Pacira Pharmaceuticals, Inc.
Form 10-K
February 28, 2019
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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, 2018

Or

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

For the transition period from to

Commission File Number: 001-35060

PACIRA PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	51-0619477
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

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

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

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

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

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

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

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 every Interactive Data File required to be submitted 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 such files). Yes x No o

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

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

Large accelerated filer x	Accelerated filer o
Non-accelerated filer o	Smaller reporting company o
	Emerging growth company o

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards pursuant to Section 13(a) of the Exchange Act. o

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 the registrant's voting stock held by non-affiliates of the registrant, based upon the closing sale price of the common stock as reported on the NASDAQ on June 29, 2018, the last trading day of the registrant's most recently completed second fiscal quarter, of $32.05 per share was approximately $1.3 billion. Shares of common stock held by each director and executive officer (and their respective affiliates) and by each person who owns 10 percent or more of the outstanding common stock or who is otherwise believed by the registrant to be in a control position have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 24, 2019, 41,229,766 shares of the registrant's common stock, $0.001 par value per share, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates certain information by reference from the registrant's proxy statement for the 2019 annual meeting of stockholders to be filed no later than 120 days after the end of the registrant's fiscal year ended December 31, 2018.

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PACIRA PHARMACEUTICALS, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2018

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Forward-Looking Statements

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

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

PART I

Item 1. Business

References

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

Corporate Information

We were incorporated in Delaware under the name Blue Acquisition Corp. in December 2006 and changed our name to Pacira, Inc. in June 2007. In October 2010, we changed our name to Pacira Pharmaceuticals, Inc. Our principal executive offices are in Parsippany, New Jersey.

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

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

Overview

We are a specialty pharmaceutical company focused on becoming a global leader in delivering innovative non-opioid pain management and regenerative health solutions to surgeons and anesthesiologists. Our corporate mission is to provide an opioid alternative to as many appropriate patients as possible. To that end, we are advancing a three-part growth strategy focusing on: (i) expanding the use of EXPAREL® (bupivacaine liposome injectable suspension), our

long-acting, non-opioid for postsurgical pain, (ii) leveraging our proprietary DepoFoam platform for new clinical candidates and (iii) pursuing innovative acquisition targets that align with our strategy, while complementing our EXPAREL commercial infrastructure and physician audience.

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Recent Highlights

- As of February 2019, commercial production of EXPAREL is now underway at a custom suite in Swindon, England, created under our partnership with Thermo Fisher Scientific Pharma Services (formerly Patheon UK Limited), or Thermo Fisher. This first suite mirrors our existing facility at the Pacira Science Center Campus in San Diego, California, and is expected to double our manufacturing capacity. Through the partnership, we are developing a second dedicated suite that is expected to enable another doubling of EXPAREL manufacturing capacity in approximately two years. Our investment in this facility is an integral component of our strategy to meet the growing customer demand in the U.S. and to support expansion into new global markets, such as Europe, Canada and Asia.

- On February 7, 2019, we received FDA approval for our sNDA to extend the shelf life of EXPAREL from 12 months to 24 months.

- In January 2019, we announced that our Phase 4 study of EXPAREL in patients undergoing Cesarean section, or C-section, achieved its primary endpoint with a statistically significant reduction in total postsurgical opioid consumption through 72 hours ($p<0.05$). EXPAREL also achieved statistical significance for reduction in pain intensity scores through 72 hours ($p<0.05$). The full study results will be submitted for publication in peer-reviewed medical literature.

EXPAREL was approved by the FDA in October 2011 and was commercially launched in April 2012. EXPAREL is currently indicated for single-dose infiltration in adults to produce postsurgical local analgesia and as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia. Safety and efficacy have not been established in other nerve blocks. EXPAREL consists of bupivacaine, an amide-type local anesthetic, encapsulated in DepoFoam, our proprietary extended release drug delivery technology, that delivers bupivacaine over time for extended analgesia. We believe that EXPAREL addresses a significant medical need for a long-acting non-opioid postsurgical analgesic and plays a significant role in opioid minimization strategies. EXPAREL is designed for recovery with minimal opioid use by (i) delivering targeted local analgesia at the surgical site; (ii) reliably releasing bupivacaine over time for prolonged analgesia; (iii) eliminating the need for catheters and pumps that may hinder recovery and (iv) providing long-lasting pain control while reducing the need for opioids. Our net product sales of EXPAREL in 2018 were $331.1 million. For the years ended December 31, 2018, 2017 and 2016, net product sales of EXPAREL accounted for 98%, 99% and 96% of our total revenues, respectively. In addition to EXPAREL, DepoFoam is also the basis for future clinical candidates.

Our current product portfolio and product candidate pipeline, along with anticipated milestones over the next 12 to 18 months, are summarized in the table below:

PROPRIETARY PIPELINE

Product / Product Candidates	Status	Next Expected Milestone
EXPAREL (bupivacaine liposome injectable suspension):		
Surgical Infiltration	Approved (U.S.)	Geographic expansion
Interscalene Brachial Plexus Nerve Block	Approved (U.S.)	Publish results / geographic expansion
C-section TAP field block [1]	Phase 4	Publish results
C-section TAP field block follow-on study	Phase 4	Commence enrollment
Hip fracture	Phase 4	Initiate study
Spine	Phase 4	Initiate study
Surgical Infiltration/Nerve Block	MAA (E.U.)	File marketing applications in E.U., Canada & China
Pediatrics infiltration	Phase 3	Complete enrollment

Pediatrics Interscalene Brachial Plexus Nerve Block	Phase 3	Finalize clinical / regulatory strategy with the FDA
DepoFoam product candidates	Preclinical	Name clinical candidate(s)
Product / Product Candidates	Status	Next Expected Milestone
NOCITA® (bupivacaine liposome injectable suspension): [2]		
Surgical infiltration in dogs	Approved (U.S.)	Marketed by Aratana Therapeutics

[1] TAP block is a transversus abdominis plane field block
[2] NOCITA® is a registered trademark of Aratana Therapeutics, Inc.

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Our Strategy

We continue to drive forward on our goal to be a global leader in delivering innovative non-opioid pain management and regenerative health solutions. To achieve this, we are advancing a three-pronged strategy:

- Maximizing the EXPAREL opportunity: As the only opioid-free, long-acting local and regional analgesic approved for infiltration, field blocks and interscalene brachial plexus nerve block, we believe EXPAREL is well-positioned to continue delivering strong sustainable growth from multiple sources. We are focusing on expanding the use of EXPAREL in key surgical settings, such as spine, hip fracture and C-section. We are also seeing increased use within the anesthesiology community after the FDA's approval of our sNDA to include administration via interscalene brachial plexus nerve block to produce postsurgical regional analgesia for upper extremity procedures. In addition, we are advancing clinical and regulatory activities to support the approval of EXPAREL in the pediatric setting, as well as in new target markets.

- Leveraging our proprietary DepoFoam platform for new clinical candidates: We are developing a pipeline based on our DepoFoam platform, our established safe and effective multivesicular liposomal drug delivery technology. DepoFoam consists of microscopic, spherical, lipid-based particles composed of a honeycomb of numerous, non-concentric, internal aqueous chambers containing the encapsulated drug. DepoFoam provides flexible delivery and can be designed to offer an immediate release dose followed by sustained delivery. We are defining a development program for the intrathecal delivery of a non-opioid analgesic for acute and chronic pain, and we are awaiting readouts from animal and other feasibility studies for additional DepoFoam-based clinical candidates.

- Pursuing innovative acquisition targets that align with our strategy: We believe EXPAREL and the DepoFoam platform offer a strong foundation to address the opioid epidemic. Building on these company assets, we are also pursuing innovative acquisition targets ranging from devices, therapeutics, cell therapies, and regenerative medicines. Our goal is to build a portfolio of customer-focused non-opioid solutions to improve patients' journeys along the neural pain pathway.

EXPAREL

Opioid addiction in the U.S. has reached epidemic proportions, with the Centers for Disease Control and Prevention (CDC) estimating that 91 people die every day from an opioid overdose. Overreliance on opioids in the postsurgical setting has caused a rapid deluge of opioid misuse, abuse and addiction. In 2018, new research showed that patients received nearly 100 to 200 opioid pills to help manage pain from four common procedures ranging from rotator cuff repair and hip replacement to knee replacement and sleeve gastrectomy. Further, one-quarter of orthopedic surgery patients were prescribed a daily dose of opioids equal to 90 milligrams of morphine or more, which are doses so potent that the CDC says they put patients at high risk for overdose. The report shows that across the seven orthopedic and soft tissue surgical procedures examined, patients were prescribed an average of 82 opioid pills each to help manage postsurgical pain. The research indicates that close to nine percent of surgical patients became newly persistent users in 2017, continuing to take these opioids at least three to six months after their procedure. Among patients having knee replacement surgery or a colectomy, newly persistent opioid users climbed as high as 15 percent and 17 percent, respectively. Further, women were 40 percent more likely to become persistent opioid users than men; and among persistent users, females were prescribed 15 percent more opioids than their male counterparts. These findings come from the report, Exposing a Silent Gateway to Persistent Opioid Use - A Choices Matter Status Report, based on an analysis of 2017 adjudicated medical and pharmacy claims data conducted by the IQVIA Institute for Human Data Science and a nationwide survey of surgical patients and surgeons fielded in 2018 by Wakefield Research.

Based on our clinical data, EXPAREL provides continuous and extended postsurgical analgesia and reduces the consumption of opioid medications. We believe EXPAREL simplifies postsurgical pain management, minimizes

breakthrough episodes of pain and has the potential to result in improved patient care and outcomes, as well as enhanced hospital economics.

Our EXPAREL growth strategy is summarized below:

- First, expanding the use of EXPAREL in key surgical settings. In April 2018, the FDA approved our sNDA to broaden the use of EXPAREL to include administration via interscalene brachial plexus nerve block to produce postsurgical regional analgesia. Safety and efficacy have not been established in other nerve blocks. With this approval, EXPAREL is the first long-acting, single-dose nerve block available for patients undergoing upper extremity surgeries, such as total shoulder arthroplasty or rotator cuff repair. We have published positive results from a Phase 4 multicenter, randomized, double-blind trial in total knee arthroplasty, or TKA, and we recently reported positive topline results from our Phase 4 study of EXPAREL in patients undergoing C-section procedures. Our Phase 4 plan also includes a

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follow-on study in C-section procedures, which will include an opioid-free arm, as well as studies in hip fracture and spine surgeries. We are also seeing EXPAREL incorporated into an increasing number of Enhanced Recovery After Surgery, or ERAS, protocols from major academic centers for a wide range of procedures. In addition, we are advancing clinical and regulatory activities to support the future expansion of EXPAREL to the pediatric setting, as well as new global markets, such as Europe, Canada and China.

- Second, expanding access to EXPAREL and driving education and awareness around the need for opioid-sparing strategies. We continue to advance our Choices Matter national educational campaign, aimed at empowering patients to proactively discuss postsurgical pain management, including non-opioid options, with their doctors. We also have a focused team in the field consisting of outpatient account managers who are working with ambulatory centers and commercial payers to facilitate EXPAREL reimbursement and support the transition of procedures commonly thought of as inpatient to the ambulatory setting. The Centers for Medicare and Medicaid Services (CMS) is now providing Medicare reimbursement for EXPAREL when administered in Ambulatory Surgical Centers (ASCs) through the product-specific Healthcare Common Procedure Coding System (HCPCS) code of C9290, which became effective January 1, 2019 (also known as a C-code). We believe having a product-specific reimbursement code for EXPAREL will support a more efficient reimbursement process as commercial payers standardize around Medicare rates and practices. In addition, a Current Dental Terminology (CDT) code became effective on January 1, 2019 (also known as a D-code) to report infiltration of a sustained-release therapeutic drug in oral surgery procedures. We believe the D-code will meaningfully enhance the use of non-opioid options in oral surgery procedures, where young adult patients are often exposed to an opioid for the first time.

Third, partnering with those who share our commitment to innovative opioid-sparing procedural solutions. We have a growing network of strategic collaborations to expand education on the importance of non-opioid multimodal alternatives for post-surgical pain management and broaden our commercial reach. These include agreements with industry partners, as well as healthcare providers and hospital systems to support their implementation of opioid-sparing enhanced recovery protocols. In January 2017, we formed a partnership with DePuy Synthes Sales Inc., or DePuy Synthes, part of the Johnson & Johnson family of companies, to support the promotion, education and training of EXPAREL in orthopedics. Our growing coalition of collaborators also includes Aetna, the American Association of Oral and Maxillofacial Surgeons, or AAOMS, the American College of Surgeons, the American Society for Enhanced Recovery, Cancer Treatment Centers of America, the Illinois Surgical Quality Improvement Collaborative, MEDNAX, WellStar Health System and Shatterproof.org.

EXPAREL Clinical Benefits

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

- provides long-lasting local or regional analgesia;
- is a ready-to-use formulation;
- expands easily with saline or lactated Ringer’s to reach a desired volume;
- leverages existing interscalene brachial plexus nerve block, field block and infiltration administration techniques; and
- facilitates treatment of both small and large surgical sites.

We believe EXPAREL can become the foundation of a long-acting postsurgical pain management regimen to reduce the need for opioids. Based on the clinical data from our Phase 3 hemorrhoidectomy trial, our Phase 3 interscalene brachial plexus nerve block trial, our Phase 4 TKA trial, as well as our retrospective health outcomes studies data, EXPAREL significantly reduces opioid usage while improving postsurgical pain management.

In our Phase 3 hemorrhoidectomy trial, EXPAREL:

- delayed the median time to rescue analgesic use (opioids) to 15 hours for patients treated with EXPAREL versus one hour for patients treated with placebo;

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- significantly increased the percentage of patients requiring no opioid rescue medication through 72 hours post-surgery to 28%, compared to 10% for placebo;
- resulted in 45% less opioid usage through 72 hours post-surgery compared to placebo; and
- increased the percentage of patients who were pain free at 24 hours post-surgery compared to placebo.

In our Phase 3 trial as an interscalene brachial plexus nerve block for upper extremity surgeries, EXPAREL:

- decreased total opioid consumption by 78 percent ($p<0.0001$) from zero to 48 hours after surgery;
- reduced pain scores by 46 percent versus placebo ($P<0.0001$); and
- 13 percent of patients who received EXPAREL did not require any opioids for 48 hours after surgery ($p<0.01$).

In our Phase 4 trial of EXPAREL versus bupivacaine HCl in TKA, EXPAREL:

- decreased total opioid consumption by 78 percent ($p=0.0048$) from zero to 48 hours after surgery;
- reduced pain scores by 14 percent ($p=0.0381$) from 12 to 48 hours after surgery; and
- 10 percent of patients in the EXPAREL arm remained opioid-free through 48 and 72 hours (compared to zero patients in the bupivacaine arm; $p<0.01$).

EXPAREL can improve patient satisfaction and outcomes. We believe EXPAREL:

- provides effective pain control without the need for expensive and difficult-to-use delivery technologies that extend the duration of action for bupivacaine, such as elastomeric bags, or opioids administered through patient-controlled analgesia, or PCA, when used as part of a multimodal postsurgical pain regimen;
- reduces the need for patients to be constrained by elastomeric bags and PCA systems, which are barriers to earlier ambulation and may introduce catheter-related issues, including infection; and
- promotes maintenance of early postsurgical pain management, which may reduce the time spent in the intensive care unit.

EXPAREL Health Economic Benefits

In addition to being efficacious and safe, we believe that EXPAREL provides health economic benefits that play an important role in formulary decision-making that are often overlooked. Several members of our management team have extensive experience applying health economic outcomes research to support commercial success. Our strategy is to work directly with the senior leadership of our hospital customers, integrated health networks, quality improvement organizations, key opinion leaders, or KOLs, in the field of postsurgical pain management and leading influencer hospitals to provide them with retrospective and prospective studies to demonstrate the economic benefits of EXPAREL.

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

In November 2018, new data was published by the Journal of Medical Economics on the use of EXPAREL to manage postsurgical pain following TKA. The study showed that patients receiving EXPAREL had a significant reduction in

opioid use, hospital LOS and total hospitalization costs compared to TKA patients who did not receive EXPAREL. Patients receiving EXPAREL also had an increased likelihood to be discharged home rather than to a skilled nursing facility.

This retrospective analysis utilized hospital chargemaster data from the Premier Healthcare Database from January 2011 through April 2017 for the 10 hospitals in the U.S. with the highest number of primary TKA procedures using EXPAREL. Patients undergoing TKA who received EXPAREL were matched in a one-to-one ratio to a control group of patients whose pain

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management strategy did not include EXPAREL. The study population included 20,907 Medicare-insured TKA patients and 12,505 TKA patients with commercial insurance.

Results showed that patients undergoing TKA who received EXPAREL demonstrated a significant:

- Decrease in opioid consumption, expressed in oral morphine equivalent dosing (MED), when controlled for LOS in both the Medicare and commercial insurance groups (69 mg MED and 64 MED reductions, respectively; P<0.0001);
- Decrease in average hospital LOS by 0.6 days in both the Medicare and commercial insurance groups (P<0.0001);
- Decrease in total hospitalization costs in both the Medicare and commercial insurance groups (-$616 and -$775, respectively; P<0.0001); and
- An increase in likelihood to be discharged home in both the Medicare and commercial insurance groups (1.58 times more likely and 1.63 times more likely, respectively; P<0.0001).

Approximately 700,000 TKA procedures were performed in the United States in 2012, making it one of the most common hospital-based surgical procedures in the country. The number of annual TKA procedures is estimated to reach 3.5 million by 2030. Additionally, total Medicare hospital reimbursement for inpatient TKA and total hip arthroplasty (collectively known as total joint arthroplasty, or TJA) was $6.6 billion in 2013 and is likely to continue rising with the projected increases in TJA procedures.

Third Molar Procedures

In September 2017, we announced a collaboration with Aetna, one of the nation’s leading diversified health care benefits companies, with the support of AAOMS. This national program aims to reduce the number of opioid tablets dispensed to patients undergoing impacted third molar (wisdom tooth) extractions by at least 50 percent through the utilization of EXPAREL to provide prolonged non-opioid postsurgical pain control. Aetna now includes the cost of EXPAREL as a covered expense for impacted third molar extractions performed by surgeons who have completed training on use of the product.

According to a Journal of the American Medical Association (JAMA) study, more than two-thirds of patients who underwent surgical tooth extractions reported unused prescription opioids, with the majority also indicating that these medications are neither safely stored nor disposed of. These facts suggest that there is a dangerous accumulation of opioids in the home, which are available for potential diversion or misuse.

EXPAREL Dosing, Volume Expansion and Admixing with Bupivacaine HCl

EXPAREL is available as a 266 mg/20 mL single-use vial and a 133 mg/10 mL single-use vial. The recommended dose of EXPAREL is based on (i) the size of the surgical site; (ii) the volume needed to cover the width and depth of the surgical site and (iii) patient-specific factors that could impact safety of an amide-type local anesthetic. The maximum dose should not exceed 266 mg.

EXPAREL can be expanded in volume to optimize results. Physicians consider the size of the surgical site and neuroanatomy to determine dosing and volume expansion. The 266 mg (20 mL) EXPAREL vial can be expanded with up to 280 mL of normal (0.9%) saline or lactated Ringer’s solution for a total volume of 300 mL (a 1:14 ratio). For smaller surgical sites where 20 mL is too much volume, the 133 mg (10 mL) vial should be considered.

To ensure early analgesic activity, EXPAREL can be admixed with bupivacaine HCl so long as the ratio does not exceed 1:2. For example, the 266 mg/20mL vial may be administered with up to 30 mL of 0.5% bupivacaine HCl or up to 60 mL of 0.25% bupivacaine HCl. Bupivacaine HCl may be administered immediately before EXPAREL or admixed in the same syringe.

EXPAREL Label Expansion—Pediatrics

The Pediatric Research Equity Act requires pharmaceutical companies to study their products in children for the same use for which they are approved in adults. There is no long-lasting local anesthetic approved for use in children under the age of 12, meaning that pediatric patients currently have no approved alternatives to opioids for the management of severe postsurgical pain and need additional pain control options.

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We have completed our first pharmacokinetic and safety study in children aged 12 to 17 undergoing corrective spine surgery. In addition, we have secured FDA approval of our protocol for an extended pharmacokinetic and safety study for local analgesia in children aged 6 to 17 undergoing cardiovascular or spine surgeries and site activation for this study is underway. For Pediatrics, we are seeking a broad infiltration approval, similar to that of adults under the existing EXPAREL label. We are also working with the FDA to define a program to study the administration of EXPAREL as a nerve block in the pediatric setting.

EXPAREL Global Expansion

We have defined a global expansion strategy for EXPAREL that we believe provides us with the opportunity to increase our revenue and leverage our fixed cost infrastructure. We have prioritized the European, Canadian and Chinese markets. In the E.U., we have secured a positive opinion for our Pediatric Investigation Plan (PIP) and we plan to submit our Marketing Authorization Application (MAA) around the middle of 2019. In Canada, which is a concentrated market driven by four provinces, we are also planning a New Drug Submission around the middle of 2019. In both the European and Canadian markets, we do not intend to pursue a commercial partnership to commercialize EXPAREL. In China, we have received feedback from the National Medical Products Administration regarding the regulatory requirements for securing approval of EXPAREL. We believe we have the clarity we need and we are in the process of finalizing our regulatory path forward. We have an agreement with Nuance Biotech Co. Ltd., a China-based specialty pharmaceutical company, for the development and commercialization of EXPAREL in China.

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 by erosion and/or reorganization of the particles' lipid membranes. Release rates are determined by the choice and relative amounts of lipids in the formulation.

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

- Convenience. Our DepoFoam products are ready to use, do not require reconstitution or mixing with another solution, and can be used with patient-friendly narrow gauge needles and pen systems;
- Multiple regulatory precedents. Our current and past DepoFoam products have been approved in the U.S. and Europe, making regulatory authorities familiar with our DepoFoam technology;
- Extensive safety history. Our DepoFoam products have nearly 20 years of safety data;
- Proven manufacturing capabilities. We make EXPAREL, a DepoFoam-based product, in our current Good Manufacturing Practices, or cGMP, facilities;
- Flexible time release. Encapsulated drug releases over a desired period, 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.

Given the safety profile and flexibility of our DepoFoam platform, we are advancing a development plan for intrathecal delivery of a non-opioid analgesic for acute and chronic pain. This program is underway with EXPAREL, as well as other local anesthetic and novel active pharmaceutical ingredient (API) products. We also have several DepoFoam-based products in preclinical development. Following data readouts from animal and other feasibility studies for these candidates, we will determine the best programs to advance into the clinic.

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Sales and Marketing

We have built our marketing and sales organization to commercialize EXPAREL and potential future commercial products. The primary target audience for EXPAREL is healthcare practitioners who influence pain management decisions including surgeons, anesthesiologists, pharmacists and nurses.

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

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

- working in tandem with hospital staff, such as registered nurses, surgeons, heads of quality, pharmacists and executives, to provide access and resources for drug utilization or medication use evaluations and health outcomes studies, which provide retrospective and prospective analyses for our hospital customers using their own hospital data to demonstrate the true cost of opioid-based postsurgical pain control;

- working with KOLs and advisory boards to address topics of best practice techniques as well as guidelines and protocols for the use of EXPAREL, meeting the educational and training needs of our physician, surgeon, anesthesiologist, pharmacist and registered nurse customers;

- undertaking education initiatives such as center of excellence programs; preceptorship programs; pain protocols and predictive models for enhanced patient care; interactive discussion forums; patient education platforms leveraging public relations, advocacy partnerships and public affairs efforts where appropriate; web-based training and virtual launch programs;

- collaborating with surgeons towards improving the knowledge and management of pain in surgical patients with a focus on opioid risk and non-opioid alternatives and engaging our field-based medical teams in system-wide partnerships to address the national opioid epidemic, with a goal of studying alternative postsurgical pain management options that focus on optimization and opioid alternative strategies; and

- expanding our field team to include outpatient account managers to facilitate EXPAREL reimbursement and the shift of procedures to ambulatory surgery centers.

DePuy Synthes Sales Inc.

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

DePuy Synthes field representatives, specializing in joint reconstruction, spine, sports medicine and trauma, collaborate with, and supplement, our field teams by expanding the reach and frequency of EXPAREL education in the hospital surgical suite and ambulatory surgery center settings. DePuy Synthes is also including EXPAREL in their Orthopedic Episode of Care Approach for health systems and surgeons, and is including EXPAREL in all of their professional education programs. In addition to supporting orthopedic specialties, we are focusing on soft tissue surgeons in key specialties and anesthesiologists and we continue to act as the overall EXPAREL account manager. We will also work with DePuy Synthes to develop ERAS protocols to improve procedure-specific patient care and to then rapidly communicate opportunities to utilize EXPAREL-based multimodal pain strategies to minimize opioids and improve patient satisfaction and hospital economics.

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

We and DePuy Synthes have mutual termination rights under the agreement, subject to certain terms, conditions, and notice; provided that neither party may terminate the agreement, without cause, within three years of the effective date of the agreement. We also have additional unilateral termination rights under certain circumstances. The agreement contains customary representations, warranties, covenants and confidentiality provisions, and mutual indemnification obligations. DePuy

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Synthes is also subject to certain obligations and restrictions, including required compliance with certain laws and regulations and our policies, in connection with fulfilling their obligations under the agreement.

Other Agreements

TELA Bio, Inc.

In October 2017, we made an investment of $15.0 million in TELA Bio, Inc., a privately-held surgical reconstruction company that markets its proprietary OviTex™ portfolio of products for ventral hernia repair and abdominal wall reconstruction. OviTex Reinforced BioScaffolds (RBSs) are intended for use as a surgical mesh to reinforce and/or repair soft tissue where weakness exists.

SkyePharma Holdings, Inc. (Now a Subsidiary of Vectura Group plc)

In connection with the stock purchase agreement related to the Skyepharma Acquisition, we agreed to certain earn-out and milestone payments. Milestone payments are based on net sales of DepoBupivacaine products collected, including EXPAREL, and certain other yet-to-be-developed products. For purposes of meeting future potential milestone payments, annual net sales are measured on a rolling quarterly basis. The milestones are as follows:

- $10.0 million upon first commercial sale in the U.S. (met April 2012);
- $4.0 million upon first commercial sale in a major E.U. country (United Kingdom, France, Germany, Italy and Spain);
- $8.0 million when annual net sales collected reach $100.0 million (met September 2014);
- $8.0 million when annual net sales collected reach $250.0 million (met June 2016); and
- $32.0 million when annual net sales collected reach $500.0 million.

The earn-out payments were based on a percentage of net sales of DepoBupivacaine products collected, including EXPAREL, for the term during which such sales were covered by a valid claim in certain patent rights. The last patents during which a valid claim existed expired on September 18, 2018, and thus, the only remaining obligations to Skyepharma are the above-referenced unmet milestone payments totaling $36.0 million.

See Note 7, Goodwill, to our consolidated financial statements included herein for further information related to the Skyepharma agreement.

Research Development Foundation

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

DepoCyt(e)

DepoCyt(e) was a sustained-release liposomal formulation of the chemotherapeutic agent cytarabine that utilized our DepoFoam technology. DepoCyt(e) was indicated for the intrathecal treatment of lymphomatous meningitis, a life-threatening complication of lymphoma, a cancer of the immune system. In June 2017, we discontinued production of DepoCyt® (U.S. and Canada) and DepoCyte® (E.U.) due to persistent technical issues specific to the DepoCyt(e) manufacturing process.

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 E.U. and certain other European countries. In April 2014, we amended the agreements to extend the term of the agreements by an additional 15 years to June 2033 and we expanded Mundipharma's exclusive territory to include all countries other than the U.S., Canada and Japan. In connection with the amendments, in May 2014, we received a non-refundable upfront payment of $8.0 million. Since the production of DepoCyte was discontinued in June 2017, we no longer have the ability to supply DepoCyte to Mundipharma in the future. In April 2018, we received formal notice of the termination of the supply and distribution agreements (and all related agreements) from Mundipharma and its affiliates. We may be required to make additional payments or incur additional costs relating to the DepoCyte discontinuation which could be material to our results of operations and/or cash flows in a given period.

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Aratana Therapeutics, Inc.

In December 2012, we entered into an Exclusive License, Development and Commercialization Agreement and related Supply Agreement with Aratana Therapeutics, Inc., or Aratana. Under the agreements, we granted Aratana an exclusive royalty-bearing license, including the limited right to grant sublicenses, for the development and commercialization of our bupivacaine liposome injectable suspension product for use in animals. In August 2016, the FDA's Center for Veterinary Medicine approved NOCITA® (bupivacaine liposome injectable suspension) as a local post-operative analgesia for cranial cruciate ligament surgery in dogs. Aratana began purchasing bupivacaine liposome injectable suspension product in 2016.

In connection with its entry into the license agreement, we received a one-time payment of $1.0 million. In December 2013, we received a $0.5 million milestone payment under the agreement. In June 2016, we recorded $1.0 million in milestone revenue for Aratana's filing of an FDA Administrative New Animal Drug Application, or ANADA, and in August 2016 recorded $1.0 million related to the FDA's approval of the ANADA. We are eligible to receive up to an additional aggregate $40.0 million upon the achievement of commercial milestones. Aratana is required to pay us a tiered double-digit royalty on net sales made in the U.S. If the product is approved by foreign regulatory agencies for sale outside of the U.S., Aratana will be required to pay us a tiered double-digit royalty on such net sales. Royalty rates will be reduced by a certain percentage upon the entry of a generic competitor for animal health indications into a jurisdiction or if Aratana must pay royalties to third parties under certain circumstances.

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

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

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

Nuance Biotech Co. Ltd.

In June 2018, the Company entered into an agreement with Nuance Biotech Co. Ltd., or Nuance, a China-based specialty pharmaceutical company, to advance the development and commercialization of EXPAREL in China. Under the terms of the agreement, the Company agreed to be the sole supplier of EXPAREL to Nuance and has granted Nuance the exclusive rights to develop and commercialize EXPAREL in China. The Company received an upfront payment of $3.0 million in July 2018 and is eligible to receive future milestone payments of up to $60.0 million that are triggered by filing for and securing regulatory approval(s) and annual sales in China exceeding certain levels. The Company is also entitled to tiered royalties as a percentage of net sales.

Significant Customers

We had three wholesalers each comprising 10% or more of our total revenue for the year ended December 31, 2018: Cardinal Health, Inc., McKesson Drug Company and AmerisourceBergen Health Corporation, which accounted for 34%, 30% and 26% of our revenues, respectively. These wholesalers process orders for EXPAREL under a drop-ship program. EXPAREL is delivered directly to end-users without the wholesalers ever taking physical possession of the product.

Manufacturing and Research Facilities

Internal Facilities

We manufacture EXPAREL at our facility in San Diego, California. This facility is designated as Building 1. We also have a research and development facility, Building 2, which sits adjacent to Building 1, and a warehouse, Building 7, located within

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five miles of our manufacturing facilities. We refer to these three buildings as the Science Center Campus, and together these three buildings consist of approximately 150,000 square feet. Our manufacturing facilities are inspected regularly and approved for pharmaceutical manufacturing by the FDA, the European Medicines Agency, or EMA, the Medicines and Healthcare Products Regulatory Agency, or MHRA, and the Environmental Protection Agency (EPA). We also have a lease for our former DepoCyt(e) production facility in San Diego which is currently idle and expires in August 2020.

We purchase raw materials and components from third-party suppliers 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. While we have not experienced shortages of our raw materials in the past, such suppliers may not sell these raw materials to us at the times that we need them or on commercially reasonable terms and we do not have direct control over the availability of these raw materials from our suppliers.

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

Building 1 is an approximately 84,000 square foot concrete structure located on a five acre site. It was custom built as a pharmaceutical research and development and manufacturing facility in 1995. Activities in this facility include the manufacture of EXPAREL bulk product on dedicated production lines and its fill/finish into vials, microbiological and quality control testing, product storage, development of analytical methods and manufacturing of development products. We are expanding our EXPAREL manufacturing capacity directly and through agreements with a third-party, Thermo Fisher, as demand for EXPAREL increases, as explained below.

Building 2 is an approximately 45,000 square foot research and development lab and office building located adjacent to Building 1, built in 2003. This building houses our Science Center related general and administrative functions. The other half of the building is being used for research and development activities as it includes both laboratories and the building infrastructure necessary to support the formulation, analytical testing, clinical and process development activities for additional commercial product indications and new pipeline products. Our pilot plant suite for early-stage clinical product production is located in this building.

Building 7 is an approximately 21,000 square foot building built in 1988 that serves as the main cGMP warehouse for our San Diego operations, primarily being used for the storage of production materials. It contains ambient as well as cold temperature cGMP warehouse storage and also features a quality control clean room for sampling incoming materials.

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

Co-Production Facilities

In April 2014, we and Thermo Fisher entered into a Strategic Co-Production Agreement, Technical Transfer and Service Agreement and Manufacturing and Supply Agreement (the “Thermo Fisher Agreements”) to collaborate in the manufacture of EXPAREL. Thermo Fisher undertook certain technical transfer activities and construction services needed to prepare Thermo Fisher’s Swindon, England facility for the manufacture of EXPAREL in two dedicated manufacturing suites. We provided Thermo Fisher with the equipment necessary to manufacture EXPAREL and pay fees to Thermo Fisher based on Thermo Fisher’s achievement of certain technical transfer and construction milestones. We also reimburse Thermo Fisher for certain nominal expenses and additional services. In February 2019, we announced that commercial production of EXPAREL is underway at the first Thermo Fisher suite, and that we are developing a second dedicated suite that is expected to enable another doubling of EXPAREL manufacturing capacity in approximately two years.

The initial term of the Manufacturing and Supply Agreement is 10 years from the date of FDA approval of the initial manufacturing suite, which was received in May 2018. We pay fees to Thermo Fisher for their operation of the manufacturing suites and the amount of EXPAREL produced by Thermo Fisher. We also reimburse Thermo Fisher for purchases made on our behalf, certain nominal expenses and additional services. We may terminate this agreement upon one month’s notice if a regulatory authority causes the withdrawal of EXPAREL from the U.S. or any other

market that represents 80% of our overall sales, or at any time for convenience by providing between 18 and 36 months notice (depending on the number of years after the FDA approval date). Either party may terminate the Manufacturing and Supply Agreement in the event of the breach or bankruptcy of the other party.

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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, 2018, there are over nine families of patents and patent applications relating to various aspects of the DepoFoam delivery technology. Patents have been issued in numerous countries, with an emphasis on the North American, European and Japanese markets. These patents generally have a term of 20 years from the date of the non-provisional filing unless referring to an earlier filed application. Some of our expired U.S. patents had a term of 17 years from the grant date. Our issued patents expire at various dates in the future, as discussed below, with the last currently issued patent expiring in 2033.

We received an issue notification from the United States Patent and Trademark Office, or USPTO, stating that a patent relating to product-by-process and process in connection with the production of multivesicular liposomes was issued on March 7, 2017. This patent is listed on the Orange Book for EXPAREL, and includes a patent term adjustment that equates to an expiration date of December 24, 2021.

Issued patents for EXPAREL in the U.S. relating to methods for modifying the rate of drug release of the product candidate and the composition of the product candidate expired in January 2017 and September 2018, respectively. Pursuant to 35 U.S.C. § 156, an application for patent term extension was filed with the USPTO in October 2016 in connection with the regulatory approval of Aratana Therapeutics, Inc.'s NOCITA®. That application was subsequently withdrawn after the product-by-process patent, referenced above, was issued on March 7, 2017. In the U.S., a patent relating to the composition of the product was issued in September 2014 and expired in September 2018. A patent relating to the method of treatment using EXPAREL was issued in December 2015 and expired in September 2018. In Europe, granted patent(s) related to the composition of EXPAREL expired in September 2018. A patent relating to methods of modifying the rate of drug release of the product candidate expired in January 2018. In addition, a patent relating to the process for making the product candidate expired in November 2018.

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 an international patent application providing the basis for several national phase patent applications, for example in Europe, China, Japan, Israel and India which, if granted, could potentially prevent others from using this process until at least 2031. In the U.S., we also filed a series of patent applications directed to the new manufacturing process. Seven of the patent applications were issued as patents as of December 2018. Patents that claim the process and apparatus will expire at the latest in November 2033. One of the patents claims a product made by the process and expires in April 2031. As of December 31, 2018, we have four granted patents in China, one granted patent in Japan and one granted patent in Israel, protecting various aspects of the new process, including the methods of using the apparatus and the apparatus itself. Furthermore, a non-exclusively licensed patent of ours relating to EXPAREL was allowed in Europe with an expiration date in October 2021 and the patent term was extended in the U.S. 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

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consultants also typically contain similar assignment of invention obligations. Further, we require confidentiality agreements from third parties that receive our confidential data or materials.

Competition

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

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

EXPAREL competes with well-established products with similar indications. Competing products available for postsurgical pain management include opioids such as morphine, fentanyl, meperidine and hydromorphone, each of which is available generically from several manufacturers, and several of which are available as proprietary products using novel delivery systems. Ketorolac, a non-steroidal anti-inflammatory drug, or NSAID, is also available generically in the U.S. from several manufacturers, and Caldolor (ibuprofen for injection), an NSAID, has been approved by the FDA for pain management and fever in adults. EXPAREL also competes with currently-marketed non-opioid products such as bupivacaine, marcaine, ropivacaine and other anesthetics/analgesics, all of which are also used in the treatment of postsurgical pain and are available as either oral tablets, injectable dosage forms or administered using novel delivery systems. Additional products may be developed for the treatment of acute pain, including new injectable NSAIDs, novel opioids, new formulations of currently available opioids and NSAIDs, long-acting local anesthetics and new chemical entities as well as alternative delivery forms of various opioids and NSAIDs. Currently EXPAREL also competes with elastomeric pump/catheter devices intended to provide bupivacaine over several days. I-FLOW Corporation (acquired by Kimberly-Clark Corporation in 2009 and spun off into Halyard Health, Inc. in 2014) has marketed these medical devices in the U.S. since 2004.

Government Regulation

In the U.S., prescription drug products are subject to extensive pre- and post-market regulation by the FDA, including regulations that govern the research, development, testing, manufacturing, distribution, safety, efficacy, approval, labeling, storage, record keeping, reporting, advertising and promotion of such products under the Federal Food, Drug and Cosmetic Act, or FDCA, and its implementing regulations. Outside the U.S., prescription drug products are regulated by comparable agencies, laws and regulations. Failure to comply with applicable regulatory requirements in the U.S. or elsewhere may result in, among other things, refusal to approve pending applications, withdrawal of an approval, warning letters, clinical holds, civil or criminal penalties, recall or seizure of products, injunction, debarment, partial or total suspension of production or withdrawal of the product from the market. Any agency or judicial enforcement action could have a material adverse effect on the Company.

United States Regulatory Environment

Generally, the FDA must approve any new drug, including a new use of a previously approved drug, before marketing of the drug occurs in the U.S. This process generally involves:

- completion of preclinical laboratory and animal testing and formulation studies in compliance with the FDA's Good Laboratory Practice regulations (21 CFR 58);

- submission to the FDA of an Investigational New Drug, or IND, application for human clinical testing, which must become effective before human clinical trials may begin for unapproved use in the U.S.;

- approval by an independent Institutional Review Board, or IRB, at each clinical trial site before each trial may be initiated;

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- performance of adequate and well-controlled human clinical trials in accordance with the FDA's Good Clinical Practices, or GCP, to establish the safety and efficacy of the proposed drug product for each intended use;

- completion of process validation, quality product release and stability;

- submission of a New Drug Application, or NDA, to the FDA;

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

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

- review and approval by the FDA of the NDA.

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

Clinical trials involve the administration of the product candidate to healthy volunteers or patients having the disease being studied under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Sponsors of clinical trials generally must register at the NIH-maintained website www.clinicaltrials.gov and report key findings and parameters. For purposes of an NDA submission and approval, typically, the conduct of human clinical trials occurs in the following three pre-market sequential phases, which may overlap or be combined:

- Phase 1: Sponsors initially conduct clinical trials in a limited population, either patients or healthy volunteers, to test the product candidate for safety, dose tolerance, absorption, metabolism, distribution, excretion and clinical pharmacology, and, if possible, to gain early evidence of effectiveness. In the cases of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing often is conducted only on patients having the specific disease.

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

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

Some clinical trials may be overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move

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forward at designated check points based on access to certain data from the trial. The process of completing clinical testing and obtaining FDA approval for a new drug is likely to take a number of years and requires the expenditure of substantial resources. If an application is submitted, there can be no assurance that the FDA will review and approve the NDA. In addition, sponsors may elect to conduct, or be required by the FDA to, conduct post-approval clinical trials to further assess the drug's safety or effectiveness after NDA approval, generate new data and best-practice administration techniques. Such post approval trials are typically referred to as Phase 4 clinical trials.

U.S. Review and Approval Process

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, sponsors submit the results of product development, preclinical studies and clinical trials to the FDA as part of an NDA requesting approval to market the product for one or more indications. NDAs must also contain extensive information relating to the product's pharmacology, chemistry, manufacture, controls and proposed labeling, among other things. In addition, 505(b)(2) applications must contain a patent certification for each patent listed in FDA's "Orange Book" that covers the drug referenced in the application and upon which the third-party studies were conducted. For some drugs, the FDA may require Risk Evaluation and Mitigation Strategies, or REMS, which could include medication guides, physician communication plans or restrictions on distribution and use, such as limitations on who may prescribe the drug or where it may be dispensed or administered. Upon receipt of an NDA, the FDA has 60 days to determine whether it is sufficiently complete to initiate a substantive review. If the FDA identifies deficiencies that would preclude substantive review, the FDA will refuse to accept the NDA ("refuse to file") and will inform the sponsor of the deficiencies that must be corrected prior to resubmission. The resubmitted application is also subject to review before the FDA accepts it for filing. If the FDA accepts the submission for substantive review, the FDA typically reviews the NDA in accordance with established timeframes. Under the Prescription Drug User Fee Act, or PDUFA, the FDA establishes goals for NDA review time through a two-tiered classification system: Priority Review and Standard Review. A Priority Review designation is given to drugs that address an unmet medical need by offering major advances in treatment or providing a treatment where no adequate therapy currently exists. Standard Review applies to all applications that are not eligible for Priority Review. The FDA aims to complete Standard Reviews of NDAs within 12 months of submission (ten months after the Day 60 filing date) and Priority Reviews within eight months of submission (six months after the Day 60 filing date). Review processes may sometimes extend beyond these target completion dates due to FDA requests for additional information or clarification, difficulties scheduling an advisory committee meeting, negotiations regarding REMS or FDA workload issues, but in general under PDUFA the FDA is supposed to complete its reviews within the target timeframes despite these factors. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to the application's approval. The recommendations of an advisory committee do not bind the FDA, but the FDA generally follows such recommendations.

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

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

After the FDA evaluates the NDA and the manufacturing facilities, it may issue an approval letter or a Complete Response Letter, or CRL, to indicate that the review cycle for an application is complete and that the application is not ready for approval. CRLs generally outline the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we do. The FDA could also require a REMS plan which could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may

approve an NDA contingent on, among other things, changes to proposed labeling, a commitment to conduct one or more post-market studies or clinical trials and the correction of identified manufacturing deficiencies, including the development of adequate controls and specifications. If and when the deficiencies have been addressed to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

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Section 505(b)(2) New Drug Applications

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

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

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

Post-Approval Requirements

After approval, the NDA sponsor must comply with comprehensive requirements governing, among other things, drug listing, recordkeeping, manufacturing, marketing activities, product sampling and distribution, annual reporting and adverse event reporting.

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

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;

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- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

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

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

In December 2015, we announced that we achieved an amicable resolution with the U.S. in our lawsuit filed in September 2015 against the FDA and other governmental defendants. The resolution confirmed that EXPAREL is, and has been since its approval in 2011, broadly indicated for single-dose infiltration into the surgical site to produce postsurgical analgesia. In April 2018, the FDA approved an expansion of the label for EXPAREL to include interscalene brachial plexus nerve block. The new indication statement in the label for EXPAREL now reads: "EXPAREL is indicated for single-dose infiltration in adults to produce postsurgical local analgesia and as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia. Safety and efficacy has not been established in other nerve blocks."

International Regulation

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

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

In addition to the centralized procedure, Europe also has (i) a nationalized procedure, which requires a separate application to and approval determination by each country; (ii) a decentralized procedure whereby applicants submit identical applications to several countries and receive simultaneous approval and (iii) a mutual recognition procedure, where applicants submit an application to one country for review and the other countries may accept or reject the

initial decision. Regardless of the approval process employed, various parties share responsibilities for the monitoring, detection and evaluation of adverse events post-approval, including national authorities, the EMA, the EC and the marketing authorization holder.

As with FDA approval, we may not be able to secure regulatory approvals in Europe in a timely manner, if at all. Additionally, as in the U.S., 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.

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

Third-Party Payer Coverage and Reimbursement

The commercial success of our products and product candidates will depend, in part, upon the availability of coverage and reimbursement from third-party payers at the federal, state and private levels. Government payer programs, including Medicare and Medicaid, private health care insurance companies and managed care plans may deny coverage or reimbursement for a product or therapy in whole or in part if they determine that the product or therapy is not medically appropriate or necessary. Also, third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular procedures or drug treatments. The United States Congress and state legislatures from time to time propose and adopt initiatives aimed at cost containment that could impact our ability to sell our products at a price level high enough to realize an appropriate return on our investment, which would materially impact our results of operations.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, which we refer to collectively as the Affordable Care Act, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The Affordable Care Act revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates owed to states by pharmaceutical manufacturers for covered outpatient drugs. The Affordable Care Act also established a new Medicare Part D coverage gap discount program, in which drug manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand name drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare practitioners. There have been proposed in Congress a number of legislative initiatives regarding healthcare, including possible repeal of the Affordable Care Act. At this time, it remains unclear whether there will be any changes made to the Affordable Care Act. The full impact that the Affordable Care and other new laws will have on our business is uncertain. However, such laws appear likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products.

The marketability of our products may suffer if the government and third-party payers fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the U.S. has increased, and we expect will continue to increase, the pressure on pharmaceutical pricing. Some third-party payers require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers that use such therapies, or place limits on the amount of reimbursement. Coverage policies and third-party payer reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for our products, less favorable coverage policies and reimbursement rates may be implemented in the future.

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

Marketing/Data Exclusivity

The FDA may grant three or five years of marketing exclusivity in the U.S. 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 U.S. is available under Section 505A of the FDCA if, in response to a written request from the FDA, a sponsor submits and the agency accepts requested information relating to the use of the approved drug in the pediatric population. This six month

pediatric exclusivity period is not a standalone exclusivity period, but rather is added to any existing patent or non-patent exclusivity period for which the drug product is eligible. Based on our clinical trial program for EXPAREL, the FDA granted three years of marketing exclusivity to EXPAREL, which expired on October 28, 2014.

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Manufacturing Requirements

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

Regulations Pertaining to Sales and Marketing

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

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

In April 2015, we received a subpoena from the U.S. Department of Justice, U.S. Attorney's Office for the District of New Jersey, requiring the production of a broad range of documents pertaining to marketing and promotional practices related to EXPAREL. We are cooperating with the government's inquiry. We can make no assurances as to

the time or resources that will need to be devoted to this inquiry or its final outcome, or the impact, if any, of this inquiry or any proceedings on our business, financial condition, results of operations and cash flows.

Healthcare Privacy and Security Laws

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

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

Environmental Matters

Our research and development processes and our manufacturing processes involve the controlled use of hazardous materials and chemicals and produce waste products. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. We do not expect the cost of complying with these laws and regulations to be material. While we believe we are in compliance with applicable environmental regulations, the failure to fully comply with any such regulations could result in the imposition of penalties, fines and/or sanctions which could have a material adverse effect on our business.

Employees

As of December 31, 2018, we had 518 employees. All of our employees are located in the U.S. except for eight located in England. None of our employees are represented by a labor union, and we consider our current employee relations to be good.

Available Information

Our company website is located at www.pacira.com. We file reports and other information with the United States Securities and Exchange Commission, or SEC, as required by the Exchange Act, which are accessible on the SEC's website at www.sec.gov. We also make available free of charge through our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and any 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 sections entitled "Investors" and "News," as a source of information about us. The foregoing references to our website are not intended to, nor shall they be deemed to, incorporate information on our website into this Annual Report on Form 10-K by reference.

Item 1A. Risk Factors

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

Risks Related to the Development and Commercialization of our Products and Product Candidates

Our success depends on our ability to successfully commercialize EXPAREL.

We have invested a significant portion of our efforts and financial resources in the development and commercialization of our lead product, EXPAREL, which was approved by the FDA on October 28, 2011 and commercially launched in April 2012. During 2018, sales of EXPAREL constituted substantially all of our total revenue, and we expect it will do so for the foreseeable future. Our success depends on our ability to continue to effectively commercialize EXPAREL. Our ability to effectively generate revenues from EXPAREL will depend on our ability to, among other things:

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

- train, deploy and support a qualified sales force;
- secure formulary approvals for EXPAREL at a substantial number of targeted hospitals;

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- 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 and distributors on commercially reasonable terms;
- receive adequate levels of coverage and reimbursement for EXPAREL from commercial health plans and governmental health programs;
- maintain compliance with regulatory requirements;
- obtain regulatory approvals for additional indications for the use of EXPAREL;
- ensure that our entire supply chain efficiently and consistently delivers EXPAREL to our customers; and
- maintain and defend our patent protection and regulatory exclusivity for EXPAREL.

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

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

EXPAREL has been a commercialized drug since 2012. We continue to expend significant time and resources to train our sales force to be credible and persuasive in convincing physicians and hospitals to use EXPAREL. In addition, we also must train our sales force to ensure that a consistent and appropriate message about EXPAREL is delivered to our potential customers. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits and risks of EXPAREL and its proper administration, our efforts to successfully commercialize EXPAREL could be put in jeopardy, which could have a material adverse effect on our future revenues and profits.

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

If EXPAREL does not achieve broad market acceptance, the revenues that we generate from its sales will be limited.

The degree of market acceptance of EXPAREL also depends on a number of other factors, including:

- changes in the standard of care for the targeted indications for EXPAREL, which could reduce the marketing impact of any claims that we can make;
- the relative efficacy, convenience and ease of administration of EXPAREL;

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

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- 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. We will also need to demonstrate acceptable evidence of safety and efficacy, as well as relative convenience and ease of administration. Market acceptance could be further limited depending on the prevalence and severity of any expected or unexpected adverse side effects associated with our product candidates.

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

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

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

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

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

entities as well as alternative delivery forms of various opioids and NSAIDs.

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

Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated, and allegations of our failure to comply with such approved indications could limit our sales efforts and have a material adverse effect on our business.

The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities,

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promotional activities involving the internet and off-label promotion. Any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA. For example, the FDA-approved label for EXPAREL does not include an indication in obstetrical paracervical block anesthesia. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products and product candidates, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians in the U.S. may choose, and are generally permitted to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, our ability to promote the products is narrowly limited to those indications that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the U.S. generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. Although recent court decisions suggest that certain off-label promotional activities may be protected under the First Amendment, the scope of any such protection is unclear. If our promotional activities fail to comply with the FDA's regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to issue warning letters or untitled letters, bring an enforcement action against us, suspend or withdraw an approved product from the market, require a recall or institute fines or civil fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our reputation and our business.

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

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

We are continuing to build our commercial infrastructure for the marketing, sale and distribution of pharmaceutical products. In order to continue commercializing EXPAREL effectively, we must continue to build our marketing, sales and distribution capabilities. The establishment, development and training of our sales force and related compliance plans to market EXPAREL is expensive and time consuming. In the event we are not successful in developing our marketing and sales infrastructure, we may not be able to successfully commercialize EXPAREL, which would limit our ability to generate product revenues.

In addition to our internal marketing and sales efforts, we have entered into agreements with third-party distributors to promote and sell EXPAREL in certain territories. For example, in January 2017, we entered into a co-promotion agreement with DePuy Synthes to market and promote the use of EXPAREL for orthopedic procedures in the U.S. market, and in June 2018, we entered into an agreement with Nuance to advance the development and commercialization of EXPAREL in China. There can be no assurance that such distributors and promoters will be successful in marketing and promoting EXPAREL.

We may seek additional distribution arrangements in the future, including arrangements with third-party distributors to commercialize and sell EXPAREL in certain foreign countries. The use of distributors involves certain risks, including risks that such distributors will:

- not effectively distribute or support our products;
-

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

- fail to comply with their obligations to us;
- fail to comply with laws and regulations to which they are subject, whether in the U.S. or in foreign jurisdictions;
- reduce or discontinue their efforts to sell or promote our products; or
- cease operations.

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

We rely on third parties to perform many essential services for EXPAREL and will rely on third parties for any other products that we commercialize. If these third parties fail to perform as expected or to comply with legal and regulatory requirements, our ability to commercialize EXPAREL will be significantly impacted and we may be subject to regulatory sanctions.

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

Distribution of our DepoFoam-based products, including EXPAREL, requires cold-chain distribution provided by third parties, whereby the product must be maintained between specified temperatures. 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 may 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, 2018, we had 518 employees. We may need to expand our personnel resources in order to manage our operations and sales of EXPAREL. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. In addition, we may not be able to recruit and retain qualified personnel in the future, particularly marketing positions, due to competition for personnel among pharmaceutical businesses, and the failure to do so could have a significant negative impact on our future product revenues and business results. Our need to effectively manage our operations, growth and various projects requires that we:

- continue the hiring and training of an effective commercial organization for the commercialization of EXPAREL, and establish appropriate systems, policies and infrastructure to support that organization;
- continue to establish and maintain effective relationships with distributors and commercial partners for the promotion and sale of our products;
- ensure that our distributors, partners, suppliers, consultants and other service providers successfully carry out their contractual obligations, provide high quality results and meet expected deadlines;
- manage our development efforts and clinical trials effectively;
- expand our manufacturing capabilities and effectively manage our co-production arrangement with Thermo Fisher;
- continue to carry out our own contractual obligations to our licensors and other third parties; and

- continue to improve our operational, financial and management controls, reporting systems and procedures.

We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our development and commercialization goals. Additionally, these tasks may impose a strain on our administrative and operational infrastructure. If we are unable to effectively manage our growth, our product sales and resulting revenues will be negatively impacted.

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

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

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

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

The use of EXPAREL, DepoCyt(e) and any product candidates that we may develop, license or acquire in clinical trials and the sale of any products for which we obtain regulatory approval expose us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers or others using, administering or selling our products. We have been a party of these suits in the past and may be again in the future. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- loss of revenue from decreased demand for our products and/or product candidates;
- impairment of our business reputation or financial stability;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- diversion of management attention;
- loss of revenues;
- withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs; and
- the inability to commercialize our product candidates.

We have obtained limited product liability insurance coverage for our products and our clinical trials with a $10.0 million annual aggregate coverage limit. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer, including our indemnification obligations to other parties. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage on acceptable terms, at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of additional commercial products upon FDA approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing, or at all. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A

successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

If we fail to manufacture EXPAREL in sufficient quantities and at acceptable quality and pricing levels, or to fully comply with cGMP regulations, we may face delays in the commercialization of this product or be unable to meet market demand, and may lose potential revenues.

The manufacture of EXPAREL requires significant expertise and capital investment, including the development of advanced manufacturing techniques, process controls and the use of specialized processing equipment. We must comply with

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federal, state and foreign regulations, including the FDA's regulations governing cGMP, enforced by the FDA through its facilities inspection program and by similar regulatory authorities in other jurisdictions where we do business. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The FDA or similar foreign regulatory authorities at any time may implement new standards, or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of our products. Any failure by us or our manufacturing partner to comply with applicable regulations may result in fines and civil penalties, suspension of production, product seizure or recall, operating restrictions, imposition of a consent decree, modification or withdrawal of product approval or criminal prosecution and would limit the availability of our product. Any manufacturing defect or error discovered after products have been produced and distributed also could result in significant consequences, including costly recall procedures, re-stocking costs, damage to our reputation and potential for product liability claims.

If we are unable to produce the required commercial quantities of EXPAREL to meet market demand for EXPAREL on a timely basis or at all, or if we fail to comply with applicable laws for the manufacturing of EXPAREL, we will suffer damage to our reputation and commercial prospects and we will lose potential revenues.

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

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

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

In addition, the procurement time for the equipment that we use to manufacture EXPAREL requires long lead times. Therefore, we may experience delays, additional or unexpected costs and other adverse events in connection with our capacity expansion projects, including those associated with potential delays in the procurement of manufacturing equipment required to manufacture EXPAREL, including the equipment for the construction of a second dedicated suite at the Thermo Fisher site that is expected to enable another doubling of EXPAREL manufacturing capacity in approximately two years.

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

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

Our inability to continue manufacturing adequate supplies of the product could result in a disruption in the supply to our customers and partners, which could have a material adverse impact on our business and results of operations. EXPAREL is currently manufactured at our facilities in San Diego, California and at the Thermo Fisher facility in Swindon, England, which are the only currently-FDA approved sites for manufacturing EXPAREL in the world. We may experience temporary or prolonged suspensions in production of our products due to issues in our manufacturing process that must be remediated or in response to inspections conducted by the FDA or similar foreign regulatory authorities, which could have a material adverse effect on our business, financial position and results of operations. For example, in June 2017, we discontinued production of DepoCyt(e) due to persistent technical issues specific to the DepoCyt(e) manufacturing process.

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Our San Diego, California facilities and Thermo Fisher facility in Swindon, England are also subject to the risks of a natural or man-made disaster, including earthquakes, floods and fires, or other business disruptions. In addition, we have obtained limited property and business interruption insurance coverage for our manufacturing sites in San Diego and England. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. There can be no assurance that we would be able to meet our requirements for EXPAREL if there were a catastrophic event or failure of our current manufacturing system. If we are required to change or add a new manufacturer or supplier, the process would likely require prior FDA and/or equivalent foreign regulatory authority approval, and would be very time consuming. An inability to continue manufacturing adequate supplies of EXPAREL at our facilities in San Diego, California or at the Thermo Fisher facility in Swindon, England could result in a disruption in the supply of EXPAREL to our customers and partners and a breach of our contractual obligations to such counterparties.

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

We and Thermo Fisher have entered into a Co-Production Agreement, Technical Transfer and Service Agreement and Manufacturing and Supply Agreement. Under these agreements, Thermo Fisher will undertake certain technical transfer activities and construction services to prepare Thermo Fisher's Swindon, England facility for the manufacture of EXPAREL in two dedicated manufacturing suites, of which one suite received FDA approval in May 2018 and began commercial production in February 2019. We have agreed with Thermo Fisher, among other things, to provide them with the process equipment necessary to manufacture EXPAREL in these suites. We have anticipated and budgeted for capital expenditures associated with the two Thermo Fisher suites, including the equipment purchase and construction of the suites as well as payments to be made to Thermo Fisher.

The Thermo Fisher facilities require FDA approval prior to any production and manufacturing of EXPAREL. If the construction of the second Thermo Fisher suite is delayed, if Thermo Fisher experiences unanticipated cost overruns, or if the additional Thermo Fisher suite does not receive or maintain regulatory approvals in the timeframe anticipated (if at all), this could have a material adverse effect on our business, financial position and results of operations. Further, the production under these agreements involve additional risks, many of which would be outside of our control, such as disruptions or delays in production, manufactured products that do not meet our required specifications, the failure of Thermo Fisher to comply with cGMP regulations or other regulatory requirements, protection of our intellectual property and manufacturing process, loss of control of our complex manufacturing process and inabilities to fulfill our commercial needs.

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

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

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

An important part of our business strategy is to continue to develop a pipeline of product candidates by developing, acquiring or in-licensing products, businesses or technologies that we believe are a strategic fit with our focus on the

hospital marketplace. However, these business activities may entail numerous operational and financial risks, including:

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

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- incurrence of substantial debt or dilutive issuances of securities to pay for development, acquisition or in-licensing of new products;
- the successful integration of acquired products, businesses or technologies into our operations, and achieving the expected benefits and synergies from such acquisitions;
- disruption of our business and diversion of our management's time and attention;
- higher than expected development, acquisition or in-license and integration costs;
- exposure to unknown liabilities;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- inability to retain key employees of any acquired businesses;
- difficulty entering markets in which we have limited or no direct experience;
- difficulty in managing multiple product development programs; and
- inability to successfully develop new products or clinical failure.

We have limited resources to identify and execute the development, acquisition or in-licensing of products, businesses and technologies and integrate them into our current infrastructure. We may compete with larger pharmaceutical companies and other competitors, including public and private research organizations, academic institutions and government agencies, in our efforts to establish new collaborations and in-licensing opportunities. These competitors may have access to greater financial resources, research and development staffs and facilities than us and may have greater expertise in identifying and evaluating new opportunities. We may not be successful in locating and acquiring or in-licensing additional desirable product candidates on acceptable terms or at all. We may also not be successful in developing or commercializing our current product candidates. Such efforts may require the dedication of significant financial and personnel resources, and any diversion of resources may also disrupt our management from expanding on EXPAREL sales. Moreover, we may devote resources to potential development, acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts.

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

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

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

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, human error, unauthorized access, natural disasters, intentional acts of vandalism, terrorism, war

and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed clinical trials for EXPAREL could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability, reputation damage and harm to our business operations.

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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 products in the U.S. and abroad, occasionally seeking collaboration arrangements with pharmaceutical or biotechnology companies for the development or commercialization of our products in other countries. Accordingly, we may enter into collaboration arrangements in the future on a selective basis. Any future collaboration arrangements that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaboration arrangements.

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

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

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

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

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

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

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

We may rely on contract research organizations, or CROs, to perform preclinical testing and clinical trials for drug candidates that we choose to develop without a collaborator. If the CROs that we hire to perform our preclinical testing and clinical trials or our collaborators or licensees do not meet deadlines, do not follow proper procedures or a conflict arises between us and our CROs, our preclinical testing and clinical trials may take longer than expected, may be delayed or may be terminated. If we were forced to find a replacement CRO to perform any of our preclinical

testing or clinical trials, we may not be able to find a suitable replacement on favorable terms, if at all. Even if we were able to find another CRO to perform a preclinical test or clinical trial, any material delay in a test or clinical trial may result in significant additional expenditures that could adversely affect our operating results. Events such as these may also delay regulatory approval for our drug candidates or our ability to commercialize our products.

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

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

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

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

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

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

Regulatory Risks

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

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

If, as a result of this inquiry, proceedings are initiated and we are found to have violated one or more applicable laws, we may be subject to significant liability, including without limitation, civil fines, criminal fines and penalties, civil damages and exclusion from federal funded healthcare programs such as Medicare and Medicaid, as well as potential liability under the federal False Claims Act and state false claims acts, and/or be required to enter into a corporate integrity or other settlement with the government, any of which could materially affect our reputation, business,

financial condition, results of operations and cash flows. Conduct giving rise to such liability could also form the basis for private civil litigation by third-party payors or other persons allegedly harmed by such conduct. In addition, if some of our existing business practices are challenged as unlawful, we may have to change those practices, including changes and impacts on the practices of our sales force, which could also have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet and off-label promotion. According to these regulations, companies may not

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promote drugs for "Off-label" uses—that is, uses that are not described in the product's labeling and that differ from those that were approved by the FDA. For example, the FDA-approved label for EXPAREL does not include an indication in obstetrical paracervical block anesthesia. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products and product candidates, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians in the U.S. may choose, and are generally permitted to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, under the FDA's regulations our ability to promote the products is narrowly limited to those indications that are approved by the FDA. "Off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the U.S. generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. Although recent court decisions suggest that certain off-label promotional activities may be protected under the First Amendment, the scope of such protection is unclear. Moreover, while we promote our products consistent with what we believe to be the approved indication for our drugs, the FDA may disagree. If the FDA determines that our promotional activities fail to comply with the FDA's regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to issue warning letters or untitled letters, bring an enforcement action against us, suspend or withdraw an approved product from the market, require a recall or institute fines or civil fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our reputation and our business.

In September 2014, we received a warning letter from the OPDP pertaining to certain promotional aspects of EXPAREL. We took actions to immediately address the FDA's concerns and minimize further disruption to our business. Ultimately, however, in September 2015, we, along with two independent physicians, filed a lawsuit in federal court against the FDA and other governmental defendants seeking to exercise our lawful rights to communicate truthful and non-misleading information about EXPAREL. The complaint outlined our belief that the FDA's warning letter received in September 2014 and regulations restricting our truthful and non-misleading speech about EXPAREL violate the Administrative Procedure Act and the First and Fifth Amendments of the U.S. Constitution. The lawsuit sought a declaration and injunctive relief to permit us to promote EXPAREL consistent with its approved indication and pivotal trials that supported FDA approval. On December 15, 2015, we announced that the FDA had formally withdrawn the September 2014 Warning Letter via a "Rescission Letter," and that the FDA and Pacira had reached an amicable resolution of the lawsuit. As part of the resolution of this matter, the FDA confirmed that EXPAREL was broadly approved for "administration into the surgical site to produce postsurgical analgesia" in a variety of surgeries not limited to those studied in its pivotal trials. The FDA also approved a labeling supplement for EXPAREL that further clarified that EXPAREL was not limited to any specific surgery type or site, that the proper dosage and administration of EXPAREL is based on various patient and procedure-specific factors, that there was a significant treatment effect for EXPAREL compared to placebo over the first 72 hours in the pivotal hemorrhoidectomy trial and that EXPAREL may be admixed with bupivacaine, provided certain medication ratios are observed. The Warning Letter and labeling supplement only applied to the infiltration indication that was approved at that time, and does not apply to the interscalene brachial plexus nerve block indication approved in April 2018. We and the FDA agreed that, in future interactions, the parties will deal with each other in an open, forthright and fair manner.

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

reputation and business.

We may not receive regulatory approval for any of our product candidates, or the approval may be delayed for various reasons, including successful challenges to the FDA's interpretation of Section 505(b)(2), which would have a material adverse effect on our business and financial condition.

We may experience delays in our efforts to obtain regulatory approval from the FDA for any of our product candidates, and there can be no assurance that such approval will not be delayed, or that the FDA will ultimately approve these product candidates. Although the FDA's longstanding position has been that the Agency may rely upon prior findings of safety or effectiveness to support approval of a 505(b)(2) application, this policy has been controversial and subject to challenge in the past. If the FDA's policy is successfully challenged administratively or in court, we may be required to seek approval of our products via full NDAs that contain a complete data package demonstrating the safety and effectiveness of our product candidates, which would be time-consuming, expensive and would have a material adverse effect on our business and financial condition.

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The FDA, as a condition of the EXPAREL NDA 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 successive pediatric patient subpopulations. These trials will be expensive and time consuming and we are required to meet the timelines for submission of protocols and data and for completion as agreed with the FDA, and we may be delayed in meeting such timelines. We are required to conduct these trials even if we believe that the costs and potential benefits of conducting the trials are not warranted from a scientific or financial perspective. The failure to conduct these pediatric trials or to meet applicable deadlines could result in the imposition of sanctions, including, among other things, issuance of warnings letters or imposition of seizures or injunctions.

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

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

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

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

- regulatory authorities may require the addition of unfavorable labeling statements, specific warnings or contraindications (including boxed warnings);
- regulatory authorities may suspend or withdraw their approval of the product, or require it to be removed from the market;
- regulatory authorities may impose restrictions on the distribution or use of the product;
- we may be required to change the way the product is administered, conduct additional clinical trials, reformulate the product, change the labeling of the product or change or obtain re-approvals of manufacturing facilities;
- sales of the product may be significantly decreased from projected sales;
- we may be subject to government investigations, product liability claims and litigation; and
- our reputation may suffer.

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

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

Any regulatory approval is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA. For example, the FDA-approved label for EXPAREL does not include an indication in obstetrical paracervical block anesthesia. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products and product candidates, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

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While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the U.S. generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. Although recent court decisions suggest that certain off-label promotional activities may be protected under the First Amendment, the scope of any such protection is unclear. If our promotional activities fail to comply with the FDA's regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to issue warning letters or untitled letters, suspend or withdraw an approved product from the market, require a recall or institute fines or civil fines or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business.

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

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

- the Federal Anti-Kickback Law, which prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual or furnishing or arranging for a good or service for which payment may be made under federal health care programs such as Medicare and Medicaid;

- other Medicare laws and regulations that prescribe the requirements for coverage and payment for services performed by our customers, including the amount of such payment;

- the Federal False Claims Act, which imposes civil and criminal liability on individuals and entities who submit, or cause to be submitted, false or fraudulent claims for payment to the government;

- the Federal False Statements Act, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with delivery of or payment for health care benefits, items or services; and

- various state laws that impose similar requirements and liability with respect to state healthcare reimbursement and other programs.

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

The design, development, manufacture, supply and distribution of EXPAREL are highly regulated and technically complex.

The design, development, manufacture, supply and distribution of EXPAREL are all 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 EXPAREL are subject to inspection by regulatory

authorities at any time to determine compliance with applicable regulations.

The manufacturing techniques and facilities used for the manufacture and supply of our products must be operated in conformity with cGMP and other FDA and MHRA regulations, including potentially prior regulatory approval. In addition, any expansion of our existing manufacturing facilities or the introduction of any new manufacturing facilities, including the manufacturing suites at Thermo Fisher's facility, also require conformity with cGMP and other FDA and MHRA regulations. In complying with these requirements, we, along with our co-production partners and suppliers, must continually expend time, money and effort in production, record keeping and quality assurance and control to ensure that our products meet applicable

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specifications and other requirements for safety, efficacy and quality. In addition, we, along with our co-production partners and suppliers, are subject to unannounced inspections by the FDA, MHRA and other regulatory authorities. Any failure to comply with regulatory and other legal requirements applicable to the manufacture, supply and distribution of our products could lead to remedial action (such as recalls), civil and criminal penalties and delays in manufacture, supply and distribution of our products.

The design, development, manufacture, supply and distribution of EXPAREL are all highly complex. As part of our routine stability monitoring that occurred in October 2016, it came to our attention that one of two test batches of EXPAREL made in early 2016 had fallen slightly out of specification for one of the 21 acceptance criteria measured during testing. This test result was unexpected and suggestive of some deviation from a consistency of manufacturing output. In connection with this issue, in 2016, we recorded a $20.7 million charge to cost of goods sold. An internal investigation tied this unexpected result to a modification in the manufacturing process that existed when this product was made, which has subsequently been corrected. As a result, we had discussions with the FDA about both a modification of that specification as well as the development of a new analytical test for this attribute. Until that process was complete, we agreed with the FDA that all EXPAREL manufactured beginning in October 2016 would include 12 month expiration dating. That process was completed on February 7, 2019, when we received FDA approval for our sNDA to extend the shelf life of EXPAREL from 12 months to 24 months for product manufactured on or after this date. If we are unable to manufacture EXPAREL in compliance with our specifications, we may be subject to product exchanges or other corrective measures.

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

The testing, manufacturing, quality control, labeling, safety, effectiveness, advertising, promotion, storage, sales, distribution, import, export and marketing, among other things, of EXPAREL and our product candidates are subject to extensive regulation by governmental authorities in the U.S. and elsewhere throughout the world. Quality control and manufacturing procedures regarding EXPAREL and our product candidates must conform to cGMP. Regulatory authorities, including the FDA and the MHRA, periodically inspect manufacturing facilities to assess compliance with cGMP. Our failure, or the failure of any contract manufacturers with whom we may work in the future, to comply with the laws administered by the FDA, the MHRA or other governmental authorities could result in, among other things, any of the following:

- product recall or seizure;
- suspension or withdrawal of an approved product from the market;
- interruption of production;
- reputational concerns of our customers or the medical community;
- operating restrictions;
- warning letters;
- injunctions;
- refusal to permit import or export of an approved product;
- refusal to approve pending applications or supplements to approved applications that we submit;
- denial of permission to file an application or supplement in a jurisdiction;
- consent decrees;

- suspension or termination of ongoing clinical trials;
- fines and other monetary penalties;
- criminal prosecutions; and
- unanticipated expenditures.

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If the government or third-party payers fail to provide adequate coverage and payment rates for EXPAREL or any future products, or if hospitals choose to use therapies that are less expensive, our revenue and prospects for profitability will be limited.

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

Third-party payers, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. For example, third-party payers may limit the indications for which our products will be reimbursed to a smaller set of indications than we believe is appropriate or limit the circumstances under which our products will be reimbursed to a smaller set of circumstances than we believe is appropriate. In addition, in the U.S., 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 U.S. and in international markets, as federal, state and foreign governments continue to propose and pass new legislation designed to reduce or contain the cost of healthcare. Third-party coverage and reimbursement for our products or product candidates for which we receive regulatory approval may not be available or adequate in either the U.S. or international markets, which could have a negative effect on our business, results of operations, financial condition and prospects.

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

In light of widely publicized events concerning the safety risk of certain drug products, the FDA, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and the establishment of risk management programs that may, for example, restrict distribution of drug products after approval. The Food and Drug Administration Amendments Act of 2007, or FDAAA, grants significant expanded authority to the FDA, much of which is aimed at improving the safety of drug products before and after approval. In particular, the FDAAA authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. The FDAAA also significantly expands the federal government’s clinical trial registry and results databank, which we expect will result in significantly increased government oversight of clinical trials. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties. The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of data from our clinical trials. Data from clinical trials may receive greater

scrutiny, particularly with respect to safety, which may make the FDA or other regulatory authorities more likely to require additional preclinical studies or clinical trials. If the FDA requires us to provide additional clinical or preclinical data for EXPAREL, the indications for which this product candidate was approved may be limited or there may be specific warnings or limitations on dosing, and our efforts to commercialize EXPAREL may be otherwise adversely impacted.

Risks Related to Intellectual Property

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

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The active ingredient in EXPAREL is bupivacaine. Patent protection for the bupivacaine 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 ingredient as EXPAREL so long as the competitors do not infringe any process, use or formulation patents that we have developed for drugs encapsulated in our DepoFoam drug delivery technology.

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

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

Because EXPAREL has been approved by the FDA, one or more third parties may challenge the patents covering this product, which could result in the invalidation or unenforceability of some or all of the relevant patent claims. For example, if a third-party files an Abbreviated New Drug Application, or ANDA, for a generic drug product containing bupivacaine and relies in whole or in part on studies conducted by or for us, the third-party will be required to certify to the FDA that either: (i) there is no patent information listed in the FDA's Orange Book with respect to our NDA for EXPAREL; (ii) the patents listed in the Orange Book have expired; (iii) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third-party's generic drug product. A certification that the new product will not infringe the Orange Book-listed patents for EXPAREL, or that such patents are invalid, is called a paragraph IV certification. If the third-party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third-party's ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third-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, 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 U.S. Patent positions and policies outside the U.S. are even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the U.S. 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;

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- the issued patents covering our product candidates may not provide a basis for commercially viable active products, may not provide us with any competitive advantages, may not have sufficient scope or strength to protect the technologies they were intended to protect or may be challenged by third parties;
- others may design around our patent claims to produce competitive products that fall outside the scope of our patents;
- we may not develop or in-license additional proprietary technologies that are patentable;
- patents of others may have an adverse effect on our business; or
- competitors may infringe our patents and we may not have adequate resources to enforce our patents.

Patent applications in the U.S. 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 USPTO to determine priority of invention in the U.S. 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 U.S. and foreign patents or published applications that affect our business either by blocking our ability to commercialize our drugs or by covering similar technologies that affect our drug market.

In addition, some countries, including many in Europe, do not grant patent claims directed to methods of treating humans, and in these countries patent protection may not be available at all to protect our product candidates. Even if patents are issued, we cannot guarantee that the claims of those patents will be valid and enforceable or provide us with any significant protection against competitive products, or otherwise be commercially valuable to us. Furthermore, while we generally apply for patents in those countries where we intend to make, have made, use or sell patented products, we may not accurately predict all of the countries where patent protection will ultimately be desirable. If we fail to timely file a patent application in any such country, we may be precluded from doing so at a later date. We also cannot assure you that the patents issuing as a result of our foreign patent applications will have the same scope of coverage as our U.S. patents.

Some of our older patents have already expired. In the case of EXPAREL, the European and U.S. patents protecting the formulation of EXPAREL expired in 2018. An existing formulation patent for EXPAREL expired in November 2013. An existing formulation patent for EXPAREL expired in the U.S. in 2013 and its equivalents in Canada, Germany, France, Spain, Italy and the United Kingdom expired in 2014. Once our patents covering EXPAREL have expired, we will be more reliant on trade secrets to protect against generic competition.

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

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

If we fail to obtain or maintain patent protection or trade secret protection for EXPAREL, 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

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the general fields of pain management and cancer treatment and cover the use of numerous compounds and formulations in our targeted markets. Because of the uncertainty inherent in any patent or other litigation involving proprietary rights, we and our licensors may not be successful in defending intellectual property claims by third parties, which could have a material adverse effect on our results of operations. Regardless of the outcome of any litigation, defending the litigation may be expensive, time-consuming and distracting to management. In addition, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that EXPAREL or DepoCyt(e) may infringe. There could also be existing patents of which we are not aware that EXPAREL or DepoCyt(e) may inadvertently infringe.

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

- infringement and other intellectual property claims which, with or without merit, can be expensive and time consuming to litigate and can divert management's attention from our core business;
- substantial damages for past infringement which we may have to pay if a court decides that our product infringes on a competitor's patent;
- a court prohibiting us from selling or licensing our product unless the patent holder licenses the patent to us, which it would not be required to do;
- if a license is available from a patent holder, we may have to pay substantial royalties or grant cross licenses to our patents; and
- redesigning our processes so they do not infringe, which may not be possible or could require substantial funds and time.

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

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Cybersecurity

If we do not maintain the privacy and security of personal and business information, we could damage our reputation with customers and employees, incur substantial additional costs and become subject to litigation.

We receive, retain and transmit personal information about our customers and employees and entrust that information to third-party suppliers, including cloud service-providers that perform activities for us. Our business depends upon the secure transmission of encrypted confidential information over public networks, including information permitting payments. A compromise of our security systems or defects within our hardware or software, or those of our suppliers, that results in our customers' or employees' information being obtained by unauthorized persons, could adversely affect our reputation with our customers and others, as well as our operations, results of operations, financial condition and liquidity, and could result in litigation, government actions, or the imposition of penalties. In addition, a breach could require that we expend significant additional resources related to the security of information systems and could disrupt our operations.

The use of data by our business is regulated at the national and state or local level in all of our operating countries. Privacy and information-security laws and regulations change, and compliance with them may result in cost

increases due to, among other things, systems changes and the development of new processes. If we or those with whom we share information fail to comply with these laws and regulations, our reputation could be damaged, possibly resulting in lost future business, and we could be subjected to additional legal risk as a result of non-compliance.

We have security measures and controls to protect personal and business information and continue to make investments to secure access to our information technology network. These measures may be undermined, however, due to the actions of outside parties, employee error, internal or external malfeasance, or otherwise, and, as a result, an unauthorized party may obtain access to our data systems and misappropriate business and personal information. Because the techniques used to obtain

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unauthorized access, disable or degrade service, or sabotage systems change frequently and may not immediately produce signs of intrusion, we may be unable to anticipate these techniques, timely discover or counter them, or implement adequate preventative measures. Any such breach or unauthorized access could result in significant legal and financial exposure, damage to our reputation, and potentially have an adverse effect on our business and results of operations.

Changes in data privacy and protection laws and regulations, particularly in Europe, or any failure to comply with such laws and regulations, could adversely affect our business and financial results.

We are subject to a variety of continuously evolving and developing laws and regulations globally regarding privacy, data protection and data security, including those related to the collection, storage, handling, use, disclosure, transfer and security of personal data. Significant uncertainty exists as privacy and data protection laws may be interpreted and applied differently from country to country and may create inconsistent or conflicting requirements. These laws apply to transfers of information among our affiliates, as well as to transactions we enter into with third party vendors. For example, the E.U. adopted a comprehensive General Data Privacy Regulation, or GDPR, in May 2016 that replaced the then-current E.U. Data Protection Directive and related country-specific legislation in May 2018. GDPR requires companies to satisfy new requirements regarding the handling of personal and sensitive data, including its use, protection and the ability of persons whose data is stored to correct or delete such data about themselves. Failure to comply with GDPR requirements could result in penalties of up to 4% of worldwide revenue. Complying with the enhanced obligations imposed by the GDPR may result in significant costs to our business and require us to revise certain of our business practices. In addition, legislators and regulators in the U.S. are proposing new and more robust cybersecurity rules in light of the recent broad-based cyberattacks at a number of companies. These and similar initiatives around the world could increase the cost of developing, implementing or securing our servers and require us to allocate more resources to improved technologies, adding to our information technology and compliance costs. In addition, enforcement actions and investigations by regulatory authorities related to data security incidents and privacy violations continue to increase. The enactment of more restrictive laws, rules, regulations, or future enforcement actions or investigations could impact us through increased costs or restrictions on our business, and noncompliance could result in regulatory penalties and significant legal liability.

Risks Related to our Financial Condition and Capital Requirements

Cumulatively, we have incurred significant losses since our inception and may incur additional losses in the future. To date, we have focused primarily on developing and commercializing EXPAREL. We had a net loss of $0.5 million for the year ended December 31, 2018, a net loss of $42.6 million for the year ended December 31, 2017 and a net loss of $37.9 million for the year ended December 31, 2016. As of December 31, 2018, we had an accumulated deficit of $388.2 million. Our losses, among other things, have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. We incurred significant pre-commercialization expenses as we prepared for the commercial launch of EXPAREL, and we incur significant sales, marketing and manufacturing expenses, as well as continued development expenses related to the commercialization of EXPAREL. As a result, we had not been profitable prior to 2015 and have not been since. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses.

We may not return to profitability.

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

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

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

We may need additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

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

- continue to fund our operations;

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- continue our efforts to hire additional personnel and build a commercial infrastructure to commercialize EXPAREL;
- qualify, outsource or build additional commercial-scale manufacturing of our products under cGMP;
- in-license and develop additional product candidates; and
- refinance our current 2.375% convertible senior notes, due April 2022.

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

- the costs of maintaining a commercial organization to sell, market and distribute EXPAREL;
- the success of the commercialization of EXPAREL;
- the cost and timing of manufacturing sufficient supplies of EXPAREL to meet customer demand, including the cost of expanding our manufacturing facilities to produce EXPAREL;
- the rate of progress and costs of our efforts to prepare for the submission of an NDA for any product candidates that we may in-license or acquire in the future, and the potential that we may need to conduct additional clinical trials to support applications for regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates, including any such costs we may be required to expend if our licensors are unwilling or unable to do so;
- the effect of competing technological and market developments;
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish; and
- the potential that we may be required to file a lawsuit to defend our patent rights or regulatory exclusivities from challenges by companies seeking to market generic versions of extended-release liposome injection of bupivacaine.

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

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

Our quarterly operating results may fluctuate significantly.

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

- the level of underlying hospital demand for EXPAREL and end-user buying patterns;
- maintaining our existing manufacturing facilities, expanding our manufacturing capacity and constructing a second suite for the manufacture of EXPAREL with our co-production partner, Thermo Fisher, including installing specialized processing equipment for the manufacturing of EXPAREL;
- our execution of other collaborative, licensing, distribution, manufacturing or similar arrangements and the timing of payments we may make or receive under these arrangements;

- variations in the level of expenses related to our future development programs;

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- any product liability or intellectual property infringement lawsuit in which we may become involved; and

- regulatory developments, lawsuits and investigations affecting EXPAREL or the product candidates of our competitors;

If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

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

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

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

We have significant federal and state net operating loss, or NOL, carryforwards and federal and state research and development tax credit carryforwards. Our NOL carryforwards and research and development tax credits may expire and not be used. Our NOL carryforwards will begin expiring in 2027 for federal purposes and in 2024 for state purposes if we have not used them prior to that time. For any federal NOLs generated after December 31, 2017, the NOLs will have an indefinite life and utilization will be subject to a limitation of 80% of taxable income. The non-U.S. NOLs do not expire. Additionally, our ability to use certain NOLs and credit carryforwards to offset taxable income or tax, respectively, in the future will be limited under Internal Revenue Code Sections 382 and 383 because we experienced cumulative changes in ownership of more than 50% within a three-year period. Such ownership changes were triggered by the cumulative ownership changes arising as a result of the initial acquisition of the Company's stock in 2007 and the completion of our initial public offering and our other financing transactions. Because of the ownership changes, we will be limited regarding the amount of NOL carryforwards and research tax credits that we can utilize annually in the future to offset taxable income or tax, respectively. Such an annual limitation will significantly reduce the utilization of the NOLs and research tax credits before they expire. In addition, California and certain states have suspended use of NOL 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 NOL carryforwards in states in which we are subject to income tax could have an adverse impact on our results of operations and financial condition.

Risks Related to our Indebtedness and our Common Stock

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

Our stock price is volatile, and from February 3, 2011, the first day of trading of our common stock, to February 27, 2019, the trading prices of our stock have ranged from $6.16 to $121.95 per share.

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

- the commercial success of EXPAREL;

- results of clinical trials of our product candidates or those of our competitors;

- changes or developments in laws or regulations applicable to our product candidates;

- introduction of competitive products or technologies;

- failure to meet or exceed financial projections we provide to the public;

- actual or anticipated variations in quarterly operating results;
- failure to meet or exceed the estimates and projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;

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- regulatory concerns or government actions
- general economic and market conditions and overall fluctuations in U.S. equity markets;
- developments concerning our sources of manufacturing supply;
- disputes or other developments relating to patents or other proprietary rights;
- additions or departures of key scientific or management personnel;
- the extent to which we acquire or invest in products, businesses and technologies;
- issuances of debt, equity or convertible securities;
- changes in the market valuations of similar companies; and
- the other factors described in this "Risk Factors" section.

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

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

Our ability to make payments of the principal of, to pay interest on or to refinance our indebtedness, including the 2.375% convertible senior notes due 2022, or 2022 Notes, issued in our private offering completed on March 13, 2017, as described below, or to make cash payments in connection with any conversion of the 2022 Notes depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our indebtedness and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring indebtedness or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

On March 13, 2017, the Company completed a private placement of $345.0 million in aggregate principal amount of 2.375% convertible senior notes due 2022, or 2022 Notes, and entered into an indenture agreement, or 2022 Indenture, with
respect to the 2022 Notes. The 2022 Notes accrue interest at a fixed rate of 2.375% per year, payable semiannually in arrears on
April 1 and October 1 of each year. The 2022 Notes mature on April 1, 2022.

As of December 31, 2018, our total consolidated gross indebtedness was $345.3 million, all of which was unsecured indebtedness, and our subsidiaries had no indebtedness (in each case, excluding trade payables, intercompany liabilities and income tax-related liabilities). The total consists of $345.0 million of principal outstanding on the 2022 Notes and $0.3 million of principal outstanding on our 3.25% convertible senior notes due 2019, or 2019 Notes. The 2019 Notes matured on February 1, 2019.

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

Despite our current consolidated indebtedness levels, we and our subsidiaries may be able to incur substantial additional indebtedness in the future, subject to any restrictions contained in our then-existing debt instruments, some of which may be secured indebtedness. We are not restricted under the terms of the indenture governing the 2022 Notes from incurring additional indebtedness, securing existing or future indebtedness, recapitalizing our indebtedness or taking a number of other actions that could have the effect of diminishing our ability to make payments on the 2022 Notes or any future indebtedness.

We may not have the ability to raise the funds necessary to settle conversions of the 2022 Notes in cash to the extent elected or to repurchase the 2022 Notes upon a fundamental change, and our future indebtedness may contain limitations on our ability to pay cash upon conversion of the 2022 Notes or limitations on our ability to repurchase the 2022 Notes.

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Holders of the 2022 Notes will have the right to require us to repurchase their 2022 Notes upon the occurrence of a fundamental change at a repurchase price equal to 100% of their principal amount, plus accrued and unpaid interest, if any. In addition, upon conversion of the 2022 Notes, (if we choose to settle the principal amount in cash at our option) we will be required to make cash payments for each $1,000 in principal amount of 2022 Notes converted of at least the lesser of $1,000 and the sum of the daily conversion values. However, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of 2022 Notes surrendered therefor or 2022 Notes being converted. Any credit facility or other agreement that we may enter into may limit our ability to make cash payments at the time of a fundamental change or upon conversion of the 2022 Notes. Further, our ability to repurchase the 2022 Notes or to pay cash upon conversions of the 2022 Notes may be limited by law, by regulatory authority or by agreements governing our future indebtedness. Our failure to repurchase 2022 Notes at a time when the repurchase is required by the indenture or to pay any cash payable on future conversions of the 2022 Notes as required by the indenture would constitute a default under the indenture. A default under the indenture or the fundamental change itself could also lead to a default under agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the 2022 Notes or make cash payments upon conversions thereof.

The conditional conversion feature of the 2022 Notes, if triggered and elected, may adversely affect our financial condition and operating results.

Under certain circumstances, holders of the 2022 Notes are entitled to convert their 2022 Notes to common stock at any time during specified periods at their option. If one or more holders elect to convert their 2022 Notes, we would be required to settle any converted principal through the payment of cash, shares of our common stock or a combination of cash and shares of our common stock, at our option, which could adversely affect our liquidity to the extent cash is paid.

Conversion of the 2022 Notes may dilute the ownership interest of existing stockholders, including holders who had previously converted their 2022 Notes, or may otherwise depress the price of our common stock.

The conversion of the 2022 Notes into shares of our common stock, to the extent that we choose not to deliver all cash for the conversion value in excess of the principal amount (or if we elect to settle the principal amount in shares of our common stock at our option), will dilute the ownership interests of existing stockholders. Any sales in the public market of the common stock issuable upon conversion of the 2022 Notes could adversely affect prevailing market prices of our common stock. In addition, the existence of the 2022 Notes may encourage short selling by market participants due to this dilution or may facilitate trading strategies involving the 2022 Notes and our common stock.

Future sales in the public market or issuances of our common stock could lower the market price for our common stock.

In the future, we may sell additional shares of our common stock to raise capital. Except under limited circumstances, we are not restricted from issuing additional common stock, including securities that are convertible into or exchangeable for, or that represent the right to receive, common stock. The issuance of additional shares of our common stock or convertible securities, including upon exercise of our outstanding options or otherwise, will dilute the ownership interest of our common stockholders. In addition, our greater than 5% stockholders may sell a substantial number of their shares in the public market, which could also affect the market price for our common stock. We cannot predict the size of future sales or issuances of our common stock or the effect, if any, that they may have on the market price for our common stock. The liquidity and trading volume of our common stock is limited. For the three months ended December 31, 2018, the average per day trading volume of our common stock was 502,444 shares. The issuance and/or sale of substantial amounts of common stock, or the perception that such issuances and/or sales may occur, could adversely affect the market price of our common stock and impair our ability to raise capital through the sale of additional equity or debts securities.

The accounting method for convertible debt securities that may be settled in cash, such as the 2022 Notes, could have a material effect on our reported financial results.

In May 2008, the Financial Accounting Standards Board, or FASB, issued FASB Staff Position No. APB 14-1, Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash

Settlement), which has subsequently been codified as Accounting Standards Codification 470-20, Debt with Conversion and Other Options, or ASC 470-20. Under ASC 470-20, an entity must separately account for the liability and equity components of the convertible debt instruments (such as the 2022 Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. The effect of ASC 470-20 on the accounting for the 2022 Notes is that the equity component is required to be included in the additional paid-in capital section of stockholders' equity on our consolidated balance sheet at the issuance date and the value of the equity component would be treated as debt discount for purposes of accounting for the debt component of the 2022 Notes. As a result, we are required to record a greater amount of non-cash interest expense in current periods presented as a result of the amortization of the discounted carrying value of the 2022 Notes to their face amount over the term of the 2022 Notes. We will report larger net losses in our financial results because ASC 470-20 will require interest to include both the current period's amortization of the debt discount and the instrument's coupon interest, which could

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adversely affect our reported or future financial results, the trading price of our common stock and the trading price of the 2022 Notes.

In addition, under certain circumstances, convertible debt instruments (such as the 2022 Notes) that may be settled entirely or partly in cash are currently accounted for utilizing the treasury stock method, the effect of which is that the shares issuable upon conversion of the 2022 Notes are not included in the calculation of diluted earnings per share except to the extent that the conversion value of the 2022 Notes exceeds their principal amount. Under the treasury stock method, for diluted earnings per share purposes, the transaction is accounted for as if the number of shares of common stock that would be necessary to settle such excess, if we elected to settle such excess in shares, are issued. We cannot be sure that the accounting standards in the future will continue to permit the use of the treasury stock method. If we are unable to use the treasury stock method in accounting for the shares issuable upon conversion of the 2022 Notes, then our net losses per share would be increased.

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

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

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

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

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

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We occupy three facilities totaling approximately 150,000 square feet at our Science Center Campus in San Diego, California. We use these facilities for research and development, manufacturing, general and administrative purposes and the storage of inventory and raw materials. Our research and development property lease expires in October 2020, our warehouse lease expires in August 2020 and our EXPAREL manufacturing facility lease expires in December

2025. In addition, we maintain our executive offices and our commercial and business development facility in Parsippany, New Jersey, where we occupy approximately 42,000 square feet under a lease expiring in March 2028. We also have a lease for our former DepoCyt(e) production facility in San Diego which is currently idle and expires in August 2020.

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

Item 3. Legal Proceedings

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

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

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Our common stock is listed and traded under the ticker symbol "PCRX" on the NASDAQ Global Select Market. As of February 24, 2019, we had approximately 13 holders of record of our common stock.

Performance Graph

The following graph shows the value of an investment of $100.00 on December 31, 2013, in each of our common stock (PCRX), the NASDAQ Composite index (^IXIC) and the NASDAQ Biotechnology index (^NBI). The indices are included for comparative purposes only and do not necessarily reflect management's opinion that such indices are an appropriate measure of the relative performance of our common stock. All results assume the reinvestment of dividends, if any, and are calculated as of December 31st of each year. The historical stock price performance of our common stock shown in the performance graph is not necessarily indicative of future stock price performance.

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Comparison of Cumulative Total Returns

	Cumulative Total Return as of December 31,					
	2013	2014	2015	2016	2017	2018
Pacira Pharmaceuticals, Inc. (PCRX)	$100.00	$154.22	$133.57	$56.18	$79.41	$74.83
NASDAQ Composite (^IXIC)	$100.00	$113.40	$119.89	$128.89	$165.29	$158.87
NASDAQ Biotechnology (^NBI)	$100.00	$134.10	$149.42	$117.02	$141.66	$128.45

Dividend Policy

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

Item 6. Selected Financial Data

The following tables provide selected consolidated financial data. We have prepared this information using our audited consolidated financial statements as of and for the years ended December 31, 2018, 2017, 2016, 2015 and 2014. The following consolidated financial data should be read in conjunction with our consolidated financial statements and related notes and Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in this report.

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	Year Ended December 31,				
	2018	2017	2016	2015	2014
Consolidated Statements of Operations Data	(In thousands, except per share data)				
Revenues:					
Net product sales	$332,427	$284,342	$270,073	$244,487	$193,526
Collaborative licensing and milestone revenue	3,000	387	3,426	1,426	1,287
Royalty revenue	1,850	1,901	2,872	3,084	2,855
Total revenues	337,277	286,630	276,371	248,997	197,668
Operating expenses:					
Cost of goods sold	86,845	87,915	110,104 [3]	71,837	77,440
Research and development	55,688	57,290	45,678	28,662	18,731
Selling, general and administrative	177,265	161,494	152,613 [4]	139,043	106,662
Product discontinuation	1,564 [1]	4,868 [2]	—	—	—
Total operating expenses	321,362	311,567	308,395	239,542	202,833
Income (loss) from operations	15,915	(24,937)	(32,024)	9,455	(5,165)
Other (expense) income:					
Interest income	6,497	4,078	1,323	678	382
Interest expense	(21,949)	(18,047)	(7,061)	(7,725)	(8,278)
Loss on early extinguishment of debt	—	(3,732)	—	(52)	—
Royalty interest obligation	—	—	—	(71)	(323)
Other, net	(888)	167	(82)	(165)	(159)
Total other expense, net	(16,340)	(17,534)	(5,820)	(7,335)	(8,378)
Income (loss) before income taxes	(425)	(42,471)	(37,844)	2,120	(13,543)
Income tax expense	(46)	(140)	(105)	(264)	(173)
Net income (loss)	$(471)	$(42,611)	$(37,949)	$1,856	$(13,716)
Net income (loss) per share:					
Basic net income (loss) per common share	$(0.01)	$(1.07)	$(1.02)	$0.05	$(0.39)
Diluted net income (loss) per common share	$(0.01)	$(1.07)	$(1.02)	$0.04	$(0.39)
Weighted average common shares outstanding:					
Basic	40,911	39,806	37,236	36,540	35,299
Diluted	40,911	39,806	37,236	41,301	35,299

(1) Relates to non-recurring charges of $1.6 million related to the discontinuation of our DepoCyt(e) manufacturing activities for lease costs, asset retirement obligations and other estimated exit costs. The charges incurred in 2018 primarily represent additional lease and facility costs due to the fact that we have not been able to sub-lease the property where DepoCyt(e) was manufactured considering the short period of time remaining on our existing lease. For further discussion of these charges, see Note 16, Commercial Partners and Other Agreements, to our consolidated financial statements included herein.

(2) Relates to non-recurring charges of $5.4 million related to the discontinuation of our DepoCyt(e) manufacturing activities, including $0.5 million for DepoCyt(e) related inventory, which is recorded in cost of goods sold, and $4.9 million for the remaining lease costs less an estimate of potential sublease income for the facility where DepoCyt(e) was manufactured, the write-off of property, plant and equipment, employee severance, asset retirement obligations and other estimated exit costs. For further discussion of these charges, see Note 16, Commercial Partners and Other Agreements, to our consolidated financial statements included herein.

(3) Includes a $20.7 million charge for inventory and related reserves for the cost of EXPAREL batches impacted by a routine stability test that did not meet required specifications. For further discussion of this charge, see Note 5, Inventories, to our consolidated financial statements included herein.

(4) Includes a $7.1 million contract termination charge due to CrossLink Bioscience, LLC. For further discussion of this charge, see Note 16, Commercial Partners and Other Agreements, to our consolidated financial statements

included herein.

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	December 31,				
	2018	2017	2016	2015	2014
Consolidated Balance Sheet Data	(In thousands)				
Cash and cash equivalents, restricted cash, short-term and long-term investments	$409,325	$371,394	$172,597	$172,427	$182,598
Working capital	417,308	334,893	198,251	102,794	71,715
Total assets	689,353	628,371	391,466	387,735	323,540
Long-term liabilities	307,466	292,671	127,652	19,555	14,917
Accumulated deficit	(388,226)	(389,136)	(346,238)	(308,289)	(310,145)
Total stockholders' equity	321,226	279,483	218,976	218,392	171,145

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

Management's Discussion and Analysis of Financial Condition and Results of Operations is based upon our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States of America (GAAP) and in accordance with the rules and regulations of the United States Securities and Exchange Commission (SEC). The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the notes to those consolidated financial statements appearing in Part IV, Item 15 of this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are a specialty pharmaceutical company focused on becoming a global leader in delivering innovative non-opioid pain management and regenerative health solutions to surgeons and anesthesiologists. Our corporate mission is to provide an opioid alternative to as many appropriate patients as possible. Our current product pipeline is based on our proprietary DepoFoam® extended release drug delivery technology, for use primarily in hospitals and ambulatory surgery centers. EXPAREL® (bupivacaine liposome injectable suspension), an opioid free, amide-type local anesthetic, is currently indicated for single-dose infiltration in adults to produce postsurgical local analgesia and as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia. Since its initial approval in 2011 for single-dose infiltration, more than five million patients have been treated with EXPAREL. We drop-ship EXPAREL directly to the end-user based on orders placed to wholesalers or directly to us, and there is no product held by wholesalers.

We expect to continue to incur significant expenses as we pursue the expanded use of EXPAREL in additional procedures; expand into new global markets; progress our earlier-stage product candidate pipeline; advance regulatory activities for EXPAREL and other product candidates; invest in sales and marketing resources; expand and enhance our manufacturing capacity for EXPAREL; invest in products, businesses and technologies and support legal matters.

Recent Highlights

- As of February 2019, commercial production of EXPAREL is now underway at a custom suite in Swindon, England, created under our partnership with Thermo Fisher Scientific Pharma Services (formerly Patheon UK Limited), or Thermo Fisher. This first suite mirrors our existing facility at the Pacira Science Center Campus in San Diego, California, and is expected to double our manufacturing capacity. Through the partnership, we are developing a second dedicated suite that is expected to enable another doubling of EXPAREL manufacturing capacity in approximately two years. Our investment in this facility is an integral component of our strategy to meet the growing customer demand in the U.S. and to support expansion into new global markets, such as Europe, Canada and Asia.

- On February 7, 2019, we received United States Food and Drug Administration, or FDA, approval for our supplemental New Drug Application, or sNDA, to extend the shelf life of EXPAREL from 12 months to 24 months.

- In January 2019, we announced that our Phase 4 study of EXPAREL in patients undergoing Cesarean section (C-section) achieved its primary endpoint with a statistically significant reduction in total postsurgical opioid consumption through 72 hours ($p<0.05$). EXPAREL also achieved statistical significance for reduction in pain intensity scores through 72 hours ($p<0.05$). The full study results will be submitted for publication in peer-reviewed medical literature.

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Results of Operations

Comparison of Years Ended December 31, 2018, 2017 and 2016

Revenues

Net product sales primarily consist of sales of EXPAREL in the U.S. Other product sales include sales of our bupivacaine liposome injectable suspension to a third party licensee for use in animals and sales of DepoCyt(e) to third party licensees in the U.S. and Europe prior to the discontinuation of DepoCyt(e) production in June 2017. Licensing, milestone and royalty revenues are from our collaborative licensing agreements.

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

	Year Ended December 31,			2018 versus 2017	2017 versus 2016
	2018	2017	2016	% Increase / (Decrease)	
Net product sales:					
EXPAREL	$331,112	$282,905	$265,802	17 %	6 %
Other product sales	1,315	1,437	4,271	(8)%	(66)%
Total net product sales	332,427	284,342	270,073	17 %	5 %
Collaborative licensing and milestone revenue	3,000	387	3,426	100% +	(89)%
Royalty revenue	1,850	1,901	2,872	(3)%	(34)%
Total revenues	$337,277	$286,630	$276,371	18 %	4 %

EXPAREL revenue grew 17% and 6% in the years ended December 31, 2018 and 2017, respectively, primarily due to increased unit volumes of 23% and 7%, respectively, offset primarily by the mix of EXPAREL product sizes. The demand for EXPAREL has continued to increase as a result of a number of key growth initiatives, such as the expansion of the EXPAREL label in April 2018 to include interscalene brachial plexus nerve block, the success of our co-promotion agreement with DePuy Synthes Sales, Inc., or DePuy Synthes, and the continued implementation of EXPAREL-based Enhanced Recovery After Surgery (ERAS) protocols across a wide range of surgical procedures, all of which are driving growth in new and existing accounts due to the continued adoption of EXPAREL as a critical component of multimodal pain management strategies for soft tissue and orthopedic procedures.

Other product sales decreased 8% in 2018 versus 2017 and 66% in 2017 versus 2016, respectively, primarily due to the discontinuation of DepoCyt(e) in June 2017, partially offset by an increase in sales of our bupivacaine liposome injectable suspension to Aratana Therapeutics, Inc., or Aratana, for use in animals.

Collaborative licensing and milestone revenue increased by more than 100% in 2018 versus 2017, due to a $3.0 million upfront payment earned under a license agreement with Nuance Biotech Co. Ltd., or Nuance, for the development and commercialization of EXPAREL in China. The decrease in collaborative licensing and milestone revenue of 89% in 2017 versus 2016 was primarily due to $2.0 million in milestones earned in 2016 under our agreement with Aratana and the conclusion of recognizing deferred revenue from a development and licensing agreement with Amylin Pharmaceuticals, Inc. which expired in January 2017.

In 2018, royalty revenue primarily reflects royalties earned on sales to Aratana. Royalty revenue decreased 3% in 2018 versus 2017 and 34% in 2017 versus 2016 due to the discontinuation of our DepoCyt(e) manufacturing activities in June 2017, partially offset by increased Aratana royalties earned.

Cost of Goods Sold

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

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

	Year Ended December 31,			2018 versus 2017	2017 versus 2016
	2018	2017	2016	% Increase / (Decrease)	
Cost of goods sold	$86,845	$87,915	$110,104	(1)%	(20)%
Gross margin	74 %	69 %	60 %		

The five percentage point improvement in our gross margin for 2018 versus 2017 was primarily due to lower manufacturing costs per vial resulting from increased utilization of our facilities to manufacture EXPAREL, impacting gross margins by four percentage points. In addition, gross margin improved by one percentage point as a result of scrapped lots of DepoCyt(e) that were expensed in 2017 before manufacturing was discontinued in June 2017.

The nine percentage point improvement in our gross margin in 2017 versus 2016 was largely due to a $20.7 million charge for inventory and related reserves in second half of 2016 related to a single stability batch for EXPAREL that was outside of specification for one of 21 acceptance criteria, improving 2017 gross margin by seven percentage points. The manufacturing issue that existed when this batch was made was subsequently corrected. We also had $5.9 million of unplanned manufacturing shutdown charges in 2016 related to this event, improving gross margin in 2017 by two percentage points.

Research and Development Expenses

Research and development expenses primarily consist of costs related to clinical trials and related outside services, product development and other research and development costs, including Phase 4 trials that we are conducting to generate new data and best-practice administration techniques for EXPAREL and stock-based compensation expense. Clinical development expenses include costs for clinical personnel, clinical trials performed by third-parties, materials and supplies, database management and other third-party fees. Product development and other research and development expenses include development costs for our products and medical information expenses, which include personnel, equipment, materials and contractor costs for process development and product candidates, toxicology studies, development costs related to significant scale-ups of our manufacturing capacity, facility costs for our research space and regulatory activities related to unapproved products and indications. Stock-based compensation expense relates to the costs of stock option grants, awards of restricted stock units, or RSUs, and our employee stock purchase plan, or ESPP.

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

	Year Ended December 31,			2018 versus 2017	2017 versus 2016
	2018	2017	2016	% Increase / (Decrease)	
Clinical development	$17,641	$33,138	$23,566	(47)%	41 %
Product development and other	34,113	20,811	18,815	64 %	11 %
Stock-based compensation	3,934	3,341	3,297	18 %	1 %
Total research and development expense	$55,688	$57,290	$45,678	(3)%	25 %
% of total revenue	17 %	20 %	17 %		

Total research and development expense decreased 3% in 2018 versus 2017. The 47% decrease in clinical development expense in 2018 versus 2017 was primarily due to the prior completion of our two Phase 3 trials evaluating EXPAREL as a single-dose nerve block for prolonged regional analgesia. Enrollment in these studies concluded in June 2017. There were also decreases in costs related to the completion of product-related bioequivalence trials. The decreases in clinical development expense were partially offset by increased costs related to

our sNDA submission for nerve block, including expenses related to an FDA Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) meeting held in February 2018, increased clinical personnel and increased global expansion activities for EXPAREL.

Product development and other expenses increased 64% in 2018 versus 2017 due to development costs related to a significant scale-up of our manufacturing capacity for EXPAREL in Swindon, England in partnership with Thermo Fisher, additional expenditures for pipeline candidates, increased regulatory expense related to EXPAREL in certain territories not yet approved (including the European Union, or E.U.) and indications and products currently in development. In February 2019,

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we announced that commercial production of EXPAREL was underway at the first of two dedicated manufacturing suites at the Swindon facility.

Stock-based compensation increased 18% in 2018 versus 2017 primarily due to an increase in personnel as well as the number of awards granted during 2018.

Total research and development expenses increased 25% in 2017 versus 2016 largely due to a 41% increase in clinical development expenses driven by the completion of our two Phase 3 trials evaluating EXPAREL as a single-dose nerve block for prolonged regional analgesia. Enrollment in these studies began in the second quarter of 2016 and concluded in June 2017. The increase in clinical development expense was partially offset by a decrease in research grants. Product development and other expense increased 11% which reflects higher research and development facility costs at our Science Center Campus in San Diego, increased support from commercial manufacturing and quality organizations to support research and development functions and expenditures to develop a 200-liter manufacturing skid as part of a scale-up of our manufacturing capacity in Swindon, England. These increases were partially offset by reduced expenditures investigating the 2016 stability issue and fewer preclinical toxicology studies. Stock-based compensation increased 1%.

Selling, General and Administrative Expenses

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

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

	Year Ended December 31,			2018 versus 2017 % Increase / (Decrease)	2017 versus 2016 % Increase / (Decrease)
	2018	2017	2016		
Sales and marketing	$107,106	$94,803	$89,218	13 %	6 %
General and administrative	46,846	43,898	41,882	7 %	5 %
Stock-based compensation	23,313	22,793	21,513	2 %	6 %
Total selling, general and administrative expenses	$177,265	$161,494	$152,613	10 %	6 %
% of total revenue	53 %	56 %	55 %		

Total selling, general and administrative expenses increased 10% in 2018 versus 2017.

Sales and marketing expenses increased 13% in 2018 versus 2017. In 2018, we expanded our public affairs campaign focused on driving policy change to improve patient access to non-opioid treatment options. Selling and promotional activities also increased to support the growth of EXPAREL, including additional sales representatives focused on the outpatient market, initiatives and commissions related to our co-promotion agreement with DePuy Synthes and additional marketing spend for the commercial launch of EXPAREL as a brachial plexus nerve block. We continued our marketing investment in EXPAREL—including educational initiatives and programs to create product awareness within key surgical markets. We also continued to support multiple educational programs related to the impact of opioids and postsurgical pain management and our national advocacy campaign to educate patients about non-opioid treatment options.

General and administrative expenses increased 7% in 2018 versus 2017. The increase was primarily due to an increase in business development activities and an increase in legal expenditures related to securing ambulatory and dental reimbursement codes and ongoing costs related to a DOJ subpoena received in April 2015.

Stock-based compensation increased 2% in 2018 versus 2017, primarily due to accelerated stock-based compensation expense that occurred in the second half of 2018.
Total selling, general and administrative expenses increased 6% in 2017 versus 2016.

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Sales and marketing expenses increased by 6% in 2017 versus 2016. The year over year increase was driven by an increase in spending for EXPAREL marketing, educational initiatives and programs to create product awareness within key surgical markets. Included in this increase are salaries and related personnel costs for field-based medical and sales professionals to better support and educate our customers, initiatives related to our co-promotion agreement with DePuy Synthes and a new EXPAREL website that includes a surgeon selector tool. We also supported multiple educational programs related to the impact of opioids and postsurgical pain management along with our "Choices Matter" campaign, designed to raise awareness about non-opioid treatment options. The increase was partially offset by a $7.1 million contract termination charge due to CrossLink BioScience, LLC, or CrossLink, which was recognized in 2016.

General and administrative expenses increased 5% in 2017 versus 2016. The increase in general and administrative expenses was largely attributable to an increase in regulatory expenses, primarily in preparation for a European Medicines Agency Marketing Authorization Application for EXPAREL in the E.U. Other increased expenditures included support related to our expanded manufacturing facility in England and the development and launch of new corporate and EXPAREL.com websites.

Stock-based compensation increased 6% in 2017 versus 2016, primarily due to new awards granted in mid-to-late 2016 and 2017.

Product Discontinuation Expenses

In June 2017, we discontinued production of DepoCyt(e) due to persistent technical issues specific to the DepoCyt(e) manufacturing process. The following table provides information regarding product discontinuation expenses during the periods indicated, including percent changes (dollar amounts in thousands):

	Year Ended December 31,			2018 versus 2017	2017 versus 2016
	2018	2017	2016	% Increase / (Decrease)	
Product discontinuation	$1,564	$4,868	$ —	(68)%	N/A

In 2018, we recorded non-recurring charges of $1.6 million related to the discontinuation of our DepoCyt(e) manufacturing activities for lease costs, asset retirement obligations and other estimated exit costs. The charges incurred in 2018 primarily represent additional lease and facility costs due to the fact that we do not expect to be able to sub-lease the property where DepoCyt(e) was manufactured considering the short period of time remaining on our existing lease.

In 2017, we recorded a non-recurring charge of $5.4 million, of which $0.5 million was for related inventory recorded in cost of goods sold, and the remaining $4.9 million was recorded in product discontinuation expense, including $2.0 million for lease costs less an estimate of potential sub-lease income, $1.9 million for the write-off of fixed assets and $1.0 million relating to employee severance, asset retirement obligations and other product discontinuation costs.

Other (Expense) Income

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

	Year Ended December 31,			2018 versus 2017	2017 versus 2016
	2018	2017	2016	% Increase / (Decrease)	
Interest income	$6,497	$4,078	$1,323	59 %	100% +
Interest expense	(21,949)	(18,047)	(7,061)	22 %	100% +
Loss on early extinguishment of debt	—	(3,732)	—	(100)%	N/A
Other, net	(888)	167	(82)	N/A	N/A

Total other expense, net	$(16,340)	$(17,534)	$(5,820)	(7)%	100% +
% of total revenue	(5)%	(6)%	(2)%		

Total other expense, net decreased 7% in 2018 versus 2017. The impacts of the March 2017 issuance of $345.0 million of 2.375% convertible senior notes due 2022, or 2022 Notes, and the 2017 repurchase of $118.2 million of our 3.25% convertible senior notes due 2019, or 2019 Notes, resulted in an increase in interest expense of $3.9 million and a reduction in loss on early extinguishment of debt of $3.7 million. Interest income increased $2.4 million as a result of additional investments from the net

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proceeds of the 2022 Notes. In addition, there was a $0.9 million loss on an unexercised purchase option related to an investment which expired on September 15, 2018 (see Note 10, Financial Instruments, to our Consolidated Financial Statements for further discussion).

Total other expense, net increased by more than 100% in 2017 versus 2016 almost entirely due to the March 2017 issuance of the 2022 Notes and the repurchase of $118.2 million of our 2019 Notes, which resulted in an increase in interest expense of $11.0 million and a $3.7 million loss on early extinguishment of debt in 2017 versus 2016. Partially offsetting this was an increase in interest income of $2.8 million as a result of additional investments from the net proceeds of the 2022 Notes and $0.2 million of favorable foreign currency gains.

Income Tax Expense

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

	Year Ended December 31,			2018 versus 2017 % Increase / (Decrease)	2017 versus 2016
	2018	2017	2016		
Income tax expense	$46	$140	$105	(67)%	33 %
Effective tax rate	(10)%	0 %	0 %		

We recorded a tax provision of less than $0.1 million for the year ended December 31, 2018 and $0.1 million for each of the years ended December 31, 2017 and 2016. Since our deferred tax assets are fully offset by a valuation allowance, our total income tax expense includes only current tax expense. The tax provisions consist principally of minimum state taxes.

On December 22, 2017, the U.S. federal government enacted comprehensive tax legislation (the “Tax Act”), which significantly revised the U.S. corporate income tax law by, among other things, lowering the U.S. federal corporate income tax rate from 35% to 21%, implementing a territorial tax system, imposing a one-time transition tax on foreign unremitted earnings, setting limitations on the deductibility of certain costs (e.g., interest expense) and the utilization of net operating losses, or NOLs. Any federal NOLs generated after December 31, 2017 now have an indefinite life. The lower U.S. corporate income tax rate was effective January 1, 2018, however the U.S. deferred tax assets and liabilities were adjusted in 2017 when the new tax law was enacted. The estimated impact of the re-measurement of U.S. deferred tax assets and liabilities resulting from the Tax Act was a charge of $55.7 million which was offset by a change in the year-end valuation allowance. We had no foreign subsidiary earnings as a result of the historical losses of our foreign subsidiaries.

Liquidity and Capital Resources

Since our inception in 2006, we have devoted most of our cash resources to manufacturing, research and development and selling, general and administrative activities related to the development and commercialization of EXPAREL. We are highly dependent on the commercial success of EXPAREL. We have financed our operations primarily with the proceeds from the sale of convertible senior notes, convertible preferred stock, common stock, secured and unsecured notes, borrowings under debt facilities, product sales and collaborative licensing and milestone revenue. As of December 31, 2018, we had an accumulated deficit of $388.2 million, cash and cash equivalents, short-term investments and long-term investments of $409.3 million and working capital of $417.3 million.

Summary of Cash Flows

The following table summarizes our cash flows from operating, investing and financing activities for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	Year Ended December 31,		
Consolidated Statement of Cash Flows Data:	2018	2017	2016
Net cash provided by (used in):			
Operating activities	$48,870	$17,785	$33,453
Investing activities	20,576	(223,765)	(61,754)

Financing activities	8,954	224,162	7,261
Net increase (decrease) in cash and cash equivalents	$78,400	$18,182	$(21,040)

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Operating Activities

In 2018, net cash provided by operating activities was $48.9 million compared to $17.8 million in 2017. The increase of $31.1 million was primarily attributable to a 17% increase in net product sales of EXPAREL and the receipt of a $3.0 million upfront payment earned under our license agreement with Nuance, partially offset by the associated increased commissions related to our co-promotion agreement with DePuy Synthes, increased spending for our expanded public affairs campaign focused on driving policy change to improve patient access to non-opioid treatment options and increased legal expenditures.

In 2017, our net cash provided by operating activities was $17.8 million compared to $33.5 million in 2016. The decrease of $15.7 million was largely driven by increased expenditures for clinical trials including our two Phase 3 EXPAREL nerve block trials and our Phase 4 EXPAREL infiltration trials and payments to terminate a distribution agreement with CrossLink.

Investing Activities

In 2018, net cash provided by investing activities was $20.6 million, which reflected $41.9 million of short-term and long-term investment maturities net of purchases. These proceeds were partially offset by purchases of fixed assets of $14.5 million and contingent consideration payments on collections of net sales of DepoBupivacaine products, including EXPAREL, of $6.8 million related to the March 2007 acquisition of the California operating subsidiary of Skyepharma Holding, Inc. (now a subsidiary of Vectura Group plc), or Skyepharma. Major fixed asset purchases included continuing expenditures for expanding our EXPAREL manufacturing capacity in Swindon, England in partnership with Thermo Fisher and facility upgrades at our Science Center Campus in San Diego, California.

In 2017, net cash used in investing activities was $223.8 million. This included purchases of fixed assets of $19.3 million, including continued expenditures for expanding our EXPAREL manufacturing capacity in Swindon, England in partnership with Thermo Fisher and facility upgrades at our Science Center Campus in San Diego. We also purchased $181.0 million of short-term and long-term investments (net of maturities) primarily funded from the net proceeds of the 2022 Notes, made $8.5 million of contingent consideration payments to Skyepharma on collections of net sales of DepoBupivacaine products, including EXPAREL and made an equity investment in TELA Bio, Inc. of $15.0 million.

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

Financing Activities

In 2018, net cash provided by financing activities was $9.0 million, which consisted of proceeds from the exercise of stock options of $7.2 million and $1.8 million from the issuance of shares under our ESPP.

In 2017, net cash provided by financing activities was $224.2 million, which consisted of proceeds from the issuance of the 2022 Notes of $345.0 million, partially offset by $11.0 million of debt issuance and financing costs. In addition, a portion of the net proceeds from the 2022 Notes was used to retire $118.2 million in principal of the 2019 Notes and for $0.3 million in related costs. Proceeds from the exercise of stock options were $6.8 million and proceeds from the issuance of shares under our ESPP were $1.9 million.

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

Equity Financings

From our inception through December 31, 2018, we have raised $344.5 million of net proceeds from the sale of common stock and other equity securities via public offerings.

Debt

2022 Convertible Senior Notes

On March 13, 2017, we completed a private placement of $345.0 million in aggregate principal amount of our 2022 Notes, and entered into an indenture, or 2022 Indenture, with respect to the 2022 Notes. The 2022 Notes accrue interest at a fixed rate of 2.375% per annum, payable semiannually in arrears on April 1 and October 1 of each year. The 2022 Notes mature on April 1, 2022. At December 31, 2018, the outstanding principal on the 2022 Notes was $345.0 million.

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On or after October 1, 2021, until the close of business on the second scheduled trading day immediately preceding April 1, 2022, holders may convert their 2022 Notes at any time. Upon conversion, holders will receive the principal amount of their 2022 Notes and any excess conversion value. For both the principal and excess conversion value, holders may receive cash, shares of our common stock or a combination of cash and shares of our common stock, at our option. The initial conversion rate for the 2022 Notes is 14.9491 shares of common stock per $1,000 principal amount, which is equivalent to an initial conversion price of approximately $66.89 per share of our common stock. The conversion rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest.

Prior to the close of business on the business day immediately preceding October 1, 2021, holders may convert the 2022 Notes under certain circumstances—including, but not limited to—if during any given calendar quarter, our stock price closes at or above 130% of the conversion price then applicable during a period of at least 20 out of the last 30 consecutive trading days of the previous quarter.

While the 2022 Notes are currently classified on our consolidated balance sheet at December 31, 2018 as long-term debt, the future convertibility and resulting balance sheet classification of this liability will be monitored at each quarterly reporting date and will be analyzed dependent upon market prices of our common stock during the prescribed measurement periods. In the event that the holders of the 2022 Notes have the right to convert the 2022 Notes at any time during the prescribed measurement period, the 2022 Notes would then be considered a current obligation and classified as such.

Prior to April 1, 2020, we may not redeem the 2022 Notes. On or after April 1, 2020, we may redeem for cash, shares of our common stock or a combination of cash and shares of our common stock, at our option, all or part of the 2022 Notes if the last reported sale price (as defined in the 2022 Indenture) of our common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading-day period ending within five trading days prior to the date on which we provide notice of redemption.

See Note 9, Debt, to our consolidated financial statements included herein for further discussion of the 2022 Notes.

Future Capital Requirements

We believe that our existing cash and cash equivalents, short-term investments, long-term investments and cash received from product sales will be sufficient to enable us to fund our operating expenses, capital expenditure requirements, payment of the principal on any conversions of the 2022 Notes and to service our indebtedness through at least February 28, 2020. Our future use of operating cash and capital requirements will depend on many forward-looking factors, including, but not limited to, the following:

- our ability to successfully continue to expand the commercialization of EXPAREL, including outside of the U.S.;
- the cost and timing of expanding our manufacturing facilities for EXPAREL and other product candidates, including costs associated with certain technical transfer activities and the construction of an additional manufacturing suite at Thermo Fisher's facility;
- the timing of and extent to which the holders of our 2022 Notes elect to convert their notes;
- the cost and timing of potential milestone payments to Skyepharma, which could be up to an aggregate of $36.0 million if certain milestones pertaining to net sales of DepoBupivacaine products, including EXPAREL, are met, or upon the first commercial sale in a major E.U. country;
- costs related to legal and regulatory issues;
- the costs of performing additional clinical trials for EXPAREL, including the pediatric trials required by the FDA as a condition of approval;
- the costs for the development and commercialization of other product candidates; and
- the extent to which we acquire or invest in products, businesses and technologies.

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

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Contractual Obligations

The table below presents a summary of our contractual obligations as of December 31, 2018 (in thousands):

	Payments Due by Period				
Contractual Obligations (1)	Total	Less Than One Year	1-3 Years	3-5 Years	More Than 5 Years
Convertible senior notes - principal (2)	$345,338	$338	$—	$345,000	$—
Convertible senior notes - interest	28,684	8,199	16,388	4,097	—
Lease obligations (3)	46,345	8,140	12,916	10,960	14,329
Purchase obligations (4)	24,470	7,981	16,489	—	—
Total	$444,837	$24,658	$45,793	$360,057	$14,329

(1) This table does not include potential future milestone payments to Skyepharma which could be up to an aggregate of $36.0 million if certain milestones pertaining to net sales of DepoBupivacaine products, including EXPAREL are met, including $32.0 million when annual net sales of DepoBupivacaine products, including EXPAREL collected reach $500.0 million (measured on a rolling quarterly basis) and $4.0 million upon the first commercial sale in a major E.U. country. This contingency is described further in Note 7, Goodwill, to our consolidated financial statements included herein. In addition, this table does not include various agreements that we have entered into for services with third-party vendors, including agreements to conduct clinical trials, and for consulting and other contracted services due to the cancelable nature of the services.

(2) The amounts represent the February 2019 maturity of our 2019 Notes and April 2022 maturity of our 2022 Notes. See Note 9, Debt, to our consolidated financial statements included herein for further discussion. Additionally, it excludes any conversion premium on the 2019 Notes and/or 2022 Notes, which may be settled in cash or stock at our discretion. The remaining principal, interest and $0.2 million conversion premium on the 2019 Notes were paid in cash on the maturity date of February 1, 2019. The 2022 Notes were not convertible as of December 31, 2018.

(3) The amounts consist of operating leases for our corporate headquarters in Parsippany, New Jersey and manufacturing, research and development and warehouse space in San Diego, California. In addition, the lease component for the use of the Thermo Fisher facility in Swindon, England under the Thermo Fisher Agreements has also been included. As of and through the year ended December 31, 2018, operating lease costs have been recorded in our consolidated financial statements as incurred. Effective January 1, 2019, we will begin recognizing right-of-use assets and lease liabilities for our existing operating lease commitments on our consolidated balance sheet.

(4) The amounts consist of minimum, non-cancelable contractual commitments for contract manufacturing services.

In April 2014, we and Thermo Fisher entered into a Strategic Co-Production Agreement, a Technical Transfer and Service Agreement and a Manufacturing and Supply Agreement to collaborate in the manufacture of EXPAREL. Under the terms of the Technical Transfer and Service Agreement, Thermo Fisher has agreed to undertake certain technical transfer activities and construction services needed to prepare its Swindon, England facility for the manufacture of EXPAREL in two dedicated manufacturing suites. Under these agreements, we are required to make monthly base fee payments to Thermo Fisher. Under the terms of the Manufacturing and Supply Agreement, following FDA approval of the suites (which occurred in May 2018), we agreed to purchase EXPAREL product from Thermo Fisher. Unless earlier terminated by giving notice of up to three years (other than termination by us in the event of a material breach by Thermo Fisher), this agreement will expire in May 2028.

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 U.S. The preparation of these financial statements require us to make estimates that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our

estimates and judgments, including those related to revenue recognition, inventory costs, liabilities and accruals, clinical trial expenses, stock-based compensation and the valuation of deferred tax assets. We base our estimates on historical experience, contract terms and on other factors we believe to be appropriate under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

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

Revenue Recognition

Our sources of revenue include (i) sales of EXPAREL in the U.S.; (ii) sales of our bupivacaine liposome injectable suspension product for use in animals in the U.S.; (iii) royalties based on sales of our bupivacaine liposome injectable suspension product for use in animals and (iv) license fees and milestone payments. The majority of our revenue is derived from sales of EXPAREL. We do not consider revenue from other product sales, collaborative licensing, milestones and royalties to be material sources of our consolidated revenue.

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Net Product Sales

We sell EXPAREL through a drop-ship program under which orders are processed through wholesalers based on orders of the product placed by end-users which include hospitals, ambulatory surgery centers and doctors. EXPAREL is delivered directly to the end-user without the wholesaler ever taking physical possession of the product. Product revenue is recognized when control of the promised goods are transferred to the customers, in an amount that reflects the consideration we expect to be entitled to in exchange for transferring those goods. EXPAREL revenue is recorded at the time the product is delivered to the end-user.

Collaborative Licensing and Milestone Revenue

Our collaboration agreements generally involve licenses to our products. In determining how and when to recognize the revenue under a collaboration agreement, we must assess whether the license is distinct, which depends upon whether the customer can benefit from the license and whether the license is separate from other performance obligations in the agreement. If the license is distinct, we must further assess whether the customer has a right to access or a right to use the license depending on whether the functionality of the license is expected to substantively change over time. If the license is not expected to substantively change, the revenue is recognized at the point in time when the license is provided. If the license is expected to substantively change, the revenue is recognized over the license period.

Revenue recognition from milestone payments is dependent upon the facts and circumstances surrounding the milestone payments. Milestone payments based on a non-sales metric such as a development-based milestone (e.g. obtaining regulatory approval) represent variable consideration and are included in the transaction price subject to any constraints. If the milestone payments relate to future development, the timing of recognition depends upon historical experience and the significance a third party has on the outcome. For milestone payments to be received upon the achievement of a sales threshold, the revenue from the milestone payments is recognized at the later of when the actual sales are incurred or the performance obligation to which the sales relate to has been satisfied.

Equity Investments

We historically accounted for our equity investment in a minority interest of a company over which we do not exercise significant influence using the cost method. The equity investment does not have a readily determinable fair value. Effective January 1, 2018, we elected to measure this equity investment at its fair value at acquisition, minus any impairment and adjusted for changes in observable prices when available.

The investment is reviewed on a regular basis for possible impairment. Factors considered in the review include whether a significant deterioration in earnings, credit rating, asset quality or business prospects has occurred, in addition to whether there has been a significant adverse change in regulations, economic market, technology, issuances of the same or similar investment to a third party or factors that raise significant concerns about the investee’s ability to continue as a going concern.

Recent Accounting Pronouncements

See Note 3, Recent Accounting Pronouncements, to our Consolidated Financial Statements for further discussion of recent accounting pronouncements.

Off-Balance Sheet Arrangements

We do not have any material off-balance sheet arrangements as of December 31, 2018, except for operating leases, nor do we have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities.

Effective January 1, 2019, lease assets and liabilities will be recognized on the consolidated balance sheet. See Note 3, Recent Accounting Pronouncements, to our Consolidated Financial Statements for further discussion.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

The primary objective of our cash equivalents and investment activities is to preserve principal while at the same time maximizing the income that we receive from our investments without significantly increasing risk. We invest in corporate bonds, commercial paper and asset-backed securities, which are reported at fair value. These securities are subject to interest rate risk. This means that a change in prevailing interest rates may cause the principal amount of the

investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the interest rate later rises, we expect that the fair value of our investment will decline. A hypothetical 100 basis point increase in interest rates would have reduced the fair value of our available-for-sale securities at December 31, 2018 by $1.2 million.

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In March 2017, we issued $345.0 million in aggregate principal amount of 2.375% convertible senior notes, which mature in April 2022. Holders may convert their 2022 Notes prior to maturity under certain circumstances. Upon conversion, holders will receive the principal amount of the 2022 Notes and any excess conversion value in cash, shares of our common stock or a combination of cash and shares, at our option. The fair value of the 2022 Notes is impacted by both the fair value of our common stock and interest rate fluctuations. As of December 31, 2018, the estimated fair value of the 2022 Notes was $998 per $1,000 principal amount. See Note 9, Debt, to our Consolidated Financial Statements for additional information on the 2022 Notes. At December 31, 2018, all $345.0 million of principal remains outstanding on the 2022 Notes.

We have agreements with certain vendors and partners that operate in foreign jurisdictions. The transactions under these agreements are primarily denominated in the U.S. dollar, subject to periodic adjustment based on changes in currency exchange rates.

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

Item 8. Financial Statements and Supplementary Data

Our consolidated financial statements required by this item, together with the reports of our independent registered public accounting firm, appear on pages F-1 through F-34 of this Annual Report on Form 10-K.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Based on their evaluation as of December 31, 2018, our Chief Executive Officer and Chairman and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2018.

Management’s Report on Internal Control over Financial Reporting

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chairman and Chief Financial Officer, management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2018, based on the criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based upon the results of the evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2018.

The effectiveness of our internal control over financial reporting as of December 31, 2018 was audited by KPMG LLP, our independent registered public accounting firm, as stated in their report appearing below, which expressed an unqualified opinion on the effectiveness of our internal control over financial reporting as of December 31, 2018.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2018, that materially affected, or are reasonably likely to materially affect, our internal control over

financial reporting.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
To the Stockholders and Board of Directors
Pacira Pharmaceuticals, Inc.:

Opinion on Internal Control Over Financial Reporting

We have audited Pacira Pharmaceuticals, Inc.'s and subsidiaries' (the Company) internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2018, and the related notes (collectively, the consolidated financial statements), and our report dated February 28, 2019 expressed an unqualified opinion on those consolidated financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

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

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

/s/ KPMG LLP

Short Hills, NJ
February 28, 2019

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Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information required by this item will be included in the proxy statement for our 2019 annual stockholders' meeting and is incorporated by reference into this report.

Item 11. Executive Compensation

Information required by this item will be included in the proxy statement for our 2019 annual stockholders' meeting and is incorporated by reference into this report.

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

Information required by this item will be included in the proxy statement for our 2019 annual stockholders' meeting and is incorporated by reference into this report.

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

Information required by this item will be included in the proxy statement for our 2019 annual stockholders' meeting and is incorporated by reference into this report.

Item 14. Principal Accounting Fees and Services

Information required by this item will be included in the proxy statement for our 2019 annual stockholders' meeting and is incorporated by reference into this report.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) Documents filed as part of this Annual Report on Form 10-K:

(1) Financial Statements

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

(2) Schedules

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

(3) Exhibits

The following exhibits are filed with, or incorporated by reference in this Form 10-K.

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EXHIBIT INDEX

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant.(1)
3.2	Amended and Restated Bylaws of the Registrant.(1)
4.1	Specimen Certificate evidencing shares of common stock.(2)
4.2	Indenture (including form of 2019 Notes), dated January 23, 2013, between the Registrant and Wells Fargo Bank, National Association, as trustee.(3)
4.3	Indenture (including form of 2022 Notes), dated March 13, 2017, between the Registrant and Wells Fargo Bank, National Association, as trustee.(19)
10.1	Second Amended and Restated 2007 Stock Option/Stock Issuance Plan.(2)***
10.2	Form of Stock Option Agreement under the Second Amended and Restated 2007 Stock Option/Stock Issuance Plan.(2)***
10.3	Assignment Agreement, dated February 9, 1994, amended April 15, 2004, between the Registrant and Research Development Foundation.(2)
10.4	Stock Purchase Agreement, dated January 8, 2007, between SkyePharma, Inc. and the Registrant.(2)
10.5	Industrial Real Estate Triple Net Lease, dated August 17, 1993, between the Registrant and HCP TPSP, LLC.(2)
10.6	Fifth Amendment, dated March 13, 2013, to the Industrial Real Estate Triple Net Lease, dated August 17, 1993, between the Registrant and HCP TPSP, LLC (and successor-in-interest to Equitable Life Assurance Society of the United States).(4)
10.7	Industrial Real Estate Lease, dated December 8, 1994, amended July 2, 2009, between the Registrant and LASDK Limited Partnership.(2)
10.8	Third Amendment, dated March 13, 2013, to the Industrial Real Estate Lease between the Registrant and LASDK Limited Partnership.(4)
10.9	Fourth Amendment, dated December 28, 2017, to the Industrial Real Estate Lease between the Registrant and LASDK Limited Partnership.(20)*
10.10	Employment Agreement between the Registrant and David Stack.(2)***
10.11	Amendment No. 1 to Executive Employment Agreement, dated March 13, 2013, between the Registrant and David Stack.(4)***
10.12	Amendment No. 2 to Executive Employment Agreement, dated June 30, 2015, between the Registrant and David Stack.(14)***
10.13	Employment Agreement, dated November 29, 2012, between the Registrant and Kristen Williams.(13)***
10.14	Amendment No. 1 to Employment Agreement, dated March 13, 2013, between the Registrant and Kristen Williams.(13)***
10.15	Amendment No. 2 to Employment Agreement, dated June 30, 2015, between the Registrant and Kristen Williams.(14)***
10.16	Executive Employment Agreement, dated May 2, 2016, between the Registrant and Charles A. Reinhart, III.(16)***
10.17	Executive Employment Agreement, dated March 13, 2013, between the Registrant and Richard Scranton, M.D.***(22)
10.18	Amendment No. 1 to Executive Employment Agreement, dated June 30, 2015, between the Registrant and Richard Scranton, M.D.***(22)
10.19	Form of Indemnification Agreement between the Registrant and its directors and officers.(2)***
10.20†	Commercial Outsourcing Services Agreement entered into as of August 25, 2011 by the Registrant and Integrated Commercialization Solutions, Inc.(5)
10.21†	First Amendment to Commercial Outsourcing Services Agreement, dated August 1, 2013, between the Registrant and Integrated Commercialization Solutions, Inc.(7)
10.22†	

	Second Amendment to Commercial Outsourcing Services Agreement, dated August 25, 2014, between the Registrant and Integrated Commercialization Solutions, Inc.(12)
10.23†	Third Amendment to Commercial Outsourcing Services Agreement, dated April 29, 2015, between the Registrant and Integrated Commercialization Solutions, Inc.(14)
10.24	Amended and Restated 2011 Stock Incentive Plan.(8)***
10.25	Form of Nonstatutory Stock Option Agreement under the Amended and Restated 2011 Stock Incentive Plan.(8)***

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10.26	Form of Restricted Stock Unit Award Agreement (Employees) under the Amended and Restated 2011 Stock Incentive Plan.(14)***
10.27	Form of Restricted Stock Unit Award Agreement (Non-Employee Directors) under the Amended and Restated 2011 Stock Incentive Plan.(14)***
10.28	License, Development and Commercialization Agreement, dated December 5, 2012 between the Registrant and Aratana Therapeutics, Inc.(9)
10.29	Supply Agreement, dated December 5, 2012 between the Registrant and Aratana Therapeutics, Inc.(9)
10.30	2014 Inducement Plan.(10)***
10.31	2014 Employee Stock Purchase Plan.(8)***
10.32†	Strategic Co-Production Agreement dated April 4, 2014, by and between the Registrant and Patheon UK Limited.(11)
10.33†	Manufacturing and Supply Agreement dated April 4, 2014, by and between the Registrant and Patheon UK Limited.(11)
10.34†	Technical Transfer and Service Agreement dated April 4, 2014, by and between the Registrant and Patheon UK Limited.(11)
10.35	Amended and Restated Consulting Agreement, dated April 3, 2012, between the Registrant and Gary Pace.(6)***
10.36	Second Amended and Restated Consulting Agreement, dated August 17, 2012, between the Registrant and Gary Pace.(15)***
10.37	Third Amendment to Consulting Agreement, dated September 11, 2013, between the Registrant and Gary Pace.(7)***
10.38	Fourth Amendment to Consulting Agreement, dated November 25, 2015, between the Registrant and Gary Pace.(17)***
10.39†	Co-Promotion Agreement, dated January 24, 2017, between the Registrant and DePuy Synthes Sales, Inc.(19)
10.40	First Amendment to Co-Promotion Agreement, dated April 19, 2018, between the Registrant and DePuy Synthes Sales, Inc.(21)
10.41†	Second Amendment to Co-Promotion Agreement, dated December 21, 2018, between the Registrant and DePuy Synthes Sales, Inc.*
21.1	Subsidiaries of the Registrant.*
23.1	Consent of KPMG LLP.*
31.1	Certification of Chief Executive Officer and Chairman pursuant to Exchange Act Rule 13a-14(a).*
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a).*
32.1	Certification of Chief Executive Officer and Chairman pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.**

101.INS	XBRL Instance Document.*
101.SCH	XBRL Taxonomy Schema Document.*
101.CAL	XBRL Taxonomy Calculation Linkbase Document.*
101.LAB	XBRL Taxonomy Label Linkbase Document.*
101.PRE	XBRL Taxonomy Presentation Linkbase Document.*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.*

(1) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed on February 11, 2011.

(2) Incorporated by reference to the exhibits to the Registrant's Registration Statement on Form S-1 (SEC File 333-170245).

(3) Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on January 23, 2013.

(4) Incorporated by reference to the exhibits to the Registrant's Current Report on Form 8-K, filed on March 18, 2013.
(5) Incorporated by reference to the exhibits to the Registrant's Quarterly Report on Form 10-Q, filed on October 31, 2011.
(6) Incorporated by reference to the exhibits to the Registrant's Quarterly Report on Form 10-Q, filed on May 9, 2012.
(7) Incorporated by reference to the exhibits to the Registrant's Quarterly Report on Form 10-Q, filed on October 31, 2013.
(8) Incorporated by reference to the exhibits to the Registrant's Current Report on Form 8-K, filed on June 4, 2014.
(9) Incorporated by reference to the exhibits to the Registrant's Annual Report on Form 10-K, filed on March 7, 2013.

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(10) Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed on May 1, 2014.

(11) Incorporated by reference to the exhibits to the Registrant's Quarterly Report on Form 10-Q, filed on July 31, 2014.

(12) Incorporated by reference to the exhibits to the Registrant's Quarterly Report on Form 10-Q, filed on October 30, 2014.

(13) Incorporated by reference to the exhibits to the Registrant's Quarterly Report on Form 10-Q, filed on April 30, 2015.

(14) Incorporated by reference to the exhibits to the Registrant's Quarterly Report on Form 10-Q, filed on July 30, 2015.

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

(16) Incorporated by reference to the exhibits to the Registrant's Quarterly Report on Form 10-Q, filed on August 4, 2016.

(17) Incorporated by reference to Exhibit 10.57 to the Registrant's Annual Report on Form 10-K, filed on February 25, 2016.

(18) Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on March 13, 2017.

(19) Incorporated by reference to the exhibits to the Registrant's Quarterly Report on Form 10-Q, filed on May 4, 2017.

(20) Incorporated by reference to Exhibit 10.14 to the Registrant's Annual Report on Form 10-K, filed on February 28, 2018.

(21) Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed on May 3, 2018.

(22) Incorporated by reference to the exhibits to the Registrant's Quarterly Report on Form 10-Q, filed on August 2, 2018.

* Filed herewith.

** Furnished herewith.

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

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

Item 16. Form 10-K Summary

None.

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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: February 28, 2019 By: /s/ DAVID STACK
David Stack
Chief Executive Officer and Chairman

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

Signature	Title	Date
/s/ DAVID STACK David Stack	Director, Chief Executive Officer and Chairman (Principal Executive Officer)	February 28, 2019
/s/ CHARLES A. REINHART, III Charles A. Reinhart, III	Chief Financial Officer (Principal Financial Officer)	February 28, 2019
/s/ LAUREN RIKER Lauren Riker	Vice President, Finance (Principal Accounting Officer)	February 28, 2019
/s/ LAURA BREGE Laura Brege	Director	February 28, 2019
/s/ MARK FROIMSON Mark Froimson	Director	February 28, 2019
/s/ YVONNE GREENSTREET Yvonne Greenstreet	Director	February 28, 2019
/s/ MARK KRONENFELD Mark Kronenfeld	Director	February 28, 2019
/s/ JOHN LONGENECKER John Longenecker	Director	February 28, 2019
/s/ GARY PACE Gary Pace	Director	February 28, 2019
/s/ ANDREAS WICKI Andreas Wicki	Director	February 28, 2019
/s/ PAUL HASTINGS Paul Hastings	Lead Director	February 28, 2019

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PACIRA PHARMACEUTICALS, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2018
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors
Pacira Pharmaceuticals, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Pacira Pharmaceuticals, Inc. and subsidiaries (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2018, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated February 28, 2019 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2015.

Short Hills, NJ
February 28, 2019

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PACIRA PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	December 31,	
	2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	$132,526	$54,126
Short-term investments	250,928	257,221
Accounts receivable, net	38,000	31,658
Inventories, net	48,569	41,411
Prepaid expenses and other current assets	7,946	6,694
Total current assets	477,969	391,110
Long-term investments	25,871	60,047
Fixed assets, net	108,670	107,046
Goodwill	62,040	55,197
Equity investment	14,146	14,146
Other assets	657	825
Total assets	$689,353	$628,371
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$14,368	$14,658
Accrued expenses	45,865	41,057
Convertible senior notes	338	324
Current portion of deferred revenue	—	102
Income taxes payable	90	76
Total current liabilities	60,661	56,217
Convertible senior notes	290,592	276,173
Other liabilities	16,874	16,498
Total liabilities	368,127	348,888
Commitments and contingencies (Note 18)		
Stockholders' equity:		
Preferred stock, par value $0.001; 5,000,000 shares authorized; none issued and outstanding at December 31, 2018 and 2017	—	—
Common stock, par value $0.001; 250,000,000 shares authorized; 41,222,799 shares issued and outstanding at December 31, 2018; 40,668,877 shares issued and outstanding at December 31, 2017	41	41
Additional paid-in capital	709,691	669,032
Accumulated deficit	(388,226)	(389,136)
Accumulated other comprehensive loss	(280)	(454)
Total stockholders' equity	321,226	279,483
Total liabilities and stockholders' equity	$689,353	$628,371

See accompanying notes to consolidated financial statements.

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PACIRA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)

	Year Ended December 31,		
	2018	2017	2016
Revenues:			
Net product sales	$332,427	$284,342	$270,073
Collaborative licensing and milestone revenue	3,000	387	3,426
Royalty revenue	1,850	1,901	2,872
Total revenues	337,277	286,630	276,371
Operating expenses:			
Cost of goods sold	86,845	87,915	110,104
Research and development	55,688	57,290	45,678
Selling, general and administrative	177,265	161,494	152,613
Product discontinuation	1,564	4,868	—
Total operating expenses	321,362	311,567	308,395
Income (loss) from operations	15,915	(24,937)	(32,024)
Other (expense) income:			
Interest income	6,497	4,078	1,323
Interest expense	(21,949)	(18,047)	(7,061)
Loss on early extinguishment of debt	—	(3,732)	—
Other, net	(888)	167	(82)
Total other expense, net	(16,340)	(17,534)	(5,820)
Loss before income taxes	(425)	(42,471)	(37,844)
Income tax expense	(46)	(140)	(105)
Net loss	$(471)	$(42,611)	$(37,949)
Net loss per share:			
Basic and diluted net loss per common share	$(0.01)	$(1.07)	$(1.02)
Weighted average common shares outstanding:			
Basic and diluted	40,911	39,806	37,236

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,		
	2018	2017	2016
Net loss	$(471)	$(42,611)	$(37,949)
Other comprehensive income (loss):			
Net unrealized gain (loss) on investments	174	(424)	22
Total other comprehensive income (loss)	174	(424)	22
Comprehensive loss	$(297)	$(43,035)	$(37,927)

See accompanying notes to consolidated financial statements.

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PACIRA PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2018, 2017 AND 2016
(In thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
	Shares	Amount				
Balance at December 31, 2015	36,848	$ 37	$526,696	$ (308,289)	$ (52)	$218,392
Exercise of stock options	518	—	5,770	—	—	5,770
Vested restricted stock units	62	—	—	—	—	—
Shares issued under employee stock purchase plan	53	—	1,495	—	—	1,495
Stock-based compensation	—	—	31,248	—	—	31,248
Retirement of equity component of 2019 convertible senior notes	—	—	(2)	—	—	(2)
Net unrealized gain on investments	—	—	—	—	22	22
Net loss	—	—	—	(37,949)	—	(37,949)
Balance at December 31, 2016	37,481	37	565,207	(346,238)	(30)	218,976
Cumulative effect adjustment of the adoption of Accounting Standards Update 2016-09 (Note 3)	—	—	287	(287)	—	—
Exercise of stock options	540	1	6,777	—	—	6,778
Vested restricted stock units	101	—	—	—	—	—
Shares issued under employee stock purchase plan	57	—	1,862	—	—	1,862
Stock-based compensation	—	—	31,601	—	—	31,601
Issuance of common stock upon conversion of 2019 convertible senior notes	2,490	3	120,957	—	—	120,960
Retirement of equity component of 2019 convertible senior notes	—	—	(126,328)	—	—	(126,328)
Equity component of 2022 convertible senior notes issued, net	—	—	68,669	—	—	68,669
Net unrealized loss on investments	—	—	—	—	(424)	(424)
Net loss	—	—	—	(42,611)	—	(42,611)
Balance at December 31, 2017	40,669	41	669,032	(389,136)	(454)	279,483
Cumulative effect adjustment of the adoption of Accounting Standards Update 2014-09 (Note 3)	—	—	—	1,361	—	1,361
Cumulative effect adjustment of the adoption of Accounting Standards Update 2018-07 (Note 3)	—	—	(20)	20	—	—
Exercise of stock options	333	—	7,170	—	—	7,170
Vested restricted stock units	156	—	—	—	—	—
Shares issued under employee stock purchase plan	65	—	1,784	—	—	1,784
Stock-based compensation	—	—	31,725	—	—	31,725
Net unrealized gain on investments	—	—	—	—	174	174
Net loss	—	—	—	(471)	—	(471)

Balance at December 31, 2018	41,223	$ 41	$709,691	$ (388,226)	$ (280)	$321,226

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,		
	2018	2017	2016
Operating activities:			
Net loss	$(471)	$(42,611)	$(37,949)
Adjustments to reconcile net loss to net cash provided by operating activities:			
Depreciation of fixed assets and amortization of intangibles	13,165	13,833	12,919
Amortization of unfavorable lease obligation and debt issuance costs	1,590	1,248	479
Amortization of debt discount	12,799	10,423	4,088
Loss on disposal of fixed assets	65	2,133	389
Loss on early extinguishment of debt	—	3,732	—
Stock-based compensation	31,725	31,601	31,248
Loss on unexercised investment purchase option	854	—	—
Changes in operating assets and liabilities:			
Accounts receivable, net	(5,999)	(1,721)	(4,082)
Inventories, net	(7,157)	(10,133)	30,367
Prepaid expenses and other assets	(3,228)	3,476	(3,377)
Accounts payable	(573)	5,712	(350)
Accrued expenses and income taxes payable	5,203	3,647	1,060
Other liabilities	897	(3,555)	(1,339)
Net cash provided by operating activities	48,870	17,785	33,453
Investing activities:			
Purchases of fixed assets	(14,514)	(19,266)	(24,709)
Purchases of investments	(363,255)	(502,752)	(192,815)
Sales of investments	405,188	321,713	171,627
Payment of contingent consideration	(6,843)	(8,460)	(15,857)
Equity investment	—	(15,000)	—
Net cash provided by (used in) investing activities	20,576	(223,765)	(61,754)
Financing activities:			
Proceeds from exercises of stock options	7,170	6,778	5,770
Proceeds from shares issued under employee stock purchase plan	1,784	1,862	1,495
Proceeds from issuance of 2022 convertible senior notes	—	345,000	—
Repayment of 2019 convertible senior notes	—	(118,193)	(4)
Payment of debt issuance and financing costs	—	(11,000)	—
Costs for conversions of convertible senior notes	—	(285)	—
Net cash provided by financing activities	8,954	224,162	7,261
Net increase (decrease) in cash and cash equivalents	78,400	18,182	(21,040)
Cash and cash equivalents, beginning of year	54,126	35,944	56,984
Cash and cash equivalents, end of year	$132,526	$54,126	$35,944
Supplemental cash flow information:			
Cash paid for interest	$8,205	$6,896	$3,852
Cash paid for income taxes, net of refunds	$128	$129	$247
Non-cash investing and financing activities:			
Issuance of common stock from conversion of 2019 convertible senior notes	$—	$120,960	$—
Retirement of equity component of 2019 convertible senior notes	$—	$(126,328)	$—
Net increase (decrease) in accrued fixed assets	$(98)	$2,189	$(789)

See accompanying notes to consolidated financial statements.

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PACIRA PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
NOTE 1—DESCRIPTION OF BUSINESS

Pacira Pharmaceuticals, Inc. and its subsidiaries (collectively, the "Company" or "Pacira") is a specialty pharmaceutical company focused on the development, manufacture and commercialization of pharmaceutical products, based on its proprietary DepoFoam® extended release drug delivery technology, for use primarily in hospitals and ambulatory surgery centers. Pacira is committed to becoming a global leader in delivering innovative non-opioid pain management solutions to surgeons and anesthesiologists. The Company's mission is to provide an opioid alternative to as many appropriate patients as possible.

The Company's flagship product, EXPAREL® (bupivacaine liposome injectable suspension), which consists of bupivacaine encapsulated in DepoFoam, was approved by the United States Food and Drug Administration, or FDA, on October 28, 2011 and launched commercially in April 2012. The Company also sells its bupivacaine liposome injectable suspension product to a commercial partner for use in animals.

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

NOTE 2—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Principles of Consolidation

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

Use of Estimates

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

Revenue From Contracts With Customers

The Company's sources of revenue include (i) sales of EXPAREL in the United States, or U.S.; (ii) sales of its bupivacaine liposome injectable suspension product for use in animals in the U.S.; (iii) royalties based on sales of its bupivacaine liposome injectable suspension product for use in animals and (iv) license fees and milestone payments. See Note 4, Revenue, for further information on the Company's accounting policies related to revenue from contracts with customers.

Collaborative Licensing and Milestone Revenue

The Company's collaboration agreements generally involve a license to the Company's products. In determining how and when to recognize the revenue under a collaboration agreement, the Company must assess whether the license is distinct, which depends upon whether the customer can benefit from the license and whether the license is separate from other performance obligations in the agreement. If the license is distinct, the Company must further assess whether the customer has a right to access or a right to use the license depending on whether the functionality of the

license is expected to substantively change over time. If the license is not expected to substantively change, the revenue is recognized at the point in time when the license is provided. If the license is expected to substantively change, the revenue is recognized over the license period.

Revenue recognition from milestone payments is dependent upon the facts and circumstances surrounding the milestone payments. Milestone payments based on a non-sales metric such as a development-based milestone (e.g. obtaining regulatory

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

approval) represent variable consideration and are included in the transaction price subject to any constraints. If the milestone payments relate to future development, the timing of recognition depends upon historical experience and the significance a third party has on the outcome. For milestone payments to be received upon the achievement of a sales threshold, the revenue from the milestone payments is recognized at the later of when the actual sales are incurred or the performance obligation to which the sales relate to has been satisfied.

Royalty Revenue

Royalties are estimated and recognized as revenue when sales to the Company's commercial partners occur, unless some constraint exists, as the royalties predominately relate to a supply agreement. Royalties are based on sales of the Company's bupivacaine liposome injectable suspension product to serve animal indications.

Concentration of Major Customers

The Company sells EXPAREL through a drop-ship program under which orders are processed through wholesalers (including AmerisourceBergen Health Corporation, Cardinal Health, Inc. and McKesson Drug Company), but shipments of the product are sent directly to individual accounts, such as hospitals, ambulatory surgery centers and individual doctors. The Company also sells EXPAREL directly to ambulatory surgical centers and physicians. The table below includes the percentage of net product sales comprised by the Company's three largest wholesalers in each period presented:

	Year Ended December 31,		
	2018	2017	2016
Largest wholesaler	34%	35%	32%
Second largest wholesaler	30%	30%	28%
Third largest wholesaler	26%	26%	26%
Total	90%	91%	86%

Revenue from outside the U.S. accounted for less than 1% of the Company's total revenue for the years ended December 31, 2018 and 2017, and 1% of the Company's total revenue for the year ended December 31, 2016.

Research and Development Expenses

Research and development expenditures are expensed as incurred. These include both internal and external costs, of which a significant portion of development activities are outsourced to third parties, including contract research organizations. Clinical trial costs are accrued over the service periods specified in contracts and adjusted as necessary based on an ongoing review of the level of effort and actual costs incurred. Research and development costs are presented net of reimbursements from commercial partners.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to basis differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. As of December 31, 2018 and 2017, all deferred tax assets were fully offset by a valuation allowance because there is significant doubt regarding the Company's ability to utilize such net deferred tax assets.

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

Stock-Based Compensation

The Company's stock-based compensation includes grants of stock options and restricted stock units, or RSUs, to employees, consultants and non-employee directors in addition to the opportunity for employees to participate in an employee stock purchase plan. The expense associated with these programs is recognized in the Company's

consolidated statements of operations based on their fair values as they are earned under the applicable vesting terms or the length of an offering period.

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

In calculating the estimated fair value of stock options granted, the Company uses the Black-Scholes option valuation model, or Black-Scholes model, which requires the consideration of the following variables for purposes of estimating fair value:

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

The Company utilizes its available historic volatility data to determine expected volatility over the expected option term. The Company uses an expected term based on its historical data from stock option activity. The risk-free interest rate is based on the implied yield on U.S. Department of the Treasury zero-coupon bonds for periods commensurate with the expected term of the options. The dividend yield on the Company's common stock is estimated to be zero as the Company has not paid any dividends since inception, nor does it have any intention to do so in the foreseeable future. The Company records forfeitures as they occur rather than estimating forfeitures during each period.

Cash and Cash Equivalents

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

Short-Term and Long-Term Investments

Short-term investments consist of asset-backed securities collateralized by credit card receivables, investment grade commercial paper and corporate bonds with maturities of greater than three months, but less than one year. Long-term investments consist of asset-backed securities collateralized by credit card receivables and corporate bonds with maturities greater than one year. The Company determines the appropriate classification of its investments at the time of purchase and reevaluates such determination at each balance sheet date. The Company's investment policy sets minimum credit quality criteria and maximum maturity limits on its investments to provide for preservation of capital, liquidity and a reasonable rate of return. Available-for-sale securities are recorded at fair value, based on current market valuations. Unrealized holding gains and losses on available-for-sale securities are excluded from net income (loss) and are reported as a separate component of accumulated other comprehensive income (loss) until realized. Realized gains and losses are included in interest income in the consolidated statements of operations and are derived using the specific identification method for determining the cost of the securities sold.

Inventories

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

Fixed Assets

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

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

Asset Category	Useful Life
Computer equipment and software	1 to 3 years
Office furniture and equipment	5 years
Manufacturing and laboratory equipment	5 to 10 years

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

Asset Retirement Obligations

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

Goodwill

Goodwill represents the excess of purchase price over fair value acquired in a business combination and is not amortized, but is subject to impairment at least annually or when a triggering event occurs that could indicate a potential impairment.

Equity Investments

The Company historically accounted for its equity investment in a minority interest of a company over which it does not exercise significant influence using the cost method. The equity investment held by the Company does not have a readily determinable fair value. Effective January 1, 2018, the Company elected to account for its equity investment at its cost less impairment, if any, plus or minus any changes resulting from observable price changes in orderly transactions for a similar investment in the same investee. The Company performs a qualitative assessment for impairment each reporting period. Such an assessment is judgmental and dependent on specific facts and circumstances. Factors considered in determining whether a decline in value has occurred include, but are not limited to: (i) a significant deterioration in the earnings performance, credit rating, asset quality, or business prospects of the investee; (ii) a significant adverse change in the regulatory, economic or technological environment of the investee; (iii) a sale of the same or similar investment for an amount less than the carrying amount of that investment and (iv) factors that raise significant concerns about the investee’s ability to continue as a going concern. If an impairment exists, the Company will estimate the fair value of the equity investment and an impairment will be recognized in its consolidated statements of operations based on the difference between the fair value and carrying amount.

Impairment of Long-Lived Assets

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

Convertible Debt Transactions

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

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

statements of operations. Any remaining consideration is allocated to the reacquisition of the equity component and is recognized as a reduction of additional paid-in capital.

Per Share Data

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

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

Diluted net income (loss) per common share is calculated by dividing net income (loss) available (attributable) to common stockholders as adjusted for the effect of dilutive securities, if any, by the weighted average number of shares of common stock and dilutive common stock outstanding during the period. Potential common shares include the shares of common stock issuable upon the exercise of outstanding stock options, the vesting of RSUs and the purchase of shares from the Company's employee stock purchase plan (using the treasury stock method), as well as the excess conversion value on the Company's convertible senior notes.

Segment Reporting

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

NOTE 3—RECENT ACCOUNTING PRONOUNCEMENTS

Recently Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2014-09, Revenue from Contracts with Customers, and subsequently issued a number of amendments to this update. The new standard, as amended in Accounting Standards Codification, or ASC, 606, provides a single comprehensive model to be used in accounting for revenue arising from contracts with customers and supersedes previously applicable revenue recognition guidance, ASC 605. The standard's stated core principle is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In addition, the standard requires disclosure of the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers.

The Company adopted this standard on January 1, 2018 using the modified retrospective method and recorded a cumulative effect adjustment of $1.4 million to accumulated deficit upon adoption—the impact related to the acceleration of $1.0 million of deferred revenue and $0.4 million of royalties. Under the modified retrospective method of adoption, the comparative information in the consolidated financial statements has not been revised and continues to be reported under ASC 605. The implementation of ASC 606 did not have a material impact on the Company's consolidated statements of operations because the timing of revenue recognition for EXPAREL product sales did not change. The Company is recognizing existing collaborative licensing, milestone and royalty revenue earlier than it would have under the previous standard, subject to the variable consideration constraints. If ASC 605 had been applied to the year ended December 31, 2018, deferred revenue would have been $0.9 million higher on the consolidated balance sheet, with $0.1 million in current portion of deferred revenue and $0.8 million in other liabilities. Under ASC 605, royalty revenue for the year ended December 31, 2018 would have been lower by $0.4 million and the related royalty receivable as of December 31, 2018 would have been lower by $0.7 million.

For additional information regarding the Company's revenue, see Note 4, Revenue.

In January 2016, the FASB issued ASU 2016-01, Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities. ASU 2016-01 changes accounting for equity investments and presentation and disclosure requirements for financial instruments. ASU 2016-01 does not apply to equity investments in consolidated subsidiaries or those accounted for under the equity method of accounting. Equity investments with readily determinable fair values will be measured at fair value with changes in fair value recognized in net income (loss). Entities have the option to measure equity investments without readily determinable fair values either at fair value or at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. The standard requires a qualitative assessment to identify impairment. When a qualitative assessment indicates that impairment exists, an entity is required to measure the investment at fair value. ASU 2016-01 became effective for the Company beginning January

1, 2018. The Company elected to measure its equity investment without a readily determinable fair value at cost minus impairment and will adjust for changes in observable prices when available. The guidance related to equity investments without readily determinable fair values is being applied prospectively to the Company's investment in TELA Bio, Inc. The implementation of this standard did not have a material impact on the Company's consolidated financial statements and related disclosures. Refer to Note 10, Financial Instruments, for further information.

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments, which clarifies existing guidance on how companies present and classify certain cash receipts and cash payments in the statement of cash flows by addressing specific cash flow issues in an effort to reduce diversity in practice, including guidance on debt prepayment or extinguishment costs and contingent consideration payments made after a business

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combination. ASU 2016-15 became effective for the Company on January 1, 2018 and did not have a material impact on the Company's consolidated statement of cash flows.

In June 2018, the FASB issued ASU 2018-07, Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting, which aligns accounting for share-based payments issued to nonemployees to that of employees under the existing guidance of Topic 718, with certain exceptions. This update supersedes previous guidance for equity-based payments to nonemployees under Subtopic 505-50, Equity—Equity-Based Payments to Non-Employees. The Company chose to early adopt ASU 2018-07 in June 2018 and recorded a cumulative effect adjustment of less than $0.1 million to accumulated deficit upon adoption.

In March 2016, the FASB issued ASU 2016-09, Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. This update included multiple provisions intended to simplify various aspects of accounting for share-based payment transactions including accounting for excess tax benefits and tax deficiencies, classification of excess tax benefits and tax deficiencies in the statement of cash flows and accounting for award forfeitures. The update also removed the requirement to delay recognition of an excess tax benefit until it reduces current taxes payable, instead, it is required to be recognized at the time of settlement, subject to normal valuation allowance considerations. This update became effective for the Company beginning January 1, 2017. The Company elected an accounting policy change to record forfeitures as they occur rather than estimating forfeitures during each period and recorded a charge of $0.3 million to retained earnings as of January 1, 2017 related to the reversal of cumulative forfeiture estimates. The adoption of this standard also resulted in the recognition of $29.3 million of previously unrecognized excess tax benefits in deferred tax assets, fully offset by a valuation allowance. The changes were applied prospectively in accordance with the update, and prior periods were not adjusted. All tax-related cash flows resulting from stock-based compensation, including the excess tax benefits related to the settlement of stock-based awards, are now classified as cash flows from operating activities in the Company's consolidated statements of cash flows.

Recent Accounting Pronouncements Not Adopted as of December 31, 2018

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842) and subsequently issued clarifications and corrections to the update by issuing ASU 2018-10 in July 2018. This update requires lessees to recognize lease assets and lease liabilities on the consolidated balance sheet for those leases classified as operating leases under previous authoritative guidance. Upon adoption, the lease liability will be equal to the present value of future lease payments and a right-of-use, or ROU, asset will be based on the lease liability, subject to adjustment for items such as initial direct costs. For income statement purposes, the new standard retains a dual model similar to ASC 840, requiring leases to be classified as either operating or financing. Operating leases will continue to result in straight-line expense while financing leases will result in a front-loaded expense pattern (similar to current accounting guidance by lessees for operating and capital leases, respectively, under ASC 840).
There are a number of practical expedients available to the Company at transition. The transition practical expedients are that the Company may elect to not re-assess: (i) whether its contracts contain a lease under the new definition, (ii) the classification of those leases and (iii) the accounting for any initial direct costs previously incurred. In addition, the Company may apply hindsight in determining the lease terms and in assessing a purchase option on its existing leases and any potential impairments that may exist on the ROU assets to be recognized at adoption. The Company may also elect to not recognize an ROU asset and lease liability for those leases with a remaining lease term of 12 months or less. The Company will apply these practical expedients upon adoption.
Upon adoption, ROU assets and lease liabilities are being recognized on the Company's consolidated balance sheets. The lease liability recognized upon adoption is based upon the present value of the sum of the remaining minimum

lease payments (as previously identified under ASC 840) and any amounts probable of being owed under a residual value guarantee (if applicable), to be determined using the discount rate then in effect. The interest rate is based on the Company's ability to borrow on a collateralized basis over a similar remaining term and in a similar economic environment. The ROU asset to be recorded is based on the lease liability and adjusted for any prepaid or accrued lease payments, the remaining balance of any lease incentives, initial indirect costs and impairments (if applicable). The standard is effective for the Company beginning January 1, 2019. The Company elected to adopt the new standard at the beginning of the period of adoption through a cumulative-effect adjustment. The Company will reflect its ROU assets, lease liabilities and any cumulative-effect adjustment to retained earnings in its consolidated financial statements beginning on January 1, 2019.

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

The Company continues to evaluate the impact of ASU 2016-02 on its consolidated financial statements. The recognition of lease liabilities and corresponding ROU assets is expected to have a material impact on the Company's consolidated balance sheet. The Company estimates that it will record approximately $35.0 million to $38.0 million of lease liabilities and $26.0 million to $29.0 million of ROU assets as of January 1, 2019, the difference representing previously recorded lease-related assets and liabilities. The Company does not believe the adoption of this standard will have a material impact on its consolidated statements of operations, stockholders' equity or cash flows. Refer to Note 18, Commitments and Contingencies, for further information on the Company's existing leases.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, which requires entities to measure all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions and reasonable and supportable forecasts. Entities will now use forward-looking information to better form their credit loss estimates. This update also requires enhanced disclosures to help financial statement users better understand significant estimates and judgments used in estimating credit losses, as well as the credit quality and underwriting standards of an entity's portfolio. This standard will become effective for the Company beginning January 1, 2020, with early adoption permitted. The Company is currently evaluating the impact of ASU 2016-13 on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework. The purpose of the update is to improve the effectiveness of the fair value measurement disclosures that allows for clear communication of information that is most important to the users of financial statements. There were certain required disclosures that have been removed or modified. In addition, the update added the following disclosures: (i) changes in unrealized gains and losses for the period included in other comprehensive income (loss) for recurring Level 3 fair value measurements held at the end of the reporting period and (ii) the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. The standard will become effective for the Company beginning January 1, 2020, with early adoption permitted. The Company is currently evaluating the impact of ASU 2018-13 on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15, Intangibles—Goodwill and Other Internal-Use Software (Subtopic 350-40: Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That is a Service Contract, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The update provides guidance to determine which implementation costs to capitalize as they relate to the service contract and which costs to expense. In addition, the update further defines the term of the hosting arrangement to include the non-cancelable period of the arrangement plus periods covered by (i) an option to extend the arrangement if the customer is reasonably certain to exercise that option; (ii) an option to terminate the arrangement if the customer is reasonably certain not to exercise the termination option and (iii) an option to extend (or not to terminate) the arrangement in which exercise of the option is in the control of the vendor. Any expense related to the capitalized implementation costs should be recorded in the same financial statement line item in the consolidated statements of operations as the fees associated with the hosting element of the arrangement, and the payments for capitalized implementation costs should be classified in the same manner as payments made for fees associated with the hosting element in the consolidated statements of cash flows. This standard will become effective for the Company beginning January 1, 2020. The amendments may be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company is currently evaluating the impact of ASU 2018-15 on its consolidated financial statements.

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

NOTE 4—REVENUE

Revenue from Contracts with Customers

The Company's sources of revenue include (i) sales of EXPAREL in the U.S.; (ii) sales of its bupivacaine liposome injectable suspension product for use in animal health indications in the U.S.; (iii) royalties based on sales of its bupivacaine liposome injectable suspension product for use in animal health indications and (iv) license fees and milestone payments. The majority of the Company's revenue is derived from sales of EXPAREL. The Company does not consider revenue from other product sales, collaborative licensing, milestones and royalties to be material sources of its consolidated revenue. As such, the following disclosure only relates to revenue associated with net EXPAREL product sales.

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

Net Product Sales

The Company sells EXPAREL through a drop-ship program under which orders are processed through wholesalers based on orders of the product placed by end-users which include hospitals, ambulatory surgery centers and doctors. EXPAREL is delivered directly to the end-user without the wholesaler ever taking physical possession of the product. Product revenue is recognized when control of the promised goods are transferred to the customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for transferring those goods. EXPAREL revenue is recorded at the time the product is delivered to the end-user.

Revenues from sales of products are recorded net of returns allowances, prompt payment discounts, wholesaler service fees, volume rebates and chargebacks. These reserves are based on estimates of the amounts earned or to be claimed on the related sales. These amounts are treated as variable consideration, estimated and recognized as a reduction of the transaction price at the time of the sale, using the most likely amount method for the gross to net adjustments, except for returns, which is based on the expected value method. The Company includes these estimated amounts in the transaction price to the extent it is probable that a significant reversal of cumulative revenue recognized for such transaction will not occur, or when the uncertainty associated with the variable consideration is resolved. The calculation of some of these items requires management to make estimates based on sales data, historical return data, contracts and other related information that may become known in the future. The adequacy of these provisions is reviewed on a quarterly basis. The following table provides a summary of activity with respect to the Company's sales related allowances and accruals for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	Returns Allowances	Prompt Payment Discounts	Wholesaler Service Fees	Volume Rebates and Chargebacks	Total
Balance at December 31, 2015	$ 1,733	$ 625	$ 745	$ 797	$3,900
Provision	694	5,448	4,118	2,611	12,871
Payments/Adjustments	(1,081)	(5,478)	(4,128)	(2,284)	(12,971)
Balance at December 31, 2016	1,346	595	735	1,124	3,800
Provision	716	5,806	4,403	4,656	15,581
Payments/Adjustments	(1,241)	(5,744)	(4,299)	(5,084)	(16,368)
Balance at December 31, 2017	821	657	839	696	3,013
Provision	680	6,802	5,194	6,645	19,321
Payments/Adjustments	(1,157)	(6,680)	(4,866)	(6,331)	(19,034)
Balance at December 31, 2018	$ 344	$ 779	$ 1,167	$ 1,010	$3,300

Accounts Receivable

The majority of accounts receivable arise from product sales and represent amounts due from wholesalers, hospitals, ambulatory surgery centers and doctors. Payment terms generally range from zero to 37 days from the date of the transaction, and accordingly, there is no significant financing component.

Performance Obligations

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in ASC 606. A contract's transaction price is allocated to each distinct performance obligation and recognized as revenue when, or as, the performance obligation is satisfied. At contract inception, the Company assesses the goods promised in its contracts with customers and identifies a performance obligation for each promise

to transfer to the customer a good that is distinct. When identifying individual performance obligations, the Company considers all goods promised in the contract regardless of whether explicitly stated in the customer contract or implied by customary business practices. The Company's contracts with customers require it to transfer an individual distinct product, which represents a single performance obligation. The Company's performance obligation with respect to its product sales are satisfied at a point in time, which transfers control upon delivery of EXPAREL to its customers. The Company considers control to have transferred upon delivery because the customer has legal title to the asset, physical possession of the asset has been transferred, the customer has significant risks and rewards of ownership of the asset, and the Company has a present right to payment at that time.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

Disaggregated Revenue

The following table represents disaggregated net product sales in the periods presented (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Net product sales:			
EXPAREL	$331,112	$282,905	$265,802
Other product sales	1,315	1,437	4,271
Total net product sales	$332,427	$284,342	$270,073

NOTE 5—INVENTORIES

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

	December 31,	
	2018	2017
Raw materials	$19,193	$16,500
Work-in-process	9,711	8,371
Finished goods	19,665	16,540
Total	$48,569	$41,411

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

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NOTE 6—FIXED ASSETS

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

	December 31,	
	2018	2017
Machinery and laboratory equipment	$67,431	$39,002
Leasehold improvements	57,955	34,933
Computer equipment and software	8,131	7,086
Office furniture and equipment	1,548	1,603
Construction in progress	35,163	73,632
Total	170,228	156,256
Less: accumulated depreciation	(61,558)	(49,210)
Fixed assets, net	$108,670	$107,046

Depreciation expense for the years ended December 31, 2018, 2017 and 2016 was $13.2 million, $13.8 million and $12.8 million, respectively. During the years ended December 31, 2018, 2017 and 2016, the Company capitalized interest of $0.7 million, $1.1 million and $1.5 million, respectively.

As of December 31, 2018 and 2017, total fixed assets, net, includes leasehold improvements and manufacturing process equipment located in England in the amount of $64.6 million and $59.8 million, respectively.

As of December 31, 2018 and 2017, the Company had AROs of $2.2 million and $1.5 million, respectively, included in other liabilities on its consolidated balance sheet, for costs associated with returning leased space to its original condition upon the termination of certain lease agreements. The increase in 2018 related to a $0.4 million revision in estimated future cash flows related to the AROs and $0.1 million of accretion expense.

NOTE 7—GOODWILL

In March 2007, the Company acquired from SkyePharma Holding, Inc. (now a subsidiary of Vectura Group plc), or Skyepharma, its California operating subsidiary (Pacira California), referred to herein as the Skyepharma Acquisition. The Company's goodwill arose in April 2012 from a contingent milestone payment to Skyepharma in connection with the Skyepharma Acquisition. The Skyepharma Acquisition was accounted for under Statement of Financial Accounting Standards 141, Accounting for Business Combinations, which was the effective GAAP standard at the Skyepharma Acquisition date. In connection with the Skyepharma Acquisition, the Company agreed to milestone payments for DepoBupivacaine products, including EXPAREL, as follows:

(i) $10.0 million upon the first commercial sale in the U.S. (met April 2012);
(ii) $4.0 million upon the first commercial sale in a major E.U. country (United Kingdom, France, Germany, Italy and Spain);
(iii) $8.0 million when annual net sales collected reach $100.0 million (met September 2014);
(iv) $8.0 million when annual net sales collected reach $250.0 million (met June 2016); and
(v) $32.0 million when annual net sales collected reach $500.0 million.

For purposes of meeting future potential milestone payments, annual net sales are measured on a rolling quarterly basis.

As part of the Skyepharma Acquisition, the Company agreed to pay certain earn-out payments based on a percentage of net sales of DepoBupivacaine products collected, including EXPAREL, for the term during which such sales were covered by a valid claim in certain patent rights related to EXPAREL and other biologics products. The last patents during which a valid claim existed expired on September 18, 2018 and thus, the only remaining obligations to Skyepharma are the two unmet milestone payments totaling $36.0 million. Any remaining milestone payments will be treated as additional costs of the Skyepharma Acquisition and, therefore, recorded as goodwill if and when each contingency is resolved.

The Company recorded goodwill related to contingent payments due under the Skyepharma Acquisition during the years ended December 31, 2018 and 2017, which are not deductible for income tax purposes.

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

	Carrying Value
Balance at December 31, 2016	$46,737
Percentage payments on collections of net sales of DepoBupivacaine products, including EXPAREL	8,460
Balance at December 31, 2017	55,197
Percentage payments on collections of net sales of DepoBupivacaine products, including EXPAREL	6,843
Balance at December 31, 2018	$62,040

NOTE 8—ACCRUED EXPENSES

Accrued expenses consist of the following (in thousands):

	December 31,	
	2018	2017
Accrued operating expenses	$23,019	$20,646
Compensation and benefits	16,974	12,295
Accrued royalties	2,286	4,091
Accrued interest	2,053	2,053
Product returns, rebates and other fees	1,533	1,972
Total	$45,865	$41,057

NOTE 9—DEBT

Convertible Senior Notes Due 2022

On March 13, 2017, the Company completed a private placement of $345.0 million in aggregate principal amount of 2.375% convertible senior notes due 2022, or 2022 Notes, and entered into an indenture, or 2022 Indenture, with respect to the 2022 Notes. The 2022 Notes accrue interest at a fixed rate of 2.375% per year, payable semiannually in arrears on April 1 and October 1 of each year. The 2022 Notes mature on April 1, 2022.

The total debt composition of the 2022 Notes is as follows (in thousands):

	December 31,	
	2018	2017
2.375% convertible senior notes due 2022	$345,000	$345,000
Deferred financing costs	(5,850)	(7,482)
Discount on debt	(48,558)	(61,345)
Total debt, net of debt discount and deferred financing costs	$290,592	$276,173

The net proceeds from the issuance of the 2022 Notes were $334.0 million, after deducting commissions and the offering expenses paid by the Company. A portion of the net proceeds from the 2022 Notes were used by the Company to repurchase the majority of its then-outstanding convertible senior notes due 2019 in privately-negotiated transactions.

Holders may convert the 2022 Notes at any time prior to the close of business on the business day immediately preceding October 1, 2021, only under the following circumstances:

(i) during any calendar quarter commencing after June 30, 2017 (and only during such calendar quarter), if the last reported sale price of the Company’s common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than 130% of the conversion price on each applicable trading day;

(ii) during the five business-day period immediately after any five consecutive trading-day period (the ‘‘measurement period’’) in which the trading price (as defined in the 2022 Indenture) per $1,000 principal amount of the 2022 Notes for each

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trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such trading day;

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

(iv) if the Company calls the 2022 Notes for redemption, until the close of business on the business day immediately preceding the redemption date.

On or after October 1, 2021, until the close of business on the second scheduled trading day immediately preceding April 1, 2022, holders may convert their 2022 Notes at any time.

Upon conversion, holders will receive the principal amount of their 2022 Notes and any excess conversion value, calculated based on the per share volume-weighted average price for each of the 40 consecutive trading days during the observation period (as more fully described in the 2022 Indenture). For both the principal and excess conversion value, holders may receive cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock, at the Company's option. The initial conversion rate for the 2022 Notes is 14.9491 shares of common stock per $1,000 principal amount, which is equivalent to an initial conversion price of $66.89 per share of the Company's common stock. The conversion rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. The initial conversion price of the 2022 Notes represents a premium of approximately 37.5% to the closing sale price of $48.65 per share of the Company's common stock on the NASDAQ Global Select Market on March 7, 2017, the date that the Company priced the private offering of the 2022 Notes.

As of December 31, 2018, the 2022 Notes had a market price of $998 per $1,000 principal amount. In the event of conversion, holders would forgo all future interest payments, any unpaid accrued interest and the possibility of stock price appreciation. Upon the receipt of conversion requests, the settlement of the 2022 Notes will be paid pursuant to the terms of the 2022 Indenture. In the event that all of the 2022 Notes are converted, the Company would be required to repay the $345.0 million in principal value and any conversion premium in any combination of cash and shares of its common stock (at the Company's option).

Prior to April 1, 2020, the Company may not redeem the 2022 Notes. On or after April 1, 2020, the Company may redeem for cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock, at the Company's option, all or part of the 2022 Notes if the last reported sale price (as defined in the 2022 Indenture) of the Company's common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading-day period ending within five trading days prior to the date on which the Company provides notice of redemption. The redemption price will equal the sum of (i) 100% of the principal amount of the 2022 Notes being redeemed, plus (ii) accrued and unpaid interest, including additional interest, if any, to, but excluding, the redemption date. In addition, calling the 2022 Notes for redemption will constitute a "make whole fundamental change" (as defined in the 2022 Indenture) and will, in certain circumstances, increase the conversion rate applicable to the conversion of such notes if it is converted in connection with the redemption. No sinking fund is provided for the 2022 Notes.

If the Company undergoes a fundamental change, as defined in the 2022 Indenture, subject to certain conditions, holders of the 2022 Notes may require the Company to repurchase for cash all or part of their 2022 Notes at a repurchase price equal to 100% of the principal amount of the 2022 Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. In addition, if a ''make-whole fundamental change''

(as defined in the 2022 Indenture) occurs prior to April 1, 2022, the Company will, in certain circumstances, increase the conversion rate for a holder who elects to convert its notes in connection with the make-whole fundamental change.

The 2022 Notes are the Company's general unsecured obligations that rank senior in right of payment to all of its indebtedness that is expressly subordinated in right of payment to the 2022 Notes, and equal in right of payment to the Company's unsecured indebtedness. The 2022 Notes are also effectively junior in right of payment to any of the Company's secured indebtedness to the extent of the value of the assets securing such indebtedness, and are structurally subordinated to any debt or other liabilities (including trade payables) of the Company's subsidiaries.

While the 2022 Notes are currently classified on the Company's consolidated balance sheet at December 31, 2018 as long-term debt, the future convertibility and resulting balance sheet classification of this liability will be monitored at each

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quarterly reporting date and will be analyzed dependent upon market prices of the Company's common stock during the prescribed measurement periods. In the event that the holders of the 2022 Notes have the right to convert the 2022 Notes at any time during the prescribed measurement period, the 2022 Notes would then be considered a current obligation and classified as such.

Under ASC 470-20, Debt with Conversion and Other Options, an entity must separately account for the liability and equity components of convertible debt instruments (such as the 2022 Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. The liability component of the instrument is valued in a manner that reflects the market interest rate for a similar nonconvertible instrument at the date of issuance. The initial carrying value of the liability component of $274.1 million was calculated using a 7.45% assumed borrowing rate. The equity component of $70.9 million, representing the conversion option, was determined by deducting the fair value of the liability component from the par value of the 2022 Notes and was recorded in additional paid-in capital on the consolidated balance sheet at the issuance date. That equity component is treated as a discount on the liability component of the 2022 Notes, which is amortized over the five-year term of the 2022 Notes using the effective interest rate method. The equity component is not re-measured as long as it continues to meet the conditions for equity classification.

The Company allocated the total transaction costs of $11.0 million related to the issuance of the 2022 Notes to the liability and equity components of the 2022 Notes based on their relative values. Transaction costs attributable to the liability component are amortized to interest expense over the five-year term of the 2022 Notes, and transaction costs attributable to the equity component are netted with the equity component in stockholders' equity.

The 2022 Notes do not contain any financial or operating covenants or any restrictions on the payment of dividends, the issuance of other indebtedness or the issuance or repurchase of securities by the Company. The 2022 Indenture contains customary events of default with respect to the 2022 Notes, including that upon certain events of default, 100% of the principal and accrued and unpaid interest on the 2022 Notes will automatically become due and payable.

Convertible Senior Notes Due 2019

On January 23, 2013, the Company completed a private placement of $120.0 million in aggregate principal amount of 3.25% convertible senior notes due 2019, or 2019 Notes. The 2019 Notes accrued interest at a fixed rate of 3.25% per year, payable semiannually in arrears on February 1 and August 1 of each year. In 2017, the Company used part of the net proceeds from the issuance of the 2022 Notes discussed above to repurchase $118.2 million aggregate principal of the 2019 Notes in cash and the issuance of approximately 2.5 million shares of common stock in privately-negotiated transactions. The partial repurchase of the 2019 Notes resulted in a $3.7 million loss on early extinguishment of debt. At both December 31, 2018 and 2017, the principal outstanding on the 2019 Notes was $338 thousand, which was paid in full upon maturity on February 1, 2019. As of February 1, 2019, no amounts under the 2019 Notes remained outstanding.

Interest Expense

The following table sets forth the total interest expense recognized in the periods presented (dollar amounts in thousands):

	Year Ended December 31,		
	2018	2017	2016
Contractual interest expense	$8,205	$7,344	$3,852

Amortization of debt issuance costs	1,634	1,381	612
Amortization of debt discount	12,799	10,423	4,088
Capitalized interest and other (Note 6)	(689)	(1,101)	(1,491)
Total	$21,949	$18,047	$7,061
Effective interest rate on convertible senior notes	7.81%	7.77%	7.22%

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

NOTE 10—FINANCIAL INSTRUMENTS

Fair Value Measurements

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

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

The carrying value of financial instruments including cash and cash equivalents, accounts receivable and accounts payable approximate their respective fair values due to the short-term nature of these items. The fair value of the Company's convertible senior notes at December 31, 2018 are calculated utilizing market quotations from an over-the-counter trading market for these notes (Level 2). The carrying amount and fair value of the Company's convertible senior notes are as follows (in thousands):

Financial Liabilities Carried at Historical Cost	Carrying Value	Fair Value Measurements Using		
December 31, 2018		Level 1	Level 2	Level 3
2.375% convertible senior notes due 2022 (1)	$290,592	$—	$344,353	$—
3.25% convertible senior notes due 2019 (2)	$338	$—	$586	$—

(1) The closing price of the Company's common stock was $43.02 per share at December 31, 2018 compared to a conversion price of $66.89 per share. Currently, the conversion price is above the stock price. The maximum conversion premium that can be due on the 2022 Notes is approximately 5.2 million shares of the Company's common stock, which assumes no increases in the conversion rate for certain corporate events.

(2) The closing price of the Company's common stock was $43.02 per share at December 31, 2018 compared to a conversion price of $24.82 per share which, if converted, would have resulted in an approximate conversion premium of fewer than 10,000 shares of the Company's common stock or $0.2 million of cash. The maximum conversion premium that can be due on the 2019 Notes is approximately 10,000 shares of the Company's common stock, which assumes no increases in the conversion rate for certain corporate events. On February 1, 2019, the 2019 Notes were paid in full upon maturity.

Short-term investments consist of asset-backed securities collateralized by credit card receivables, investment grade commercial paper and corporate bonds with maturities greater than three months, but less than one year. Long-term investments consist of asset-backed securities collateralized by credit card receivables and corporate bonds with maturities greater than one year. Net unrealized gains or losses from the Company's short-term and long-term investments are reported in other comprehensive income (loss). At December 31, 2018, all of the Company's short-term investments are classified as available for sale investments and are determined to be Level 2 instruments, which are measured at fair value using standard industry models with observable inputs. The fair value of the commercial paper is measured based on a standard industry model that uses the three-month U.S. Treasury bill rate as an observable input. The fair value of the asset-backed securities and corporate bonds is principally measured or corroborated by trade data for identical issues in which related trading activity is not sufficiently frequent to be considered a Level 1 input or that of comparable securities. At December 31, 2018, all short-term and long-term investments were rated A or better by Standard & Poor's.

The following summarizes the Company's investments at December 31, 2018 and 2017 (in thousands):

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December 31, 2018 Investments:	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value (Level 2)
Short-term:				
Asset-backed securities	$34,873	$ —	$ (33)	$34,840
Commercial paper	45,035	—	(30)	45,005
Corporate bonds	171,289	—	(206)	171,083
Subtotal	251,197	—	(269)	250,928
Long-term:				
Asset-backed securities	9,383	5	—	9,388
Corporate bonds	16,499	—	(16)	16,483
Subtotal	25,882	5	(16)	25,871
Total	$277,079	$ 5	$ (285)	$276,799

December 31, 2017 Investments:	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value (Level 2)
Short-term:				
Asset-backed securities	$28,338	$ —	$ (37)	$28,301
Commercial paper	48,999	—	(23)	48,976
Corporate bonds	180,119	—	(175)	179,944
Subtotal	257,456	—	(235)	257,221
Long-term:				
Asset-backed securities	23,836	—	(79)	23,757
Corporate bonds	36,430	—	(140)	36,290
Subtotal	60,266	—	(219)	60,047
Total	$317,722	$ —	$ (454)	$317,268

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

TELA Bio, Inc.

In October 2017, the Company made a cash investment of $15.0 million in convertible preferred B shares of TELA Bio, Inc., or TELA Bio, a privately-held surgical reconstruction company that markets its proprietary OviTex™ portfolio of products for ventral hernia repair and abdominal wall reconstruction. In conjunction with the investment in TELA Bio, the Company acquired an option to purchase an additional $10.0 million of convertible preferred B shares of TELA Bio under the same terms and conditions as existed on the initial purchase date. The investment in TELA Bio and the purchase option were recorded at fair value based on integrated valuation pricing models with the equity investment in the TELA Bio Series B Preferred Stock recorded at $14.1 million and the purchase option recorded in prepaid expenses and other current assets at $0.9 million. The purchase option expired unexercised on September 15, 2018. Accordingly, the Company recorded a loss of $0.9 million on the unexercised purchase option, which was recorded in other (expense) income in the consolidated statement of operations for the year ended December 31, 2018.

Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents, short-term investments, long-term investments and accounts receivable. The Company maintains its cash and cash equivalents with high-credit quality financial institutions. Such amounts may exceed

federally-insured limits.

As of December 31, 2018, three wholesalers accounted for over 10% of the Company's accounts receivable: 32%, 32% and 29%, respectively. At December 31, 2017, three wholesalers accounted for over 10% of the Company's accounts receivable: 35%, 30% and 27%, respectively. Revenues are primarily derived from major wholesalers and pharmaceutical companies which generally have significant cash resources. The Company performs ongoing credit evaluations of its customers

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as warranted and generally does not require collateral. Allowances for doubtful accounts receivable are maintained based on historical payment patterns, aging of accounts receivable and actual write-off history. As of December 31, 2018 and 2017, no allowances for doubtful accounts were deemed necessary by the Company on its accounts receivable.

NOTE 11—STOCKHOLDERS' EQUITY

Common Stock

The Company is authorized to issue up to 250,000,000 shares of common stock, of which 41,222,799 and 40,668,877 were issued and outstanding at December 31, 2018 and 2017, respectively.

Preferred Stock

The Company is authorized to issue up to 5,000,000 shares of preferred stock. No preferred stock was issued or outstanding at either December 31, 2018 or 2017.

Accumulated Other Comprehensive Income (Loss)

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

	Net Unrealized Gains (Losses) From Available For Sale Investments
Balance at December 31, 2016	$ (30)
Other comprehensive loss before reclassifications	(424)
Amounts reclassified from accumulated other comprehensive income (loss)	—
Balance at December 31, 2017	(454)
Other comprehensive income before reclassifications	174
Amounts reclassified from accumulated other comprehensive income (loss)	—
Balance at December 31, 2018	$ (280)

NOTE 12—STOCK PLANS

Stock Incentive Plans

The Company's amended and restated 2011 stock incentive plan, or 2011 Plan, was originally adopted by its board of directors and approved by its stockholders in June 2014, and amended in June 2016. The 2011 Plan allows the granting of incentive stock options, non-statutory stock options, restricted stock awards and other stock-based awards. Since the adoption of the 2011 Plan, any remaining shares available for issuance under a 2007 stock incentive plan, or 2007 Plan, are automatically reallocated to the 2011 Plan. In April 2014, the Company's board of directors also adopted the 2014 Inducement Plan.

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

2014 Employee Stock Purchase Plan

The Company's 2014 Employee Stock Purchase Plan, or ESPP, was adopted by its board of directors in April 2014 and approved by the Company's stockholders in June 2014. The purpose of the ESPP is to provide a vehicle for eligible

employees to purchase shares of the Company's common stock at a discounted price and to help retain and motivate current employees as well as attract new talent. Under the ESPP, up to 500,000 shares of common stock may be sold. The plan expires in June 2024. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Internal Revenue Code. The maximum fair market value of stock which can be purchased by a participant in a calendar year is $25,000. Six-month offering periods begin on January 1 and July 1 of each year. During an offering period, eligible employees have the opportunity to elect to purchase shares of the Company's common stock on the purchase dates of June 30 and December 31 (or

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the last trading day of an offering period). The per share purchase price will be equal to the lesser of 85% of the fair market value of the Company's common stock on either the offering date or the purchase date. During the year ended December 31, 2018, 64,740 shares were purchased and issued under the ESPP.

The following tables contain information about the Company's stock incentive plans at December 31, 2018:

Stock Incentive Plan	Awards Reserved For Issuance	Awards Issued	Awards Available For Grant
2007 Plan	2,022,837	2,022,837	—
2011 Plan	9,931,700	8,392,572	1,539,128
2014 Inducement Plan	175,000	36,576	138,424
	12,129,537	10,451,985	1,677,552

Employee Stock Purchase Plan	Shares Reserved For Purchase	Shares Purchased	Shares Available For Purchase
2014 ESPP	500,000	224,887	275,113

Stock-Based Compensation

Compensation expense for stock options and RSUs is based on the estimated grant date fair value of options recognized over the requisite service period on a straight-line expense attribution method. This applies to employees and non-employee directors, as well as nonemployees upon the Company's adoption of ASU 2018-07 in June 2018, which aligned the accounting for share-based payments to nonemployees with that of employees and directors. Subsequent to the adoption of ASU 2018-07, compensation expense for options and RSUs granted to nonemployees are measured at the estimated grant date fair value and are no longer required to be revalued at each reporting period until vested. For more information on the Company's adoption of ASU 2018-07, refer to Note 3, Recent Accounting Pronouncements. Compensation expense for ESPP share options is based on the estimated grant date fair value of the ESPP shares and the grant date number of shares that can be purchased, which is recognized as expense over the length of an offering period.

The Company recognized stock-based compensation expense in its consolidated statements of operations for the years ended December 31, 2018, 2017 and 2016 as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Cost of goods sold	$4,478	$5,467	$6,438
Research and development	3,934	3,341	3,297
Selling, general and administrative	23,313	22,793	21,513
Total	$31,725	$31,601	$31,248
Stock-based compensation from:			
Stock options (employee awards)	$21,980	$24,056	$24,505
Stock options (consultant awards)	663	167	841
RSUs	8,371	6,698	5,117
ESPP	711	680	785
Total	$31,725	$31,601	$31,248

The following table summarizes the Company's stock option activity and related information for the period from December 31, 2015 to December 31, 2018:

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	Number of Options	Weighted Average Exercise Price (Per Share)	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in Thousands)
Outstanding at December 31, 2015	4,645,722	$ 44.03	7.31	$ 162,340
Granted	1,656,598	38.20		
Exercised	(518,226)	11.13		$ 21,750
Forfeited	(401,048)	70.27		
Expired	(175,303)	80.91		
Outstanding at December 31, 2016	5,207,743	42.16	7.39	$ 37,581
Granted	1,072,625	43.93		
Exercised	(539,989)	12.55		$ 15,865
Forfeited	(555,897)	48.66		
Expired	(232,989)	74.65		
Outstanding at December 31, 2017	4,951,493	43.51	6.91	$ 57,021
Granted	1,994,332	39.35		
Exercised	(332,732)	21.55		$ 7,418
Forfeited	(481,126)	42.30		
Expired	(409,149)	68.01		
Outstanding at December 31, 2018	5,722,818	$ 41.69	7.07	$ 49,166
Exercisable at December 31, 2018	3,009,133	$ 43.03	5.38	$ 37,629
Vested and expected to vest at December 31, 2018	5,722,818	$ 41.69	7.07	$ 49,166

As of December 31, 2018, $47.5 million of total unrecognized compensation cost related to non-vested stock options is expected to be recognized over a weighted average period of 2.9 years. The Company’s stock options have a maximum expiration date of ten years from the date of grant.

The weighted average fair value of stock options granted for the years ended December 31, 2018, 2017 and 2016 was $19.34, $20.78 and $19.13 per share, respectively. The fair values of stock options granted were estimated using the Black-Scholes model with the following weighted average assumptions:

	Year Ended December 31,		
	2018	2017	2016
Expected dividend yield	None	None	None
Risk-free interest rate	2.26% - 3.05%	1.68% - 2.42%	1.03% - 2.48%
Expected volatility	53.3%	51.4%	53.5%
Expected term of options	5.14 years	5.31 years	5.77 years

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The following table summarizes the Company's RSU activity and related information for the period from December 31, 2015 to December 31, 2018:

	Number of Units	Weighted Average Grant Date Fair Value (Per Share)	Aggregate Intrinsic Value (in Thousands)
Unvested at December 31, 2015	216,198	$ 78.59	$ 16,602
Granted	256,631	40.21	
Vested	(61,487)	78.33	
Forfeited	(46,939)	68.84	
Unvested at December 31, 2016	364,403	52.85	$ 11,824
Granted	343,583	44.23	
Vested	(101,379)	53.76	
Forfeited	(107,061)	49.98	
Unvested at December 31, 2017	499,546	47.32	$ 22,804
Granted	331,129	38.36	
Vested	(156,450)	49.59	
Forfeited	(96,261)	43.92	
Unvested and expected to vest at December 31, 2018	577,964	$ 42.14	$ 24,864

As of December 31, 2018, $19.2 million of total unrecognized compensation cost related to non-vested RSUs is expected to be recognized over a weighted average period of 2.8 years. The Company's RSUs have a maximum vest date of four years from the date of grant. The fair values of RSUs awarded are equal to the closing price of the Company's common stock on the date of grant.

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

	Year Ended December 31,		
	2018	2017	2016
ESPP share option fair value	$10.40 - $13.15	$10.80 - $13.85	$10.57 - $25.28
Expected dividend yield	None	None	None
Risk-free interest rate	1.53% - 2.14%	0.62% - 1.14%	0.37% - 0.49%
Expected volatility	52.2%	53.8%	63.4%
Expected term of ESPP share options	6 months	6 months	6 months

NOTE 13—NET INCOME (LOSS) PER SHARE

Potential common shares are excluded from the diluted net income (loss) per share computation to the extent that they would be antidilutive. Because the Company reported a net loss for the years ended December 31, 2018, 2017 and 2016, no potentially dilutive securities have been included in the computation of diluted net loss per share for those periods. As discussed in Note 9, Debt, the Company has the option to pay cash for the aggregate principal amount due upon the conversion of its 2022 Notes. Since it is the Company's intent to settle the principal amount of its 2022 Notes in cash, the potentially dilutive effect of such notes on net income (loss) per share is computed under the treasury stock method. In 2018, because it was the Company's intent to settle the conversion premium of its 2019 Notes in cash (as it did upon maturity on February 1, 2019), there was no potentially dilutive effect on the computation of diluted securities.

The following table sets forth the computation of basic and diluted net income (loss) per share for the years ended December 31, 2018, 2017 and 2016 (in thousands, except per share amounts):

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	Year Ended December 31,		
	2018	2017	2016
Numerator:			
Net loss	$(471)	$(42,611)	$(37,949)
Denominator:			
Weighted average shares of common stock outstanding	40,911	39,806	37,236
Net loss per share:			
Basic and diluted net loss per common share	$(0.01)	$(1.07)	$(1.02)

The following outstanding stock options, RSUs, conversion premiums on the Company's convertible senior notes, warrants and ESPP purchase options are antidilutive in the periods presented (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Weighted average number of stock options	5,492	5,171	4,482
Weighted average number of RSUs	542	449	290
Conversion premium on the 2019 Notes	—	411	2,022
Weighted average number of warrants	—	—	1
Weighted average ESPP purchase options	31	29	21
Total	6,065	6,060	6,816

NOTE 14—INCOME TAXES

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

	Year Ended December 31,		
	2018	2017	2016
Income (loss) before income taxes:			
Domestic	$5,169	$(39,898)	$(36,339)
Foreign	(5,594)	(2,573)	(1,505)
Total loss before income taxes	$(425)	$(42,471)	$(37,844)
Current taxes:			
Federal	$(96)	$—	$11
State	142	140	94
Total income tax expense	$46	$140	$105

The tax provisions for each of the years ended December 31, 2018, 2017 and 2016 are principally the result of minimum state taxes.

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

	Year Ended December 31,		
	2018	2017	2016
U.S. federal statutory rate	21.00 %	35.00 %	35.00 %
State taxes	(24.84)%	2.26 %	2.20 %
Foreign taxes	(92.04)%	(1.28)%	(0.81)%
Change in valuation allowance	369.27 %	4.58 %	(43.96)%
Stock-based compensation	(874.29)%	(1.21)%	(0.54)%
Tax credits	700.35 %	4.96 %	8.77 %
Interest expense	218.47 %	2.90 %	5.75 %
Effect of rate changes	13.44 %	(130.88)%	(4.65)%
Convertible senior notes refinancing	— %	6.55 %	— %
Effect of the adoption of ASU 2016-09	— %	68.89 %	— %
Nondeductible expenses	(132.96)%	— %	— %
Reserves	(202.98)%	— %	— %
Other	(6.15)%	7.90 %	(2.04)%
Effective tax rate	(10.73)%	(0.33)%	(0.28)%

The Company's effective tax rates of (10.73)%, (0.33)% and (0.28)% for the years ended December 31, 2018, 2017 and 2016, respectively, differed from the expected U.S. statutory tax rate of 21.0% (previously 35.0%). This difference was primarily driven by pretax losses for which the Company concluded that a majority of its tax benefits are not more-likely-than-not to be realized, resulting in the recording of a full valuation allowance.

Deferred taxes reflect the tax effects of the differences between the amounts recorded as assets and liabilities for financial reporting purposes and the comparable amounts recorded for income tax purposes. Significant components of the Company's deferred tax assets and liabilities at December 31, 2018 and 2017 are as follows (in thousands):

	December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carry-forwards	$79,446	$95,067
Federal and state credits	17,730	15,048
Depreciation and amortization	2,851	2,593
Accruals and reserves	11,009	2,743
Deferred revenue	—	1,841
Stock based compensation	18,302	16,925
Inventory	848	552
Other	127	139
Total deferred tax assets	130,313	134,908
Deferred tax liabilities:		
Discount on convertible senior notes	(11,655)	(14,678)
Deferred tax assets, net of deferred tax liabilities	118,658	120,230
Less: valuation allowance	(118,658)	(120,230)
Net deferred tax assets	$—	$—

As of December 31, 2018, the Company's federal net operating losses, or NOLs, and federal tax credit carryforwards totaled $346.2 million and $12.7 million, respectively. The Company also had state NOLs and state tax credit carryforwards of $159.2 million and $6.3 million, respectively, which are subject to change on an annual basis due to variations in the

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Company's annual state apportionment factors. The Company had non-U.S. tax NOLs of $11.4 million at December 31, 2018. The existing federal NOLs will begin expiring in 2027 while the existing state NOLs begin expiring in 2024, if the Company has not used them prior to that time. The non-U.S. NOLs do not expire.

Since the Company had cumulative changes in ownership of more than 50% within a three-year period, under Internal Revenue Code sections 382 and 383, the Company's ability to use certain net operating loss and credit carryforwards to offset taxable income or tax will be limited. Such ownership changes were triggered by the initial acquisition of the Company's stock in 2007 as well as cumulative ownership changes arising as a result of the completion of the Company's initial public offering and other financing transactions. As a result of these ownership changes, the Company estimates that approximately $191.1 million of federal net operating losses are subject to annual limitations. At December 31, 2018, $108.0 million of these federal net operating losses were available. The Company estimates that an additional $10.3 million will come available each year from 2019 through 2022, $3.5 million in 2023, $1.4 million each from 2024-2025 and that the remaining $35.8 million will expire unused. In addition, California and certain states have previously suspended or limited the use of NOL carryforwards for certain taxable years, and certain states are considering similar future measures. As a result, the Company may incur higher state income tax expense in the future.

In accordance with ASC Topic 740, the Company establishes a valuation allowance for deferred tax assets that, in its judgment, are not more-likely-than-not realizable. These judgments are based on projections of future income, including tax-planning strategies, by individual tax jurisdictions. In each reporting period, the Company assesses the likelihood that its deferred tax assets will be realized and determines if adjustments to its valuation allowance is appropriate. The Company had a net reduction in its valuation allowance of $1.6 million and $28.5 million in the years ended December 31, 2018 and 2017, respectively, and a net increase in its valuation allowance of $0.8 million for the year ended December 31, 2016. There is significant doubt regarding the Company's ability to utilize its net deferred tax assets and, therefore, the Company has recorded a full valuation allowance reducing its net deferred tax assets to zero at both December 31, 2018 and 2017.

In December 2017, new legislation was signed into law reducing the corporate U.S. tax rate from 35% to 21% for tax years beginning after December 31, 2017, fully repealing the corporate alternative minimum tax and making the NOL carryforward period indefinite for NOLs generated after 2017. In accordance with ASC Topic 740, deferred tax assets and liabilities are required to be measured at the enacted tax rate expected to apply when temporary differences are to be realized or settled. As of December 31, 2017, the Company re-measured its deferred tax balances based upon the new 21% tax rate. This resulted in a reduction of $55.7 million in the Company's deferred tax assets, which was offset by a change in its year-end valuation allowance.

In March 2017, the Company established a deferred tax liability with an offset to additional paid-in capital resulting from the conversion feature of the 2022 Notes. The initial difference between the book value of the convertible debt, issued with a beneficial conversion feature, and its tax basis was $70.9 million, a temporary difference. The net effect of the deferred tax liability recorded to additional paid-in capital was zero because the Company has a full valuation allowance against its net deferred tax assets.

In 2018, the Company recorded a reserve of $0.4 million related to unrecognized tax benefits, or UTBs, which relates to tax positions taken in 2018. The Company's UTB liability at December 31, 2018 was $2.9 million. The change in the Company's UTBs in 2018 is summarized as follows (in thousands):

	Unrecognized Tax Benefit
Balance at December 31, 2017	$ 2,473
Additions for current year positions	408
Balance at December 31, 2018	$ 2,881

The Company regularly assesses the likelihood of additional tax assessments by jurisdiction and, if necessary, adjusts its reserve for UTBs based on new information or developments. Due to the Company's tax credit carryforwards, the

reserve was recorded as a reduction of the Company's deferred tax assets, and any potential deficiency would not result in a tax liability. Therefore, no interest or penalties were recognized in income tax expense for the years ended December 31, 2018 and 2017. Due to the Company's full valuation allowance against deferred tax assets, none of the UTBs, if recognized, would affect the effective income tax rate.

The Company estimates that it is not reasonably possible that within the next twelve months, any of the unrecognized tax benefits will significantly increase or decrease. The Company is currently subject to audit by the U.S. Internal Revenue Service,

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or IRS, for the years 2015 through 2018, and state tax jurisdictions for the years 2014 through 2018. However, the IRS or states may still examine and adjust an NOL arising from a closed year to the extent it is utilized in a year that remains subject to audit. The Company's previously filed income tax returns are not presently under audit by the IRS or state tax authorities.

NOTE 15—OTHER EMPLOYEE BENEFITS

The Company sponsors a 401(k) savings plan. Under this plan, employees may make contributions which are eligible for a discretionary percentage match as defined in the plan and determined by the Company's board of directors. The Company recognized $1.6 million, $1.3 million and $1.5 million of related compensation expense for the years ended December 31, 2018, 2017 and 2016, respectively.

NOTE 16—COMMERCIAL PARTNERS AND OTHER AGREEMENTS

DepoCyt(e) Discontinuation

In June 2017, the Company's board of directors approved a decision to discontinue production of DepoCyt® (U.S. and Canada) and DepoCyte® (E.U.) due to persistent technical issues specific to the DepoCyt(e) manufacturing process. As of June 30, 2017, the Company had ceased all production of DepoCyt(e).

In 2017, the Company recorded a non-recurring charge of $5.4 million related to the discontinuation of its DepoCyt(e) manufacturing activities, including $0.5 million for DepoCyt(e) related inventory, which is recorded in cost of goods sold, and $4.9 million was recorded in product discontinuation, including the remaining lease costs less an estimate of potential sublease income for the facility where DepoCyt(e) was manufactured, the write-off of property, plant and equipment, employee severance, asset retirement obligations and other estimated exit costs.

In 2018, the Company recorded a non-recurring charge of $1.6 million related to the discontinuation of its DepoCyt(e) manufacturing activities for lease costs, asset retirement obligations and other estimated exit costs. The charges incurred in 2018 represent additional lease and facility costs due to the fact that the Company does not expect to be able to sub-lease the property considering the short period of time remaining on the Company's existing lease.

Cash payments related to the lease on the DepoCyt(e) manufacturing facility are expected to continue through the end of the lease term in August 2020.

A summary of the Company's costs and reserves related to the DepoCyt(e) discontinuation are as follows (in thousands):

	Severance and Related Costs	Lease Costs	Write-Off of Property, Plant & Equipment and Inventory	Asset Retirement Obligations and Other Discontinuation Costs	Total
Balance at December 31, 2016	$ —	$—	$ —	$ —	$—
Charges incurred	303	2,018	2,470	656	5,447
Cash payments made	(303)	(744)	—	(420)	(1,467)
Disposal of property, plant & equipment and inventory	—	—	(2,470)	—	(2,470)
Balance sheet reclassifications	—	494	—	73	567
Balance at December 31, 2017	—	1,768	—	309	2,077

Charges incurred	—	1,513	—	51	1,564
Cash payments made	—	(1,311)	—	(91)	(1,402)
Balance sheet reclassifications	—	—	—	13	13
Balance at December 31, 2018	$ —	$1,970	$ —	$ 282	$2,252

Prior to the discontinuation, the Company received a fixed payment for the supply of DepoCyt(e) and double-digit royalties, net of supply price, on the sales of DepoCyt by Leadiant Bioscience, Ltd. in the U.S. and Canada, and on the sales of DepoCyte by Mundipharma International Corporation Limited, or Mundipharma, in the E.U. and other European countries. In

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addition, the Company also received a non-refundable upfront payment of $8.0 million in connection with a 15 year extension and concurrent expansion of the territories where Mundipharma can market and distribute DepoCyte. In April 2018, the Company received formal notice of the termination of the supply and distribution agreements (and all related agreements) from Mundipharma and its affiliates. The Company may be required to make additional payments or incur additional costs relating to the DepoCyt(e) discontinuation which could be material to the Company's results of operations and/or cash flows in a given period.

Commercial Partners

Thermo Fisher Scientific Pharma Services (Formerly Patheon UK Limited)

In April 2014, the Company and Thermo Fisher Scientific Pharma Services (formerly Patheon UK Limited), or Thermo Fisher, entered into a Strategic Co-Production Agreement, a Technical Transfer and Service Agreement and a Manufacturing and Supply Agreement to collaborate in the manufacture of EXPAREL. Under the terms of the Technical Transfer and Service Agreement, Thermo Fisher agreed to undertake certain technical transfer activities and construction services needed to prepare its Swindon, England facility for the manufacture of EXPAREL in two dedicated manufacturing suites. The Company contracted to purchase EXPAREL from Thermo Fisher, beginning with FDA approval of the suites, which occurred in May 2018. Commercial production began in February 2019. Under these agreements, the Company makes monthly base fee payments to Thermo Fisher. Unless earlier terminated by giving notice of up to three years (other than termination by the Company in the event of a material breach by Thermo Fisher), this agreement will expire in May 2028.

DePuy Synthes Sales, Inc.

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

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

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

Aratana Therapeutics, Inc.

On December 5, 2012, the Company entered into a worldwide license, development and commercialization agreement with Aratana Therapeutics, Inc., or Aratana. Under the agreement, the Company granted Aratana an exclusive royalty-bearing license, including the limited right to grant sublicenses, for the development and commercialization of the Company's bupivacaine liposome injectable suspension product for use in animals. Under the agreement, Aratana developed and obtained FDA approval for the use of the product in veterinary surgery to manage postsurgical pain. In connection with its entry into the license agreement, the Company received a one-time payment of $1.0 million. In December 2013, the Company received a $0.5 million milestone payment under the agreement. In June 2016, the Company recorded $1.0 million in milestone revenue for Aratana's filing of an FDA Administrative New Animal Drug Application, or ANADA, and in August 2016 recorded $1.0 million related to the FDA's approval of the ANADA. The Company is eligible to receive up to an additional aggregate $40.0 million upon the achievement of commercial milestones. Aratana is required to pay the Company a tiered double digit royalty on net sales made in the U.S. If the product is approved by foreign regulatory agencies for sale outside of the U.S., Aratana will be required to pay the Company a tiered double digit royalty on such net sales. Royalty rates will be reduced by a certain

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percentage upon the entry of a generic competitor for animal health indications into a jurisdiction or if Aratana must pay royalties to third parties under certain circumstances. Unless terminated earlier pursuant to its terms, the license agreement is effective until December 2027, after which Aratana has the option to extend the agreement for an additional five-year term, subject to certain requirements.

Aratana began purchasing bupivacaine liposome injectable suspension product in 2016, which they market under the trade name NOCITA® (a registered trademark of Aratana Therapeutics, Inc.) to serve animals.

CrossLink BioScience, LLC

In October 2013, the Company and CrossLink BioScience, LLC, or CrossLink, commenced a five-year arrangement for the promotion and sale of EXPAREL, pursuant to the terms of a Master Distributor Agreement. On June 30, 2016, the Company provided notice to CrossLink electing to terminate this agreement effective September 30, 2016. In connection with the termination of the agreement, the Company recorded a $7.1 million charge to selling, general and administrative expense in its consolidated statement of operations. There was nothing payable to CrossLink at December 31, 2018. $2.4 million was classified in accrued expenses at December 31, 2017.

Nuance Biotech Co. Ltd.

In June 2018, the Company entered into an agreement with Nuance Biotech Co. Ltd., or Nuance, a China-based specialty pharmaceutical company, to advance the development and commercialization of EXPAREL in China. Under the terms of the agreement, the Company agreed to be the sole supplier of EXPAREL to Nuance and has granted Nuance the exclusive rights to develop and commercialize EXPAREL in China. In June 2018, the Company recognized an upfront payment of $3.0 million since collaborative licensing revenue is recognized at the point in time when the license is provided and is not expected to substantively change. This payment was received in July 2018 and the Company is eligible to receive future milestone payments of up to $60.0 million that are triggered by filing for and securing regulatory approval(s) and annual sales in China exceeding certain levels. The Company is also entitled to tiered royalties as a percentage of net sales.

NOTE 17—RELATED PARTY TRANSACTIONS

The Company’s former Chief Medical Officer, Dr. Gary Patou, is a partner of MPM Asset Management LLC, or MPM, an investor in the Company. The Company incurred no consulting expenses with MPM or Dr. Patou in the years ended December 31, 2018 and 2017, and expenses of $0.1 million for the year ended December 31, 2016. At both December 31, 2018 and 2017, there were no amounts payable to MPM. The Company’s agreement with MPM expired on December 31, 2015, and the Company contracted with Dr. Patou directly for his services for the first six months of 2016.

In December 2012, the Company entered into a worldwide license, development and commercialization agreement with Aratana as discussed in Note 16, Commercial Partners and Other Agreements. MPM and its affiliates are holders of capital stock of Aratana. David Stack, the Company’s Chief Executive Officer and Chairman, was a managing director at MPM from 2005 through March 2017.

In April 2012, the Company entered into a consulting agreement with Dr. Gary Pace, a director of the Company. The Company recorded no expense under the consulting agreement in the years ended December 31, 2018 and 2017 and expenses of less than $0.1 million for the year ended December 31, 2016. In connection with the consulting agreement, Dr. Pace received an option to purchase 20,000 shares of common stock at an exercise price of $11.02 per share and an option to purchase 70,000 shares of common stock at an exercise price of $16.67 per share. At December 31, 2018 and 2017, there was nothing payable to Dr. Pace for consulting services.

NOTE 18—COMMITMENTS AND CONTINGENCIES

Leases

The Company leases its EXPAREL manufacturing, research and development, warehouse and DepoCyt(e) facilities in San Diego, California, and its corporate headquarters in Parsippany, New Jersey. Many of these leases provide

renewal options at the then-current market value. In addition, the Company has a lease for the use of Thermo Fisher's facility in Swindon, England embedded in the Thermo Fisher agreements and a portion of the monthly base fee has been allocated to the lease component based on a relative fair value basis.

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As of December 31, 2018, aggregate annual minimum payments due under the Company's lease obligations are as follows (in thousands):

Year	Aggregate Minimum Payments Due
2019	$ 8,140
2020	7,621
2021	5,295
2022	5,417
2023	5,543
2024 through 2028	14,329
Total	$ 46,345

Total rent expense, net of amortization of unfavorable lease obligations and tenant improvements, under all operating leases for the years ended December 31, 2018, 2017 and 2016 was $7.2 million, $7.5 million and $6.0 million, respectively. Deferred rent was $6.9 million at December 31, 2018 and $6.8 million at December 31, 2017.

Litigation

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

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

Purchase Obligations

The Company has approximately $24.5 million of minimum, non-cancelable contractual commitments for contract manufacturing services as of December 31, 2018.

Other Commitments and Contingencies

The FDA, as a condition of EXPAREL approval, has required the Company to study EXPAREL in pediatric patients. The Company was granted a deferral for the required pediatric trials in all age groups for EXPAREL in the setting of wound infiltration and plans to conduct these pediatric trials as a post-marketing requirement, which was stated in the New Drug Application (NDA) approval letter for EXPAREL. The Company recently began activating a study site for an extended pharmacokinetic and safety study for local analgesia in children aged 6 to 17 undergoing cardiovascular or spine surgeries and is working with the FDA to define a program to study the administration of EXPAREL as a nerve block in the pediatric setting.

In addition to the initial $19.6 million purchase price for the Skyepharma Acquisition, the Company entered into an earn-out agreement with Skyepharma based on the Company reaching certain revenue milestones following the Skyepharma Acquisition. Pursuant to this agreement, the Company is required to pay Skyepharma milestone payments up to an aggregate of $62.0 million, of which $36.0 million are for milestones not yet met. The Company also agreed to pay certain earn-out payments based on a percentage of net sales of DepoBupivacaine products collected, including EXPAREL, for the term during which such sales were covered by a valid claim in certain patent rights related to EXPAREL and other biologics products. The last patents during which a valid claim existed expired

on September 18, 2018. Refer to Note 7, Goodwill, for further discussion.

Pursuant to an agreement with the Research Development Foundation, or RDF, the Company is required to pay RDF a low single-digit royalty on the collection of revenues from its DepoFoam-based products, for as long as certain patents assigned to the Company under the agreement remain valid. RDF has the right to terminate the agreement for an uncured material breach

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

by the Company, in connection with its bankruptcy or insolvency or if it directly or indirectly opposes or disputes the validity of the assigned patent rights.

NOTE 19—SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

The following tables present selected quarterly financial data for the years ended December 31, 2018 and 2017 (in thousands, except per share amounts):

	Three Months Ended			
	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018
Total revenues	$74,607	$84,107	$83,448	$95,115
Cost of goods sold	22,885	20,916	19,065	23,979
Total operating expenses	81,544	77,566	79,400	82,852
Net income (loss)	(10,680)	2,564	(640)	8,285
Basic and diluted net income (loss) per common share	$(0.26)	$0.06	$(0.02)	$0.20

	Three Months Ended			
	March 31, 2017	June 30, 2017	September 30, 2017	December 31, 2017
Total revenues	$69,283	$70,934	$67,335	$79,078
Cost of goods sold	24,581	23,811	18,228	21,295
Total operating expenses	83,333	86,714	70,907	70,613
Net income (loss)	(19,866)	(19,743)	(7,597)	4,595
Basic and diluted net income (loss) per common share	$(0.52)	$(0.49)	$(0.19)	$0.11

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