inability to continue manufacturing adequate supplies of DepoCyt(e) and DepoDur could result in a disruption in the supply of DepoCyt(e) and DepoDur to our partners.

We are the sole manufacturer of DepoCyt(e) and DepoDur. We develop and manufacture DepoCyt(e) and DepoDur at our facilities in San Diego, California, which are the only FDA approved sites for manufacturing DepoCyt(e) and DepoDur in the world. Our San Diego facilities are subject to the risks of a natural or man-made disaster, including earthquakes and fires, or other business disruption. 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) and DepoDur if there were a catastrophic event or failure of our current manufacturing system. If we are required to change or add a new manufacturer or supplier, the process would likely require prior FDA and/or equivalent foreign regulatory authority approval, and would be very time consuming. An inability to continue manufacturing adequate supplies of DepoCyt(e) and DepoDur at our facility in San Diego, California could result in a disruption in the supply of DepoCyt(e) and DepoDur to our partners and breach of our contractual obligations.

If we fail to manufacture DepoCyt(e) and DepoDur we will lose revenues and be in breach of our licensing obligations.

We have licensed the commercial rights in specified territories of the world to market and sell our products, DepoCyt(e) and DepoDur. Under those licenses we have obligations to manufacture commercial product for our commercial partners. 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 will be effective 180 days from the date of the notice or July 1, 2012. If we are unable to timely fill the orders placed with us by our commercial partners, we will potentially lose revenue and be in breach of our licensing obligations under the agreements. In addition, we may be in breach of our obligations to comply with our supply and distribution agreements for DepoCyt(e) and DepoDur, which would in turn be a breach of our obligations under our amended and restated royalty interests assignment agreement, or the Amended and Restated Royalty Interests Assignment Agreement, with Royalty Securitization Trust I, an affiliate of Paul Capital Advisors, LLC, or Paul Capital. See Risk Factors Risks Related to Our Financial Condition and Capital Requirements Under our financing arrangement with Paul Capital, upon the occurrence of certain events, Paul Capital may require us to repurchase the right to receive royalty payments that we assigned to it, or may foreclose on certain assets that secure our obligations to Paul Capital. Any exercise by Paul Capital of its right to cause us to repurchase the assigned right or any foreclosure by Paul Capital would adversely affect our results of operations and our financial condition.

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

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls, and the use of specialized processing equipment. We must comply with federal, state and foreign regulations, including current Good Manufacturing Practices, or cGMP, regulations and in the case of the manufacturing of DepoDur required government licenses and quotas regarding the manufacture, procurement, storage and use of controlled substances. 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.

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

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

- difficulty or inability to secure financing to fund development activities for such development, acquisition or in-licensed products or technologies;
- incurrence of substantial debt or dilutive issuances of securities to pay for development, acquisition or in-licensing of new products;
- disruption of our business and diversion of our management s time and attention;
- higher than expected development, acquisition or in-license and integration costs;
- exposure to unknown liabilities;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- inability to retain key employees of any acquired businesses;
- difficulty in managing multiple product development programs; and
- inability to successfully develop new products or clinical failure.

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

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

Our manufacturing activities involve the controlled storage, use and disposal of hazardous materials, including the components of our products, product candidates and other hazardous compounds. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling, release and disposal of, and exposure to, these hazardous materials. Violation of these laws and regulations could lead to substantial fines and penalties. Although we believe that our safety procedures for handling and disposing of these materials

comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials 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 development or commercialization of our product

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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 FDA s longstanding 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 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 completion as agreed with the FDA. 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 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 of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing and generating revenues from the sale of EXPAREL or any product candidate.

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

Following approval of EXPAREL or any of our product candidates, if we or others later identify undesirable side effects caused by such products:

- regulatory authorities may require the addition of unfavorable labeling statements, specific warnings or a contraindication;

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- 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. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to issue warning letters or untitled letters, suspend or withdraw an approved product from the market, require a recall or institute fines or civil fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business.

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

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

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

For example, the FDA informed us that certain adverse event reports related to DepoCyt(e) and DepoDur submitted to us during the previous two years were not submitted by us to the FDA within the required 15-day timeframe for reporting such

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events. In response to the FDA s observations, we enhanced our reporting procedures and hired additional personnel to support our pharmacovigilance efforts.

If we fail to comply with federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

As a pharmaceutical company, even though we do not provide healthcare services or receive payments directly from or bill directly to Medicare, Medicaid or other third-party payers for our products, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients rights are and will be applicable to our business. We would be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which constrains our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

- federal physician self-referral laws, such as the Stark law, which prohibit a physician from making a referral to a provider of certain health services with which the physician or the physician s family member has a financial interest, and prohibit submission of a claim for reimbursement pursuant to a prohibited referral;

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

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

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under the U.S. federal Anti-Kickback Statute, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Recently, several pharmaceutical and other healthcare companies have been prosecuted under the federal false claims laws for allegedly inflating drug prices they report to pricing services, which in turn are used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. To the extent that any product we make is sold in a foreign country, we may be subject to similar foreign laws and regulations.

Further, there has been a recent trend in the increase of federal and state laws and regulations regarding consulting arrangements with physicians. Some states, such as California, Massachusetts and Vermont, mandate that we comply with a state code of conduct, disclose marketing payments made to physicians, and 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

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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, DepoCyt(e) and DepoDur is highly regulated and technically complex.

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

The manufacturing techniques and facilities used for the manufacture and supply of our products must be operated in conformity with cGMP and other FDA and DEA regulations. 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 and DEA 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 and other regulatory authorities.

Any failure to comply with regulatory and other legal requirements applicable to the manufacture, supply and distribution of our products could lead to remedial action (such as recalls), civil and criminal penalties and delays in manufacture, supply and distribution of our products. For instance, in connection with routine inspections of one of our manufacturing facilities in April and May 2008, the FDA issued a Form 483 Notice of Inspectional Observations identifying certain deficiencies with respect to our laboratory control system for Depocyt(e). As a result, we did not release new lots of Depocyt(e) for a limited time period as we validated a new assay. We also submitted the new assay to the FDA in July 2008 and in August 2008 we began releasing new lots of DepoCyt(e).

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

The testing, manufacturing, labeling, safety, advertising, promotion, storage, sales, distribution, export and marketing, among other things, of our products EXPAREL, DepoCyt(e) and DepoDur are subject to extensive regulation by governmental authorities in the United States and elsewhere throughout the world. Quality control and manufacturing procedures regarding EXPAREL, DepoCyt(e) and DepoDur must conform to cGMP. Regulatory authorities, including the FDA, periodically inspect manufacturing facilities to assess compliance with cGMP. Our failure or the failure of our contract manufacturers to comply with the laws administered by the FDA or other governmental authorities could result in, among other things, any of the following:

- product recall or seizure;
- suspension or withdrawal of an approved product from the market;
- interruption of production;
- operating restrictions;
- warning letters;
- injunctions;
- fines and other monetary penalties;
- criminal prosecutions; and
- unanticipated expenditures.

If the government or third-party payers fail to provide coverage and adequate coverage and payment rates for EXPAREL, DepoCyt(e), DepoDur or any future products we may develop, license or acquire, if any, or if hospitals choose to use therapies that are less expensive, our revenue and prospects for profitability will be limited.

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

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

- new requirements to report certain financial arrangements with physicians and others, including reporting any transfer of value made or distributed to prescribers and other healthcare providers and reporting any investment interests held by physicians and their immediate family members during each calendar year beginning in 2012, with reporting starting in 2013;

- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians, effective April 1, 2012;

- a licensure framework for follow-on biologic products;

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical

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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. A number of states have challenged the constitutionality of certain provisions of the Health Care Reform Law, and many of these court challenges are still pending final adjudication. 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. Most recently, on August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, creates the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee may consider all elements of discretionary and non-discretionary spending, and its recommendations could result in reduced spending under Medicare and Medicaid for prescription drugs. In the event that the Joint Select Committee is unable to achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, or Congress does not act on the committee s recommendation, without amendment, by December 23, 2011, an automatic reduction is triggered. These automatic cuts would be made to several government programs and, with respect to Medicare, would include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. The full impact on our business of the new law 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.

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

Public concern regarding the safety of drug products such as EXPAREL could result in the inclusion of unfavorable information in our labeling, or require us to undertake other activities that may entail additional costs.

In light of widely publicized events concerning the safety risk of certain drug products, the FDA, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and the establishment of risk management programs that may, for example, restrict distribution of drug products after approval. The Food and Drug Administration

Amendments Act of 2007, or FDAAA, grants significant expanded authority to the FDA, much of which is aimed at improving the safety of drug products before and after approval. In particular, the FDAAA authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. It also significantly expands the federal government s clinical trial registry and results databank, which we expect will result in significantly increased government oversight of clinical trials. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties. The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of data from our clinical trials. Data from clinical trials may receive greater scrutiny, particularly with respect to safety, which may make the FDA or other regulatory authorities more likely to require additional preclinical studies or clinical trials. If the FDA requires us to 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.

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Our product, DepoDur, is subject to regulation by the Drug Enforcement Administration and such regulation may affect the sale of DepoDur.

Products used to treat and manage pain, especially in the case of opioids, are from time to time subject to negative publicity, including illegal use, overdoses, abuse, diversion, serious injury and death. These events have led to heightened regulatory scrutiny. The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use, and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential abuse liability and Schedule V substances the lowest potential abuse liability relative to other controlled substances. DepoDur contains morphine, and it is regulated as a Schedule II controlled substance. Despite the strict regulations on the marketing, prescribing and dispensing of such substances, illicit use and abuse of morphine does occur. Thus, the marketing of DepoDur by our partners may generate public controversy that may adversely affect sales of DepoDur and decrease the revenue we receive from the sale of DepoDur.

In addition, we and our contract manufacturers are subject to ongoing DEA regulatory obligations, including, among other things, annual registration renewal, security, recordkeeping, customer verification and suspicious order identification systems, theft and loss reporting, periodic inspection and obtaining sufficient quota allotments for the manufacture and procurement of raw material for commercial production of our products. The DEA, and some states, conduct periodic inspections of registered establishments that handle controlled substances. Facilities that conduct research, manufacture, store, distribute, import or export controlled substances must be registered to perform these activities and have the security, control and inventory mechanisms required by the DEA to prevent drug loss and diversion. Failure to maintain compliance, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, results of operations, financial condition and prospects. The DEA may fail to grant requested quota allocations, may seek civil penalties, may refuse to renew necessary registrations, or may initiate proceedings to revoke those registrations. In certain circumstances, alleged violations of DEA requirements could lead to criminal proceedings.

Individual states also have controlled substances laws. Though state controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs, as well. While some states automatically schedule a drug when the DEA does so, in other states there has to be rulemaking or a legislative action. State scheduling may delay commercial sale of any controlled substance drug product for which we obtain federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product. We or our partners must also obtain separate state registrations in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions from the states in addition to those from the DEA or otherwise arising under federal law.

Risks Related to Intellectual Property

The patents and the patent applications that we have covering our products are limited to specific injectable formulations, processes and uses of drugs encapsulated in our DepoFoam drug delivery technology and our market opportunity for our product candidates may be limited by the lack of patent protection for the active ingredient itself and other formulations and delivery technology and systems that may be developed by competitors.

The active ingredients in EXPAREL, DepoCyt(e) and DepoDur are bupivacaine, cytarabine and morphine, respectively. Patent protection for the bupivacaine, cytarabine and morphine molecules themselves has expired and generic immediate-release products are available. As a result, competitors who obtain the requisite regulatory approval can offer products with the same active ingredients as EXPAREL, DepoCyt(e) and

DepoDur so long as the competitors do not infringe any process, use or formulation patents that we have developed for these drugs encapsulated in our DepoFoam drug delivery technology.

For example, we are aware of at least one long acting injectable bupivacaine product in development which utilizes an alternative delivery system to EXPAREL. Such a product is similar to EXPAREL in that it also extends the duration of effect of bupivacaine, but achieves this clinical outcome using a completely different drug delivery system compared to our DepoFoam drug delivery technology.

The number of patents and patent applications covering products in the same field as EXPAREL indicates that competitors have sought to develop and may seek to market competing formulations that may not be covered by our patents and patent applications. The commercial opportunity for EXPAREL could be significantly harmed if competitors are able to develop and commercialize alternative formulations of bupivacaine that are long acting but outside the scope of our patents.

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Now that EXPAREL is approved by the FDA, one or more third parties may challenge the patents covering this product, which could result in the invalidation or unenforceability of some or all of the relevant patent claims. For example, if a third party files an Abbreviated New Drug Application, or ANDA, for a generic drug product containing bupivacaine and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA s Orange Book with respect to our NDA for EXPAREL; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third-party s generic drug product. A certification that the new product will not infringe the Orange Book-listed patents for EXPAREL, or that such patents are invalid, is called a paragraph IV certification. If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third-party s ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third-party s ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party. If we do not file a patent infringement lawsuit within the required 45-day period, the third-party s ANDA will not be subject to the 30-month stay. Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management s attention from our 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), DepoDur, 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. The patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

The degree of future protection for our proprietary rights is uncertain, because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we may not have been the first to make the inventions covered by each of our pending patent applications and issued patents;
- we may not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our product candidates or technologies;
- it is possible that none of the pending patent applications will result in issued patents;

- the issued patents covering our product candidates may not provide a basis for commercially viable active products, may not provide us with any competitive advantages, or may be challenged by third parties;

- we may not develop additional proprietary technologies that are patentable; or

- patents of others may have an adverse effect on our business.

Patent applications in the United States are maintained in confidence for at least 18 months after their earliest effective filing date. Consequently, we cannot be certain we were the first to invent or the first to file patent applications on EXPAREL, our DepoFoam drug delivery technology or any 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.

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In addition, some countries, including many in Europe, do not grant patent claims directed to methods of treating humans, and in these countries patent protection may not be available at all to protect our product candidates. Even if patents issue, we cannot guarantee that the claims of those patents will be valid and enforceable or provide us with any significant protection against competitive products, or otherwise be commercially valuable to us.

Some of our older patents have already expired. In the cases of DepoCyt(e) and DepoDur, key patents providing protection in Europe have expired. In the case of EXPAREL 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, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

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

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

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

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

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

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

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

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

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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 $43.3 million, $27.1 million and $31.7 million, for the years ended December 31, 2011, 2010, and 2009, respectively. As of December 31, 2011, we had an accumulated deficit of $180.2 million. These losses, among other things, have had, and will continue to have, an adverse effect on our stockholders equity and working capital. We incurred increased pre-commercialization expenses during 2010 and 2011 as we prepared for the potential commercial launch of EXPAREL, and we expect to incur significant sales, marketing and manufacturing expenses, as well as continued development expenses related to the commercialization of EXPAREL. As a result, we expect to continue to incur significant losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

We may never become profitable.

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

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

We anticipate incurring significant additional costs associated with the commercialization of EXPAREL. We also do not anticipate that we will achieve profitability for a period of time after generating material revenues, if ever. If we are unable to generate revenues, we will not become profitable and may be unable to continue operations without continued funding.

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

adversely affect our results of operations and our financial condition.

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

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repurchase the assigned right or any foreclosure by Paul Capital would adversely affect our results of operations and our financial condition.

Our debt obligations expose us to risks that could adversely affect our business, operating results and financial condition. We may need to raise additional capital to pay our indebtedness as it comes due.

We have a substantial level of debt. As of December 31, 2011, we had $26.3 million in aggregate principal amount of indebtedness outstanding, not including our obligation under the Amended and Restated Royalty Interests Assignment Agreement with Paul Capital. We may need to raise additional capital to pay our indebtedness as it comes due. If we are unable to obtain funds necessary to make required payments, or if we fail to comply with the various requirements of our indebtedness, we would be in default, which would permit the holders of our indebtedness to accelerate the maturity of the indebtedness and could cause defaults under any indebtedness we may incur in the future. Any default under our indebtedness would have a material adverse effect on our business, operating results and financial condition. If we are unable to refinance or repay our indebtedness as it becomes due, we may become insolvent and be unable to continue operations. The level and nature of our indebtedness, among other things, could:

- make it difficult for us to make payments on our outstanding debt from time to time or to refinance it;
- make it difficult for us to obtain any necessary financing in the future for working capital, capital expenditures, debt service, product and company acquisitions or general corporate purposes;
- limit our flexibility in planning for or reacting to changes in our business including life cycle management;
- reduce funds available for use in our operations;
- impair our ability to incur additional debt because of financial and other restrictive covenants;
- make us more vulnerable in the event of a downturn in our business;
- place us at a possible competitive disadvantage relative to less leveraged competitors and competitors that have better access to capital resources;
- restrict the operations of our business as a result of provisions in the Amended and Restated Royalty Interests Assignment Agreement with Paul Capital that restrict our ability to (i) amend, waive any rights under, or terminate any material agreements relating to DepoCyt(e) and DepoDur, (ii) enter into any new agreement or amend or fail to exercise any of our material rights under existing agreements that would materially adversely affect Paul Capital s royalty interest, and (iii) sell any material assets related to DepoCyt(e) or DepoDur; or
- impair our ability to merge or otherwise effect the sale of the Company due to the right of the holders of certain of our indebtedness to accelerate the maturity date of the indebtedness in the event of a change of control of the Company.

We may need to raise additional capital to pay our indebtedness as it comes due. If we are unable to obtain funds necessary to make required payments, or if we fail to comply with the various requirements of our indebtedness, we would be in default, which would permit the holders of our indebtedness to accelerate the maturity of the indebtedness and could cause defaults under any indebtedness we may incur in the future. Any default under our indebtedness would have a material adverse effect on our business, operating results and financial condition. If we are unable to refinance or repay our indebtedness as it becomes due, we may become insolvent and be unable to continue operations.

For example, our loan and security agreement governing our $26.3 million credit facility with Hercules Technology Growth Capital, Inc. and Hercules Technology III, L.P., as lenders, or the Hercules Credit Facility, contains a number of affirmative and restrictive covenants, including reporting requirements and other collateral limitations, certain limitations on liens and indebtedness, dispositions, mergers and acquisitions, restricted payments and investments, corporate changes and limitations on waivers and amendments to certain agreements, our organizational documents, and documents relating to debt that is subordinate to our obligations under the Hercules Credit Facility. Our failure to comply with the covenants in the loan and security agreement governing the Hercules Credit Facility could result in an event of default that, if not cured or waived, could result in the acceleration of all or a substantial portion of our debt and potential foreclosure on the assets pledged to secure the debt.

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

We were incorporated in December 2006 and have only been conducting operations with respect to EXPAREL since March 2007. Our operations to date have been limited to organizing and staffing our company, conducting product development activities, including clinical trials and manufacturing development activities, for EXPAREL and manufacturing and related activities for DepoCyt(e) and DepoDur. Further, in 2010 and 2011 we began to establish our commercial infrastructure for EXPAREL. 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.

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Developing and commercializing products for use in the hospital setting, conducting clinical trials, establishing outsourced manufacturing relationships and successfully manufacturing and marketing drugs that we may develop is expensive. We may need to raise additional capital to:

- continue to fund our operations
- continue our efforts to hire, and outsource through our relationship with Quintiles, 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, including certain launch activities for EXPAREL. 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 launch EXPAREL without substantial delays, including engaging additional sales and marketing personnel and contracting with third parties for warehousing, distribution, cash collection and related commercial activities;

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

- our execution of other collaborative, licensing 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,

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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 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.

Compliance with Section 404 of the Sarbanes-Oxley Act of 2002 requires our management to devote substantial time to compliance initiatives, and if our independent registered public accounting firm is required to provide an attestation report on our internal controls but is unable to provide an unqualified attestation report, 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 will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, hire

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

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

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 2018 for state purposes if we have

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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 if we have a cumulative change in ownership of more than 50% within a three-year period. Such an ownership change may be triggered by the completion of our initial public offering, private placements and other transactions that have occurred, coupled with any future offering that we may undertake to fulfill our need to raise substantial additional funding to finance our operations. In the event such an ownership change occurs, we will be limited regarding the amount of net operating loss carryforwards and research tax credits that could be utilized annually in the future to offset taxable income or tax, respectively. Any such annual limitation may significantly reduce the utilization of the net operating loss carryforwards and research tax credits before they expire. In addition, California and certain states have suspended use of net operating loss carryforwards for certain taxable years, and other states are considering similar measures. As a result, we may incur higher state income tax expense in the future. Depending on our future tax position, continued suspension of our ability to use net operating loss carryforwards in states in which we are subject to income tax could have an adverse impact on our results of operations and financial condition.

Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic 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 to Ownership of Our Common Stock

The market price of our common stock is highly volatile.

Our stock price is volatile, and from February 3, 2011, the first day of trading of our common stock, to December 31, 2011, the trading prices of our stock have ranged from $6.16 to $15.34 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;

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- additions or departures of key scientific or management personnel;

- issuances of debt, equity or convertible securities;

- changes in the market valuations of similar companies; and

- the other factors described in this Risk Factors section.

In addition, the stock market in general, and the market for small pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

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.

Our executive officers, directors and 5% stockholders and their affiliates beneficially own approximately 61% 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 control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This concentration of ownership could delay or prevent any acquisition of our company on terms that other stockholders may desire.

Sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise adequate capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

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.

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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 102,000 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 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 material litigation and we are not aware of any pending or threatened litigation against us that could have a material adverse effect on our business, operating results, financial condition or cash flows.

Item 4. Mine Safety Disclosures

Not applicable

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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 on The NASDAQ Global Market under the symbol PCRX since our initial public offering on February 3, 2011. Prior to that 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 The NASDAQ Global Market:

Year Ended 2011	High	Low
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 March 22, 2012, the closing price of our common stock as reported on The NASDAQ Global Market was $10.98 per share and we had approximately 29 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 current or future financing instruments, provisions of applicable law and other factors the board deems relevant. Our ability to pay dividends on our common stock is limited by the covenants of our loan and security agreement governing the Hercules Credit Facility and may be further restricted by the terms of any of our future indebtedness. See Risk Factors Risks Related to Our Financial Condition and Capital Requirements Our debt obligations expose us to risks that could adversely affect our business, operating results and financial condition.

USE OF PROCEEDS

In February 2011, we completed the initial public offering of our common stock pursuant to a registration statement on Form S-1, as amended (File No. 333-170245) that was declared effective on February 2, 2011.

As of December 31, 2011, we estimate that we have used all of the net proceeds from the initial public offering for the planned manufacture and commercialization of EXPAREL in the United States and for working capital and other general corporate purposes.

Purchases and Sales of Unregistered Securities

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

Item 6. Selected Financial Data

Not applicable

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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.

On October 28, 2011, the United States Food and Drug Administration, or FDA, approved our New Drug Application, or NDA, for our lead product candidate, EXPAREL, a liposome injection of bupivacaine, an amide-type local anesthetic, indicated for administration into the surgical site to produce postsurgical analgesia. We have developed a sales force entirely dedicated to commercializing EXPAREL comprised of approximately 60 representatives, seven regional managers and a national sales manager. We have developed this sales force pursuant to a contract with Quintiles Commercial US, Inc., a division of Quintiles, Inc., or Quintiles, and under the terms of this contract we have the flexibility to hire all or a portion of the sales force dedicated to commercializing EXPAREL as full-time employees of Pacira, upon 60 days notice to Quintiles. We expect to have successfully resolved the commercial manufacturing challenges for EXPAREL to allow product to be commercially available in April 2012, and we believe that our pre-launch activities including significant personal interactions with our hospital customers, position us for a successful launch of EXPAREL.

Our two marketed products, DepoCyt(e) and DepoDur, and our proprietary DepoFoam extended release drug delivery technology were acquired as part of the acquisition of PPI-California on March 24, 2007, or the Acquisition. DepoCyt(e) is a sustained release liposomal formulation of the chemotherapeutic agent cytarabine and is indicated for the intrathecal treatment of lymphomatous meningitis. DepoCyt(e) was granted accelerated approval by the FDA in 1999 and full approval in 2007. DepoDur is an extended release injectable formulation of morphine indicated for epidural administration for the treatment of pain following major surgery. DepoDur was approved by the FDA in 2004.

Since inception, we have incurred significant operating losses. Our net loss was $43.3 million for the year ended December 31, 2011, including research and development expenses of $14.9 million. We do not expect our currently marketed products, other than EXPAREL, to generate revenue that is sufficient for us to achieve profitability because we expect to continue to incur significant expenses as we commercially launch EXPAREL and advance the development of our 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

On January 3, 2012, EKR delivered a notice to terminate the licensing, distribution and marketing agreement with us. Pursuant to the terms of the agreement, the termination of the agreement will be effective 180 days from the date of the notice or July 1, 2012. Pursuant to the terms of the agreement the associated supply agreement will also terminate concurrently with the termination of the agreement. As a result, we expect the supply and royalty revenues from DepoDur to decrease in the future and we do not intend to re-license out the rights to DepoDur.

License and Development Agreements

In January 2011, we entered into an agreement with Novo Nordisk A/S, or Novo, pursuant to which it 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. 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. Novo is obligated to pay for all costs incurred by us in conducting such development, manufacturing and technology transfer activities. We are also entitled to

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receive single-digit royalties on sales of such Novo product for up to twelve years following the first commercial sale of such Novo product. In addition, we are entitled to receive up to $24.0 million in milestone payments based on achievement of specified development events, and up to an additional $20.0 million in milestone payments based on sales of such Novo product exceeding specified amounts. 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.

Financial Operations Overview

Revenues

Our revenue derived from DepoCyt(e) and DepoDur, our products manufactured by us and sold by our commercial partners, is comprised of two components: supply revenue and royalties. Supply revenue is derived from a contractual supply price paid to us by our commercial partners. Royalties are recognized as the product is sold by our commercial partners and are typically calculated as a percentage of the net selling price, which is net of discounts, returns, and allowances incurred by our commercial partners, net of the agreed upon supply price. Accordingly, the primary factors that determine our revenues derived from DepoCyt(e) and DepoDur are:

- the level of orders submitted by our commercial partners;
- the level of prescription and institutional demand for our products;
- unit sales prices;
- the amount of gross-to-net sales adjustments realized by our commercial partners; and
- exchange rates on European sales, denominated in euros, that are repatriated in dollars.

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. We expect the supply and royalty revenues from DepoDur to decrease in the future due to the upcoming termination of our licensing, distribution and marketing agreement with EKR in July 2012.

Cost of Revenues

Cost of revenues consists of the costs associated with producing our products for our commercial partners and providing research and development services to our collaboration partners. In particular, our cost of revenues includes:

- manufacturing overhead and fixed costs associated with running two cGMP manufacturing facilities, including salaries and related costs of personnel involved with our manufacturing activities;

- allocated overhead, personnel conducting research and development, as well as research and development performed by outside contractors or consultants for our collaborative licensing and development activities;

- royalties due to third parties on our revenues;

- packaging, testing, freight and shipping;

- the cost of active pharmaceutical ingredients; and

- overhead costs associated with excess manufacturing capacity are charged to cost of revenue as incurred.

We expect the cost of revenues to increase in the future due to the classification of EXPAREL manufacturing expenses from research and development expenses to costs of revenues based on the FDA approval of EXPAREL on October 28, 2011, and the anticipated commercial launch of EXPAREL in April 2012.

Research and Development Expenses

Our research and development expenses consist of expenses incurred in developing, testing, manufacturing and seeking regulatory approval of EXPAREL and our product candidates, including:

- expenses associated with regulatory submissions, clinical trials and manufacturing, including additional expenses to prepare for the commercial manufacture of EXPAREL, such as the hiring and training of additional personnel;

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

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- 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

- facility, maintenance, and allocated rent, utilities, and depreciation and amortization, and other related expenses.

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

From the Acquisition Date through December 31, 2011, we incurred research and development expenses of $113.6 million, of which $109.5 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. These expenditures are subject to numerous uncertainties regarding timing and cost to completion. Completion of clinical trials may take several years or more and the length of time generally varies according to the type, complexity, novelty and intended use of a product candidate. We are currently unable to determine our future research and development expenses related to EXPAREL because the requirements of any additional clinical trials of EXPAREL for additional indications have yet to be determined. The cost of clinical development may vary significantly due to factors such as the scope, rate of progress, expense and outcome of our clinical trials and other development activities.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries, benefits and other related costs, including stock-based compensation, for personnel serving in our executive, finance, accounting, legal, human resource, and sales and marketing functions. Our selling, general and administrative expenses also include facility and related costs not included in research and development expenses and cost of revenues, professional fees for legal, patent expenses, consulting, tax and accounting services, insurance, depreciation and general corporate expenses. We also include the cost our prospective outcome studies, which are designed for commercial purposes and do not have any regulatory endpoints, in selling, general and administrative expenses. We expect that our selling, general and administrative expenses will increase with the continued development and potential commercialization of our product candidates and increased expenses associated with us operating as a public company. Additionally, in 2011 we built a commercial infrastructure for the launch of EXPAREL and we expect our selling costs to increase in the future due to the launch efforts of our commercial organization and our Quintiles sales force, which will increase our selling, general and administrative expenses.

Interest Income (Expense)

Interest income (expense) consists of interest income, interest expense, and royalty interest obligation. Interest income consists of interest earned on our cash and cash equivalents, short-term investments and amortization of discount on a note receivable from one of our commercial partners. Interest expense consists primarily of cash and non-cash interest costs related to our credit facility, our secured and unsecured notes issued to certain of our investors that converted into common stock upon completion of our initial public offering, and negotiated rent deferral payments.

Royalty Interest Obligation

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.

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Critical Accounting Policies and Use of Estimates

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

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

Revenue Recognition

We recognize revenue in accordance with SEC Staff Accounting Bulletin, or SAB, No. 104, *Revenue Recognition*, and ASC 605, *Revenue Recognition*.

We recognize supply revenue from products manufactured and supplied to our commercial partners, when the following four basic revenue recognition criteria under the related accounting guidance are met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. Prior to the shipment of our manufactured products, we conduct initial product release and stability testing in accordance with cGMP. Our commercial partners can return the products within contracted specified timeframes if the products do not meet the applicable inspection tests. We estimate our return reserves based on our experience with historical return rates. Historically, our product returns have not been material.

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.

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 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.

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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 payments made to employees and directors based on estimated grant date fair values. We use the straight-line method to allocate compensation cost to reporting periods over each optionee s requisite service period, which is generally the vesting period. We estimate the fair value of our stock-based awards to employees and directors using the Black-Scholes option valuation model, or Black-Scholes model. The Black-Scholes model requires the input of subjective assumptions, including the expected stock price volatility, the calculation of expected term and the fair value of the underlying common stock on the date of grant, among other inputs.

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

	Years Ended December 31,		
	2011	**2010**	**2009**
Expected dividend yield	None	None	None
Risk free interest rate	1.1-2.7%	1.6 -3.4%	2.1-2.7%
Expected volatility	76.8%	80.8%	82.0%
Expected life of options	6.73 years	6.25 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.

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Results of Operations

Comparison of Years Ended December 31, 2011, 2010 and 2009

Revenues

The following table sets forth a summary of our supply and royalty revenue and collaborative licensing and development revenue for the years ended December 31, 2011, 2010 and 2009, including changes as a percentage (dollar amounts in thousands):

	Year Ended December 31,			2011 versus 2010	2010 versus 2009
	2011	2010	2009	% Increase/ (Decrease)	
DepoCyt(e)					
Supply revenue	$ 6,895	$ 6,843	$ 5,882	1%	16%
Royalties	3,547	3,411	3,708	4%	(8)%
	10,442	10,254	9,590	2%	7%
DepoDur					
Supply revenue		797	442	(100)%	80%
Royalties	173	294	336	(41)%	(13)%
	173	1,091	778	(84)%	40%
Total DepoCyt(e) and DepoDur supply and royalty revenue	10,615	11,345	10,368	(6)%	9%
Collaborative licensing and development revenue	5,074	3,217	4,638	58%	(31)%
Total revenues	$ 15,689	$ 14,562	$ 15,006	8%	(3)%

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 are both deferred and recognized on a straight line basis over the expected contract period. This was partially offset by a $0.7 million decrease in supply and royalty revenue primarily due to the lower number of DepoDur lots sold to our commercial partners. In December 2011, the Company was notified of EKR s intent to exit the DepoDur market.

Revenues decreased by $0.4 million, or 3%, in the year ended December 31, 2010 as compared to 2009. The decrease was primarily due to a decrease in collaborative licensing by $1.4 million due to a reduction in contract development activities for Amylin as well as a one-time reimbursement of equipment by Amylin in 2009. This was partially offset by supply and royalty revenue increase of $1.0 million primarily due to higher sales of DepoCyt(e) to our European partner, driven by fulfillment of an order backlog during 2010 offset by the foreign exchange rate impact on sales in Europe.

Cost of Revenues

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

	Year Ended December 31,			2011 versus 2010	2010 versus 2009
	2011	2010	2009	% Increase/ (Decrease)	
Cost of goods sold	$ 15,310	$ 11,374	$ 10,088	35%	13%
Cost of collaborative licensing and development	1,429	902	2,213	58%	(59)%
Total cost of revenues	$ 16,739	$ 12,276	$ 12,301	36%	(0)%

Total cost of revenues increased $4.5 million, or 36% for 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.

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Total cost of revenues of $12.3 million, remained consistent in 2010 as compared to 2009. Cost of collaborative licensing and development decreased, as our personnel were re-assigned subsequent to the reduction in contract development activities for Amylin. The reduction was offset by an increase in cost of goods sold due to higher volume of DepoCyt(e) supply sales and higher cost of maintenance activities.

Research and Development Expenses

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

	Year Ended December 31,			2011 versus 2010	2010 versus 2009
	2011	2010	2009	% Increase/ (Decrease)	
Research and development	$ 14,873	$ 18,628	$ 26,233	(20)%	(29)%

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.

Research and development expenses decreased by $7.6 million, or 29%, in the year ended December 31, 2010 as compared to 2009. This decrease resulted primarily from a $6.7 million decrease in third party clinical trials costs due to the completion of our pivotal Phase 3 placebo controlled studies.

In the years ended December 31, 2011, 2010 and 2009, research and development expenses attributable to EXPAREL were $14.4, or 97%, $18.4 million, or 99%, and $25.2 million, or 96%, of total research and development expenses, respectively. The EXPAREL-related research and development expenses incurred during the year ended December 31, 2011 include manufacturing-related costs that we expensed prior to regulatory approval of the product. The remaining research and development expenses 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,			2011 versus 2010	2010 versus 2009
	2011	2010	2009	% Increase/ (Decrease)	
Selling, general and administrative	$ 20,159	$ 6,367	$ 5,020	217%	27%

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 $9.8 million to $10.2 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.

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Selling, general and administrative expenses increased by $1.3 million, or 27%, in the year ended December 31, 2010 as compared to 2009. Selling expenses remained constant at $0.4 million for the year ended December 31, 2010 and 2009. General and administrative expenses increased by $1.4 million to $6.0 million in the year ended December 31, 2010 as compared to $4.6 million in 2009. The increase was primarily due to higher costs associated with completing three years of audits and tax filings during 2010.

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,			2011 versus 2010	2010 versus 2009
	2011	2010	2009	% Increase/ (Decrease)	
Impairment of long-lived assets	$ 3,019	$	$	n/a	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 upcoming termination of our licensing, distribution and marketing agreement with EKR in July 2012; and

- $1.3 million impairment of property, plant and equipment due to a 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,			2011 versus 2010	2010 versus 2009
	2011	2010	2009	% Increase/ (Decrease)	
Interest expense, net	$ (4,525)	$ (3,813)	$ (1,646)	19%	132%
Royalty interest obligation	227	(930)	(1,880)	(124)%	(51)%
Loss on extinguishment of debt		(184)		n/a	n/a

Other income, net	71	487	367	(85)%	33%
Total other expense, net	$ (4,227)	$ (4,440)	$ (3,159)	(5)%	41%

Interest expense, net increased $0.7 million, or 19%, 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.

Interest expense, net increased by $2.2 million, or 132%, in the year ended December 31, 2010 as compared to 2009 primarily due to an increase in interest expenses resulting from our debt financing activities that occurred during 2010.

Royalty interest obligation decreased $1.2 million, or 124%, in the year ended December 31, 2011 as compared to 2010 due 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 upcoming termination of our licensing, distribution and marketing agreement with EKR in July 2012. The royalty interest obligation is due under an Amended and Restated Royalty Interests Assignment Agreement, further discussed below 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 is composed of (1) the difference in the revaluation of our obligations between each reporting period and (2) the actual royalty interest payments payable for such reporting period.

Royalty interest obligation decreased $1.0 million, or 51%, in the year ended December 31, 2010 as compared to 2009 due to lower estimates of future end user sales of DepoCyt(e) sales in the U.S.

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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 represents the final payment fees and the balance of deferred financing cost which were written off when the debt was paid off.

Other income, net decreased by $0.4 million, or 85%, for the year ended December 31, 2011 as compared to 2010 and increased $0.1 million, or 33%, for the year ended December 31, 2010 as compared to 2009. During 2010 and 2009, we entered into trade settlement agreements with certain of our trade creditors. We realized gains on these settlements with trade creditors as a result of lower proportionate settlement payments. Further, during 2010 we received research and development grants totaling $0.3 million.

Liquidity and Capital Resources

Since our inception in 2007, we have devoted most of our cash resources to 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, secured and unsecured notes and borrowings under debt facilities, supply and royalty revenue and collaborative licensing and development revenue. We raised approximately $37.1 million in net proceeds through an initial public offering completed on February 8, 2011 and approximately $49.0 million in net proceeds through a follow-on offering completed on November 21, 2011. We have generated limited supply and royalty revenue, and we do not anticipate generating any revenues from the sale of EXPAREL prior to the second quarter of 2012. We have incurred losses and generated negative cash flows from operations since inception. As of December 31, 2011, we had an accumulated deficit of $180.2 million, cash and cash equivalents and short-term investments of $76.2 million and working capital of $50.7 million.

The following table summarizes our cash flows from operating, investing and financing activities for the years ended December 31, 2011, 2010, and 2009 (dollar amounts in thousands):

	Year Ended December 31,		
	2011	**2010**	**2009**
Consolidated Statement of Cash Flows Data:			
Net cash provided by (used in):			
Operating activities	$ (31,000)	$ (24,880)	$ (20,838)
Investing activities	(36,123)	(6,769)	(5,509)
Financing activities	87,158	50,705	21,038
Net increase (decrease) in cash and cash equivalents	$ 20,035	$ 19,056	$ (5,309)

Operating Activities

For the years ended December 31, 2011, 2010 and 2009, our net cash used in operating activities was $31.0 million, $24.9 million and $20.8 million, respectively. 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 prepare to manufacture and launch EXPAREL (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.

The 4.0 million increase in net cash used in operating activities in 2010 as compared to 2009 resulted from the receipt of $5.0 million of license fees from one of our commercial partners in 2009 and $0.7 million of higher cash paid for interest on our credit facilities. This was offset by lower expenses on research and development activities in 2010.

Investing Activities

For the years ended December 31, 2011, 2010 and 2009, our net cash used in investing activities was $36.1 million, $6.8 million and $5.5 million, respectively. The net cash used in investing activities in 2011was primarily for the investment of the proceeds from the initial public offering and follow-on 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 manufacturing sites. In 2010 and 2009 net cash used in investing activities was primarily for the purchases of fixed assets relating to our manufacturing sites of $6.8 million and $5.5 million, respectively.

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Financing Activities

For the years ended December 31, 2011, 2010 and 2009, our net cash provided by financing activities was $87.2 million, $50.7 million and $21.0 million, respectively. 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. The net cash provided by financing activities in 2009 was primarily due to the sale and issuance of notes payable, for total net proceeds of $21.0 million.

Equity Financings

From inception through December 31, 2011, we raised approximately $86 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 million in cash.

Common Stock

In connection with our formation, we issued in March 2007 an aggregate of 464,900 shares of common stock for total aggregate consideration of $50,000.

In February 2011, we completed an initial public offering of our common stock pursuant to a registration statement on Form S-1, as amended (File No. 333-170245) that was declared effective on February 2, 2011. Under the registration statement, we registered the offering and sale of an aggregate of 6,900,000 shares of our common stock. An aggregate of 6,000,000 shares of common stock registered under the registration statement were sold at a price to the public of $7.00 per share. Barclays Capital Inc. and Piper Jaffray & Co. acted as joint book running managers of the offering and as representatives of the underwriters. The offering commenced on February 3, 2011 and closed on February 8, 2011. The over-allotment option was not exercised by the underwriters. As a result of our initial public offering, we raised approximately $37.1 million in net proceeds after deducting approximately $4.9 million in underwriting discounts and commissions and estimated offering expenses.

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 2009 Convertible Notes, 2009 Secured Notes, 2010 Secured Notes, 2010 Convertible Notes, and HBM Secured Notes were converted into an aggregate of 10,647,549 shares of common stock, as shown in the table below.

	Conversion Shares
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
	10,647,549

In November 2011, we completed a follow-on offering in a 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.

Warrants

On January 22, 2009, we issued warrants in connection with the issuance of the 2009 Convertible Notes. The warrants are exercisable for an aggregate of 158,061 of shares of our common stock at an exercise price of $2.69 per share and will expire on January 21, 2014.

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On July 2, 2009, we issued warrants to the landlord of our two San Diego facilities in connection with amendments to respective lease agreements that deferred minimum annual rental obligations. The warrants are exercisable for an aggregate of 23,244 shares of our common stock at a price of $13.44 per share and will expire on February 8, 2016.

On November 24, 2010, we issued warrants to the lenders under the Hercules Credit Facility. The warrants are exercisable for an aggregate of 178,986 shares of our common stock at an exercise price of $13.44 per share and will expire on February 2, 2016.

On December 29, 2010, we issued a warrant in connection with the December 2010 Convertible Notes. The warrant is exercisable for an aggregate of 167,361 of shares of our common stock with an exercise price of $13.44 per share and will expire on December 29, 2017.

Debt Facilities

As of December 31, 2011, we had $26.3 million of indebtedness under the Hercules Credit Facility.

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. As of December 31, 2011, the entire term loan of $26.3 million was outstanding. The term loan under the Hercules Credit Facility is comprised of two tranches, Tranche A and Tranche B. The Tranche A portion of the term loan is comprised of $11.3 million in principal and carries a floating per annum interest rate equal to 11.00% plus the amount, if any, by which the prime rate exceeds 4.00%. The Tranche B portion of the term loan is comprised of $15.0 million in principal and carries a floating per annum interest rate equal to 12.65% plus the amount, if any, by which the prime rate exceeds 4.00%. As of December 31, 2011, the interest rate on the Tranche A portion was 11.00% and on the Tranche B portion was 12.65%. Interest on the term loan is payable monthly. If there is an event of default under the Hercules Credit Facility, we will be obligated to pay interest at a higher default rate. The proceeds of the term loan under the Hercules Credit Facility have been used to repay the GECC Credit Facility in full and the remainder will be used for other general corporate purposes.

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

The Hercules Credit Facility provides for an interest only period when no principal amounts are due and payable. The interest only period runs through February 28, 2012. Following the end of the interest only period, the term loan is to be repaid in 33 monthly installments of principal and interest beginning on the first business day after the month in which the interest only period ends. Amounts repaid may not be re-borrowed. We can, at any time, prepay all or any part of the term loan. Any prepayments are to be applied pro rata across the outstanding balance of both portions of the term loan. In connection with any prepayments of the term loan under the Hercules Credit Facility, we are required to pay, in addition to all principal and accrued and unpaid interest on such term loan, a prepayment charge equal to 1.25% of the principal amount being

prepaid. In addition, there is an end of term charge that is payable to the lenders upon the earliest to occur of the maturity date, the prepayment in full of our obligations under the Hercules Credit Facility and the acceleration of our obligations under the Hercules Credit Facility.

The Hercules Credit Facility is secured by a first priority lien on all of our assets other than the assets that secure our obligations under Amended and Restated Royalty Interests Assignment Agreement (as described below). The Hercules loan and security agreement contains events of default including payment default, default arising from the breach of the provisions of the Hercules loan and security agreement and related documents (including the occurrence of certain changes in control, including if our chief executive officer ceases under certain conditions to be involved in the daily operations or management of the business, or if certain holders of our capital stock cease to retain, after the consummation of certain corporate transactions, shares representing more than 50% of the surviving entity after such or the inaccuracy of representations and warranties contained in the loan and security agreement, attachment default, bankruptcy and insolvency, cross-default with respect to certain other indebtedness (including certain events under the Amended and Restated Royalty Interests Assignment Agreement), breach of the terms of any guarantee (including the investors guarantee) of the Hercules Credit Facility, the occurrence of a material adverse effect (as defined in the Hercules loan and security agreement).

The occurrence of an event of default under the Hercules Credit Facility could trigger the acceleration of our obligations under the Hercules Credit Facility or allow the lenders to exercise other rights and remedies, including rights against our assets

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that secure the Hercules Credit Facility and rights under guarantees provided to support the obligations under the Hercules Credit Facility.

The Hercules loan and security agreement contains a number of affirmative and restrictive covenants, including reporting requirements and other collateral limitations, certain limitations on liens and indebtedness, dispositions, mergers and acquisitions, restricted payments and investments, corporate changes and waivers and amendments to certain agreements, our organizational documents, and documents relating to debt that is subordinate to our obligations under the Hercules Credit Facility. We were in compliance with all covenants at December 31, 2011.

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, 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 as we prepare to launch EXPAREL in April 2012. In addition, we expect to incur additional expenses to add operational, financial and information systems and personnel, including personnel to support our planned product commercialization efforts. We also expect to incur significant costs to comply with corporate governance, internal controls and similar requirements applicable to us as a public company.

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;
- 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;

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- 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 Hercules Credit Facility and the Amended and Restated Royalty Interests Assignment Agreement and the pledge of our assets as collateral limit our ability to obtain additional debt financing. We have no committed external sources of funds. Additional equity or debt financing or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all.

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

Off-Balance Sheet Arrangements

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

Recent Accounting Pronouncements

See Note 2 to the Notes to Financial Statements in Item 8 below for further 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-35, of this Annual Report on Form 10-K.

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

There have been no disagreements with our independent registered public accounting firm on accounting and financial disclosure matters.

Item 9A. Controls and Procedures

(a) 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.

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Based on their evaluation as of December 31, 2011, our President and Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective..

(b) 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, 2011, 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.

Based on the results of our evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2011.

(c) 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, 2011, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

(d) 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.

Item 9B. Other Information

None.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance

BOARD OF DIRECTORS

Name	Age	Position(s)
David Stack	60	President and Chief Executive Officer, Director
Fred Middleton(2) (3)	61	Chairman of the Board of Directors
Laura Brege(1) (3)	54	Director
Luke Evnin, Ph.D.(2)	48	Director
Paul Hastings(1) (2) (3)	52	Director
John Longenecker, Ph.D.(1)(2)(3)	64	Director
Gary Pace, Ph.D.(3)	64	Director
Andreas Wicki, Ph.D.	53	Director

(1) Member of audit committee.

(2) Member of compensation committee.

(3) Member of nominating and corporate governance committee.

Our board of directors currently consists of eight members, six of whom were elected as directors prior to our initial public offering and two of whom were recommended by non-management members of our board of directors to our Nominating and Corporate Governance Committee, which in turn nominated them to our board of directors. These two directors were elected by the board of directors in June of 2011 to fill two vacancies. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal.

In accordance with the terms of our restated certificate of incorporation and bylaws, our board of directors is divided into three classes, class I, class II and class III, with each class serving staggered three-year terms. Upon the expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of stockholders in the year in which their term expires. The members of the classes are divided as follows:

- Class I: Laura Brege and Luke Evnin and their term expires at the 2012 Annual Meeting.

- Class II: Paul Hastings, John Longenecker and Andreas Wicki, and their term expires at the annual meeting of stockholders to be held in 2013.

- Class III: Fred Middleton, Gary Pace and David Stack, and their term expires at the annual meeting of stockholders to be held in 2014.

Our restated certificate of incorporation and amended and restated bylaws provide that the authorized number of directors may be changed only by resolution of the board of directors. Our restated certificate of incorporation and amended and restated bylaws also provide that our directors may be removed only for cause by the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in an annual election of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

Director Nominees for 2012 Annual Meeting

Biographical information for our directors who are up for re-election at our 2012 Annual Meeting is set forth below.

Laura Brege recently retired from her position as executive vice president, corporate affairs for Onyx Pharmaceuticals, Inc. and has served as our director since June 2011. Previously, Ms. Brege held the roles of chief operating officer and executive vice president and chief business officer for Onyx. Prior to joining Onyx in 2006, Ms. Brege was a general partner at Red Rock Capital Management, a venture capital firm, and senior vice president and chief financial officer at COR Therapeutics, Inc. Ms. Brege currently serves as a director of Acadia Pharmaceuticals Inc. (NASDAQ: ACAD). She previously served as a member of the board of directors of Angiotech Pharmaceuticals Inc. from 2007 to 2011. Ms. Brege earned her undergraduate degree from Ohio University and has an M.B.A. from the University of Chicago. We believe Ms. Brege s qualifications to sit on our board of directors include her extensive experience in the pharmaceutical and biotechnology industries, including as a public company director.

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Luke Evnin, Ph.D. has served as our director since our inception in December 2006. Dr. Evnin has served as a general partner or managing director at MPM Capital since co-founding the firm in 1998. Prior to joining MPM, Dr. Evnin was at Accel Partners from 1990 to 1997 serving as general partner from 1994 to 1997. Dr. Evnin has served as director of several public companies, including EnteroMedics Inc. (NASDAQ: ETRM), Epix Medical, Inc. (NASDAQ: EPIX), Metabasis Therapeutics, Inc. (NASDAQ: MBRX), Oscient Pharmaceuticals Corporation (NASDAQ: OSCI), Restore Medical, Inc., Otix Global, Inc. (NASDAQ: OTIX), formerly known as Sonic Innovations, Inc. and Signal Pharmaceuticals, Inc. and is currently or has been a director of several private healthcare companies in both the medical device and biopharmaceutical sectors. Dr. Evnin earned his Ph.D. in biochemistry from the University of California, San Francisco and his A.B. in molecular biology from Princeton University. We believe Dr. Evnin s qualifications to sit on our board of directors include his extensive experience with biopharmaceutical and biotechnology companies, his financial expertise and his years of experience providing strategic advisory services to diverse companies.

Directors Continuing in Office

Biographical information for our directors continuing in office is set forth below.

Class II Directors (Term Expires at 2013 Annual Meeting)

Paul Hastings has served as our director since June 2011. Mr. Hastings has been the president and chief executive officer of OncoMed Pharmaceuticals, Inc. since January 2006. Prior to joining OncoMed, Mr. Hastings was president and chief executive officer of QLT, Inc. Before this role, Mr. Hastings served as president and chief executive officer of Axys Pharmaceuticals, Inc., which was acquired by Celera Corporation in 2001. Prior to Axys, Mr. Hastings was president of Chiron Biopharmaceuticals and also held a variety of management positions of increasing responsibility at Genzyme Corporation, including president of Genzyme Therapeutics Europe and president of Worldwide Therapeutics. Mr. Hastings was Chairman of the Board of Proteolix (sold to Onyx) and was a member of the board of directors of ViaCell Inc (sold to Perkin Elmer). Mr. Hastings currently serves as chairman of the board of the Bay Area Biosciences Association (Bay Bio) and is Vice Chair of the Emerging Companies Section of the Biotechnology Industry Organization. He received a Bachelor of Science degree in pharmacy from the University of Rhode Island. We believe Mr. Hastings qualifications to sit on our board of directors include his financial expertise and his extensive experience in the pharmaceutical and biotechnology industries.

John Longenecker, Ph.D. has served as our director since July 2007. Dr. Longenecker has served as president and chief executive officer of HemaQuest Pharmaceuticals, Inc. since October 2010. From December 2009 to March 2010, Dr. Longenecker served as the president and chief executive officer of VitreoRetinal Technologies Inc. From February 2002 to January 2009, Dr. Longenecker was the president and chief executive officer and a member of the board of directors of Favrille, Inc. In 1992, Dr. Longenecker joined DepoTech as senior vice president of research, development and operations and then served as president and chief operating officer from February 1998 to March 1999. Under Dr. Longenecker s leadership, DepoTech took its lead product, DepoCyt(e), from early pre-clinical research and development through to commercial launch. Following SkyePharma PLC s acquisition of DepoTech in 1999, Dr. Longenecker served as president for the U.S. operations of SkyePharma, Inc. and as a member of the executive committee for SkyePharma PLC. From 1982 to 1992, Dr. Longenecker was at Scios Inc. (Cal Bio), a biotechnology company where he served as vice-president and director of development. Dr. Longenecker was also a director of a number of Cal Bio subsidiaries during this period including Meta Bio and Karo Bio. Dr. Longenecker holds a B.S. in chemistry from Purdue University and a Ph.D. in biochemistry from The Australian National University. He was a post doctoral fellow at Stanford University from 1980 to 1982. Dr. Longenecker s experience as the chief executive officer of a public company, demonstrates his leadership capability and extensive knowledge of complex financial and operational issues that public companies face and a thorough understanding of our business and industry and business acumen to our board of directors. We believe Dr. Longenecker s extensive experience in the pharmaceutical and biotechnology industries provides valuable background and insight to our board of directors.

Andreas Wicki, Ph.D. has served as our director since our inception in December 2006. Dr. Wicki is a life sciences entrepreneur and investor with over 16 years of experience in the pharmaceutical and biotechnology industries. Dr. Wicki has been chief executive officer of HBM Partners AG and HBM BioVentures AG since 2001. From 1998 to 2001, Dr. Wicki was the senior vice president of the European Analytical Operations at MDS Inc. From 1990 to 1998, he was co-owner and chief executive officer of ANAWA Laboratorien AG and Clinserve AG, two life sciences contract research companies. Dr. Wicki holds an M.Sc. and Ph.D. in chemistry and biochemistry from the University of Bern, Switzerland. He currently serves on the board of directors of Buchler GmbH, HBM BioPharma India Ltd., HBM BioVentures (Cayman) Ltd., HBM Partners AG, HBM BioCapital Ltd. and PharmaSwiss SA. We believe Dr. Wicki s qualifications to sit on our board of directors include his extensive experience with pharmaceutical companies, his financial expertise and his years of experience providing strategic and advisory services to pharmaceutical and biotechnology organizations.

Class III Directors (Term Expires at 2014 Annual Meeting)

Fred Middleton has served as our director since our inception in December 2006. Since 1987, he has been a general partner/managing director of Sanderling Ventures, a firm specializing in biomedical venture capital. From 1984 through 1986, he was

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the managing general partner of Morgan Stanley Ventures, an affiliate of Morgan Stanley & Co. Earlier in his career, Mr. Middleton was part of the of the founding management team at Genentech, Inc., a biotechnology company, serving there from 1978 through 1984 as vice president of finance and corporate development, and chief financial officer. During the last 30 years, he has participated in active management roles and as an investor and director in over 20 start-up biomedical companies. He currently serves as chairman of the board of Stereotaxis, Inc. (NASDAQ: STXS), a medical device company that markets magnetically guided robotic surgery systems in cardiology. He also currently serves as a board member of Cardionet, Inc. (NASDAQ: BEAT), a company that markets devices and services for wireless 24/7 real time monitoring of patients. He also serves as a director of seven other privately-held biomedical companies, engaged in the development of therapeutic and diagnostic products in healthcare. Mr. Middleton received a B.S. degree in chemistry from the Massachusetts Institute of Technology and an M.B.A. from Harvard Business School. We believe Mr. Middleton s qualifications to sit on our board of directors include his extensive experience with biopharmaceutical and biotechnology companies, his financial expertise and his years of experience providing strategic advisory services to diverse companies.

Gary Pace, Ph.D. has served as our director since June 2008. He is currently founder and chairman of the privately held Sova Pharmaceuticals Inc., founded in 2010. He is also founder, director and consultant to QRxPharma Ltd. (ASX:QRX) founded in 2001, a director of ResMed (NYSE:RMD) since 1994 and Transition Therapeutics Inc. (CDNX:TTH) since 2002. He previously served as a member of the board of directors at Celsion Corporation (NASDAQ: CLSN) from 2002 to 2010 and Peplin Inc. (ASX: PLI) from 2004 to 2009. From 2002 to 2007, Dr. Pace was founder, chairman and chief executive officer of QRxPharma Ltd. and from 1995 to 2001, he was president and chief executive officer of RTP Pharma and from 2000 to 2002, Dr. Pace was chairman and chief executive officer of Waratah Pharmaceuticals Inc., a spin-off company from RTP Pharma. From 1993 to 1994, he was the founding president and chief executive officer of Transcend Therapeutics Inc. (formerly Free Radical Sciences Inc.), a biopharmaceutical company. From 1989 to 1993, he was senior vice president of Clintec International, Inc., a Baxter/Nestle joint venture and manufacturer of clinical nutritional products. Dr. Pace holds a B.S. with honors from the University of New South Wales and a Ph.D. from Massachusetts Institute of Technology. We believe Dr. Pace s qualifications to sit on our board of directors include his financial expertise and his years of experience providing strategic advisory services to complex organizations, including as a public company director.

David Stack has served as our president and chief executive officer and as a director since November 2007. Mr. Stack has been a managing director of MPM Capital since 2005 and a managing partner of Stack Pharmaceuticals, Inc. since 1998. From 2001 to 2004, he was president and chief executive officer of The Medicines Company (NASDAQ: MDCO). Previously, Mr. Stack was president and general manager at Innovex, Inc. He was vice president, business development/marketing at Immunomedics from 1993 until 1995. Prior to that, he was with Roche Laboratories in positions of increasing responsibility from 1981 until 1993, including therapeutic world leader in infectious disease and director, business development and planning, infectious disease, oncology, and virology. He currently serves as a member of the board of directors of PepTx, Inc. He was a member of the boards of directors of Molecular Insight Pharmaceuticals, Inc. (NASDAQ: MIPI) from 2006 to 2010 and BioClinica, Inc. (NASDAQ: BIOC) from 1999 to 2010. Mr. Stack holds a B.S. in pharmacy from Albany College of Pharmacy and a B.S. in Biology from Siena College. We believe Mr. Stack s qualifications to sit on our board of directors include his extensive experience with pharmaceutical companies, his financial expertise and his years of experience providing strategic and financial advisory services to pharmaceutical and biotechnology organizations, including evaluating business plans involving clinical trials.

Procedures for Nominations to the Registrant s Board of Directors

No changes have been made to the procedures by which security holders may recommend nominees to our board of directors.

Audit Committee

Our board of directors has established a standing audit committee. The members of our audit committee are John Longenecker, Paul Hastings and Laura Brege, who chairs the committee. Our board of directors has determined that each of the directors serving on our audit committee are independent within the meaning of The NASDAQ Marketplace Rules and Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

Audit Committee Financial Expert

Our board of directors has determined that Ms. Brege qualifies as an audit committee financial expert within the meaning of SEC regulations and The NASDAQ Marketplace Rules.

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EXECUTIVE OFFICERS

The following sets forth certain information with respect to the executive officers of the Company, as of the date of this report.

Name	Age	Position(s)
David Stack	60	President and Chief Executive Officer, Director
James Scibetta	47	Chief Financial Officer
Gary Patou, M.D	53	Chief Medical Officer
Taunia Markvicka, Pharm D	43	Vice President, Commercial
Lauren Riker	33	Executive Director, Accounting & Reporting
John Pratt	68	General Manager, San Diego Facility

David Stack see ***Class III Directors (Term Expires at 2014 Annual Meeting)*** above.

James Scibetta has served as our chief financial officer since August 2008. Prior to that, Mr. Scibetta was chief financial officer of Bioenvision, Inc. (NASDAQ: BIVN) from 2006 until its acquisition by Genzyme, Inc. in 2007. From 2001 to 2006, Mr. Scibetta was executive vice president and chief financial officer of Merrimack Pharmaceuticals, Inc., and he was a member of the board of directors of Merrimack from 1998 to 2004. Mr. Scibetta formerly served as a senior investment banker at Shattuck Hammond Partners, LLC and PaineWebber Inc., providing capital acquisition, merger and acquisition, and strategic advisory services to healthcare companies. He currently serves as chairman of the board and audit committee of Nephros, Inc. (NASDAQ: NEPH). Mr. Scibetta holds a B.S. in physics from Wake Forest University, and an M.B.A. in finance from the University of Michigan. He completed executive education studies in the Harvard Business School Leadership & Strategy in Pharmaceuticals and Biotechnology program.

Gary Patou, M.D. has served as our chief medical officer since March 2009. Dr. Patou has been a managing director of MPM Capital since 2005. He has served as chief medical officer of the following MPM Capital portfolio companies: Peplin, Ltd. (ASX: PLI), from June 2006 to April 2007 and from June 2008 to May 2009, Cerimon Pharmaceuticals, Inc., from June 2005 to June 2006, and Oscient Pharmaceuticals, Inc., from February 2004 to April 2005. Dr. Patou currently spends part of his time as the acting chief executive officer of Cerimon Pharmaceuticals, Inc. From 2001 to 2004, he was president of Genesoft and from 1995 to 2000, Dr. Patou worked at SmithKline Beecham Pharmaceuticals, now a unit of GlaxoSmithKline (LSE: GSK), where he held positions of increasing responsibility including senior vice president and director, project and portfolio management. From 1991 to 1995, he held increasing senior, director level positions at Vernalis (LSE:VER), formerly British Biotechnology. He currently serves as a member of the board of directors of Xenon Pharmaceuticals, Inc. He served as a member of the board of directors of Oscient Pharmaceuticals Corporation (NASDAQ: OSCI) from 2005 to 2008. Dr. Patou has held a number of academic appointments at University College & Middlesex School of Medicine in London and holds an M.D. from University College, London.

Taunia Markvicka, Pharm D has served as our Vice President, Commercial since November 2010. Dr. Markvicka is a partner at Stack Pharmaceuticals, Inc., a commercialization, marketing, and strategy firm, in addition to her role at Pacira. Her most recent pharmaceutical positions include serving as a franchise marketing director at The Medicines Company for the cardiovascular and hematology acute care products. Previously, Dr. Markvicka was Marketing Director at Watson Pharmaceuticals, where she oversaw marketing, medical marketing and new product planning for urology and general products. She was also with Advantage Healthcare, a strategic marketing and new product planning firm, as a Vice President for two years. She joined the pharmaceutical industry, initially taking a two year post-doctoral fellowship position with Sandoz (now Novartis). Dr. Markvicka holds a Doctor of Pharmacy degree from the University of Nebraska, an MBA from St. Josephs University, and she maintains her license as a registered pharmacist.

Lauren Riker has served as our principal accounting officer since March 2012 and our Executive Director, Accounting and Financial Reporting since March 2011. Prior to joining us, Ms. Riker served as Senior Director of Financial Reporting at Ikaria, Inc. (Ikaria), a private critical care biopharmaceutical company, from April 2008 to April 2011, where she was responsible for the oversight, monitoring and review of Ikaria s financial reporting, technical accounting and stock-based compensation program. From December 2004 to February 2008, Ms. Riker served as the Controller and later the Chief Accounting Officer of Bioenvision, Inc., (Bioenvision) a publicly traded biotechnology company. Her responsibilities at Bioenvision included preparation of the financial statements and disclosures in accordance with United States generally accepted accounting principles and the reporting requirements of the SEC and implementation of internal controls and procedures in compliance with Sarbanes-Oxley. From 2000 to 2004, Ms. Riker worked at KPMG in the Information, Communication and Entertainment sector where she held positions of increasing responsibility, including Audit Manager. Ms. Riker holds a B.S. in accounting from Boston College and an M.B.A. from Columbia Business School.

John Pratt, has served as the General Manager of our San Diego facility since January 2012. Prior to joining us, Mr. Pratt was a general manager of Amylin Ohio LLC (Amylin Ohio), a subsidiary of Amylin Pharmaceuticals, from 2006 to 2011. In that role, Mr. Pratt managed a 305-person operations team while simultaneously directing Amylin Ohio s commercial operations and leading the design, construction and FDA acceptance of a 550,000 square foot, state-of-the-art manufacturing, inspection and packaging facility. Prior to his employment with Amylin Ohio, Mr. Pratt was employed by Novo Nordisk, where he held various senior management roles related to manufacturing operations and quality control. Mr. Pratt has a B.S. in Microbiology/Chemistry from the University of Montana and took post-graduate coursework at the University of Washington.

Family Relationships

There are no family relationships among any of our directors or executive officers.

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including

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our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A current copy of the code is posted on the Corporate Governance section of our website, which is located at www.pacira.com. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

Section 16(a) Beneficial Ownership Reporting Compliance

Under U.S. securities laws, directors, executive officers, and persons holding more than 10 percent of Pacira common stock must report their initial ownership of the common stock and any changes in that ownership in reports that must be filed with the SEC. The SEC has designated specific deadlines for these reports and Pacira must identify in this proxy statement those persons who did not file these reports when due.

Based solely on a review of reports filed with Pacira, all directors, executive officers, and 10 percent owners timely filed all reports regarding transactions in Pacira s securities required to be filed for 2011 by Section 16(a) under the Exchange Act.

Item 11. Executive Compensation

The following table sets forth information for our Chief Executive Officer, our two other most highly compensated executive officers who were serving as executive officers as of December 31, 2011 for the fiscal years indicated. We refer to these individuals as our named executive officers.

Summary Compensation Table For Fiscal Years Ended December 31, 2011 and 2010

Name and Principal Position	Year	Salary ($)	Bonus(1) ($)	Option Awards(3) ($)	All Other Compensation(4) ($)	Total ($)
David Stack	2011	409,046	206,000		1,504	616,550
Chief Executive Officer	2010	400,000		1,112,323	1,504	1,513,827
[redacted]						
Gary Patou	2011	317,604	100,000		19,056(6)	436,660
Chief Medical Officer(5)	2010	336,660	300,000(2)	295,018	19,056(6)	950,734

(1) Represents a cash bonus approved in December 2011 and paid in January 2012.

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

(3) Represents the grant date fair value of option awards granted in 2010 in accordance with ASC 718. Our named executive officers will only realize compensation to the extent the fair value of our common stock is greater than the exercise price of such stock options.

(4) Amounts represent the value of perquisites and other personal benefits which are further detailed in the table below:

Name	2010 Group Life Insurance ($)	2011 Group Life Insurance ($)	Payments to MPM ($)
David Stack	1,504	1,504	
James Scibetta	1,504	1,504	
Gary Patou			38,112

(5) Dr. Patou, a managing director at MPM, is a consultant to us and provided the services customarily expected of a chief medical officer. Pursuant to the Services Agreement with MPM AM and Dr. Patou, we paid a service fee of $26,467 per month to MPM AM for the services provided by Dr. Patou and MPM AM. For more information, see Employment Agreements, Severance and Change in Control Arrangements Services Agreement with MPM and Gary Patou below.

(6) Amount represents benefit payment made to MPM pursuant to the Services Agreement.

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Outstanding Equity Awards at Year End

The following table sets forth certain information with respect to outstanding options held by our named executive officers at December 31, 2011.

Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price ($)	Option Expiration Date
David Stack	151,095	34,865(1)	$ 1.61	9/2/2020
	79,905	175,790(2)	1.61	9/2/2020
	39,616	118,850(3)	5.49	12/29/2020
[redacted]				
Gary Patou	47,973	11,069(1)	1.61	9/2/2020
	18,451	40,591(2)	1.61	9/2/2020
	10,592	31,777(3)	5.49	12/29/2020

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

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

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

Employment Agreements, Severance and Change in Control Arrangements

We entered into employment agreements with each of our named executive officers other than Gary Patou. The agreements with each of our named executive officers provide for at will employment which means we or the executive can terminate his or her employment at any time, with or without cause. Pursuant to the agreements, each of our named executive officers will be entitled to a base salary and certain benefits as previously described.

If any of our named executive officers, other than our chief executive officer, (i) is terminated for any reason other than for cause, or (ii) terminates his or her employment for good reason, then such executive officer will be entitled to:

- earned and accrued base salary, bonus, vacation time and other benefits;

- monthly salary continuation payments for a period of nine months from the effective date of the release required to be provided as a condition to receiving these payments;

- health insurance coverage, subject to cost sharing, for 12 months following the effective date of the release required to be provided as a condition to receiving this coverage; and

- immediate vesting of the portion of the unvested options granted to him or her in connection with the agreement that would have become vested during the nine month period following the date of termination.

If our chief executive officer (i) is terminated for any reason other than for cause, or (ii) terminates his employment for good reason, then he will be entitled to:

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- earned and accrued base salary, bonus, vacation time and other benefits;

- monthly salary continuation payments for a period of 12 months from the effective date of the release required to be provided as a condition to receiving these payments;

- health insurance coverage, subject to cost sharing, for 12 months following the effective date of the release required to be provided as a condition to receiving this coverage; and

- immediate vesting of the portion of the unvested options granted to him in connection with the agreement that would have become vested during the 12 month period.

If, within 30 days prior to, or 12 months following, a change in control, any of our named executive officers, including our chief executive officer, (i) is terminated for any reason other than for cause, or (ii) terminates his or her employment during the agreement term for good reason, then, in addition to the severance payments described above, such executive officer will also be entitled to immediate vesting of the entire unvested portion of all equity compensation granted to him or her.

Our obligation to make the severance payments described above will be conditioned upon the executive officer s continued compliance with the non-competition and confidentiality obligations set forth in his or her employment agreement and the executive officer s execution of a general release of claims against us.

Under the employment agreements, cause means: (i) failure to substantially perform the duties owed to us after receiving written notice that sets forth in detail the specific respects in which our board of directors believes that the duties have not been substantially performed, and failure to correct the failure within 30 days after receiving a demand for substantial performance and opportunity to cure; (ii) fraud, misconduct, dishonesty, gross negligence or other acts either injurious to us or conducted with intentional disregard for our best interests; (iii) failure to follow reasonable and lawful instructions from our board of directors and failure to cure such failure after receiving 20 days advance written notice; (iv) material breach of the terms of the employment agreement or our employee proprietary information and inventions assignment agreement or any other similar agreement that may be in effect from time to time; or (v) conviction of, or pleading guilty or nolo contendere to, any misdemeanor involving dishonesty or moral turpitude or related to our business, or any felony.

Under the employment agreements, good reason means, without the executive officer s prior written consent: (i) any material reduction of the executive officer s then effective base salary that is not in accordance with his employment agreement or related to a cross-executive team salary reduction; (ii) any material breach by us of the executive officer s employment agreement; or (iii) a material reduction in the executive officer s responsibilities or duties, not including a mere reassignment following a change of control to a position that is substantially similar to the position held prior to the change of control; provided, however, that no such event or condition shall constitute good reason unless (x) the executive officer gives us a written notice of termination for good reason not more than 90 days after the initial existence of the condition, (y) the grounds for termination (if susceptible to correction) are not corrected by us within 30 days of our receipt of such notice and (z) the termination date occurs within one (1) year following our receipt of such notice.

Under the employment agreements, a change of control means (i) a merger or consolidation of either us or PPI-California into another entity in which the stockholders of us or PPI-California (as applicable) do not control 50% or more of the total voting power of the surviving entity (other than a reincorporation merger); (ii) the sale, transfer or other disposition of all or substantially all of our assets in a liquidation or dissolution; or (iii) the sale or transfer of more than 50% of our outstanding voting stock. In the case of each of the foregoing clauses (i), (ii) and (iii), a change of control as a result of a financing transaction entered into by us or PPI-California shall not constitute a change of control for purposes of these agreements.

Services Agreement with MPM and Gary Patou

In March 2009, we entered into a services agreement with Dr. Patou and MPM Asset Management LLC, or MPM AM. Pursuant to the services agreement, Dr. Gary Patou provided the services to us customarily expected of a chief medical officer. Dr. Patou s principal duties were to manage and lead our clinical team as well as oversee development of protocols and clinical trials designed to provide a path for regulatory approval of EXPAREL. In March 2010, we amended and restated the services agreement to, among other things, extend the term of the services until the deadline for filing the NDA for EXPAREL to October 15, 2010 or until either party gives 10 days prior written notice. In consideration of the services performed under the services agreement, we paid a service fee of $26,467 per month to MPM AM. In addition, we paid a bonus to Dr. Patou upon the successful completion of an NDA submission for EXPAREL.

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In October 2010, we entered into a new services agreement with Dr. Patou and MPM AM. Pursuant to this services agreement, Dr. Gary Patou continues to provide the services to us customarily expected of a chief medical officer. Dr. Patou s principal duties include obtaining approval for the EXPAREL NDA in the United States, filing the EXPAREL dossier in the European Union, developing additional clinical indications for EXPAREL and assisting with our product pipeline development. Under the new services agreement, we pay a service fee of $26,467 per month to MPM AM which is adjusted based on the total amount of time Dr. Patou devotes to us during the term of the services agreement. If we terminate our consulting relationship with Dr. Patou and MPM AM other than for cause or the consulting relationship is terminated by Dr. Patou and MPM AM for good reason , then MPM AM will be entitled to continuation of the then effective monthly service fee for a period of nine months following the date of termination and Dr. Patou will be entitled to immediate vesting of the portion of the unvested options that would have vested during the nine month period following the date of termination, provided that the options granted to Dr. Patou in December 2010 are subject to additional vesting. In addition, if within 30 days prior to, or 12 months following, a change of control, the consulting relationship is terminated other than for cause or for good reason , then in addition to the service payments above, Dr. Patou will also be entitled to immediate vesting of the entire unvested portion of his stock options.

On December 7, 2011, the compensation committee and the audit committee of our board of directors approved, and on December 8, 2011 the Company entered into, an Amendment to Services Agreement with MPM AM and Dr. Patou which amends the prior Services Agreement between the Company, MPM AM and Dr. Patou. Prior to amending the existing Services Agreement, the business time Dr. Patou and MPM AM would spend consulting for the Company would have been reduced from 80% in 2011 to 50% in 2012 and the monthly services fee would have been reduced from $26,467 to $15,880. Pursuant to the terms of the Amended Services Agreement, Dr. Patou and MPM AM will continue to devote 80% of the business time to consulting for the Company, and the monthly services fee will remain $26,467, through September 30, 2012. After September 30, 2012, Dr. Patou and MPM AM will provide services to the Company at a reduced rate of 50% business time and $15,880 in monthly services fees.

Director Compensation

Non-Employee Director Compensation Policy

On June 2, 2011, our board of directors approved a compensation policy for our non-employee directors. This policy provides for the following compensation to our non-employee directors:

Initial Stock Option Grant Non-Employee Directors. Each non-employee director that joins our board of directors after June 2, 2011 will receive an option under our then existing equity incentive plan to purchase an aggregate of 15,000 shares of common stock, upon his or her initial appointment to our board of directors. Subject to the non-employee director s continued service as a director, the shares underlying this option will vest in 24 equal successive monthly installments over the 24 month period following the date of grant. In the event of a change of control or our liquidation or dissolution, 100% of the then unvested shares will immediately vest upon a change of control or our liquidation or dissolution. The exercise price of the option will be equal to the fair market value of the common stock on the date of grant which our board of directors determines to be the closing price per share of common stock as reported on The Nasdaq Global Market on such date.

Annual Stock Option Grant. Each non-employee director will receive an option under the our then existing stock incentive plan to purchase an aggregate 5,000 shares of common stock on the date of our first board of directors meeting held after each annual meeting of stockholders. Unless otherwise provided at the time of grant, subject to the non-employee director s continued service as a director, the shares underlying this option will vest in 12 equal successive monthly installments over the 12 month period following the date of grant. In the event of a change of control or our liquidation or dissolution, 100% of the then unvested shares will vest in full. The exercise price of the option will be equal to the

fair market value of the common stock on the date of grant which our board of directors determines to be the closing price per share of common stock as reported on The Nasdaq Global Market on such date.

Annual Fees. Each non-employee director will receive an annual fee as follows:

Board Annual Fee each non-employee member of our board of directors will receive an annual fee of $35,000 and the chairman of the board will receive an additional annual fee of $25,000, in each case relating to such director s service on our board of directors.

Audit Committee Annual Fee the chair of the Audit Committee will receive an annual fee of $15,000 and each other non-employee member of the Audit Committee will receive an annual fee of $7,500, in each case relating to such director s service on the Audit Committee.

Compensation Committee Annual Fee the chair of the Compensation Committee will receive an annual fee of $15,000 and each other non-employee member of the Compensation Committee will receive an annual fee of $7,500, in each case relating to such director s service on the Compensation Committee.

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Nominating and Corporate Governance Committee Annual Fee the chair of the Nominating and Corporate Governance Committee will receive an annual fee of $10,000 and each other non-employee member of the Nominating and Corporate Governance Committee will receive an annual fee of $5,000, in each case relating to such director s service on the Nominating and Corporate Governance Committee.

Each annual fee shall be payable in advance in four equal quarterly installments on the first day of each calendar quarter, provided that the amount of such payment shall be prorated for any portion of such quarter that the director was not serving on our board of directors. Each non-employee director will also be reimbursed for reasonable travel and other expenses in connection with attending meetings of the Board and any committee on which he or she serves.

We do not compensate members of our board of directors who are also employees of the Company for service on our board of directors.

Director Compensation Table - 2011

The following table sets forth a summary of the compensation earned by our directors for the year ended December 31, 2011, with the exception of Mr. Stack, whose compensation is included in the Summary Compensation Table above.

Name	Fees Earned or Paid in Cash ($)	Option Awards(1) ($)	All Other Compensation(3)	Total ($)(4)
Fred Middleton	61,313	149,859	8,300	219,472
Luke Evnin, Ph.D.	38,604	149,859		188,463
Carl Gordon, Ph.D.(2)	16,528			16,528
John Longenecker, Ph.D.	52,438	47,750		100,188
Gary Pace, Ph.D.	43,354	47,750	6,384	97,488
Andreas Wicki, Ph.D.				
Paul Hastings	33,222	143,250		176,472
Laura Brege	28,899	143,250		172,149

(1) Represents the grant date fair value of option awards granted in 2011 in accordance with ASC Topic 718, or ASC 718, formerly Statement of Financial Accounting Standards No. 123(R). Our directors will only realize compensation to the extent the fair value of our common stock is greater than the exercise price of such stock options. For information regarding assumptions underlying the valuation of equity awards, see note 11 to our financial statements included in our Annual Report on Form 10-K.

(2) Dr. Gordon resigned from our board of directors effective June 2, 2011.

(3) Represents the compensation cost computed in accordance with FASB ASC Topic 718 for shares in the Company s follow-on offering times discount from market price.

(4) The aggregate number of stock awards and aggregate number of option awards outstanding for each of our directors as of December 31, 2011, are as follows:

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Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price ($)	Option Expiration Date
Fred Middleton		4,649	$ 1.61	9/2/2020
		1,395	5.49	12/29/2020
	7,846	7,846	13.98	6/2/2021
Carl Gordon				
Gary Pace, Ph.D.	7,497	9,239	$ 1.61	9/2/2020
	2,500	2,500	13.98	6/2/2021
Paul Hastings	3,750	11,250	13.98	6/2/2021

ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information, to the extent known by us or ascertainable from public filings, regarding the beneficial ownership of our common stock as of February 29, 2012 (except where otherwise noted), by:

- each of our directors;
- each of our named executive officers;
- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock; and
- all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with SEC rules. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities and include shares of common stock issuable upon the exercise of stock options and warrants that are immediately exercisable or exercisable within 60 days after February 29, 2012. Except as

otherwise indicated, all of the shares reflected in the table are shares of common stock and all persons listed below have sole voting and investment power with respect to the shares beneficially owned by them, subject to applicable community property laws. The information is not necessarily indicative of beneficial ownership for any other purpose.

Percentage ownership calculations for beneficial ownership are based on 25,357,189 shares outstanding as of February 29, 2012. Except as otherwise indicated in the table below, addresses of named beneficial owners are in care of Pacira Pharmaceuticals, Inc., 5 Sylvan Way, Suite 100, Parsippany, New Jersey 07054.

In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed shares of common stock subject to options and warrants held by that person that are currently exercisable or exercisable within 60 days of February 29, 2011 to be outstanding. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Beneficial ownership representing less than 1% is denoted with an asterisk (*).

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage Beneficially Owned
5% Stockholders		
HBM BioVentures (Cayman) Ltd.(1)	3,513,026	13.8%
MPM Capital and its affiliates(2)	3,369,511	13.2%
OrbiMed Advisors and its affiliates(3)	2,525,032	9.9%
Sanderling Ventures and its affiliates(4)	3,000,952	11.8%
T. Rowe Price Associates, Inc. (5)	3,098,450	12.2%

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Officers and Directors		
James Scibetta(7)	118,154	*
Laura Brege(9)	6,250	*
Paul Hastings(11)	6,250	*
Fred Middleton(13)	3,027,051	10.7%
Andreas Wicki(15)	3,513,026	12.5%

(1) The address for HBM BioVentures (Cayman) Ltd. is Centennial Towers, Suite 305, 2454 West Bay Road, Grand Cayman, Cayman Islands, B.V.I. Consists of (i) 3,433,933 shares of common stock held by HBM BioVentures (Cayman) Ltd., and (ii) 79,033 shares of common stock issuable upon exercise of warrants held by HBM BioVentures (Cayman) Ltd. The board of directors of HBM BioVentures (Cayman) Ltd. has sole voting and investment power with respect to the shares held by such entity and acts by majority vote. The board of directors of HBM BioVentures (Cayman) Ltd. is comprised of John Arnold, Richard Coles, Sophia Harris, Dr. Andreas Wicki and John Urquhart, none of whom has individual voting or investment power with respect to such shares.

(2) The address for funds managed by MPM Capital is 200 Clarendon St., 54th Floor, Boston, MA 02116. Consists of (i) 3,083,973 shares of common stock held by MPM BioVentures IV-QP, L.P., (ii) 118,812 shares of common stock held by MPM BioVentures IV GmbH & Co. Beteiligungs KG, (iii) 87,694 shares of common stock held by MPM Asset Management Investors BV4 LLC, (iv) 74,073 shares of common stock issuable upon exercise of warrants held by MPM BioVentures IV-QP, L.P., (v) 2,853 shares of common stock issuable upon exercise of warrants held by MPM BioVentures IV GmbH & Co. Beteiligungs KG, and (vi) 2,106 shares of common stock issuable upon exercise of warrants held by MPM Asset Management Investors BV4 LLC. Dr. Patou is a Managing Director of MPM Asset Management LLC. MPM Asset Management LLC is the Management Company of MPM BioVentures IV LLC. MPM BioVentures IV LLC is the Managing Member of MPM BioVentures IV GP LLC, which is the General Partner of MPM BioVentures IV-QP, LP. and the Managing Limited Partner of MPM BioVentures IV GmbH & Co. Beteiligungs KG. MPM BioVentures IV LLC is the Manager of MPM Asset Management Investors BV4 LLC. Dr. Evnin is a Member of MPM BioVentures IV LLC. Dr. Evnin has a shared power to vote, acquire, hold and dispose of all shares and warrants. Dr. Evnin disclaims beneficial ownership of the securities except to the extent of their pecuniary interest therein.

(3) The number of shares of common stock held is as of March 12, 2012 and is based solely upon Amendment No. 2 to the Schedule 13D filed March 19, 2012, by Orbimed Advisors LLC and its affiliates (OrbiMed). The number of warrants held is as of March 12, 2012 and is based upon the Company s records. Consists of (i) 2,423,000 shares of common stock held by OrbiMed Private Investments III, LP, (ii) 23,000 shares of common stock held by OrbiMed Associates III, LP, (iii) 78,287 shares of common stock issuable upon exercise of warrants held by OrbiMed Private Investments III, LP, and (iv) 745 shares of common stock issuable upon exercise of warrants held by OrbiMed Associates III, LP. For purposes of the reporting requirements of the Exchange Act, OrbiMed is deemed to be a beneficial owner of 2,525,032 shares of our common stock.

(4) The address for funds managed by Sanderling Ventures is 400 South El Camino Real, Suite 1200, San Mateo, California 94402. Consists of (i) 1,382,562 shares of common stock held by Sanderling Venture Partners VI, L.P., (ii) 47,754 shares of common stock held by Sanderling VI Beteiligungs GmbH & Co. KG, (iii) 56,896 shares of common stock held by Sanderling VI Limited Partnership, (iv) 1,336,113

shares of common stock held by Sanderling Venture Partners VI Co-Investment Fund, L.P., (v) 98,596 shares of common stock held by Sanderling Ventures Management VI, (vi) 38,193 shares of common stock issuable upon exercise of warrants held by Sanderling Venture Partners VI, L.P., (vii) 1,337 shares of common stock issuable upon exercise of warrants held by Sanderling VI Beteiligungs GmbH & Co. KG, (viii) 1,593 shares of common stock issuable upon exercise of warrants held by Sanderling VI Limited Partnership, and (ix) 37,908 shares of common stock issuable upon exercise of warrants held by Sanderling Venture Partners VI Co-Investment Fund, L.P. Mr. Middleton is a managing director of Middleton, McNeil, Mills & Associates VI, LLC, which has the ultimate voting and investment power over shares held of record by Sanderling Venture Partners VI, L.P., Sanderling VI Beteiligungs GmbH & Co. KG, Sanderling VI Limited Partnership and Sanderling Venture Partners VI Co-Investment Fund, L.P. and he may be deemed to have voting and investment power over shares held of record by Sanderling Venture Partners VI, L.P., Sanderling VI Beteiligungs GmbH & Co. KG, Sanderling VI Limited Partnership and Sanderling Venture Partners VI Co-Investment Fund, L.P. Mr. Middleton is the owner of Sanderling Ventures Management VI and he may be deemed to have voting and investment power over shares held of record by Sanderling Ventures Management VI. Mr. Middleton disclaims beneficial ownership over the shares held by Sanderling Ventures and its affiliates, except to the extent of his pecuniary interest therein.

(5) The number of shares is as of December 31, 2011 and based solely upon Amendment No. 1 to the Schedule 13G filed February 14, 2012, by T. Rowe Price Associates, Inc. (Price Associates). These securities are owned by various individual and institutional investors with which Price Associates serves as investment advisor with power to direct investments and/or sole power to vote the securities. For purposes of the reporting

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requirements of the Exchange Act, Price Associates is deemed to be a beneficial owner of 3,098,450 shares of our common stock.

(6) Consists of (i) 2,000 shares of common stock held by Mr. Stack, (ii) 18,596 shares of common stock held by Stack Schroon Mohawk FLP and (iii) 320,626 shares of common stock issuable upon exercise of stock options within 60 days of February 29, 2012. Mr. Stack is the general partner of Stack Schroon Mohawk FLP.

(7) Consists of (i) 5,000 shares of common stock and (ii) 113,154 shares of common stock issuable upon exercise of stock options within 60 days of February 29, 2012.

(8) Consists of 90,387 shares of common stock issuable upon exercise of stock options within 60 days of February 29, 2012.

(9) Consists of 6,250 shares of common stock issuable upon exercise of stock options within 60 days of February 29, 2012.

(10) Consists of (i) 3,083,973 shares of common stock held by MPM BioVentures IV-QP, L.P., (ii) 118,812 shares of common stock held by MPM BioVentures IV GmbH & Co. Beteiligungs KG, (iii) 87,694 shares of common stock held by MPM Asset Management Investors BV4 LLC, (iv) 74,073 shares of common stock issuable upon exercise of warrants held by MPM BioVentures IV-QP, L.P., (v) 2,853 shares of common stock issuable upon exercise of warrants held by MPM BioVentures IV GmbH & Co. Beteiligungs KG, (vi) 2,106 shares of common stock issuable upon exercise of warrants held by MPM Asset Management Investors BV4 LLC and (vii) 16,099 shares of common stock issuable upon exercise of stock options held by Dr. Evnin that are exercisable within 60 days of February 29, 2012. Dr. Evnin is a Member of MPM BioVentures IV LLC. MPM BioVentures IV LLC is the Managing Member of MPM BioVentures IV GP LLC, which is the General Partner of MPM BioVentures IV-QP, LP and the Managing Limited Partner of MPM BioVentures IV GmbH & Co. Beteiligungs KG. MPM BioVentures IV LLC is the Manager of MPM Asset Management Investors BV4 LLC. Dr. Evnin has a shared power to vote, acquire, hold and dispose of all shares and warrants. Dr. Evnin disclaims beneficial ownership of the securities except to the extent of their pecuniary interest therein.

(11) Consists of 6,250 shares of common stock issuable upon exercise of stock options within 60 days of February 29, 2012.

(12) Consists of 15,770 shares of common stock issuable upon exercise of stock options within 60 days of February 29, 2012.

(13) Consists of (i) 1,382,562 shares of common stock held by Sanderling Venture Partners VI, L.P., (ii) 47,754 shares of common stock held by Sanderling VI Beteiligungs GmbH & Co. KG, (iii) 56,896 shares of common stock held by Sanderling VI Limited Partnership, (iv) 1,336,113 shares of common stock held by Sanderling Venture Partners VI Co-Investment Fund, L.P., (v) 98,596 shares of common stock held by Sanderling Ventures Management VI, (vi) 38,193 shares of common stock issuable upon exercise of warrants held by Sanderling Venture Partners VI, L.P., (vii) 1,337 shares of common stock issuable upon exercise of warrants held by Sanderling VI Beteiligungs GmbH & Co. KG, (viii) 1,593 shares of common stock issuable upon exercise of warrants held by Sanderling VI Limited Partnership, (ix) 37,908 shares of

common stock issuable upon exercise of warrants held by Sanderling Venture Partners VI Co-Investment Fund, L.P. and (x) 16,099 shares of common stock issuable upon exercise of stock options held by Mr. Middleton that are exercisable within 60 days of February 29, 2012. Mr. Middleton is a managing director of Middleton, McNeil, Mills & Associates VI, LLC, which has the ultimate voting and investment power over shares held of record by Sanderling Venture Partners VI, L.P., Sanderling VI Beteiligungs GmbH & Co. KG, Sanderling VI Limited Partnership and Sanderling Venture Partners VI Co-Investment Fund, L.P. and he may be deemed to have voting and investment power over shares held of record by Sanderling Venture Partners VI, L.P., Sanderling VI Beteiligungs GmbH & Co. KG, Sanderling VI Limited Partnership and Sanderling Venture Partners VI Co-Investment Fund, L.P. Mr. Middleton is the owner of Sanderling Ventures Management VI and he may be deemed to have voting and investment power over shares held of record by Sanderling Ventures Management VI. Mr. Middleton disclaims beneficial ownership over the shares held by Sanderling Ventures and its affiliates, except to the extent of his pecuniary interest therein.

(14) Consists of (i) 7,692 shares of common stock and (ii) 14,996 shares of common stock issuable upon exercise of stock options within 60 days of February 29, 2012.

(15) Consists of (i) 3,433,933 shares of common stock held by HBM BioVentures (Cayman) Ltd., and (ii) 79,033 shares of common stock issuable upon exercise of warrants held by HBM BioVentures (Cayman) Ltd. The board of directors of HBM BioVentures (Cayman) Ltd. has sole voting and investment power with respect to the shares held by such entity and acts by majority vote. The board of directors of HBM BioVentures (Cayman) Ltd. is comprised of John Arnold, Richard Coles, Sophia Harris, Dr. Andreas Wicki and John Urquhart, none of whom has individual voting or investment power with respect to such shares.

Equity Compensation Plan Information

Set forth below is information as of December 31, 2011, regarding our equity compensation plans:

Plan Category	(a) Number of securities to be issued upon exercise of outstanding options, warrants, and rights	(b) Weighted-average exercise price of outstanding options, warrants, and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders:	2,337,017	$ 3.915	33,050
Equity compensation plans not approved by security holders:			
Total	2,337,017	$ 3.915	33,050

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

The following is a description of transactions entered into after January 1, 2010 to which we have been a party, in which the amount involved in the transaction exceeds the lesser of (i) $120,000 or (ii) one percent of the average of our total assets at year end for the last two completed fiscal years, and in which any of our directors, executive officers or beneficial owners of more than 5% of our voting securities, or affiliates or immediate family members of any of our directors, executive officers or beneficial owners of more than 5% of our voting securities, had or will have a direct or indirect material interest. We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that would be paid or received, as applicable, from unrelated third parties.

Debt Financings

2010 Secured Debt Financing

In March 2010, we entered into an agreement with certain of our existing investors as set forth in the table below to issue $15.0 million in aggregate principal amount of secured notes, or the 2010 Secured Notes, in a private placement and the investors purchased the entire $15.0 million of 2010 Secured Notes. To secure the performance of our obligations under the purchase agreement for the 2010 Secured Notes, we granted a subordinated security interest in substantially all of our assets, including our intellectual property assets, to the investors. In connection with entering into the Hercules Credit Facility (as described below), the holders of the 2010 Secured Notes entered into a subordination and intercreditor agreement with the lenders under the Hercules Credit Facility pursuant to which the 2010 Secured Notes were subordinated to the Hercules Credit Facility. The holders of the 2010 Secured Notes previously entered into a separate intercreditor agreement with the holders of convertible notes and secured notes we had issued in 2009 pursuant to which the 2009 convertible notes were subordinated to the 2010 Secured Notes and the 2009 secured notes, and the holders of the 2010 Secured Notes agreed to share payments pro rata with the holders of the 2009 secured notes.

The 2010 Secured Notes had an interest rate of 5% per year and all principal and accrued and unpaid interest on the 2010 Secured Notes was due on December 31, 2010. In connection with entering into the Hercules Credit Facility, the maturity date was further extended to the earliest of (1) a sale of the Company, (2) the date which is 30 days after the last day of the month that is 33 months after the expiration of the interest only period under the Hercules Credit Facility and (3) 91 days after the date that all obligations under the Hercules Credit Facility are paid in full and the Hercules Credit Facility is terminated.

All principal and interest due under the 2010 Secured Notes was converted into 1,156,606 shares of our common stock upon completion of our initial public offering. Purchasers of the 2010 Secured Notes included certain holders of more than 5% of our capital stock, or entities affiliated with them. The following table sets forth the amount of notes purchased by each such holder and the date of purchase.

Date of Purchase	Purchaser		Aggregate Principal Amount of Notes Purchased on Such Date
March 10, 2010	Entities affiliated with HBM BioVentures	$	1,875,000
	Entities affiliated with MPM Capital		1,875,000

	Entities affiliated with OrbiMed Advisors	1,875,000
	Entities affiliated with Sanderling Ventures	1,875,000
June 30, 2010	Entities affiliated with HBM BioVentures	937,500
	Entities affiliated with MPM Capital	937,500
	Entities affiliated with OrbiMed Advisors	937,500
	Entities affiliated with Sanderling Ventures	937,500
September 1, 2010	Entities affiliated with HBM BioVentures	937,500
	Entities affiliated with MPM Capital	937,500
	Entities affiliated with OrbiMed Advisors	937,500
	Entities affiliated with Sanderling Ventures	937,500

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HBM Term Loan

On April 30, 2010, we entered into a subordinated secured note purchase agreement with entities affiliated with HBM BioVentures, or HBM, to issue $3.8 million in aggregate principal amount of secured notes, or the HBM Secured Notes, in a private placement. HBM purchased the entire $3.8 million of the HBM Secured Notes. To secure the performance of our obligations under the purchase agreement for the HBM Secured Notes, we granted a subordinated security interest in substantially all of our assets, including our intellectual property assets, other than the assets that secure our obligations under the Amended and Restated Royalty Interests Assignment Agreement. The HBM Secured Notes carry an interest rate of approximately 10% per year. In addition, the HBM Secured Notes require a final payment fee if they are prepaid prior to the maturity date. The maturity date of the HBM Secured Notes is the earliest of (1) a sale of the Company, (2) the date which is 30 days after the last day of the month that is 33 months after the expiration of the interest only period under the Hercules Credit Facility and (3) 91 days after the date that all obligations under the Hercules Credit Facility are paid in full and the Hercules Credit Facility is terminated. In connection with entering into the Hercules Credit Facility, the holders of the HBM Secured Notes entered into a subordination and intercreditor agreement with the lenders under the Hercules Credit Facility pursuant to which the HBM Secured Notes were subordinated to the Hercules Credit Facility.

All principal and interest due under the HBM Secured Notes was converted into 297,359 shares of our common stock upon completion of our initial public offering. Purchasers of the HBM Secured Notes included certain holders of more than 5% of our capital stock, or entities affiliated with them.

December 2010 Convertible Notes

On December 29, 2010, we sold $7.5 million in aggregate principal amount of convertible promissory notes, or the December 2010 Convertible Notes, in a private placement to certain of our existing investors. 50% of the principal amount was funded on December 29, 2010. In connection with the issuance and sale of the December 2010 Convertible Notes, we issued warrants to the holders of the December 2010 Convertible Notes to purchase an aggregate of 167,361 shares of our common stock with an exercise price of $13.44 per share. The December 2010 Convertible Notes had an interest rate of 5% per year from and after March 31, 2011 and all principal and accrued and unpaid interest on the December 2010 Convertible Notes is due and payable upon the earliest of: (1) a sale of us, (2) the date which is 30 days after the last day of the month that is 33 months after the expiration of the interest only period under the Hercules Credit Facility and (3) 91 days after the date that all obligations under the Hercules Credit Facility are paid in full and the Hercules Credit Facility is terminated.

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

The following table sets forth the aggregate principal amount of December 2010 Convertible Notes purchased by each such holder and the warrants received in connection with the purchase of the December 2010 Convertible Notes.

Purchaser	Aggregate Principal Amount of Notes	Number of Warrant Shares

HBM BioVentures	$	1,875,000	41,841
Entities affiliated with MPM Capital	$	1,875,000	41,840
Entities affiliated with OrbiMed Advisors	$	1,875,000	41,840
Entities affiliated with Sanderling Ventures	$	1,875,000	41,840

Stockholder Guarantee under Hercules Credit Facility

On November 24, 2010, we entered into a $26.3 million credit facility with Hercules Technology Growth Capital, Inc. and Hercules Technology III, L.P., as lenders, or the Hercules Credit Facility. We borrowed under the Hercules Credit Facility an aggregate principal amount of $26.3 million.

The Hercules Credit Facility is guaranteed by MPM Capital, Sanderling Ventures and OrbiMed Advisors, and entities affiliated with them, which are holders of more than 5% of our voting securities, on a several and not joint basis, which guarantee is limited to each such stockholder s pro rata portion of the outstanding principal and accrued and unpaid interest under the Hercules Credit Facility, but in no event to exceed $11.3 million in the aggregate. The obligations of these stockholders under the guarantee is

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not triggered until the earlier to occur of (i) 30 days after written notice from the agent that our obligations under the Hercules Credit Facility have been accelerated, and (ii) the occurrence of a bankruptcy or insolvency event with respect to the borrower under the Hercules Credit Facility, us or any of the guarantors. The guarantee by these stockholders of the Hercules Credit Facility also includes covenants that require each such investor to maintain at all times unfunded commitments from its fund investors in an amount equal to at least one and one-half times the maximum amount that the investor may be obligated for under the stockholder guarantee, and also includes certain control requirements with respect to such stockholders. The guarantee by these stockholders of the Hercules Credit Facility replaced the guarantee under the GECC Credit Facility which was terminated in November 2010. In December 2011, the guarantee by these stockholders was terminated in accordance with the term of the Hercules Credit Facility.

Investors Rights Agreement

In March 2007, we entered into an investors rights agreement with purchasers of our Series A convertible preferred stock. This agreement provides these purchasers with certain rights relating to the registration of their shares of common stock that were issued upon conversion of their Series A convertible preferred stock The registration rights terminate in February 2016, five years following the completion of our initial public offering, or for any particular holder with registration rights, at such time when all securities held by that stockholder may be sold pursuant to Rule 144 under the Securities Act.

Employment Agreements

We entered into employment agreements with the following executive officers and key employees: David Stack, our chief executive officer, James Scibetta, our chief financial officer, and Taunia Markvicka, our Vice President, Commercial. For further information, see Employment Agreements, Severance and Change in Control Arrangements under Item 11 above. In addition we have entered into an offer letter with Lauren Riker, our Executive Director, Accounting & Reporting.

Services Agreements

We entered into a services agreement with Gary Patou, our chief medical officer, and MPM AM. For further information, see Services Agreement with MPM and Gary Patou under Item 11 above.

In addition to the amounts paid to Gary Patou, MPM AM provides clinical management and subscription services to us. During the period from January 1, 2010 to December 31, 2011, we paid an aggregate of $1.2 million to MPM AM for these services.

In February 2008, we entered into a services agreement with Stack Pharmaceuticals, Inc., or SPI, an entity controlled by David Stack, our chief executive officer. Pursuant to the agreement, SPI provided us with the use of SPI s office facilities which included the use of office space for our employees, office furnishings, phone system, internet connections, printers and other related office amenities such as conference rooms. The office facilities are located at 5 Sylvan Way, Parsippany, New Jersey. Pursuant to the agreement, we paid SPI amounts ranging from $10,500 to $18,250 per month during the term of the services agreement. The term of the agreement was one year and was renewable upon consent of both

parties and the agreement may be cancelled with 60 days written notice by either party. In February 2009, we renewed the agreement on a month-to-month basis, and we terminated this agreement in November 2011.

In August 2010, we entered into a new services agreement with SPI that replaced the agreement that we entered into in February 2008. Pursuant to the new agreement, SPI provides us with the use of SPI s office facilities which includes the use of office space for our employees, office furnishings, phone system, internet connections, printers and other related office amenities such as conference rooms. In addition, SPI provides consulting services and commercial leadership related to EXPAREL regarding the development of strategic plans and analyses for the commercialization of EXPAREL, support in the development of documents, data and materials for investor and commercial partner presentations and documents, and commercial leadership in support of our website. SPI provided these services from time to time as we requested from August 2010 through the termination of the Agreement in November 2011.

In addition, during 2008, 2009, 2010 and 2011, upon our request, SPI performed various projects, all of which have been completed by SPI. These projects included a business analysis and commercial recommendation for our DepoDur product, a market research project related to the development of a DepoMethotrexate product, market research and forecasting in support of clinical development of EXPAREL for the potential additional indications of nerve block and epidural administration and reimbursement for access to Datamonitor reports for commercial analysis and partnering discussions regarding EXPAREL.

During the period from January 1, 2010, through December 31, 2011, we have paid SPI an aggregate of $0.5 million for the above services provided by SPI.

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In April 2010, we signed a statement of work for a feasibility study with Rhythm Pharmaceuticals, Inc. We earned contract revenue of approximately $290,000 from this statement of work during the period from April 2010 through September 30, 2011. MPM Capital and its affiliates are holders of more than 5% of our capital stock. We have been informed that MPM Capital and its affiliates are holders of more than 10% of the capital stock of Rhythm Pharmaceuticals, Inc. and a managing director of MPM Capital is a member of the board of directors of Rhythm Pharmaceuticals, Inc.

Indemnification of Officers and Directors

Our amended and restated certificate of incorporation and amended and restated bylaws, provide that we indemnify each of our directors and officers to the fullest extent permitted by the Delaware General Corporation Law. Further, we have entered into indemnification agreements with each of our directors and officers, and we have purchased a policy of directors and officers liability insurance that insures our directors and officers against the cost of defense, settlement or payment of a judgment under certain circumstances.

Policies and Procedures for Related Person Transactions

Our board of directors has adopted a written related person transaction policy which sets forth the policies and procedures for the review and approval or ratification of related person transactions. This policy covers any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, the amount involved exceeds the lesser of (1) $120,000 or (2) one percent of the average of our total assets at year end for the last two completed fiscal year, and a related person had or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness, and employment by us of a related person.

Any related person transaction proposed to be entered into by us is required to be reported to our chief financial officer and will be reviewed and approved by the audit committee in accordance with the terms of the policy, prior to effectiveness or consummation of the transaction, whenever practicable. If our chief financial officer determines that advance approval of a related person transaction is not practicable under the circumstances, the audit committee will review and, in its discretion, may ratify the related person transaction at the next meeting of the audit committee, or at the next meeting following the date that the related person transaction comes to the attention of our chief financial officer. Our chief financial officer, however, may present a related person transaction arising in the time period between meetings of the audit committee to the chair of the audit committee, who will review and may approve the related person transaction, subject to ratification by the audit committee at the next meeting of the audit committee.

In addition, any related person transaction previously approved by the audit committee or otherwise already existing that is ongoing in nature will be reviewed by the audit committee annually to ensure that such related person transaction has been conducted in accordance with the previous approval granted by the audit committee, if any, and that all required disclosures regarding the related person transaction are made.

Transactions involving compensation of executive officers will be reviewed and approved by the compensation committee in the manner specified in the charter of the compensation committee.

A related person transaction reviewed under this policy will be considered approved or ratified if it is authorized by the audit committee in accordance with the standards set forth in our related person transaction policy after full disclosure of the related person s interests in the transaction. As appropriate for the circumstances, the audit committee will review and consider:

- the related person s interest in the related person transaction;
- the approximate dollar value of the amount involved in the related person transaction;
- the approximate dollar value of the amount of the related person s interest in the transaction without regard to the amount of any profit or loss;
- whether the transaction was undertaken in the ordinary course of business;
- whether the transaction with the related person is proposed to be, or was, entered into on terms no less favorable to us than terms that could have been reached with an unrelated third party;
- the purpose of, and the potential benefits to us of, the transaction; and

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- any other information regarding the related person transaction or the related person in the context of the proposed transaction that would be material to stockholders in light of the circumstances of the particular transaction.

The audit committee reviews all relevant information available to it about the related person transaction. The audit committee may approve or ratify the related person transaction only if the audit committee determines that, under all of the circumstances, the transaction is in, or is not inconsistent with, our best interests. The audit committee may, in its sole discretion, impose conditions as it deems appropriate on us or the related person in connection with approval of the related person transaction.

Director Independence

Rule 5605 of the NASDAQ Marketplace Rules requires a majority of a listed company s board of directors to be comprised of independent directors within one year of listing. Under The NASDAQ Marketplace Rules, a director will only qualify as an independent director if, in the opinion of our board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Our board of directors has determined that each of our directors (including Dr. Gordon, who resigned from our board of directors effective June 2, 2011), with the exception of David Stack, is an independent director as defined under Rule 5605(a)(2) of The NASDAQ Marketplace Rules. In making such independence determination, the board of directors considered the relationships that each such non-employee director has with us and all other facts and circumstances that the board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director. In considering the independence of the directors listed above, our board of directors considered the association of our directors with the holders of more than 5% of our common stock.

Item 14. Principal Accounting Fees and Services

Pacira paid the following fees to its independent registered public accounting firm for the audit of the consolidated financial statements and for other services provided in the years ended December 31, 2011 and 2010.

	2011	2010
Audit Fees(1)	$ 466,000	$ 568,000
Audit Related Fees(2)		8,000
Tax Fees(3)		1,000
All Other Fees		
Total Fees	$ 466,000	$ 577,000

(1) Audit fees consist of fees for the audit of our financial statements, the review of the interim financial statements included in our quarterly reports on Form 10-Q, and other professional services provided in connection with registration statements including: IPO and follow-on offering, and audits of 2007-2009 financial statements in connection with the IPO.

(2) Audit-related fees consist of fees for assurance and related services that are reasonably related to the performance of the audit and the review of our financial statements and which are not reported under Audit Fees .

(3) Tax fees consist of fees for tax compliance, tax advice and tax planning services.

Audit Committee Pre-approval Policy and Procedures

Our Audit Committee has adopted policies and procedures relating to the approval of all audit and non-audit services that are to be performed by our registered public accounting firm. This policy generally provides that we will not engage our registered public accounting firm to render audit or non-audit services unless the service is specifically approved in advance by our Audit Committee or the engagement is entered into pursuant to one of the pre-approval procedures described below.

From time to time, our Audit Committee may pre-approve specified types of services that are expected to be provided to us by our independent registered public accounting firm during the next 12 months. Any such pre-approval is detailed as to the particular service or type of services to be provided and is also generally subject to a maximum dollar amount.

Our Audit Committee has also delegated to the chairman of our Audit Committee the authority to approve any audit or non-audit services to be provided to us by our registered public accounting firm. Any approval of services by a member of our Audit Committee pursuant to this delegated authority is reported on at the next meeting of our Audit Committee.

During our 2011 fiscal year, no services were provided to us by J.H. Cohn LLP or any other accounting firm other than in accordance with the pre-approval policies and procedures described above.

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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 Stockholder s 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.

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SIGNATURES

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

PACIRA PHARMACEUTICALS, INC.

Date: March 27, 2012

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.

Signature	Title	Date
/s/ David Stack David Stack	Director, President and Chief Executive Officer *(Principal Executive Officer)*	March 27, 2012
/s/ James Scibetta James Scibetta	Chief Financial Officer *(Principal Financial Officer)*	March 27, 2012
/s/ Lauren Riker Lauren Riker	Executive Director, Accounting and Reporting *(Principal Accounting Officer)*	March 27, 2012
/s/ Fred Middleton Fred Middleton	Chairman	March 27, 2012
/s/ Luke Evnin Luke Evnin	Director	March 27, 2012
/s/ Laura Brege Laura Brege	Director	March 27, 2012
/s/ John Longenecker John Longenecker	Director	March 27, 2012
/s/ Gary Pace Gary Pace	Director	March 27, 2012
/s/ Andreas Wicki	Director	

Andreas Wicki