

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended: December 31, 2019

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 BIOSCIENCES, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction of
Incorporation or Organization)

51-0619477

(I.R.S. Employer
Identification No.)

5 Sylvan Way, Suite 300

Parsippany, New Jersey

07054

(Address and Zip Code of Principal Executive Offices)

(973) 254-3560

(Registrant's Telephone Number, Including Area Code)

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

Title of each class	Trading symbol	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	PCRX	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 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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 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 Global Select Market on June 28, 2019, the last trading day of the registrant’s most recently completed second fiscal quarter, of \$43.49 per share was approximately \$848.3 million. Shares of common stock held by each director and executive officer (and their respective affiliates) and by each person who owns 10 percent or more of the outstanding common stock or who is otherwise believed by the registrant to be in a control position have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 16, 2020, 42,033,039 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 2020 annual meeting of stockholders to be filed no later than 120 days after the end of the registrant’s fiscal year ended December 31, 2019.

PACIRA BIOSCIENCES, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2019

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Forward-Looking Statements

This Annual Report on Form 10-K (the “Annual Report”) and certain other communications made by us contain forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (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,” “will,” “would,” “could,” “can” and similar expressions to help identify forward-looking statements. We cannot assure you that our estimates, assumptions and expectations will prove to have been correct. These forward-looking statements include, among others, statements about: the success of our sales and manufacturing efforts in support of the commercialization of EXPAREL® (bupivacaine liposome injectable suspension); 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; our ability to realize the anticipated benefits and synergies from the acquisition of MyoScience, Inc., or MyoScience; the ability to successfully integrate iovera® and MyoScience into the Company’s existing business; the commercial success of iovera®; the related timing and success of United States Food and Drug Administration, or FDA, supplemental New Drug Applications, or sNDAs, and premarket notification 510(k)s; the outcome of the U.S. Department of Justice, or DOJ, inquiry; the Company’s plans to evaluate, develop and pursue additional DepoFoam®-based product candidates; clinical trials in support of an existing or potential DepoFoam-based product; our commercialization and marketing capabilities and our ability to successfully construct an additional EXPAREL manufacturing suite in Swindon, England and assumptions associated with contingent consideration payments. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. 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.

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 BioSciences, Inc., a Delaware corporation, changed its name from Pacira Pharmaceuticals, Inc. upon completing its acquisition of MyoScience, a privately-held medical technology company, in April 2019 (referred to herein as the “MyoScience Acquisition”) in order to better reflect a broadening portfolio of innovative non-opioid pain management and regenerative health solutions. Pacira BioSciences, Inc. is the holding company for our California operating subsidiary named Pacira Pharmaceuticals, Inc., 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 herein as the “Skyepharma Acquisition”). Pacira California retained the name Pacira Pharmaceuticals, Inc. upon the completion of the MyoScience Acquisition. Unless the context requires otherwise, references to “Pacira,” “we,” the “Company,” “us” and “our” in this Annual Report refers to Pacira BioSciences, 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. and in April 2019 changed our name to Pacira BioSciences, Inc. upon the completion of the MyoScience Acquisition. Our principal executive offices are located in Parsippany, New Jersey.

Pacira®, EXPAREL®, iovera®, 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 are the property of Pacira. In addition, references in this Annual Report 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 contains additional trade names, trademarks and service marks of other companies.

Overview

We are a leading provider of non-opioid pain management options to advance and improve outcomes for health care practitioners and their patients, 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 and iovera°, our non-opioid pain therapies; (ii) pursuing innovative opioid-sparing options through in-licensing and acquisition; and (iii) advancing a pipeline of non-opioid opportunities for acute and chronic pain management.

In April 2019, we completed the MyoScience Acquisition and added the iovera° system to our commercial offering. The iovera° system is a non-opioid handheld cryoanalgesia device used to alleviate pain.

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. Since its initial approval in 2011 for single-dose infiltration, more than six million patients have been treated with EXPAREL. 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 2019 were \$407.9 million. For the years ended December 31, 2019, 2018 and 2017, net product sales of EXPAREL accounted for 97%, 98% and 99% of our total revenues, respectively. In addition to EXPAREL, DepoFoam is also the basis for future clinical candidates.

The iovera° system is an FDA-approved medical device used to deliver precise, controlled doses of cold temperature only to targeted nerves, which has been FDA 510(k) cleared for use in pain applications since March 2014. The iovera° system is highly complementary to EXPAREL as a non-opioid therapy that alleviates pain by disrupting pain signals being transmitted to the brain from the site of injury or surgery. For the year ended December 31, 2019, net product sales of iovera° were \$7.9 million. We began recognizing sales of iovera° after completing the MyoScience Acquisition in April 2019.

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 in peer-reviewed journal
C-section TAP field block follow-on study ¹	Phase 4	Publish results in peer-reviewed journal
Spine	Phase 4	Complete study
Surgical infiltration/Nerve block	MAA (E.U.)	Advance regulatory submission
Surgical infiltration/Nerve block	NDS (Canada)	Advance regulatory submission
Surgical infiltration/Nerve block	NDA (China)	Pre-submission meeting
Pediatric infiltration	Phase 3	Submit sNDA
Lower extremity nerve block	Phase 3	Complete study
Pediatric nerve block	Defining Pathway	Seek label expansion
The iovera ^o system:		
Total knee arthroplasty (TKA)	Approved	Initiate studies
Blocking of pain	Approved	Initiate studies
DepoFoam-based local anesthetic		
DepoDexmedetomidine	Preclinical	Advance preclinical activities
DepoDexmedetomidine		
DepoDexmedetomidine		
DepoDexmedetomidine		
NOCITA [®] (bupivacaine liposome injectable suspension): ²		
Postsurgical analgesia in dogs and cats	Approved (U.S.)	Marketed by Aratana Therapeutics, Inc.

¹ TAP block is a transversus abdominis plane field block

² NOCITA[®] is a registered trademark of Aratana Therapeutics, Inc., a wholly owned subsidiary of Elanco Animal Health, Inc.

Our Strategy

We continue to advance 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:

- Expanding the use of EXPAREL and iovera^o for opioid-sparing pain management:* 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 seeing increased use within the anesthesiology community through EXPAREL-based regional approaches that are enabling the shift of complex, painful procedures to the hospital outpatient and ambulatory settings. Our partnership with DePuy Synthes Sales Inc., or DePuy Synthes, part of the Johnson & Johnson family of companies, has established the role of EXPAREL as the foundation of opioid-sparing protocols for painful orthopedic procedures, including shoulder, hip fracture, joint reconstruction, and spine surgeries. We are expanding the body of clinical evidence through Phase 4 studies in key surgical settings, such as C-section and spine. In addition, we are advancing clinical and regulatory activities to expand the EXPAREL label to include the pediatric and lower extremity nerve block settings. For iovera^o, we are focusing on iovera^o plus EXPAREL as a multimodal procedural solution for total knee arthroplasty, or TKA, as well as drug-free, opioid-free, surgery-free pain management for osteoarthritis of the knee.
- Pursuing innovative acquisition targets that align with our strategy:* We believe EXPAREL, iovera^o 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 pain and regenerative health solutions to improve patients' journeys along the neural pain pathway.

- *Advancing a pipeline of 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 advancing a program for the intrathecal delivery of a DepoFoam-based local anesthetic as a potential alternative to the use of subarachnoid opioids delivered by pumps and catheters and DepoDexmedetomidine for end-of-life pain and painful conditions in the elderly.

EXPAREL

Opioid addiction in the U.S. has reached epidemic proportions, with the Centers for Disease Control and Prevention, or CDC, reporting more than 70,000 drug overdose deaths in the U.S. in 2017, of which opioids were involved in nearly 48,000 of these overdose deaths or approximately 68% of all drug overdose deaths. 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 also indicates that close to 9% 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% and 17%, respectively. Further, women were 40% more likely to become persistent opioid users than men; and among persistent users, females were prescribed 15% 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.

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:

- *Expanding the use of EXPAREL in key surgical settings.* We are expanding the clinical evidence for EXPAREL through Phase 4 clinical trials across several surgical specialties. We have published positive results from a Phase 4 multicenter, randomized, controlled trial, or RCT, in TKA in the *Journal of Arthroplasty*. Positive findings from a multicenter RCT in C-section were presented at the most recent annual meeting of the Society for Obstetric Anesthesia and Perinatology (SOAP), and we recently reported positive topline results from a follow-on Phase 4 study in C-section procedures that compared an opioid-free EXPAREL arm to an opioid-based standard of care arm. EXPAREL is being 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 and lower extremity nerve block settings. Regulatory initiatives are also advancing in new global markets, such as Europe, Canada and China.
- *Expanding access to EXPAREL and driving education and awareness around the need for opioid-sparing strategies.* New payer policies and benefits are supporting this migration to realize cost savings while enhancing patient care through the use of opioid-sparing protocols. The Centers for Medicare and Medicaid Services, or CMS, is providing Medicare reimbursement for EXPAREL when administered in an Ambulatory Surgery Center, or ASC, through the product-specific Healthcare Common Procedure Coding System (HCPCS) code of C9290. Effective January 1, 2020, CMS removed total hip arthroplasty and six spinal procedures from its inpatient-only list, making these procedures eligible for payment by Medicare in the hospital outpatient setting. The final CMS rule for 2020 also added TKA and several other procedures to its listing of ASC covered procedures. In addition, 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 healthcare providers.

- *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 to support the promotion, education and training of EXPAREL in orthopedics. We are collaborating on national and regional training initiatives with large anesthesia physician practices, such as MEDNAX, Inc. and Envision Physician Services. 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, 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 solution 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 is a key component of long-acting postsurgical pain management regimens that reduce the need for opioids. Based on the clinical data from our Phase 3 and Phase 4 clinical studies as well as data from retrospective health outcomes studies, 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;
- 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% ($p < 0.0001$) from zero to 48 hours after surgery;
- reduced pain scores by 46% versus placebo ($p < 0.0001$); and
- allowed 13% of patients who received EXPAREL to remain opioid-free for 48 hours after surgery ($p < 0.01$) compared to zero patients in the placebo arm.

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

- decreased total opioid consumption by 78% ($p = 0.0048$) from zero to 48 hours after surgery;
- reduced pain scores by 14% ($p = 0.0381$) from 12 to 48 hours after surgery; and

- allowed 10% of patients in the EXPAREL arm to remain opioid-free through 48 and 72 hours (compared to zero patients in the bupivacaine arm; $p < 0.01$).

In our Phase 4 trial of EXPAREL versus bupivacaine administered via a transversus abdominis plane block in C-section procedures:

- Comparable pain control with a reduction in total opioid consumption with EXPAREL plus bupivacaine HCl versus bupivacaine HCl:
 - 52% reduction through 72 hours, ($p = 0.0117$)
 - 49% reduction at one week ($p = 0.0175$)
 - 41% reduction at two weeks (trending toward significance; $p = 0.0542$)
- More than a two-fold increase in the percentage of opioid-spared patients with EXPAREL versus bupivacaine HCl (defined as patients who took no more than one oxycodone 10mg tablet, or equivalent, with no opioid-related side effects through 72 hours; $p = 0.0012$)

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.

In March 2019, we reported new data showing that a patient-optimizing, opioid-sparing ERAS pathway, which includes intraoperative infiltration with EXPAREL, results in high rates of early discharge and patient satisfaction among Medicare-insured patients undergoing TKA or total hip arthroplasty, or THA. Findings also demonstrate that the vast majority of patients do not require more than a seven-day opioid prescription following discharge. The research was detailed during a podium presentation at the American Academy of Orthopaedic Surgeons (AAOS) 2019 Annual Meeting.

Retrospective chart review data were captured for 645 consecutive Medicare patients who underwent primary inpatient TKA (337 patients) or THA (308 patients) between June 1, 2015, and November 16, 2017. All patients followed a procedure-specific ERAS protocol which included EXPAREL (Van Horne A, Van Horne J. Patient-optimizing enhanced recovery pathways for total knee and hip arthroplasty in Medicare patients: implication for transition to ambulatory surgery centers. *Arthroplasty Today* 2019). Key findings included:

- 84% did not require any additional opioid prescriptions beyond the initial seven-day prescription provided at discharge (while nationally, 38% of knee replacement patients are still taking opioids two months after surgery)
- 84% of patients were same-day discharged to home, following their joint replacement
- Patients reported high satisfaction with their perioperative experience (98% were highly satisfied with their pain management)

- Comparable or lower complication rates to nationally reported rates

In June 2019, we reported new data on the use of EXPAREL following THA. The findings show that patients receiving EXPAREL had a significant reduction in opioid use, hospital length of stay, or LOS, and total hospitalization costs compared to THA patients who did not receive the product. The results were published in *The Journal of Medical Economics*.

This retrospective analysis utilized data from the Premier Healthcare Database from January 2011 through April 2017 for the ten hospitals in the U.S. with the highest number of THA procedures using EXPAREL. Patients undergoing THA who received EXPAREL were matched in a one-to-one ratio to a control group of patients whose pain management strategy did not include the product. The study population included a total of 12,589 patients, with 7,232 Medicare patients and 5,357 commercial insurance patients.

Results showed that patients undergoing THA who received EXPAREL compared to those who did not demonstrated a significant:

- Decrease in opioid consumption, expressed in oral morphine equivalent dosing (MED), among Medicare and commercial insurance patients (105 mg MED and 81 mg MED reductions, respectively; $p < 0.0001$)
- Decrease in average hospital LOS by 0.7 days in both the Medicare and commercial insurance groups ($p < 0.0001$)
- Decrease in total hospitalization costs in the Medicare population (-\$561; $p < 0.0001$)
- Increase in likelihood to be discharged home in both the Medicare and commercial insurance groups (1.66 and 1.57, respectively; $p < 0.0001$)

Results of this study are consistent with findings from several retrospective studies and RCTs on the use of EXPAREL for total joint replacement procedures, including additional data published in 2018 in *The Journal of Medical Economics* that found a decrease in opioid consumption, hospital LOS and hospitalization costs for patients receiving EXPAREL following TKA (Asche et al. Impact of treatment with liposomal bupivacaine on hospital costs, length of stay, and discharge status in patients undergoing total knee arthroplasty at high-use institutions, *Journal of Medical Economics*, DOI: 10.1080/13696998.2018.1543190).

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.

In June 2019, investigators reported results from a study confirming that patients who received EXPAREL were prescribed significantly fewer opioids compared to those who did not. In this study, researchers reviewed data from 600 patients who underwent impacted third molar extractions between 2012 and 2018 in two dental clinics; one in Connecticut and one in North Carolina. Data from 300 patients who received EXPAREL were compared to data from 300 patients who did not receive EXPAREL. Patients in the EXPAREL treatment group received:

- Fewer total prescribed opioid tablets including refills, compared to patients in the non-EXPAREL group (6.4 tablets vs. 15.5 tablets, respectively; $p < 0.0001$)
- Fewer additional opioid prescriptions compared to the non-EXPAREL group (3.3% of patients required a refill vs. 7.7% of patients, respectively)

The research was presented at the June 2019 International Association for Dental Research meeting in Vancouver, Canada and highlighted in the Aetna Fall 2019 Dental Dialog newsletter.

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 Studies

Pediatrics

In December 2019, we reported positive topline results from our Phase 3 registration study (known as "PLAY") of EXPAREL administered as a single-dose infiltration in pediatric patients undergoing spinal or cardiac surgeries. Overall findings were consistent with the pharmacokinetic and safety profiles for adult patients with no safety concerns identified at a dose of 4 mg/kg. We believe the results from this study will provide the foundation for an sNDA submission in the first half of 2020 to the FDA seeking expansion of the EXPAREL label to include children aged six and over. We are also working with the FDA to finalize a regulatory pathway to expand the EXPAREL label to include EXPAREL administered as a nerve block in the pediatric setting.

The PLAY study enrolled 98 patients to evaluate the pharmacokinetics and safety of EXPAREL for two patient groups: patients aged 12 to less than 17 years and patients aged 6 to less than 12 years. In agreement with the FDA, the primary and secondary objectives of the PLAY study were to evaluate the pharmacokinetics and safety of EXPAREL, respectively. The full study results will be submitted for publication in the peer-reviewed medical literature later this year.

Nerve Block in Lower Extremity Surgery

We have initiated a Phase 3 study for nerve block in lower extremity surgeries (known as "STRIDE") that is comparing an EXPAREL nerve block in lower extremity surgeries to a bupivacaine lower extremity nerve block in patients undergoing foot and ankle surgeries. We believe positive results from this study would support an sNDA submission seeking label expansion to include lower extremity nerve blocks. We believe the addition of this indication is significant as anesthesia-driven regional approaches using nerve and field blocks continue to expand as institutional protocols.

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 Europe, Canada and China. In Europe, we have secured a positive opinion for our Pediatric Investigation Plan (PIP) and in June 2019 our Marketing Authorization Application, or MAA, was validated by the European Medicines Agency, or EMA. In Canada, which is a concentrated market driven by four provinces, Health Canada has validated our New Drug Submission. We do not intend to pursue a commercial partnership to commercialize EXPAREL in Europe or Canada. In China, we have an agreement with Nuance Biotech Co. Ltd., or Nuance, a China-based specialty pharmaceutical company, for the development and commercialization of EXPAREL. We have received feedback from the National Medical Products Administration, or NMPA, in China and we are preparing for a meeting with the NMPA in 2020 to finalize our regulatory path forward.

iovera°

The iovera° system

The iovera° system is highly complementary to EXPAREL as a non-opioid therapy that delivers cryoanalgesia via a handheld device to alleviate pain by disrupting pain signals being transmitted to the brain from the site of injury or surgery. Initially, we will focus on two broad patient care opportunities. The iovera° system is 510(k) cleared in the U.S. for the blocking of pain, pain relief and symptoms associated with osteoarthritis of the knee as well as general surgical use.

Our first priority is iovera° and EXPAREL for opioid-sparing pain management for the TKA patient, with iovera° being administered before surgery and EXPAREL administered during surgery. As many as 30 percent of presurgical patients with end-stage knee osteoarthritis use prescription opioids. With iovera°, our goal is to provide patients with several months of non-opioid pain control to allow them to prepare for surgery with an appropriate regimen. We also believe that EXPAREL for surgical pain control and EXPAREL plus iovera° for postsurgical pain control could support rapid functional recovery.

The second target market is iovera° for osteoarthritis patients who have failed conservative treatments, such as non-steroidal anti-inflammatory drugs or viscosupplementation, and are seeking drug-free, opioid-free, surgery-free pain management for several months. We are targeting patients who are seeking an active lifestyle, as well as patients who desire to delay surgery for personal reasons.

Osteoarthritis of the Knee

There is a growing body of clinical data demonstrating success with the iovera° treatment for osteoarthritis of the knee. There are 14 million individuals in the U.S. who have symptomatic knee osteoarthritis, and nearly two million are under the age of 45. Surgical intervention is typically a last resort for patients suffering from osteoarthritis of the knee. In one study, the majority of the patients suffering from osteoarthritis of the knee experienced pain relief beyond 150 days after being treated with iovera°.

Preliminary findings demonstrated reductions in opioids, including:

- The daily morphine equivalent was significantly lower at 72 hours ($p<0.05$), 6 weeks ($p<0.05$) and 12 weeks ($p<0.05$), with an overall 35 percent reduction in daily morphine equivalents across the 12-week postoperative period in the iovera° treatment group.
- Patients who were administered iovera° were far less likely to take opioids six weeks after surgery. The number of patients taking opioids six weeks after TKA in the control group was three times the number of patients taking opioids in the cryoanalgesia group (14% vs. 44%, $p<0.01$).
- Patients in the iovera° group demonstrated a statistically significant reduction in pain scores from their baseline pain scores at 72 hours ($p<0.05$) and at 12 weeks ($p<0.05$).

We believe these data validate iovera° as a clinically meaningful non-opioid alternative for patients undergoing TKA, and that iovera° offers the opportunity to provide patients with non-opioid pain control well in advance of any necessary surgical intervention through a number of key product attributes:

- iovera° is safe and effective with immediate pain relief that can last for several months as the nerve regenerates over time;
- iovera° is repeatable;
- The iovera° technology does not risk damage to the surrounding tissue;
- iovera° is a convenient handheld device with a single-use procedure-specific smart tip; and
- iovera° can be delivered precisely using ultrasound guidance or an anatomical landmark.

We believe the combination of iovera° and EXPAREL will become the preferred procedural solution that will empower patients and their healthcare providers to take control of the patients' osteoarthritis journey, while minimizing the need for opioids. We will be investing in key clinical studies to demonstrate the synergy of iovera° and EXPAREL to manage pain while reducing or eliminating opioids. Our initial focus will be iovera° and EXPAREL as a multimodal solution for TKA.

Product Pipeline

Given the proven safety, flexibility and customizability of our DepoFoam platform for acute, sub-acute and chronic pain applications, we have several DepoFoam-based products in preclinical development. Following data readouts from animal and other feasibility studies for these candidates, we have prioritized two programs for clinical development: (i) the intrathecal delivery of a DepoFoam-based analgesic for acute and chronic pain and (ii) DepoDexmedetomidine, a sedative-analgesic for end-of-life pain and painful conditions in the elderly.

We plan to invest in clinical initiatives to broaden the scope of iovera[®] applications and improve its functionality for current and future end users. This will be accomplished through enhancements across the product line, which is comprised of single-use disposable units as well as non-disposable handheld devices.

In parallel, our business development team continues to pursue innovative acquisition targets that align with our strategy and are complementary to EXPAREL and iovera[®] by thoughtfully pursuing additional opportunities that are of great interest to the surgical and anesthesia audiences we are already calling on today. Our goal is to build a portfolio of customer-focused non-opioid and regenerative health solutions to improve patients' journeys along the neural pain pathway.

Sales and Marketing

We have built our marketing and sales organization to commercialize our products. Our primary target audiences are healthcare practitioners who influence pain management decisions including anesthesiologists, surgeons, pharmacists and nurses.

Our field team, consisting of sales representatives, account managers, scientific and medical affairs personnel and reimbursement and market access professionals, executes on a full range of activities to broaden the use of our non-opioid products for pain management, including:

- providing publications and abstracts showing clinical efficacy and safety, health outcomes and review articles;
- working in tandem with hospital staff, such as anesthesiologists, surgeons, heads of quality, pharmacists, executives and registered nurses, 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 our products, 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; opioid-sparing and ERAS 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 healthcare providers towards improving the knowledge and management of pain in surgical and osteoarthritis 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
- facilitating reimbursement and the shift of procedures to hospital outpatient and ASC sites of care.

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 have accelerated EXPAREL growth by quickly leveraging the broad reach of DePuy Synthes and their established relationships and scale within hospitals and ASCs.

DePuy Synthes field representatives, specializing in joint reconstruction, spine, sports medicine, trauma and cranio-maxillofacial (CMF) procedures, 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 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 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

MyoScience Acquisition

In April 2019, we completed the MyoScience Acquisition. The consideration included an initial cash payment of \$120.0 million, reduced by \$1.0 million for post-closing purchase price adjustments and indemnification obligations incurred to date, plus contingent milestone payments up to an aggregate of \$100.0 million. Upon the completion of the MyoScience Acquisition, we renamed MyoScience to Pacira CryoTech, Inc. For more information on the MyoScience Acquisition, refer to Note 5, *MyoScience Acquisition*, to our consolidated financial statements included herein.

TELA Bio, Inc.

In October 2017, we made an investment of \$15.0 million in TELA Bio, Inc., or TELA Bio, a 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. In 2019, we made an additional cash investment of \$1.6 million in TELA Bio. During the year ended December 31, 2019, we received a non-cash stock dividend from our investment in the amount of \$2.5 million and recognized a loss in the amount of \$5.7 million, recognized in the other, net line in our consolidated statements of operations. For more information, refer to Note 12, *Financial Instruments*, to our consolidated financial statements included herein.

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 the first commercial sale in the U.S. (met April 2012);
- \$4.0 million upon the first commercial sale in the United Kingdom, France, Germany, Italy or 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 potential remaining obligations to SkyePharma are the two above-referenced unmet milestone payments totaling \$36.0 million.

See Note 9, *Goodwill and Intangible Assets*, to our consolidated financial statements included herein for further information related to the Skyepharma Acquisition.

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 DepoCyt® (E.U.) due to persistent technical issues specific to the DepoCyt(e) manufacturing process.

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, or CVM, approved NOCITA® (bupivacaine liposome injectable suspension) as a local post-operative analgesia for cranial cruciate ligament surgery in dogs. In August 2018, the FDA's CVM expanded the NOCITA label to include its use as a peripheral nerve block to provide regional postoperative analgesia following onychectomy in cats. In June 2019, the FDA's CVM approved a 10mL vial size for NOCITA. Aratana began purchasing our 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 certain 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 July 2033, after which Aratana has the option to extend the agreement for an additional five-year term, subject to certain requirements.

NOCITA® is a registered trademark of Aratana.

Nuance Biotech Co. Ltd.

In June 2018, the Company entered into an agreement with 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, 2019: Cardinal Health, Inc., McKesson Drug Company and AmerisourceBergen Health Corporation, which accounted for 34%, 29% 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 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 and the Environmental Protection Agency (EPA). They have been inspected and approved previously by the European Medicines Agency, or EMA, and the Medicines and Healthcare Products Regulatory Agency, or MHRA, but are no longer with the discontinuation of DepoCyt(e). Our iovera^o facility in Fremont, California, consists of approximately 20,000 square feet of mixed-use manufacturing, research and development and office space. 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 and iovera^o. 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 product 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 current Good Manufacturing Practices, or cGMP.

Building 1 is an approximately 84,000 square foot 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 Scientific Pharma Services, or Thermo Fisher (formerly Patheon UK Limited), 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. Our lease for Building 2 expires in October 2020, and in April 2020, we will begin moving into new space in the adjacent Building A (which is also adjacent to Building 1), an approximately 90,000 square foot structure built in 2002. Building A which will eventually house all of the activities now occurring in Building 2 in addition to future expansion opportunities.

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.

Our Fremont, California facility was built in 1998 and has been leased since 2015. It is dedicated to the iovera[®] product line and consists of approximately 20,000 square feet of space for manufacturing, quality control, research and development and the warehousing of raw materials and finished goods. The entire iovera[®] product line of tips, cartridges and handheld systems are produced as well as developed at this site.

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 and should be available to begin commercial production in approximately one year from now.

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.

Intellectual Property and Exclusivity

We seek to protect our products, our product candidates and our technologies through a combination of patents, trade secrets, proprietary know-how, regulatory exclusivity and contractual restrictions on disclosure. We note that the patents and applications described below are only examples intended to highlight the variety of coverage provided by our existing and constantly developing portfolio.

Patents and Patent Applications

We seek to protect the proprietary position of our products and 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, 2019, there are over nine families of patents and patent applications relating to various aspects of the DepoFoam delivery technology and 25 families of patents and patent applications relating to various aspects of the technology used by iovera[®]. 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 for the DepoFoam delivery technology expiring in 2033 and the last currently issued patent for the iovera[®] technology expiring in 2037.

Patents and Patent Applications for DepoFoam and DepoFoam Products

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'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, 2019, 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.

Patents and Patent Applications for iovera°

Issued patents in the U.S. afford us a wide range of coverage of various aspects of the iovera° technology. For example, several of our earliest filed patents cover the structural aspects of a handheld cryogenic device with single needle and needle arrays, tissue-penetrating needle probes that may be detachable, fused silica tubing fluid delivery paths, methods of applying cryotherapy using the cryogenic device and methods for using replaceable needle probes. These patents are set to expire between 2025 and 2032. An important patent family specifically directed to systems and methods of treating pain offers both broad and variable coverage of cryogenic device features and methods of using the same for pain management, including single-use needle probes, particular needle sizes and shapes. Patents in this family are set to expire between 2025 and 2028. Another important patent family has broad disclosure and coverage of a variety of indications for treatment by cryogenic devices, including joint function and stiffness, osteoarthritis, occipital neuralgia, spasticity, neuroma and other nerve entrapment indications and is set to expire between 2033 and 2037.

Additionally, there are several patents and pending patent applications directed to other important aspects of the iovera° technology. For example, patents covering needle cladding and the probe filtration system are set to expire in 2033 and a patent on the smart tip technology is not set to expire until 2037. Other applications cover methods of using needles with blunt tips and aspects of cryogenic devices coupled with a neurostimulator for locating nerves. We also have three design patent families that cover the current handheld cryogenic device, its charging station dock and combinations thereof. To obtain coverage of our developing next-generation technology, we filed four new provisional applications in 2019, which if converted and granted, could potentially prevent others from using this next-generation technology until at least 2040.

Trade Secrets and Proprietary Information

Trade secrets play an important role in protecting our DepoFoam-based and iovera° products and provide protection beyond patents and regulatory exclusivity. The scale-up and commercial manufacture of DepoFoam-based and iovera° products involve 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. The iovera° system relies on manufacturing techniques that are able to provide the precision and tight tolerances required for a self-contained handheld cryogenic device. Additionally, our device includes proprietary software for device operations during cryotherapy treatments.

We seek to protect our proprietary information, including our trade secrets and proprietary know-how, by requiring our employees, consultants and other advisors to execute proprietary information and confidentiality agreements upon the commencement of their employment or engagement. These agreements generally provide that all confidential information developed or made known during the course of the relationship with us be kept confidential and not be disclosed to third parties except in specific circumstances. In the case of our employees, the agreements also typically provide that all inventions

resulting from work performed for us, utilizing our property or relating to our business and conceived or completed during employment shall be our exclusive property to the extent permitted by law. Where appropriate, agreements we obtain with our consultants also typically contain similar assignment of invention obligations. Further, we require confidentiality agreements from third parties that receive our confidential data or materials.

Competition

EXPAREL

The pharmaceutical industry is 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. Avanos Medical, Inc. markets these medical devices in the U.S.

iovera^o

The medical device industry is intensely competitive and subject to rapid and significant technological change. The cryotherapy pain management field in particular is a growing industry due to increased attention on opioid usage for pain, which has created a rapidly emerging market and has fueled an increased interest in opioid alternatives. Many of our competitors in our space 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. The rise of various small and early-stage companies in the cryotherapy pain management field may also prove to be significant competitors, particularly if they enter into collaborative arrangements with large, established companies.

Our competitors are continuously engaged in trials and attempts to develop new products or approaches in hopes of capturing the pain management market. They may succeed in developing, acquiring or licensing on an exclusive basis, technologies that are more effective or less costly than the *iovera*^o system, which could render the *iovera*^o system obsolete and noncompetitive. As a result, it is critical that we continue to innovate and to increase marketing efforts in our primary markets. 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.

Besides pharmaceutical products for pain management, *iovera*^o competes with medical devices that ablate or degenerate peripheral nerves to treat indications such as joint pain, neuralgia and osteoarthritis pain. Competing products include cryotherapy devices as well as other devices such as cooled radio-frequency ablation devices that block or degenerate

peripheral nerves involved in conducting pain signals. Avanos Medical, Inc. markets these medical devices in the U.S. Additional non-opioid products or entirely different approaches may also be developed for pain management by one or more of our competitors.

Government Regulation

In the U.S., prescription drug and medical device 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 and medical device 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

Pharmaceuticals

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;
- 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 the 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 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.

Medical Devices

In the U.S., the Medical Device Amendments of 1976 to the FDCA and its subsequent amendments regulate the design, manufacture and marketing of medical devices. Medical devices that require notification submitted as a 510(k) clearance request must be reviewed and cleared by the FDA before we can begin marketing them. To request 510(k) clearance, we must be able to demonstrate that the medical device is substantially equivalent to a previously-cleared and legally marketed 510(k) medical device. Medical devices require extensive clinical testing which consists of safety and efficacy studies, followed by pre-market approval, or PMA, applications for specific surgical indications. The FDA's Quality System Regulations, or QSRs, set forth standards for our product design and manufacturing processes, require the maintenance of certain records and provide for inspections of our facilities by the FDA. There are also certain requirements of state, local and foreign governments that must be complied with in the manufacture and marketing of our products.

U.S. Review and Approval Process

Pharmaceuticals

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.

Medical Devices

In the U.S., authorization to bring a medical device to market is generally obtained in one of two ways. The first pathway, a pre-market notification (the 510(k) process), requires demonstration that the new device is substantially equivalent to an already legally marketed medical device. The second pathway, known as pre-market approval, or PMA, requires an independent demonstration that a medical device is safe and effective for its intended use. In general, pre-market approvals require a much longer time horizon and can be much more expensive than obtaining clearance through the 510(k) process.

To obtain 510(k) clearance, we must file with the FDA a pre-market notification demonstrating that our proposed device is substantially equivalent to a previously cleared and legally marketed 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of a PMA. 510(k) clearance for iovera[®] was first obtained in March 2009 when the focus of MyoScience was cosmetic applications (i.e. facial wrinkle reduction). The MyoScience business focus shifted to pain management in 2014, and since then there have been a number of advancements that led to three additional 510(k) submissions and clearances to support iovera[®] and the subsequent growth of the iovera[®] product line.

A PMA must be submitted to the FDA if it is determined that the device is not eligible for the 510(k) clearance process. A PMA must be supported by extensive data including, but not limited to, technical, preclinical and clinical trials, manufacturing and labeling to demonstrate reasonable evidence of the device's safety and efficacy to the FDA's satisfaction.

After a device receives 510(k) clearance or a PMA approval, it may be changed or modified. Any modification that could significantly affect its safety or effectiveness, or that would constitute a significant change in its intended use, will require a new clearance or approval. Regulations provide that the manufacturer initially determines when a specific modification requires notification to FDA. The FDA has issued draft guidance that, if finalized and implemented, will result in manufacturers needing to seek a significant number of new clearances for changes made to legally marketed devices. The FDA reviews the manufacturer's decision to file a 510(k) or PMA for modifications during facility audits.

Section 505(b)(2) New Drug Applications

For pharmaceutical products, 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 the 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

Pharmaceuticals

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;
- 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."

Medical Devices

The FDA has broad post-market and regulatory obligations that we must adhere to. We are subject to unannounced inspections by the FDA to determine our compliance with QSRs and other rules and regulations.

After a medical device is placed on the market, numerous regulatory requirements apply. These include, but are not limited to:

- QSRs, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, documentation and other quality assurance procedures during product design and throughout the manufacturing process;
- Labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses; and

- Medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur.

Failure to comply with regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- 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;
- the potential withdrawal of 510(k) clearance or other approvals that were previously granted;
- 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;
- injunctions or the imposition of civil or criminal penalties; or
- requiring us to repair, replace and/or refund the cost of any medical device we have manufactured or distributed.

If any of these events were to occur, they could have a material adverse effect on our business.

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 pharmaceuticals, 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.

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.

In addition to regulations in Europe and the U.S., we will be subject to regulations governing clinical trials, product approvals, and commercial distribution in Canada, China and any other jurisdictions in which EXPAREL, iovera[®] or any other future product is approved.

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, medical devices 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 (collectively, 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 and medical device 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. In the past, based on our clinical trial program for EXPAREL, the FDA granted three years of marketing exclusivity to EXPAREL, which expired in October 2014.

Manufacturing Requirements

We must comply with the FDA’s cGMP requirements and comparable regulations in other countries. The cGMP provisions include requirements relating to 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 or medical device. 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, procedures 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 and medical device industries 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 and medical device 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 and medical device 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 and medical device 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. Refer to Item 3, *Legal Proceedings*, for an update related to this matter.

Healthcare Privacy and Security Laws

We may be subject to, or our marketing activities may be limited by the Health Insurance Portability and Accountability Act, or HIPAA and its implementing regulations, which established uniform standards for certain “covered entities” (healthcare providers, health plans and healthcare clearinghouses) governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information. The American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, included sweeping expansion of HIPAA’s privacy and security standards called the Health Information Technology for Economic and Clinical Health Act, or HITECH, which became effective on February 17, 2010. Among other things, the new law makes HIPAA’s privacy and security standards directly applicable to “business associates”— independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney’s fees and costs associated with pursuing federal civil actions.

Environmental Matters

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

Employees

As of December 31, 2019, we had 606 employees. All of our employees are located in the U.S. except for nine located in England and one located in the Netherlands. None of our employees are represented by a labor union, and we consider our current employee relations to be good.

Available Information

Our corporate 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, 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 corporate 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 corporate website are not intended to, nor shall they be deemed to, incorporate information on our website into this Annual Report by reference.

Item 1A. Risk Factors

In addition to the other information in this Annual Report, 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 primarily 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 2019, 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 and ASCs;
- 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, hospitals and ASCs 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 or anesthesiologist 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;
- 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 or ASC 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 return to profitability.

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, drug products and medical devices that are more effective or less costly than EXPAREL, iovera[®] 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, iovera[®] 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, iovera[®] or our product candidates. Our competitors may also develop drugs or medical devices 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.

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

While physicians in the U.S. may choose, and are generally permitted to prescribe drugs or treatments 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 and medical device 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 of the U.S. Constitution, 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.

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.

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 iovera[®] 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 and iovera[®] 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 and iovera[®], 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, 2019, we had 606 employees. We may need to expand our personnel resources in order to manage our operations and sales of EXPAREL and iovera[®]. 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 and medical device 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 iovera[®], 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.

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, medical device and other businesses, as well as universities, non-profit research organizations and government entities, particularly in San Diego, California, the San Francisco Bay Area and northern New Jersey. 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, iovera[®], DepoCyt(e) or product candidates that we may develop and may have to limit their commercialization.

The use of EXPAREL, iovera[®], 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 products and/or 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 or medical devices 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 our products 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 these products or be unable to meet market demand, and may lose potential revenues.

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

The FDA requires manufacturers of medical devices to adhere to certain regulations, including the FDA's QSRs, which requires periodic audits, design controls, quality control testing and documentation procedures, as well as complaint evaluations and investigations. Regulations regarding the development, manufacture and sale of medical products are evolving and are subject to change in the future.

If we are unable to produce the required commercial quantities of our products to meet market demand those products on a timely basis or at all, or if we fail to comply with applicable laws for the manufacturing of our products, we will suffer damage to our reputation and commercial prospects, we will lose potential revenues and we may be required to expend significant resources to resolve any such issues.

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

To successfully meet future customer demand for EXPAREL and iovera[®], 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 and/or medical devices 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.

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, iovera[®] 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, inability 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, and iovera[®] is currently manufactured at our facility in Fremont, California. These facilities are the only currently-FDA approved sites for manufacturing EXPAREL and iovera[®] 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.

Our San Diego and Fremont facilities in California and the 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, Fremont 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 or iovera[®] if there were a catastrophic event or failure of our current manufacturing systems. 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 or iovera[®] at our facility in Fremont, California could result in a disruption in the supply of EXPAREL or iovera[®] 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 undertook 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 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 inability to fulfill our commercial needs.

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

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

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

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

- significant capital expenditures;
- difficulty or inability to secure financing to fund development activities for such development, acquisition or in-licensed products or technologies;
- incurrence of substantial debt or dilutive issuances of securities to pay for development, acquisition or in-licensing of new products;
- 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 and medical device 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 or iovera° sales. Moreover, we may devote resources to potential development, acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts.

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

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

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

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, human error, unauthorized access, natural disasters, intentional acts of vandalism, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed clinical trials for EXPAREL could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability, reputation damage and harm to our business operations.

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

Our business model is to commercialize our 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 and/or medical device 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 or medical devices, which could prevent or significantly delay obtaining regulatory approval.

Prior to receiving approval to commercialize any of our drug products or medical devices, we must demonstrate with scientifically appropriate and statistically sound 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 and medical device products are prone to the risks of failure inherent in development. Clinical trials of new drug and medical device 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 products. In addition, the results of pre-clinical studies and early-stage clinical trials of our products do not necessarily predict the results of later-stage clinical trials. Later-stage clinical trials may fail to demonstrate that a product is safe and effective despite having progressed through initial clinical testing. Even if we believe the data collected from clinical trials of our 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, the FDA or other regulatory authorities 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 and medical devices. Any failure or significant delay in completing clinical trials for our drug products or medical devices, or in receiving regulatory approval for the sale of any drugs or medical devices resulting from our products, may severely harm our business and reputation. Even if we receive FDA and other regulatory approvals, our drug and medical device 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 or medical device products from the market.

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

We may rely on contract research organizations, or CROs, to perform preclinical testing and clinical trials for drug candidates that we choose to develop without a collaborator. If the CROs that we hire to perform our preclinical testing and clinical trials or our collaborators or licensees do not meet deadlines, do not follow proper procedures or a conflict arises between us and our CROs, our preclinical testing and clinical trials may take longer than expected, may be delayed or may be terminated. If we were forced to find a replacement CRO to perform any of our preclinical testing or clinical trials, we may not be able to find a suitable replacement on favorable terms, if at all. Even if we were able to find another CRO to perform a preclinical test or clinical trial, any material delay in a test or clinical trial may result in significant additional expenditures that could adversely affect our operating results. Events such as these may also delay regulatory approval for our drug candidates or our ability to commercialize our products.

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

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

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

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

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

From time to time, we are called upon to defend ourselves against lawsuits relating to our business. Due to the inherent uncertainties of litigation, we cannot accurately predict the ultimate outcome of any such proceedings. See Item 3 *Legal Proceedings* in Part I of this Annual Report. 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 have reached an agreement in principle regarding our inquiry by the United States Department of Justice for roughly \$3.5 million. If the agreement is not finalized, an ongoing investigation 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 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.

In December 2019, we reached an agreement in principle with the Department of Justice and more than one state Attorney General’s office (the “Plaintiffs”) on a proposal for a global civil settlement in the amount of \$3.5 million, subject to accrual of interest on the settlement amount from the date of the agreement in principle, negotiation of a definitive settlement agreement and other contingencies. As part of the settlement, Pacira will admit no wrongdoing and will explicitly deny the Plaintiffs’ allegations. Pacira has been given assurances that, if the parties can agree to negotiation of the settlement, this will conclude the investigation that originated from the U.S. Department of Justice subpoena in April 2015.

If a final settlement cannot be reached, and as a result of this inquiry that started with the April 2015 subpoena, 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 our products.

The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs and medical devices. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet and off-label promotion. According to these regulations, companies may not promote drugs or medical devices for “Off-label” uses—that is, uses that are not consistent with 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 or device enhancements, 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 and/or medical devices 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 and medical device 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 of the U.S. Constitution, 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 and medical devices, 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 violated 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 our product sales, and even if such actions are ultimately resolved favorably, our sales may suffer due to reputational or other concerns. We can make no assurances that we will not receive FDA warning letters in the future or be subject to other regulatory action. As noted above, any regulatory violation or allegations of a violation may have a material adverse effect on our reputation and business.

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

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

The FDA, as a condition of the EXPAREL NDA approval on October 28, 2011, has required us to study EXPAREL in pediatric patients as a post-marketing requirement. We have agreed to a trial timeline where we will study successive pediatric patient subpopulations. In December 2019, we announced positive results for our extended pharmacokinetic and safety study for local analgesia in children aged 6 to 17 undergoing cardiovascular or spine surgeries. Those positive results will provide the foundation for an sNDA. 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. 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.

For iovera[®] and any other potential medical device, we must obtain clearance or approval from the FDA or other regulatory authorities prior to introducing a new product or a modification to an existing product. The regulatory clearance process may result in substantial delays, unexpected or additional costs and other unforeseen factors and limitations on the types and uses of products we would be able to commercialize, any of which could have a material adverse effect on our business and financial condition.

In the U.S., before we are able to market a new medical device, or a new use, claim for or significant modification to an existing medical device, we generally must first receive clearance or approval from the FDA and certain other regulatory authorities. Many foreign jurisdictions outside the U.S. also require clearance, approval or compliance with certain standards before a medical device or other product can be marketed. The process of obtaining regulatory clearances and approvals to market a medical device can be costly, time consuming, involve rigorous pre-clinical and clinical testing, require changes in products or result in limitations on the indicated uses of products. There can be no assurance that these clearances and

approvals will be granted on a timely basis, if at all. In addition, once a medical device has been cleared or approved, a new clearance or approval may be required before the medical device may be modified, its labeling changed or marketed for a different use. Medical devices are cleared or approved for one or more specific intended uses and promoting a device for an off-label use could result in government enforcement action. Furthermore, a product approval or clearance can be withdrawn or limited due to unforeseen problems with the medical device or issues relating to its application. The regulatory clearance and approval process may result in, among other things, delayed, if at all, realization of product net sales, substantial additional costs and limitations on the types of products we may bring to market or their indicated uses, any one of which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

The FDA may determine that our products 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 or medical device or issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve the product. 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 and medical devices. Undesirable side effects caused by our products 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, iovera[®] 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, iovera[®] 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 our products 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 products or product enhancements, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired

future indications for our products and product candidates, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians may choose to prescribe drugs and medical devices 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.

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 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. If we are unable to manufacture EXPAREL in compliance with our highly complex specifications in the future, we may be subject to product exchanges, significant costs and charges, supply constraints 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, iovera[®] 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.

If the government or third-party payers fail to provide adequate coverage and payment rates for EXPAREL, iovera[®] or any future products, or if hospitals or ASCs 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 and ASCs 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 or ASC incurs, these sites may choose to use therapies which are less expensive when compared to our product candidates. Although hospitals and ASCs may receive separate reimbursement for EXPAREL, iovera[®] 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 and ASC 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, ASCs, 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 or medical device 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 and medical device products such as iovera^o 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 and medical device safety issues. These events have resulted in the withdrawal of drug and medical device products, revisions to labeling that further limits use of the drug and medical device products and the establishment of risk management programs that may, for example, restrict distribution of drug or medical device 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 and medical device 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 product labeling to reflect new safety information and require risk evaluation and mitigation strategies for certain drugs and medical devices, including certain currently approved drugs and medical devices. 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 or iovera^o, the indications for which these products were approved may be limited or there may be specific warnings or limitations on dosing, and our efforts to commercialize EXPAREL or iovera^o may be otherwise adversely impacted.

Risks Related to Intellectual Property

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

The active 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.

The patents and the patent applications that we have covering our iovera° products are primarily limited to specific handheld cryogenic needle devices that are cooled by a cryogen and methods for applying cryotherapy to nerve tissue using the cryogenic devices. Our market opportunity for our product candidates may be limited by gaps in patent coverage for the cryogenic devices, methods of use and other cryotherapy technology and systems that may be developed by competitors.

The iovera° cryogenic device is a compact, self-contained handheld device with a replaceable cryogen cartridge that delivers a cryogen through internal supply tubes to needle lumens of a replaceable needle probe, so as to cool the needle probe and thereby cool a surrounding target nerve tissue. We also have secured patents covering particular cryotherapy methods and pain treatments that provide what we deem to be optimal treatment using the iovera° cryogenic device.

Although we have patents that are broad enough to cover various alternative designs and methods, much of our patent coverage is tailored to cover the iovera° device and methods of use. It is thus possible that competitors may attempt to design around many of our patents. For example, we are aware of competitors developing cryogenic systems that are not self-contained handheld devices, or cryogenic systems that deliver cryotherapy through different mechanisms. It is also possible that competitors may attempt to develop and market cryotherapy devices and methods not covered by our patents, for example, basic cryotherapy treatment systems that are off-patent or cryoanalgesia for other nerve entrapment treatments.

The commercial opportunity for iovera° could be significantly harmed if competitors are able to develop and commercialize alternative designs and methods outside the scope of our patents.

Furthermore, our earliest patent family is scheduled to expire in 2025, thereby opening the door for competitors to copy some of our early technology. This early patent family is primarily focused on treating cosmetic defects that are no longer the focus of iovera°, but the underlying technology is nonetheless relevant enough for there to be appreciable overlap.

Finally, one or more third parties may challenge the patents covering the iovera° product, which could result in the invalidation or unenforceability of some or all of the relevant patent claims. Litigation or other proceedings to defend or enforce 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, iovera°, 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, medical device 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, medical device 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;
- 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, iovera[®], 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 medical devices or by covering similar technologies that affect our drug or medical device markets.

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. Our earliest patent family for iovera[®] is scheduled to expire in 2025. Once our patents covering EXPAREL and iovera[®] 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”, “iovera”, “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, iovera, 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, iovera, our DepoFoam drug delivery technology or any product candidates that we may develop, license or acquire depends upon our ability to avoid infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the general fields of pain management and cancer treatment and cover the use of numerous compounds, formulations and medical devices 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 iovera may infringe. There could also be existing patents of which we are not aware that EXPAREL or iovera 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, pharmaceutical and medical device industries, we employ individuals who were previously employed at other biotechnology, pharmaceutical and medical device 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 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 incurred net losses of \$11.0 million, \$0.5 million and \$42.6 million for the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, we had an accumulated deficit of \$399.4 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 and

iovera°. 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 and medical devices, 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 and iovera°. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

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

We anticipate incurring significant additional costs associated with the commercialization of both EXPAREL and iovera° 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 or ASC settings, conducting clinical trials, establishing outsourced manufacturing relationships and successfully manufacturing and marketing drugs and medical devices that we may develop is expensive. We may need to raise additional capital to:

- continue to fund our operations;
- continue our efforts to hire additional personnel and build a commercial infrastructure to commercialize EXPAREL and iovera°;
- qualify, outsource or build additional commercial-scale manufacturing of our products under cGMP;
- in-license and develop additional product candidates; and
- refinance our 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 and iovera°;
- the success of the commercialization of EXPAREL and iovera°;
- the cost and timing of manufacturing sufficient supplies of EXPAREL and iovera° to meet customer demand, including the cost of expanding our manufacturing facilities to produce EXPAREL and iovera°;
- the rate of progress and costs of our efforts to prepare for the submission of an NDA, sNDA or 510(k) pre-market notification 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 or a cryoanalgesic device that infringes on the various patents covering iovera°.

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, 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 and ASC demand for EXPAREL and iovera[®] and end-user buying patterns;
- maintaining our existing manufacturing facilities for EXPAREL and iovera[®], 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;
- any product liability or intellectual property infringement lawsuit in which we may become involved; and
- regulatory developments, lawsuits and investigations affecting EXPAREL, iovera[®] or the product candidates of our competitors;

If our quarterly or annual operating results fall below the expectations of our 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.

We may be unable to successfully integrate the businesses and personnel of acquired companies and businesses, and may not realize the anticipated synergies and benefits of such acquisitions.

From time to time, we may complete acquisitions of companies and certain businesses of companies, and we may not realize the expected benefits from such acquisitions because of integration difficulties or other challenges. For example, on April 9, 2019, we completed the MyoScience Acquisition.

The success of any acquisitions will depend, in part, on our ability to realize all or some of the anticipated synergies and other benefits from integrating the acquired businesses with our existing businesses. The integration process may be complex, costly and time-consuming. The potential difficulties we may face in integrating the operations of our acquisitions include, among others:

- failure to implement our business plans for the combined businesses and consolidation or expansion of production capacity as planned and where applicable;
- unexpected losses of key employees, customers or suppliers of our acquired companies and businesses;
- unanticipated issues in conforming our acquired companies' and businesses' standards, processes, procedures and controls with our operations;
- coordinating new product and process development;
- increasing the scope, geographic diversity and complexity of our operations;
- diversion of management's attention from other business concerns;
- adverse effects on our or our acquired companies' and businesses' existing business relationships;
- unanticipated changes in applicable laws and regulations;

- operating risks inherent in our acquired companies' and businesses' business and operations;
- unanticipated expenses and liabilities;
- potential unfamiliarity with our acquired companies and businesses technology, products and markets, which may place us at a competitive disadvantage; and
- other difficulties in the assimilation of our acquired companies and businesses operations, technologies, products and systems.

If MyoScience or any other acquired companies and businesses may have unanticipated or larger than anticipated liabilities for patent and trademark infringement claims, violations of laws, commercial disputes, taxes and other known and unknown types of liabilities, there may be liabilities that we underestimated or did not discover in the course of performing our due diligence investigation of our acquired companies and businesses. We may have no recourse or limited recourse under the applicable acquisition-related agreement to recover damages relating to the liabilities of our acquired companies and businesses.

We may not be able to maintain or increase the levels of revenue, earnings or operating efficiency that each of the acquired companies and businesses and us had historically achieved or might achieve separately. In addition, we may not accomplish the integration of any acquired companies and businesses smoothly, successfully or within the anticipated costs or timeframe. If we experience difficulties with the integration process or if the business of any acquired companies or businesses deteriorates, the anticipated cost savings, growth opportunities and other synergies of any acquired companies and businesses may not be realized fully or at all, or may take longer to realize than expected. If any of the above risks occur, our business, financial condition, results of operations and cash flows may be materially and adversely impacted, we may fail to meet the expectations of investors or analysts, and our stock price may decline as a result.

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 would 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 2026 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 19, 2020, 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 and iovera®;
- results of clinical trials of our products, product candidates or those of our competitors;
- changes or developments in laws or regulations applicable to our products or 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 and medical device industry by the public, legislatures, regulators and the investment community;
- 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, we completed a private placement of \$345.0 million in aggregate principal amount of our 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, 2019, our total consolidated gross indebtedness was \$345.0 million, all of which was the principal outstanding on the 2022 Notes and all of which was unsecured indebtedness. Additionally, our subsidiaries had no indebtedness (excluding trade payables, intercompany liabilities and income tax-related liabilities).

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.

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 2022 Indenture would constitute a default under the 2022 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.

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, vesting of our restricted stock units 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 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 debt securities.

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 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 dividends in the foreseeable future. Any future determination to declare or 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 EXPAREL manufacturing facility lease expires in June 2030 and our warehouse lease expires in August 2030. Our iovera^o facility in Fremont, California, consists of approximately 20,000 square feet of mixed-use manufacturing, research and development and office space, and its lease expires in December 2021. In addition, we maintain our executive offices and our commercial and business development facility in Parsippany, New Jersey, where we occupy approximately 53,000 square feet under a lease expiring in March 2028 and occupy approximately 4,000 square feet of office space in Tampa, Florida under a lease expiring in September 2021. Additionally, we have a lease beginning April 2020 for a new research and development and manufacturing facility consisting of approximately 90,000 square feet at our Science Center Campus in San Diego, California, which will replace our existing approximately 45,000 square foot research and development facility in San Diego whose lease expires in October 2020. 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 believe that our research and development and manufacturing facilities at our Science Center Campus, Thermo Fisher and Fremont 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 and iovera^o 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.

In December 2019, we reached an agreement in principle with the Department of Justice and more than one state Attorney General's office (the "Plaintiffs") on a proposal for a global civil settlement in the amount of \$3.5 million, subject to accrual of interest on the settlement amount from the date of the agreement in principle, negotiation of a definitive settlement agreement and other contingencies. As part of the settlement, Pacira will admit no wrongdoing and will explicitly deny the Plaintiffs' allegations. Pacira has been given assurances that, if the parties can agree to negotiation of the settlement, this will conclude the investigation that originated from the U.S. Department of Justice subpoena in April 2015.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

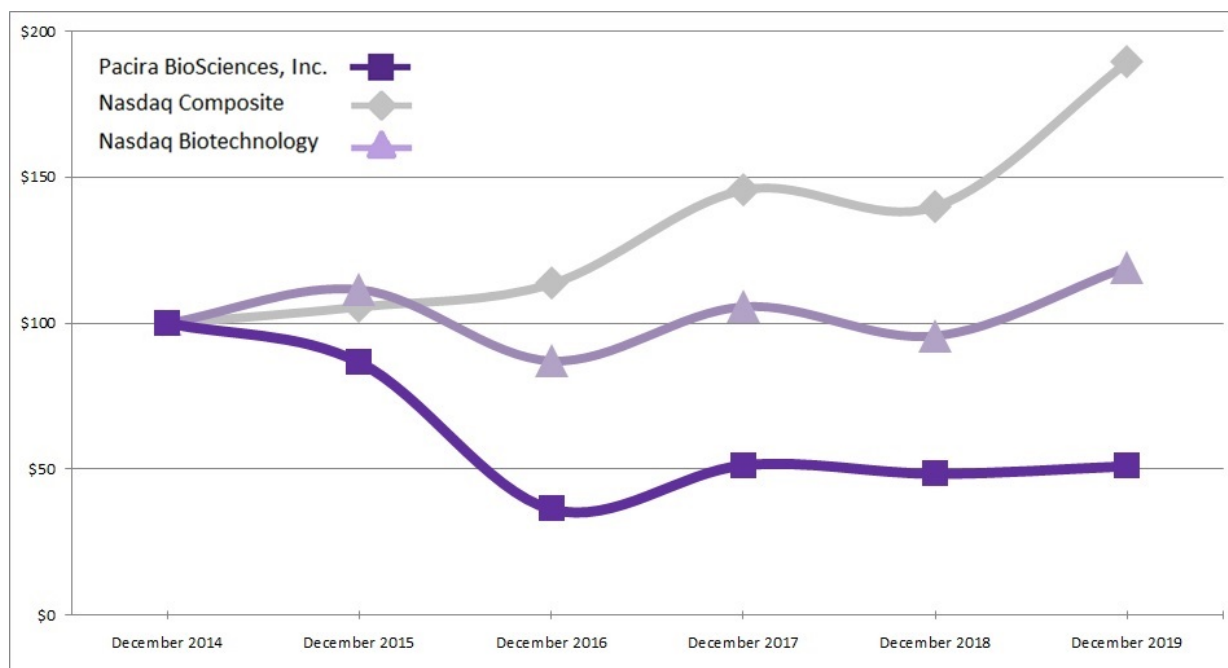
Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock is listed and traded under the ticker symbol “PCRX” on the Nasdaq Global Select Market. As of February 16, 2020, we had approximately 12 holders of record of our common stock.

Performance Graph

The following graph shows the value of an investment of \$100.00 made on December 31, 2014, in each of Pacira BioSciences, Inc. (PCRX), the Nasdaq Composite Index (^IXIC) and the Nasdaq Biotechnology Index (^NBI). The two Nasdaq 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 and the indices shown in this performance graph is not necessarily indicative of future stock price performance.

**Comparison of Five-Year Cumulative Total Returns
Among Pacira BioSciences, Inc., the Nasdaq Composite Index and the Nasdaq Biotechnology Index**



Cumulative Total Return as of December 31,

	2014	2015	2016	2017	2018	2019
Pacira BioSciences, Inc. (PCRX)	\$ 100.00	\$ 86.61	\$ 36.43	\$ 51.49	\$ 48.52	\$ 51.09
Nasdaq Composite Index (^IXIC)	\$ 100.00	\$ 105.73	\$ 113.66	\$ 145.76	\$ 140.10	\$ 189.45
Nasdaq Biotechnology Index (^NBI)	\$ 100.00	\$ 111.42	\$ 87.26	\$ 105.64	\$ 95.79	\$ 119.17

Dividend Policy

We have never declared or paid any 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 historical consolidated financial data. We have prepared this information using our audited consolidated financial statements as of and for the years ended December 31, 2019, 2018, 2017, 2016 and 2015. The following consolidated financial data should be read in conjunction with our consolidated financial statements and related notes and Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in this report.

	Year Ended December 31,				
	2019 ^A	2018	2017	2016	2015
Consolidated Statements of Operations Data					
(In thousands, except per share data)					
Revenues:					
Net product sales	\$ 418,926	\$ 332,427	\$ 284,342	\$ 270,073	\$ 244,487
Collaborative licensing and milestone revenue	—	3,000	387	3,426	1,426
Royalty revenue	2,100	1,850	1,901	2,872	3,084
Total revenues	<u>421,026</u>	<u>337,277</u>	<u>286,630</u>	<u>276,371</u>	<u>248,997</u>
Operating expenses:					
Cost of goods sold	106,712	86,845	87,915	110,104 ^E	71,837
Research and development	72,119	55,688	57,290	45,678	28,662
Selling, general and administrative	200,782	177,265	161,494	152,613 ^F	139,043
Amortization of acquired intangible assets	5,703	—	—	—	—
Acquisition-related charges, product discontinuation and other	25,230 ^B	1,564 ^C	4,868 ^D	—	—
Total operating expenses	<u>410,546</u>	<u>321,362</u>	<u>311,567</u>	<u>308,395</u>	<u>239,542</u>
Income (loss) from operations	<u>10,480</u>	<u>15,915</u>	<u>(24,937)</u>	<u>(32,024)</u>	<u>9,455</u>
Other (expense) income:					
Interest income	7,376	6,497	4,078	1,323	678
Interest expense	(23,628)	(21,949)	(18,047)	(7,061)	(7,725)
Loss on early extinguishment of debt	—	—	(3,732)	—	(52)
Royalty interest obligation	—	—	—	—	(71)
Other, net	(4,976)	(888)	167	(82)	(165)
Total other expense, net	<u>(21,228)</u>	<u>(16,340)</u>	<u>(17,534)</u>	<u>(5,820)</u>	<u>(7,335)</u>
Income (loss) before income taxes	<u>(10,748)</u>	<u>(425)</u>	<u>(42,471)</u>	<u>(37,844)</u>	<u>2,120</u>
Income tax expense	(268)	(46)	(140)	(105)	(264)
Net income (loss)	<u>\$ (11,016)</u>	<u>\$ (471)</u>	<u>\$ (42,611)</u>	<u>\$ (37,949)</u>	<u>\$ 1,856</u>
Net income (loss) per share:					
Basic net income (loss) per common share	\$ (0.27)	\$ (0.01)	\$ (1.07)	\$ (1.02)	\$ 0.05
Diluted net income (loss) per common share	\$ (0.27)	\$ (0.01)	\$ (1.07)	\$ (1.02)	\$ 0.04
Weighted average common shares outstanding:					
Basic	41,513	40,911	39,806	37,236	36,540
Diluted	41,513	40,911	39,806	37,236	41,301

A - We completed the MyoScience, Acquisition on April 9, 2019. The acquisition was accounted for using the acquisition method of accounting and, accordingly, the assets acquired, liabilities assumed and results of operations of the acquired business are included in our consolidated financial statements from the date of acquisition through December 31, 2019.

B - Includes charges of \$21.6 million related to the MyoScience Acquisition. Of this total, \$16.7 million represents increases in the fair value of contingent consideration resulting from the achievement of regulatory milestones and revised commercial forecasts (which are tied to potential future milestone payments), \$4.2 million represents advisory costs, including legal, financial, accounting and tax services. The remaining \$0.7 million represents separation costs, asset write-downs and other restructuring charges. Charges of \$0.2 million were recorded related to the discontinuation of our DepoCyt(e) manufacturing activities for lease costs, asset retirement obligations and other estimated exit costs. Additionally, this includes a charge of \$3.5 million related to an agreement in principle with the U.S. Department of Justice on a proposal for a global civil settlement related to an April 2015 inquiry. For further discussion of these charges, see Note 5, *MyoScience Acquisition*, Note 18, *Acquisition-Related Charges and Product Discontinuation, Net* and Note 21, *Commitments and Contingencies*, to our consolidated financial statements included herein.

C - Represents 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 were not 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 18, *Acquisition-Related Charges and Product Discontinuation, Net*, to our consolidated financial statements included herein.

D - Represents 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 18, *Acquisition-Related Charges and Product Discontinuation, Net*, to our consolidated financial statements included herein.

E - 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.

F - Includes a \$7.1 million contract termination charge due to CrossLink Bioscience, LLC.

	December 31,				
	2019 ^A	2018	2017	2016	2015
Consolidated Balance Sheet Data	(In thousands)				
Cash and cash equivalents, short-term and long-term investments	\$ 356,748	\$ 409,325	\$ 371,394	\$ 172,597	\$ 172,427
Working capital	300,884	417,308	334,893	198,251	102,794
Total assets	831,065	689,353	628,371	391,466	387,735
Long-term liabilities	368,448	307,466	292,671	127,652	19,555
Accumulated deficit	(399,398)	(388,226)	(389,136)	(346,238)	(308,289)
Total stockholders' equity	354,944	321,226	279,483	218,976	218,392

A - We completed the MyoScience Acquisition on April 9, 2019. The acquisition was accounted for using the acquisition method of accounting and, accordingly, the assets acquired, liabilities assumed and results of operations of the acquired business are included in our consolidated financial statements from the date of acquisition through December 31, 2019.

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, or GAAP, and in accordance with the rules and regulations of the United States Securities and Exchange Commission, or SEC. We operate and report our financial information in one segment. 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. 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, our actual results may differ materially from those anticipated in these forward-looking statements.

This section of this Annual Report discusses year-to-year comparisons between 2019 and 2018, as well as other discussions of 2019 and 2018 items. We have omitted discussion of the year ended December 31, 2017 (the earliest of the three years covered by our consolidated financial statements presented in this report) as permitted by the SEC's recent amendments to Regulation S-K. The complete Management's Discussion and Analysis of Financial Condition and Results of Operations for year-to-year comparisons between 2018 and 2017 and other discussions of 2017 items can be found within Part II, Item 7, [to our Annual Report filed with the SEC on February 28, 2019](#).

Overview

Pacira is a leading provider of non-opioid pain management options to advance and improve outcomes for health care practitioners and their patients. Our long-acting, local analgesic EXPAREL[®] (bupivacaine liposome injectable suspension) was commercially launched in April 2012. EXPAREL utilizes DepoFoam[®], a unique and proprietary delivery technology that encapsulates drugs without altering their molecular structure and releases them over a desired period of time. 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. Since its initial approval in 2011 for single-dose infiltration, more than six 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. In April 2019, we acquired iovera[®], a handheld cryoanalgesia device used to deliver a precise, controlled application of cold temperature only to targeted nerves,

which we sell directly to end users. The iovera^o system is highly complementary to EXPAREL as a non-opioid therapy that alleviates pain by disrupting pain signals being transmitted to the brain from the site of injury or surgery.

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

Recent Highlights

- In December 2019, we announced positive results from our Phase 3 PLAY study of EXPAREL administered as a single-dose infiltration in pediatric patients undergoing spinal or cardiac surgeries. Overall findings were consistent with the pharmacokinetic and safety profiles for adult patients with no safety concerns identified at a dose of 4 mg/kg. These results will provide the foundation for our sNDA submission in the first half of 2020 to the FDA seeking expansion of the EXPAREL label to include children aged six and over.
- In January 2020, we announced a collaboration with Envision Physician Services to train anesthesiology clinicians on ultrasound-guided regional anesthesia techniques utilizing long-acting local anesthetics like EXPAREL via a series of interactive workshops held across the country. The program supports ongoing efforts by both organizations to advance the delivery of high-quality, patient-centered care.
- In January 2020, we announced positive results from our Phase 4 opioid-free CHOICE study of EXPAREL in patients undergoing C-section. The study achieved its primary endpoint with a statistically significant reduction in total postsurgical opioid consumption while maintaining pain scores through 72 hours ($p \leq 0.001$). EXPAREL demonstrated statistical significance for the key secondary endpoint of a reduction in the incidence and severity of itching for 72 hours after surgery ($p \leq 0.05$). Full study results will be submitted for publication in the peer-reviewed medical literature later this year.

Results of Operations

Comparison of the Years Ended December 31, 2019 and 2018

Revenues

Net product sales consist of sales of EXPAREL in the U.S., our bupivacaine liposome injectable suspension to Aratana Therapeutics, Inc., or Aratana, for veterinary use in the U.S., and sales of iovera^o in the U.S. 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,		% Increase / (Decrease)
	2019	2018	
Net product sales:			
EXPAREL	\$ 407,877	\$ 331,112	23 %
Bupivacaine liposome injectable suspension	3,153	1,315	100% +
Total EXPAREL / bupivacaine liposome injectable suspension net product sales	411,030	332,427	24 %
iovera ^o	7,896	—	N/A
Total net product sales	418,926	332,427	26 %
Collaborative licensing and milestone revenue	—	3,000	(100)%
Royalty revenue	2,100	1,850	14 %
Total revenues	<u>\$ 421,026</u>	<u>\$ 337,277</u>	25 %

EXPAREL revenue grew 23% in 2019 compared to 2018, primarily due to an increase in net product sales of EXPAREL units of 27% and a 3% increase in gross selling price per unit, partially offset 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 which has resulted in rapid adoption among anesthesiologists, 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 these factors 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. In 2019, there was also an increase in sales of our bupivacaine liposome injectable suspension to Aratana for veterinary use.

As part of the MyoScience Acquisition, we acquired iovera°. Net product sales of iovera° were \$7.9 million for the year ended December 31, 2019 (attributable to the post-closing period of April 10, 2019 to December 31, 2019). Thus far, we have seen the greatest iovera° demand as pain relief for patients in advance of TKA procedures and in chronic pain management, particularly for people with mild to severe osteoarthritis of the knee.

Collaborative licensing and milestone revenue decreased 100% in 2019 versus 2018 due to a \$3.0 million upfront payment earned in June 2018 under a license agreement with Nuance Biotech Co. Ltd. for the development and commercialization of EXPAREL in China.

In both 2019 and 2018, royalty revenue reflected royalties earned on sales to Aratana. Royalty revenue increased 14% in 2019 versus 2018.

Cost of Goods Sold

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

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

	Year Ended December 31,		% Increase / (Decrease)
	2019	2018	
Cost of goods sold	\$ 106,712	\$ 86,845	23%
Gross margin	75%	74%	

Gross Margin increased by one percentage point in 2019 versus 2018. In 2019, EXPAREL gross margins increased as a result of completing our capacity expansion project for the commercial production of EXPAREL at our custom manufacturing suite in Swindon, England (under our partnership with Thermo Fisher Scientific Pharma Services, or Thermo Fisher). This increase was partially offset as a result of the lower gross margin of iovera°.

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 for EXPAREL and stock-based compensation expense. Clinical and preclinical development expenses include costs for clinical personnel, clinical trials performed by third-parties, toxicology studies, materials and supplies, database management and other third-party fees. Product development and manufacturing capacity expansion expenses include development costs for our products, which include personnel, equipment, materials and contractor costs for process development and product candidates, development costs related to significant scale-ups of our manufacturing capacity and facility costs for our research space. Regulatory and other expenses include regulatory activities related to unapproved products and indications, medical information expenses and related personnel. 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,		% Increase / (Decrease)
	2019	2018	
Clinical and preclinical development	\$ 31,055	\$ 18,630	67%
Product development and manufacturing capacity expansion	29,724	28,454	4%
Regulatory and other	6,226	4,670	33%
Stock-based compensation	5,114	3,934	30%
Total research and development expense	<u>\$ 72,119</u>	<u>\$ 55,688</u>	30%
% of total revenue	17%	17%	

Total research and development expense increased 30% in 2019 versus 2018. The 67% increase in clinical and preclinical development expense in 2019 versus 2018 was primarily related to completed enrollment in our Phase 3 Pediatric (“PLAY”) clinical trial and our Phase 4 Opioid Free C-Section (“CHOICE”) clinical trial and initial enrollment in our Phase 4 Spine (“FUSION”) clinical trial. There was also increased investment in investigator-initiated studies, toxicology studies, as well as increased costs related to our global expansion activities for EXPAREL.

Product development and manufacturing capacity expansion expense increased 4% in 2019 versus 2018 due to increased spend in EXPAREL support for in vitro release testing, a significant scale-up of our manufacturing capacity for EXPAREL in Swindon, England in partnership with Thermo Fisher and Iovera[®] development costs to improve the functionality of the device and enhance the Iovera[®] product line.

Regulatory and other expense increased 33% in 2019 versus 2018 due to activities related to our European Marketing Authorization Application (MAA) and Health Canada submissions for EXPAREL and the dissemination and publication of EXPAREL data in response to medical information queries.

Stock-based compensation increased 30% in 2019 versus 2018 primarily due to an increase in personnel as well as the number of awards granted during 2019 and the fourth quarter of 2018.

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 and Iovera[®], expenses related to communicating the 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,		% Increase / (Decrease)
	2019	2018	
Sales and marketing	\$ 129,663	\$ 107,106	21%
General and administrative	47,248	46,846	1%
Stock-based compensation	23,871	23,313	2%
Total selling, general and administrative expenses	<u>\$ 200,782</u>	<u>\$ 177,265</u>	13%
% of total revenue	48%	53%	

Total selling, general and administrative expenses increased 13% in 2019 versus 2018.

Sales and marketing expenses increased 21% in 2019 versus 2018. In 2019, the increases were driven by additional selling and promotional activities to support the growth of EXPAREL, including growing a team in the field consisting of account managers focused on the outpatient market, initiatives and commissions related to our co-promotion agreement with

DePuy Synthes and additional marketing spend for the launch of ambulatory and dental reimbursement codes, which became effective on January 1, 2019. We are continuing our marketing investment in EXPAREL—including educational initiatives and programs related to the impact of opioids and postsurgical pain management, our national advocacy campaign designed to educate patients about non-opioid treatment options and initiatives surrounding women’s health, especially related to C-section. Additionally, in 2019 we invested in marketing initiatives and customer outreach for iovera^o as a result of the MyoScience Acquisition.

General and administrative expenses increased 1% in 2019 versus 2018. The increase was primarily due to additional CryoTech expenditures after the MyoScience acquisition in April 2019, partially offset by a decrease in legal expenditures.

Stock-based compensation increased 2% in 2019 versus 2018, primarily due to an increase in personnel and the number of equity awards granted.

Amortization of Acquired Intangible Assets

The following table provides a summary of the amortization of acquired intangible assets during the periods indicated, including percent changes (dollar amounts in thousands):

	Year Ended December 31,		% Increase / (Decrease)
	2019	2018	
Amortization of acquired intangible assets	\$ 5,703	\$ —	N/A

As part of the MyoScience Acquisition we acquired intangible assets consisting of developed technology and customer relationships, with estimated useful lives of 14 and 10 years, respectively. Beginning in the second quarter of 2019, these are being amortized on a straight-line basis. For more information, see Note 9, *Goodwill and Intangible Assets*, to our consolidated financial statements included herein.

Acquisition-Related Charges, Product Discontinuation and Other

The following table provides a summary of the costs related to the MyoScience Acquisition, our DepoCyt(e) discontinuation and other activities during the periods indicated, including percent changes (dollar amounts in thousands):

	Year Ended December 31,		% Increase / (Decrease)
	2019	2018	
Acquisition-related charges	\$ 21,571	\$ —	N/A
Product discontinuation	159	1,564	(90)%
Other	3,500	—	N/A
Total acquisition-related charges, product discontinuation and other	<u>\$ 25,230</u>	<u>\$ 1,564</u>	100% +

In 2019, we recognized charges of \$21.6 million related to the MyoScience Acquisition. Of this total, \$16.7 million represents increases in the fair value of contingent consideration resulting from the achievement of regulatory milestones and revised commercial forecasts (which are tied to potential future milestone payments) and \$4.2 million represents advisory costs, including legal, financial, accounting and tax services. The remaining \$0.7 million represents separation costs, asset write-downs and other restructuring charges. We did not incur any acquisition-related charges in 2018.

In 2019 and 2018, we recorded charges of \$0.2 million and \$1.6 million, respectively, 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 represented additional lease and facility costs due to the fact that we were not able to sub-lease the property where DepoCyt(e) was manufactured considering the short period of time remaining on our existing lease.

In 2019, we recorded a charge of \$3.5 million related to reaching an agreement in principle with the U.S. Department of Justice on a proposal for a global civil settlement, related to an April 2015 inquiry. For more information, see Note 21, *Commitments and Contingencies*, to our consolidated financial statements included herein.

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,		% Increase / (Decrease)
	2019	2018	
Interest income	\$ 7,376	\$ 6,497	14%
Interest expense	(23,628)	(21,949)	8%
Other, net	(4,976)	(888)	100% +
Total other expense, net	<u>\$ (21,228)</u>	<u>\$ (16,340)</u>	30%

Total other expense, net increased 30% in 2019 versus 2018, primarily due to a \$5.7 million impairment of our equity investment in TELA Bio, Inc., or TELA Bio, (net of the receipt of a non-cash stock dividend) due to its decreased market value. 2018 included a \$0.9 million loss on an unexercised purchase option related to the investment (see Note 12, *Financial Instruments*, to our consolidated financial statements for further discussion). There was also more amortization of the discount on our 2.375% convertible senior notes due 2022, or 2022 Notes, and the absence of capitalized interest related to the completion of our first manufacturing suite in Swindon, England in 2018. The increase in other expense, net was partially offset by an increase in interest income due to higher overall returns on our investments and other non-operating income in 2019.

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,		% Increase / (Decrease)
	2019	2018	
Income tax expense	\$ 268	\$ 46	100% +
Effective tax rate	(2)%	(11)%	

We recorded a tax provision of \$0.3 million for the year ended December 31, 2019 and less than \$0.1 million for the year ended December 31, 2018. The tax provision for the year ended December 31, 2019 consists primarily of \$1.1 million of state income taxes in jurisdictions where the availability of carryforward losses are either limited or fully utilized as well as \$1.0 million of state taxes on the one-time gain from the deemed sale of assets resulting from a tax election pursuant to Internal Revenue Code (IRC) section 338(g) made by us related to the MyoScience Acquisition. This was partially offset by a \$1.8 million reduction in our valuation allowance on our deferred tax assets due to the MyoScience Acquisition. No federal taxes resulted from the tax election given there were sufficient net operating loss, or NOL, carryforwards. The tax provision for the year ended December 31, 2018 consists principally of minimum state taxes. No federal current tax expense was recorded for 2019 or 2018 due to NOLs carried forward and the repeal of the corporate minimum tax. The utilization of our NOLs has not resulted in any federal deferred tax expense because of a full valuation allowance recorded against the NOLs.

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, 2019, we had an accumulated deficit of \$399.4 million, cash and cash equivalents, short-term and long-term investments of \$356.7 million and working capital of \$300.9 million.

Summary of Cash Flows

The following table summarizes our cash flows from operating, investing and financing activities for the years ended December 31, 2019 and 2018 (in thousands):

Consolidated Statement of Cash Flows Data:	Year Ended December 31,	
	2019	2018
Net cash provided by (used in):		
Operating activities	\$ 70,520	\$ 48,870
Investing activities	(128,488)	20,576
Financing activities	3,670	8,954
Net (decrease) increase in cash and cash equivalents	\$ (54,298)	\$ 78,400

Operating Activities

In 2019, net cash provided by operating activities was \$70.5 million compared to \$48.9 million in 2018. The increase of \$21.7 million was primarily attributable to a 23% increase in net product sales of EXPAREL. This increase was partially offset by increased sales commissions related to our co-promotion agreement with DePuy Synthes, costs to grow our sales and marketing teams focused on the outpatient market, the launch of ambulatory and dental reimbursement codes for EXPAREL effective January 1, 2019, an increase in marketing initiatives related to women's health, transaction and other costs related to the MyoScience Acquisition and investments in marketing initiatives to grow the reach of iovera[®]. We also made a \$5.3 million payment to Mundipharma International Corporation Limited and Mundipharma Medical Company to settle claims stemming from the June 2017 discontinuation of DepoCyt(e).

Investing Activities

In 2019, net cash used in investing activities was \$128.5 million, which reflected cash used to fund the MyoScience Acquisition of \$117.7 million (net of \$1.3 million of cash acquired), purchases of fixed assets of \$10.2 million and an additional \$1.6 million investment in TELA Bio, partially offset by \$1.0 million of short-term and long-term investment maturities (net of purchases). 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 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 and facility upgrades at our Science Center Campus in San Diego, California.

Financing Activities

In 2019, net cash provided by financing activities was \$3.7 million, which consisted of proceeds from the exercise of stock options of \$8.5 million and \$2.4 million from the issuance of shares through our ESPP, partially offset by \$6.6 million of contingent consideration payments made to MyoScience securityholders and \$0.6 million of payments made to retire our 3.25% convertible senior notes due 2019.

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.

Equity Financings

From our inception through December 31, 2019, 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, 2019, the outstanding principal on the 2022 Notes was \$345.0 million.

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, 2019 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 11, *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 and 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 20, 2021. 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 costs of successfully integrating MyoScience (now known as Pacira CryoTech) into our existing business and expanding the commercialization of iovera[®];
- the cost and timing of expanding our manufacturing facilities for EXPAREL and other product candidates, including the construction of an additional manufacturing suite at Thermo Fisher's facility in Swindon, England;
- the cost and timing of potential milestone payments to MyoScience security holders, which could be up to an aggregate of \$73.0 million if certain regulatory and commercial milestones are met, which includes two milestone payments totaling \$15.0 million to be paid in the first half of 2020;
- 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 the United Kingdom, France, Germany, Italy or Spain;
- the timing of and extent to which the holders of our 2022 Notes elect to convert their notes;
- 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 of performing additional clinical trials for iovera[®];
- 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.

Contractual Obligations

The table below presents a summary of our contractual obligations as of December 31, 2019 (in thousands):

Contractual Obligations ⁽¹⁾	Payments Due by Period				
	Total	Less Than One Year	1-3 Years	3-5 Years	More Than 5 Years
Convertible senior notes - principal ⁽²⁾	\$ 345,000	\$ —	\$ 345,000	\$ —	\$ —
Convertible senior notes - interest	20,484	8,194	12,290	—	—
Lease obligations ⁽³⁾	115,208	10,382	21,076	21,677	62,073
Purchase obligations ⁽⁴⁾	25,795	8,692	17,103	—	—
Achieved milestone payments ⁽¹⁾	15,000	15,000	—	—	—
Total	\$ 521,487	\$ 42,268	\$ 395,469	\$ 21,677	\$ 62,073

(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 collected, including EXPAREL, reach \$500.0 million (measured on a rolling quarterly basis) and \$4.0 million upon the first commercial sale in the United Kingdom, France, Germany, Italy or Spain. This contingency is described further in Note 9, *Goodwill and Intangible Assets*, to our consolidated financial statements included herein. This table also does not include potential future milestone payments to MyoScience shareholders which could be up to an aggregate of \$58.0 million if certain regulatory and commercial milestones are met. However, the table above includes two achieved milestone payments totaling \$15.0 million to be paid in the first half of 2020. This contingency is described further in Note 5, *MyoScience Acquisition*, 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 April 2022 maturity of our 2022 Notes. See Note 11, *Debt*, to our consolidated financial statements included herein for further discussion. Additionally, it excludes any conversion premium on the 2022 Notes, which may be settled in cash or stock at our discretion. The 2022 Notes were not convertible as of December 31, 2019.

(3) The amounts consist of operating leases for our corporate headquarters in Parsippany, New Jersey, manufacturing, research and development and warehouse space in San Diego, California and Fremont, California and office space in Tampa, Florida. 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.

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

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 GAAP in the U.S. The preparation of these financial statements requires us to make estimates that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, contingent consideration, 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 iovera^o in the U.S.; (iii) sales of and royalties on sales of our bupivacaine liposome injectable suspension product for veterinary use in the U.S. and (iv) license fees and milestone payments. We do not consider revenue from sources other than sales of EXPAREL to be material sources of our consolidated revenue.

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.

Acquisitions

In a business combination, the acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded as of the date of the acquisition at their respective fair values with some exceptions. Assets acquired and liabilities assumed in a business combination that arise from contingencies are generally recognized at fair value. If fair value cannot be determined, the asset or liability is recognized if probable and reasonably estimable; if these criteria are not met, no asset or liability is recognized. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Any excess of the purchase price (consideration transferred) over the estimated fair values of net assets acquired is recorded as goodwill. Transaction costs and costs to restructure the acquired company are expensed as incurred. The operating results of the acquired business are reflected in our consolidated financial statements after the date of the acquisition.

Contingent Consideration

Subsequent to an acquisition, we measure contingent consideration arrangements at fair value for each period with changes in fair value recognized in the consolidated statements of operations as acquisition-related charges. Changes in contingent consideration can result from changes in the assumed achievement and timing of estimated sales, costs of goods sold and regulatory approvals. In the absence of new information, changes in fair value reflect the passage of time towards achievement of the milestones, and are accrued based on an accretion schedule.

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

Other than one lease agreement for which there are future obligations but the lease has not yet commenced, we do not have any material off-balance sheet arrangements as of December 31, 2019, 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.

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, 2019 by \$1.8 million.

We have an equity investment in the common stock of TELA Bio (traded on the Nasdaq Global Select Market under the ticker symbol "TELA"). Changes in the stock price of TELA Bio will affect the value of our investment, and we could incur impairment losses or realized losses on all or a part of the value of this investment. At December 31, 2019, the value of our investment in TELA Bio was \$10.0 million. A hypothetical 10% decrease in the market price of TELA Bio stock would have caused a decrease in our carrying amount by \$1.0 million. See Note 12, *Financial Instruments*, to our consolidated financial statements for additional information on our investment in TELA Bio.

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, 2019, the estimated fair value of the 2022 Notes was \$1,044 per \$1,000 principal amount. See Note 11, *Debt*, to our consolidated financial statements for additional information on the 2022 Notes. At December 31, 2019, 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 primarily 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 report of our independent registered public accounting firm, appear on pages F-1 through F-41 of this Annual Report.

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.

On April 9, 2019, we acquired MyoScience (now Pacira CryoTech, Inc., or CryoTech). As such, the scope of our assessment of the effectiveness of our disclosure controls and procedures did not include the internal control over financial reporting of CryoTech. These exclusions are consistent with the SEC Staff's guidance that an assessment of a recently acquired business may be omitted from the scope of our assessment of the effectiveness of disclosure controls and procedures that are also part of internal control over financial reporting in the 12 months following the acquisition. CryoTech accounted for 1% of our total assets and 2% of our total revenue as of and for the year ended December 31, 2019.

Based on their evaluation as of December 31, 2019, our Chief Executive Officer and Chairman and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2019.

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, 2019, 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, 2019.

The effectiveness of our internal control over financial reporting as of December 31, 2019 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, 2019.

Changes in Internal Control over Financial Reporting

As a result of the MyoScience Acquisition, we have commenced a project to evaluate the processes and procedures of CryoTech's internal control over financial reporting and incorporate CryoTech's internal control over financial reporting into our internal control over financial reporting framework. In addition, as a result of the MyoScience Acquisition, we have implemented new processes and controls over accounting for an acquisition, including determining the fair value of the assets acquired, liabilities assumed and adjustments to the fair value of contingent consideration. Except for the activities described above, there have been no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on Internal Control Over Financial Reporting

We have audited Pacira BioSciences, Inc. and subsidiaries' (the Company) internal control over financial reporting as of December 31, 2019, 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, 2019, 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, 2019 and 2018, and 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, 2019, and related notes (collectively, the consolidated financial statements), and our report dated February 20, 2020 expressed an unqualified opinion on those consolidated financial statements.

The Company acquired MyoScience, Inc. (now Pacira CryoTech, Inc.) during 2019, and management excluded from its assessment of the effectiveness of the Company's internal control over financial reporting as of December 31, 2019, Pacira CryoTech Inc.'s internal control over financial reporting associated with 1% of total assets and 2% of total revenues included in the consolidated financial statements of the Company as of and for the year ended December 31, 2019. Our audit of internal control over financial reporting of the Company also excluded an evaluation of the internal control over financial reporting of Pacira CryoTech, Inc.

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 20, 2020

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 2020 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 2020 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*Securities Authorized For Issuance Under Equity Compensation Plans*

The following table sets forth certain information, as of December 31, 2019, concerning shares of our common stock authorized for issuance under our equity compensation plans. We have two equity compensation plans under which shares are currently authorized for issuance, our Amended and Restated 2011 Stock Incentive Plan (the "2011 Plan") and our 2014 Employee Stock Purchase Plan (the "2014 ESPP"). We also maintain our 2007 Stock Incentive Plan ("2007 Plan"), however, no additional awards may be issued under the 2007 Plan. The 2007 Plan, the 2011 Plan and the 2014 ESPP were approved by stockholders. In April 2014, our board of directors adopted (without stockholder approval) the 2014 Inducement Plan, which authorized 175,000 shares of common stock to be granted as equity awards to new employees.

	(a)	(b)	(c)
	Number of Securities to be Issued Upon Exercise of Outstanding Options and Rights ^{(1) (2)}	Weighted Average Exercise Price of Outstanding Options and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) ⁽¹⁾
Equity compensation plans approved by stockholders ⁽³⁾	6,675,848	\$ 42.70	2,884,136
Equity compensation plans not approved by stockholders ⁽³⁾	30,530	\$ 64.21	138,424
Total equity compensation plans	6,706,378	\$ 42.80	3,022,560

(1) Awards issuable under our 2011 Plan include common stock, stock options, restricted stock, restricted stock units and other incentive awards.

(2) Does not include 631,141 unvested shares outstanding as of December 31, 2019 in the form of restricted stock units under our 2011 Plan, which do not require the payment of any consideration by the recipients.

(3) See Note 14, *Stock Plans*, to our consolidated financial statements included herein for further descriptions of our equity compensation plans.

Other information required by this item will be included in the proxy statement for our 2020 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 2020 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 2020 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.

EXHIBIT INDEX

Exhibit Number	Description	Incorporation By Reference From		
		Form	Exhibit	Date Filed
2.1†	Agreement and Plan of Merger, dated March 4, 2019, by and among Pacira Pharmaceuticals, Inc., PS Merger, Inc., MyoScience, Inc., and Fortis Advisors LLC, as the securityholders' representative. #	8-K	2.1	3/5/2019
3.1	Amended and Restated Certificate of Incorporation.	8-K	3.1	2/11/2011
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation, dated April 9, 2019.	8-K	3.1	4/9/2019
3.3	Second Amended and Restated Bylaws.	8-K	3.2	4/9/2019
4.1	Specimen Certificate Evidencing Shares of Common Stock.	10-Q	4.1	5/2/2019
4.2	Indenture (including form of 2022 Notes), dated March 13, 2017, between the Registrant and Wells Fargo Bank, National Association, as trustee.	8-K	4.1	3/13/2017
4.3	Description of Securities*			
10.1	Second Amended and Restated 2007 Stock Option/Stock Issuance Plan.***	S-1	10.1	11/1/2010
10.2	Form of Stock Option Agreement under the Second Amended and Restated 2007 Stock Option/Stock Issuance Plan.***	S-1	10.1	11/1/2010
10.3	Assignment Agreement, dated February 9, 1994, amended April 15, 2004, between the Registrant and Research Development Foundation.	S-1/A	10.4	12/3/2010
10.4	Stock Purchase Agreement, dated January 8, 2007, between SkyePharma, Inc. and the Registrant.	S-1/A	10.5	12/3/2010
10.5	Employment Agreement between the Registrant and David Stack.***	S-1/A	10.21	12/3/2010
10.6	Amendment No. 1 to Executive Employment Agreement, dated March 13, 2013, between the Registrant and David Stack.***	8-K	99.3	3/18/2013
10.7	Amendment No. 2 to Executive Employment Agreement, dated June 30, 2015, between the Registrant and David Stack.***	10-Q	10.2	7/30/2015
10.8	Employment Agreement, dated November 29, 2012, between the Registrant and Kristen Williams.***	10-Q	10.2	4/30/2015
10.9	Amendment No. 1 to Employment Agreement, dated March 13, 2013, between the Registrant and Kristen Williams.***	10-Q	10.3	4/30/2015
10.10	Amendment No. 2 to Employment Agreement, dated June 30, 2015, between the Registrant and Kristen Williams.***	10-Q	10.5	7/30/2015
10.11	Executive Employment Agreement, dated May 2, 2016, between the Registrant and Charles A. Reinhart, III.***	10-Q	10.1	8/4/2016
10.12	Executive Employment Agreement, dated March 13, 2013, between the Registrant and Richard Scranton, M.D.***	10-Q	10.1	8/2/2018
10.13	Amendment No. 1 to Executive Employment Agreement, dated June 30, 2015, between the Registrant and Richard Scranton, M.D.***	10-Q	10.2	8/2/2018
10.14	Form of Indemnification Agreement between the Registrant and its directors and officers.***	S-1/A	10.32	1/13/2011
10.15†	Commercial Outsourcing Services Agreement entered into as of August 25, 2011 by the Registrant and Integrated Commercialization Solutions, Inc.	10-Q	10.1	8/25/2011
10.16†	First Amendment to Commercial Outsourcing Services Agreement, dated August 1, 2013, between the Registrant and Integrated Commercialization Solutions, Inc.	10-Q	10.1	10/31/2013
10.17†	Second Amendment to Commercial Outsourcing Services Agreement, dated August 25, 2014, between the Registrant and Integrated Commercialization Solutions, Inc.	10-Q	10.1	10/30/2014
10.18†	Third Amendment to Commercial Outsourcing Services Agreement, dated April 29, 2015, between the Registrant and Integrated Commercialization Solutions, Inc.	10-Q	10.1	7/30/2015
10.19	Amended and Restated 2011 Stock Incentive Plan.***	10-Q	10.1	8/8/2019
10.20	Form of Nonstatutory Stock Option Agreement under the Amended and Restated 2011 Stock Incentive Plan.***	8-K	10.3	6/4/2014

Exhibit Number	Description	Incorporation By Reference From		
		Form	Exhibit	Date Filed
10.21	Form of Restricted Stock Unit Award Agreement (Employees) under the Amended and Restated 2011 Stock Incentive Plan.***	10-Q	10.6	7/30/2015
10.22	Form of Restricted Stock Unit Award Agreement (Non-Employee Directors) under the Amended and Restated 2011 Stock Incentive Plan.***	10-Q	10.7	7/30/2015
10.23	License, Development and Commercialization Agreement, dated December 5, 2012 between the Registrant and Aratana Therapeutics, Inc.	10-K	10.47	3/7/2013
10.24	Supply Agreement, dated December 5, 2012 between the Registrant and Aratana Therapeutics, Inc.	10-K	10.48	3/7/2013
10.25	2014 Inducement Plan.***	10-Q	10.1	5/1/2014
10.26	2014 Employee Stock Purchase Plan.***	8-K	10.2	6/4/2014
10.27†	Strategic Co-Production Agreement dated April 4, 2014, by and between the Registrant and Patheon UK Limited.	10-Q	10.1	7/31/2014
10.28†	Manufacturing and Supply Agreement dated April 4, 2014, by and between the Registrant and Patheon UK Limited.	10-Q	10.2	7/31/2014
10.29†	Technical Transfer and Service Agreement dated April 4, 2014, by and between the Registrant and Patheon UK Limited.	10-Q	10.3	7/31/2014
10.30	Amended and Restated Consulting Agreement, dated April 3, 2012, between the Registrant and Gary Pace.***	10-Q	10.1	5/9/2012
10.31	Second Amended and Restated Consulting Agreement, dated August 17, 2012, between the Registrant and Gary Pace.***	10-Q	10.1	11/1/2012
10.32	Third Amendment to Consulting Agreement, dated September 11, 2013, between the Registrant and Gary Pace.***	10-Q	10.3	10/31/2013
10.33	Fourth Amendment to Consulting Agreement, dated November 25, 2015, between the Registrant and Gary Pace.***	10-K	10.57	2/25/2016
10.34†	Co-Promotion Agreement, dated January 24, 2017, between the Registrant and DePuy Synthes Sales, Inc.	10-Q	10.1	5/4/2017
10.35	First Amendment to Co-Promotion Agreement, dated April 19, 2018, between the Registrant and DePuy Synthes Sales, Inc.	10-Q	10.1	5/3/2018
10.36†	Second Amendment to Co-Promotion Agreement, dated December 21, 2018, between the Registrant and DePuy Synthes Sales, Inc.	10-K	10.41	2/28/2019
10.37	Executive Employment Agreement, dated May 29, 2017, between the Registrant and Dennis McLoughlin.***	10-Q	10.1	5/2/2019
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 and 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*	Inline XBRL Instance Document.*			
101.SCH*	Inline XBRL Taxonomy Schema Document.*			
101.CAL*	Inline XBRL Taxonomy Calculation Linkbase Document.*			
101.LAB*	Inline XBRL Taxonomy Label Linkbase Document.*			
101.PRE*	Inline XBRL Taxonomy Presentation Linkbase Document.*			
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.*			
104*	Cover Page Interactive Data File (Formatted as Inline XBRL and contained in Exhibit 101).			

* 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.

Certain schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K under the Securities Exchange Act of 1934, as amended. The Company hereby undertakes to supplementally furnish copies of any omitted schedules to the Securities and Exchange Commission upon request.

Item 16. Form 10-K Summary

None.

**PACIRA BIOSCIENCES, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2019**

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Pacira BioSciences, Inc. and subsidiaries (the Company) as of December 31, 2019 and 2018, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2019, 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, 2019, 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 20, 2020 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

Change in Accounting Principle

As discussed in Note 3 to the consolidated financial statements, the Company has changed its method of accounting for leases as of January 1, 2019 due to the adoption of Accounting Standards Update 2016-02, *Leases (Topic 842)*.

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.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Evaluation of the initial fair value measurement of the developed technology intangible asset acquired in connection with the acquisition of MyoScience, Inc.

As discussed in Notes 5 and 9 to the consolidated financial statements, the acquisition of MyoScience, Inc. resulted in the recording of the developed technology intangible asset of \$110.0 million. The determination of the acquisition date fair value of the developed technology intangible asset required the Company to make significant estimates and assumptions regarding forecasted revenues and the discount rate.

We identified the evaluation of the initial fair value measurement of the developed technology intangible asset acquired in connection with the acquisition of MyoScience, Inc. as a critical audit matter. Testing the assumptions regarding forecasted revenues and the discount rate, which were used to estimate the fair value, involved a high degree of judgment. In addition, the fair value of the developed technology intangible asset was challenging to test due to the sensitivity of the fair value determination to changes in these assumptions.

The primary procedures we performed to address this critical audit matter included the following. We tested certain internal controls over the Company's acquisition-date valuation process, including controls over the development of the forecasted revenues and the discount rate. We performed sensitivity analyses over the forecasted revenues to assess the impact of changes

in those assumptions on the Company's determination of the fair value of the developed technology intangible asset. We evaluated the future revenue growth used by the Company to determine forecasted revenues, by comparing them to industry data, as well as evaluated the relevance and reliability of third-party market data points used to develop the future revenue growth. We involved valuation professionals with specialized skills and knowledge, who assisted in evaluating the Company's discount rate by comparing the Company's inputs to the discount rate, to publicly available market data for the comparable entities used by the Company and assessing the resulting discount rate. They also assisted in testing the fair value estimate of the developed technology intangible asset acquired using the Company's cash flow assumptions and the Company's discount rate, and comparing the results to the Company's fair value estimate.

Evaluation of the fair value measurement of the contingent consideration liabilities associated with the acquisition of MyoScience, Inc.

As discussed in Notes 5 and 12 to the consolidated financial statements, the initial fair value of the contingent consideration liability related to the acquisition of MyoScience, Inc. was \$28.5 million. The contingent consideration liabilities are re-measured each reporting period, with a maximum remaining payout as of December 31, 2019 of \$73.0 million. The determination of the fair value of the contingent consideration liabilities related to achieving commercial and regulatory milestones, requires the Company to make significant estimates and assumptions. These estimates and assumptions include forecasts of revenues, estimated probabilities and timing of achieving specified commercial and regulatory milestones, volatility and the risk adjusted discount rate.

We identified the evaluation of the initial and ongoing fair value measurement of the contingent consideration liabilities related to achieving commercial and regulatory milestones associated with the acquisition of MyoScience, Inc. as a critical audit matter. Testing the simulation and milestone based models, including non-observable inputs, such as the forecasted revenue, estimated probability and timing of achieving specific commercial and regulatory milestones, the volatility and the risk adjusted discount rate involved a high degree of subjectivity.

The primary procedures we performed to address this critical audit matter included the following. We tested certain internal controls over the Company's initial and ongoing fair value process for contingent consideration liabilities related to achieving commercial and regulatory milestones, including controls over the forecasted revenues, estimated probabilities and timing of achieving specified milestones, the volatility and the risk adjusted discount rate. We evaluated the forecasted revenue and commercial and regulatory milestone assumptions used in the Company's models by comparing them to industry benchmarks and other relevant and reliable third-party market data, as well as evaluated the relevance and reliability of third-party market data points used to develop the future revenue growth and commercial and regulatory milestones. We involved valuation professionals with specialized skills and knowledge, who assisted in evaluating the Company's volatility and risk adjusted discount rate, by comparing the Company's inputs to the volatility and risk adjusted discount rate, to publicly available market data for the comparable entities used by the Company and assessing the resulting volatility and the risk adjusted discount rate. They also assisted in testing the estimate of the initial and ongoing fair value of the contingent consideration liabilities using the Company's forecasted revenues, volatility and the risk adjusted discount rate, and comparing the results to the Company's fair value estimates.

/s/ **KPMG LLP**

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

Short Hills, NJ

February 20, 2020

PACIRA BIOSCIENCES, INC.
CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	December 31,	
	2019	2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 78,228	\$ 132,526
Short-term investments	213,722	250,928
Accounts receivable, net	47,530	38,000
Inventories, net	58,296	48,569
Prepaid expenses and other current assets	10,781	7,946
Total current assets	408,557	477,969
Long-term investments	64,798	25,871
Fixed assets, net	104,681	108,670
Right-of-use assets, net	38,124	—
Goodwill	99,547	62,040
Intangible assets, net	104,387	—
Equity investment and other assets	10,971	14,803
Total assets	\$ 831,065	\$ 689,353
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 12,799	\$ 14,368
Accrued expenses	70,427	45,865
Lease liabilities	4,935	—
Convertible senior notes	—	338
Contingent consideration	18,179	—
Income taxes payable	1,333	90
Total current liabilities	107,673	60,661
Convertible senior notes	306,045	290,592
Lease liabilities	40,938	—
Contingent consideration	19,963	—
Other liabilities	1,502	16,874
Total liabilities	476,121	368,127
Commitments and contingencies (Note 21)		
Stockholders' equity:		
Preferred stock, par value \$0.001; 5,000,000 shares authorized; none issued and outstanding at December 31, 2019 and 2018	—	—
Common stock, par value \$0.001; 250,000,000 shares authorized; 41,908,148 shares issued and outstanding at December 31, 2019; 41,222,799 shares issued and outstanding at December 31, 2018	42	41
Additional paid-in capital	753,978	709,691
Accumulated deficit	(399,398)	(388,226)
Accumulated other comprehensive income (loss)	322	(280)
Total stockholders' equity	354,944	321,226
Total liabilities and stockholders' equity	\$ 831,065	\$ 689,353

See accompanying notes to consolidated financial statements.

PACIRA BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

	Year Ended December 31,		
	2019	2018	2017
Revenues:			
Net product sales	\$ 418,926	\$ 332,427	\$ 284,342
Collaborative licensing and milestone revenue	—	3,000	387
Royalty revenue	2,100	1,850	1,901
Total revenues	421,026	337,277	286,630
Operating expenses:			
Cost of goods sold	106,712	86,845	87,915
Research and development	72,119	55,688	57,290
Selling, general and administrative	200,782	177,265	161,494
Amortization of acquired intangible assets	5,703	—	—
Acquisition-related charges, product discontinuation and other	25,230	1,564	4,868
Total operating expenses	410,546	321,362	311,567
Income (loss) from operations	10,480	15,915	(24,937)
Other (expense) income:			
Interest income	7,376	6,497	4,078
Interest expense	(23,628)	(21,949)	(18,047)
Loss on early extinguishment of debt	—	—	(3,732)
Other, net	(4,976)	(888)	167
Total other expense, net	(21,228)	(16,340)	(17,534)
Loss before income taxes	(10,748)	(425)	(42,471)
Income tax expense	(268)	(46)	(140)
Net loss	\$ (11,016)	\$ (471)	\$ (42,611)
Net loss per share:			
Basic and diluted net loss per common share	\$ (0.27)	\$ (0.01)	\$ (1.07)
Weighted average common shares outstanding:			
Basic and diluted	41,513	40,911	39,806

See accompanying notes to consolidated financial statements.

PACIRA BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

	Year Ended December 31,		
	2019	2018	2017
Net loss	\$ (11,016)	\$ (471)	\$ (42,611)
Other comprehensive income (loss):			
Net unrealized gain (loss) on investments	602	174	(424)
Total other comprehensive income (loss)	602	174	(424)
Comprehensive loss	\$ (10,414)	\$ (297)	\$ (43,035)

See accompanying notes to consolidated financial statements.

PACIRA BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2019, 2018 AND 2017

(In thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
	Shares	Amount				
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	—	—	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
Cumulative effect adjustment of the adoption of Accounting Standards Update 2016-02 (Note 3)	—	—	—	(156)	—	(156)
Exercise of stock options	425	1	8,468	—	—	8,469
Vested restricted stock units	193	—	—	—	—	—
Shares issued under employee stock purchase plan	67	—	2,402	—	—	2,402
Stock-based compensation	—	—	33,650	—	—	33,650
Retirement of equity component of 2019 convertible senior notes	—	—	(233)	—	—	(233)
Net unrealized gain on investments	—	—	—	—	602	602
Net loss	—	—	—	(11,016)	—	(11,016)
Balance at December 31, 2019	41,908	\$ 42	\$ 753,978	\$ (399,398)	\$ 322	\$ 354,944

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,		
	2019	2018	2017
Operating activities:			
Net loss	\$ (11,016)	\$ (471)	\$ (42,611)
Adjustments to reconcile net loss to net cash provided by operating activities:			
Depreciation of fixed assets and amortization of intangible assets	19,576	13,165	13,833
Amortization of unfavorable lease obligation and debt issuance costs	1,707	1,590	1,248
Amortization of debt discount	13,746	12,799	10,423
Loss on disposal and impairment of fixed assets	1,010	65	2,133
Loss on early extinguishment of debt	—	—	3,732
Stock-based compensation	33,650	31,725	31,601
Changes in contingent consideration (after MyoScience, Inc. acquisition)	16,672	—	—
Loss on investment (net of stock dividend) and other non-operating income, net	4,315	854	—
Changes in operating assets and liabilities (net of MyoScience, Inc. acquisition):			
Accounts receivable, net	(8,524)	(5,999)	(1,721)
Inventories, net	(8,026)	(7,157)	(10,133)
Prepaid expenses and other assets	(3,885)	(3,228)	3,476
Accounts payable	(1,822)	(573)	5,712
Accrued expenses and income taxes payable	20,213	5,203	3,647
Other liabilities	(6,726)	897	(3,555)
Payment of contingent consideration to MyoScience, Inc. securityholders	(370)	—	—
Net cash provided by operating activities	<u>70,520</u>	<u>48,870</u>	<u>17,785</u>
Investing activities:			
Acquisition of MyoScience, Inc. (net of cash acquired)	(117,691)	—	—
Purchases of fixed assets	(10,159)	(14,514)	(19,266)
Purchases of investments	(318,484)	(363,255)	(502,752)
Sales of investments	319,468	405,188	321,713
Payment of contingent consideration	—	(6,843)	(8,460)
Equity investment	(1,622)	—	(15,000)
Net cash (used in) provided by investing activities	<u>(128,488)</u>	<u>20,576</u>	<u>(223,765)</u>
Financing activities:			
Proceeds from exercises of stock options	8,469	7,170	6,778
Proceeds from shares issued under employee stock purchase plan	2,402	1,784	1,862
Proceeds from issuance of 2022 convertible senior notes	—	—	345,000
Repayment of 2019 convertible senior notes	(338)	—	(118,193)
Conversion premium on 2019 convertible senior notes	(233)	—	—
Payment of contingent consideration to MyoScience, Inc. securityholders	(6,630)	—	—
Payment of debt issuance and financing costs	—	—	(11,000)
Costs for conversions of convertible senior notes	—	—	(285)
Net cash provided by financing activities	<u>3,670</u>	<u>8,954</u>	<u>224,162</u>
Net (decrease) increase in cash and cash equivalents	<u>(54,298)</u>	<u>78,400</u>	<u>18,182</u>
Cash and cash equivalents, beginning of year	132,526	54,126	35,944
Cash and cash equivalents, end of year	<u>\$ 78,228</u>	<u>\$ 132,526</u>	<u>\$ 54,126</u>

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,		
	2019	2018	2017
Supplemental cash flow information:			
Cash paid for interest	\$ 8,199	\$ 8,205	\$ 6,896
Cash paid for income taxes, net of refunds	\$ 863	\$ 128	\$ 129
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	\$ 125	\$ (98)	\$ 2,189
Net increase in contingent consideration liabilities	\$ 28,470	\$ —	\$ —

See accompanying notes to consolidated financial statements.

PACIRA BIOSCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1—DESCRIPTION OF BUSINESS

Pacira BioSciences, Inc. and its subsidiaries (collectively, the “Company” or “Pacira”) is a leading provider of non-opioid pain management and regenerative health solutions to advance and improve outcomes for health care practitioners and their patients. The Company’s long-acting, local analgesic, EXPAREL[®] (bupivacaine liposome injectable suspension), was commercially launched in the United States in April 2012. EXPAREL utilizes DepoFoam[®], a unique and proprietary delivery technology that encapsulates drugs without altering their molecular structure, and releases them over a desired period of time. In April 2019, the Company added iovera[®] to its commercial offering with its acquisition of MyoScience, Inc., or MyoScience. The iovera[®] system is a handheld cryoanalgesia device used to deliver a precise, controlled application of cold temperature to only targeted nerves.

The Company changed its name from Pacira Pharmaceuticals, Inc. to Pacira BioSciences, Inc. upon completing the acquisition of MyoScience in order to better reflect a broadening portfolio of innovative non-opioid pain management and regenerative health solutions. See Note 5, *MyoScience Acquisition*, for more information.

Pacira is subject to risks common to companies in similar industries and stages, including, but not limited to, competition from larger companies, reliance on revenue from two products, reliance on a limited number of 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 these 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, including contingent consideration, 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 iovera[®] in the U.S.; (iii) sales of and royalties on its bupivacaine liposome injectable suspension for veterinary use in the U.S. 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

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

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 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 for veterinary use.

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 surgery centers and physicians. The Company sells its bupivacaine liposome injectable suspension for veterinary use to a third-party licensee and sells iovera[®] directly to end users. 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,		
	2019	2018	2017
Largest wholesaler	34%	34%	35%
Second largest wholesaler	29%	30%	30%
Third largest wholesaler	26%	26%	26%
Total	89%	90%	91%

The Company had no revenue from outside the U.S. during the year ended December 31, 2019. Revenue from outside the U.S. accounted for less than 1% of the Company's total revenue for the year ended 2018 and 1% of the Company's total revenue for the year ended December 31, 2017.

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, 2019 and 2018, the Company's net 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.

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

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.

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 historical 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 declared or 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. Cash equivalents include corporate debt securities, asset backed securities and money market funds. As of December 31, 2019, the carrying value of money market funds was \$28.5 million, which is included in cash and cash equivalents. As of December 31, 2018, the carrying value of money market funds was \$40.6 million, corporate debt securities was \$21.4 million and asset backed securities was \$4.9 million, all of which were included in cash and cash equivalents. The carrying values approximate fair value as of December 31, 2019 and 2018.

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. The Company classifies its investments as available-for-sale. 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.

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

Depreciation of fixed assets is provided over their estimated useful lives on a straight-line basis. Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or the related 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

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.

Leases

Effective January 1, 2019, the Company recognizes right-of-use, or ROU, assets and lease liabilities at the commencement of its lease agreements. The leases are evaluated at commencement to determine whether they should be classified as operating or financing leases. Lease costs associated with operating leases are recognized on a straight-line basis, while lease costs for financing leases are recognized over the lease term using the effective interest method. To date, the Company does not have any financing leases. The amount of ROU assets and lease liabilities to be recognized is impacted by the type of lease payments, the lease term and the incremental borrowing rate. Variable lease payments are not included at commencement and are recognized in the period in which they are incurred. The lease term is based on the contractual term and is adjusted for any renewal options or termination rights that are reasonably certain to be exercised. The incremental borrowing rate is based on the rate the Company estimates it would pay on a collateralized basis over a similar term in a similar economic environment.

Acquisitions

In a business combination, the acquisition method of accounting requires that the assets acquired and liabilities assumed be recorded as of the date of the acquisition at their respective fair values, with some exceptions. Assets acquired and liabilities assumed in a business combination that arise from contingencies are generally recognized at fair value. If fair value cannot be determined, the asset or liability is recognized if probable and reasonably estimable; if these criteria are not met, no asset or liability is recognized. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Any excess of the purchase price (consideration transferred) over the estimated fair values of net assets acquired is recorded as goodwill. Transaction costs and costs to restructure the acquired company are expensed as incurred. The operating results of the acquired business are reflected in the Company's consolidated financial statements after the date of the acquisition.

Contingent Consideration

Subsequent to an acquisition, the Company measures contingent consideration arrangements at fair value for each period with changes in fair value recognized in the consolidated statements of operations as acquisition-related charges. Changes in contingent consideration can result from changes in the assumed achievement and timing of estimated sales, costs of goods sold and regulatory approvals. In the absence of new information, changes in fair value reflect the passage of time towards achievement of the milestones, and are accrued based on an accretion schedule.

Goodwill

Goodwill represents the excess of the purchase price over the estimated fair value of the net assets 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.

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

Intangible Assets

Intangible assets with definite useful lives are amortized on a straight-line basis over their estimated useful lives and are reviewed for impairment if certain events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Intangible assets are recorded at cost, net of accumulated amortization.

Equity Investments

The Company historically accounted for its equity investment in a minority interest of a company over which it did not exercise significant influence using the cost method. The equity investment did 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. As of the fourth quarter of 2019, the equity investment held by the Company is now publicly traded and has a readily determinable fair value. The equity investment is now measured at fair value with changes in the fair value recognized in other income (expense).

Impairment of Long-Lived Assets

Management reviews long-lived assets, including fixed assets and intangible 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.

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 RSUs expected to vest, the shares to be purchased under the Company's employee stock purchase plan (using the treasury stock method), the excess conversion value on the Company's convertible senior notes and the shares of common stock that could be issued as consideration for contingent milestone payments.

Foreign Currency Translation

The balance sheet accounts of foreign subsidiaries with functional currencies other than United States Dollar are translated using the exchange rate at the respective balance sheet dates. Revenues and expenses are translated using average exchange rates for each calendar month during the year. Translation adjustments are recorded as a component of accumulated

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

other comprehensive income (loss) in the consolidated financial statements. To date, foreign currency translation has been de minimis.

Segment Reporting

The Company is managed and operated as a single business focused on the discovery, development, manufacture, marketing, distribution and sale of non-opioid pain management and regenerative health solutions. The Company is managed by a single management team, and, consistent with its organizational structure, the Chief Executive Officer and Chairman manages and allocates resources at a consolidated level. Accordingly, the Company views its business as one reportable operating segment to evaluate performance, allocate resources, set operational targets and forecast its future period financial results.

NOTE 3—RECENT ACCOUNTING PRONOUNCEMENTS

Recently Adopted Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or 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 required lessees to recognize lease assets and lease liabilities on the balance sheet for those leases classified as operating leases under previous authoritative guidance. For income statement purposes, the new standard retained a dual model similar to Accounting Standards Codification, or ASC, 840, requiring leases to be classified as either operating or financing. Operating leases continue to result in straight-line expense while financing leases result in a front-loaded expense pattern (similar to previous accounting guidance by lessees for operating and capital leases, respectively, under ASC 840).

The Company adopted ASU 2016-02 on January 1, 2019 using the effective date method. There were practical expedients available to the Company at transition that it elected to apply upon adoption. The Company did not re-assess (i) whether its contracts contained a lease under the new definition of a lease and (ii) the classification of those leases. There were no initial direct costs previously capitalized on the consolidated balance sheet. In addition, the Company applied hindsight in the determination of the lease terms, in the assessment of the likelihood that a lease renewal, termination or purchase option will be exercised, and in the assessment of any potential impairments that existed on the ROU assets recognized at adoption. The Company also elected not to recognize a ROU asset and lease liability for those leases with a remaining lease term of 12 months or less.

At adoption on January 1, 2019, the lease liability was equal to the present value of future lease payments and a ROU asset was recorded based on the lease liability, adjusted for items such as prepaid and accrued lease payments. The Company recorded \$36.5 million of lease liabilities and \$27.6 million of ROU assets as of January 1, 2019, the difference representing previously recorded lease-related assets and liabilities. There was a cumulative-effect adjustment to accumulated deficit of \$0.2 million upon adoption.

The lease liability recognized upon adoption was based upon the present value of the sum of the remaining minimum lease payments (as previously identified under ASC 840), determined using the discount rate as of the date of adoption. The discount rate was based on the Company's incremental borrowing rate on a collateralized basis over a similar remaining term and in a similar economic environment. Refer to Note 8, *Leases*, for further information on the Company's existing leases.

In May 2014, the FASB, issued Accounting Standards Update, or ASU, 2014-09, *Revenue 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 was not revised and has been 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. Refer to Note 4, *Revenue*, for further information on the Company's 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*. Under this standard, 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 for identical or similar investments of the same issuer. ASU 2016-01 became effective for the Company beginning January 1, 2018. The Company elected to measure its equity investment without a readily

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

determinable fair value (TELA Bio, Inc.) at cost minus impairment. Refer to Note 2, *Summary of Significant Accounting Policies*, for further information.

In June 2018, the FASB issued ASU 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which aligned accounting for share-based payments issued to nonemployees to that of employees under the existing guidance of Topic 718, with certain exceptions. 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.

Recent Accounting Pronouncements Not Adopted as of December 31, 2019

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which required 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. The Company now includes forward-looking information to better form its credit loss estimates. This update also required 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 is effective for the Company beginning January 1, 2020. 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.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework*. 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. The Company will apply these new disclosure requirements in its consolidated financial statements beginning with the three-month period ending March 31, 2020.

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 is effective for the Company beginning January 1, 2020. The amendments could be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company has applied this standard prospectively to its implementation costs incurred beginning in 2020. Any new implementation costs incurred are classified in other assets and the amortization classified in operating expenses, separate from depreciation expense, over the term of the hosting arrangement.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740), Simplifying the Accounting for Income Taxes*, which amends the approaches and methodologies in accounting for income taxes during interim periods and makes changes to certain income tax classifications. The new standard allows exceptions to the use of the incremental approach for intra-period tax allocation, when there is a loss from continuing operations and income or a gain from other items, and to the general methodology for calculating income taxes in an interim period, when a year-to-date loss exceeds the anticipated loss for the year. The standard also requires franchise or similar taxes partially based on income to be reported as income tax and the effects of enacted changes in tax laws or rates to be included in the annual effective tax rate computation from the date of enactment. Lastly, in any future acquisition, the Company would be required to evaluate when the step-up in the tax basis of goodwill is part of the business combination and when it should be considered a separate transaction. The standard will be effective for the Company beginning January 1, 2021, with early adoption of the amendments permitted. The Company is currently evaluating the impact from the adoption of ASU 2019-12 on its consolidated financial statements.

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

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 iovera^o in the U.S.; (iii) sales of and royalties on its bupivacaine liposome injectable suspension for veterinary use in the U.S. and (iv) license fees and milestone payments. Previously, the Company sold DepoCyt(e) to third-party licensees in the U.S. and Europe prior to its discontinuation in June 2017. The Company does not consider revenue from sources other than sales of EXPAREL to be material sources of its consolidated revenue. As such, the following disclosure only relates to revenue associated with net EXPAREL product sales.

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 related to EXPAREL for the years ended December 31, 2019, 2018 and 2017 (in thousands):

	Returns Allowances	Prompt Payment Discounts	Wholesaler Service Fees	Volume Rebates and Chargebacks	Total
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
Provision	783	8,426	6,267	11,475	26,951
Payments/Adjustments	(587)	(8,243)	(5,948)	(10,669)	(25,447)
Balance at December 31, 2019	\$ 540	\$ 962	\$ 1,486	\$ 1,816	\$ 4,804

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.

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

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 is 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.

Disaggregated Revenue

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

	Year Ended December 31,		
	2019	2018	2017
Net product sales:			
EXPAREL / bupivacaine liposome injectable suspension	\$ 411,030	\$ 332,427	\$ 283,252
iovera ^o	7,896	—	—
DepoCyt(e)	—	—	1,090
Total net product sales	\$ 418,926	\$ 332,427	\$ 284,342

NOTE 5—MYOSCIENCE ACQUISITION

On April 9, 2019, the Company acquired MyoScience (the "MyoScience Acquisition"), a privately-held medical device company, pursuant to the terms of an Agreement and Plan of Merger (the "Merger Agreement"), under which MyoScience became a wholly-owned subsidiary of the Company and was renamed Pacira CryoTech, Inc., or CryoTech. The MyoScience Acquisition added iovera^o to the Company's commercial offering. The iovera^o system is a novel, United States Food and Drug Administration, or FDA, approved, non-opioid treatment that immediately alleviates pain for up to 90 days by applying intense cold to only targeted nerves in a process called cryoanalgesia.

The consideration included an initial cash payment of \$120.0 million, reduced by \$1.0 million for post-closing purchase price adjustments and indemnification obligations incurred to date, and the initial fair value of contingent consideration in the amount of \$28.5 million. The contingent consideration consists of contingent milestone payments up to an aggregate of \$100.0 million upon the achievement of certain regulatory and commercial milestones, of which up to \$25.0 million may be payable in shares of the Company's common stock if achieved in 2020. Per the terms of the Merger Agreement, the Company's obligation to make milestone payments is limited to those milestones achieved between January 1, 2019 and December 31, 2023, and are to be paid within 60 days of the end of the fiscal quarter of achievement.

In the third quarter of 2019, the Company met a regulatory milestone which was previously accrued that resulted in a \$7.0 million cash payment in the fourth quarter of 2019. In the fourth quarter of 2019, the Company met another regulatory milestone which was previously accrued and will result in a \$5.0 million cash payment to be made in the first quarter of 2020. Additionally, in the fourth quarter of 2019, the Company recognized a third regulatory milestone in the amount of \$10.0 million that will require payment in the second quarter of 2020. The Company recorded \$8.9 million in acquisition-related charges in its consolidated statements of operations in 2019 related to this milestone. This milestone payment can be made in either cash or shares of the Company's common stock (or a combination thereof), at the election of the former MyoScience shareholders. The total potential remaining milestone payments available as of December 31, 2019 are \$73.0 million, which includes the milestone payments to be made in 2020.

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

The Company has accounted for the MyoScience Acquisition using the acquisition method of accounting and, accordingly, has included the assets acquired, liabilities assumed and results of operations in the condensed consolidated financial statements from April 10, 2019 onward, the day following the acquisition date. The excess of the purchase price over the fair value of identifiable net assets acquired represents goodwill. This goodwill is primarily attributable to the value of combining iovera[®] and EXPAREL as a safe and effective non-opioid multimodal regimen for pain management, as well as the synergies of merging operations. The primary assets and liabilities of the business acquired include developed technology and customer relationship intangible assets, equipment, inventory, receivables, payables and accrued expenses. Inventory has been recorded at its estimated selling price less costs of distribution and a reasonable profit, and the intangible assets acquired (including developed technology and customer relationships) have been recorded at fair value as determined by the Company's management with the assistance of a third-party valuation specialist. The Company subsequently made a tax election that allows the acquired goodwill and intangible assets to be tax deductible. See Note 16, *Income Taxes*, for more information.

The total consideration for the MyoScience Acquisition was \$147.5 million, which consisted of the following (in thousands):

	Amount
Cash paid, adjusted for working capital items	\$ 119,038
Fair value of contingent consideration	28,470
Total	\$ 147,508

The following table sets forth the allocation of the MyoScience Acquisition purchase price to the estimated fair value of the net assets acquired at the acquisition date (in thousands):

	Amounts Recognized at the Acquisition Date
ASSETS ACQUIRED	
Current assets	\$ 5,275
Non-current assets (other than intangible assets)	1,044
Intangible assets (excluding goodwill)	110,090
Total assets acquired (excluding goodwill)	\$ 116,409
LIABILITIES ASSUMED	
Current liabilities	\$ 4,436
Deferred tax liabilities, net	1,828
Other non-current liabilities	144
Total liabilities assumed	6,408
Total identifiable net assets acquired	110,001
Goodwill	37,507
Total consideration transferred	\$ 147,508

CryoTech results from the acquisition date of April 10, 2019 through December 31, 2019, which are included in the condensed consolidated statements of operations, are as follows (in thousands):

Classification in Condensed Consolidated Statements of Operations	Acquisition Date Through December 31, 2019
Total revenues	\$ 7,896
Net loss	\$ (10,478)

Unaudited Pro Forma Summary of Operations

The following table shows the unaudited pro forma summary of operations for the year ended December 31, 2019 and 2018, as if the MyoScience Acquisition had occurred on January 1, 2018. This pro forma information does not purport to

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

represent what the Company's actual results would have been if the acquisition had occurred as of January 1, 2018, and is not indicative of what such results would be expected for any future period (in thousands, except per share amounts):

	Year Ended December 31,	
	2019	2018
Total revenues	\$ 423,475	\$ 342,735
Net loss	\$ (16,200)	\$ (25,696)
Pro forma basic and diluted net loss per share	\$ (0.39)	\$ (0.63)

The unaudited pro forma financial information was prepared using the acquisition method of accounting and was based on the historical financial information of the Company and MyoScience. The summary pro forma financial information primarily reflects the following pro forma adjustments:

- Removal of the acquisition-related transaction fees and costs, including certain stock-based compensation and other compensation expenses related to the acquisition, from the year ended December 31, 2019;
- Removal of the income tax benefit resulting from the Company decreasing its existing valuation allowance on deferred tax assets and the income tax expense resulting from a 338(g) election recognized in the year ended December 31, 2019;
- Removal of MyoScience's loss on extinguishment of debt and warrant expense in the year ended December 31, 2019;
- Removal of MyoScience's interest expense;
- Adjustments to the Company's interest income for the cash used to acquire MyoScience; and
- The addition of amortization expense on the acquired developed technology and customer relationship intangible assets.

NOTE 6—INVENTORIES

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

	December 31,	
	2019	2018
Raw materials	\$ 20,019	\$ 19,193
Work-in-process	14,407	9,711
Finished goods	23,870	19,665
Total	<u>\$ 58,296</u>	<u>\$ 48,569</u>

The Company is required to perform stability testing on select lots of EXPAREL. In October 2019, a single validation lot of EXPAREL manufactured at the Company's contract manufacturing site did not meet its required stability specification. At December 31, 2019, \$1.3 million was reserved due to this stability investigation. In December 2019, the Company's contract manufacturer experienced a media fill failure, which is part of the routine aseptic manufacturing requalification program, and an investigation is underway. Based on the results of its investigation to date, the Company believes no additional inventory reserves are required related to the media fill failure. However, depending on the outcome of this investigation, it may be determined that up to \$4.4 million of inventory may be unsellable. None of the EXPAREL lots that could be impacted by this media fill failure have been distributed for sale. The Company has temporarily halted production on the manufacturing line while it investigates the root cause of these failures.

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

NOTE 7—FIXED ASSETS

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

	December 31,	
	2019	2018
Machinery and equipment	\$ 70,078	\$ 67,431
Leasehold improvements	60,441	57,955
Computer equipment and software	8,942	8,131
Office furniture and equipment	1,882	1,548
Construction in progress	38,778	35,163
Total	180,121	170,228
Less: accumulated depreciation	(75,440)	(61,558)
Fixed assets, net	\$ 104,681	\$ 108,670

For information on useful lives by asset category, refer to Note 2, *Summary of Significant Accounting Policies*.

Depreciation expense for the years ended December 31, 2019, 2018 and 2017 was \$14.0 million, \$13.2 million and \$13.8 million, respectively. During the years ended December 31, 2019, 2018 and 2017, the Company capitalized interest of less than \$0.1 million, \$0.7 million and \$1.1 million, respectively.

As of December 31, 2019 and 2018, total fixed assets, net, includes leasehold improvements and manufacturing process equipment located in Europe in the amount of \$64.8 million and \$64.6 million, respectively.

As of December 31, 2019 and 2018, the Company had AROs of \$2.5 million and \$2.2 million, respectively, included in accrued expenses and 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 of \$0.3 million for the year ended December 31, 2019 was due to a revision in estimated future cash flows related to the AROs (including those resulting from the MyoScience Acquisition), including \$0.2 million of accretion expense. Accretion expense was \$0.1 million for the year ended December 31, 2018.

NOTE 8—LEASES

The Company leases all of its facilities, including its EXPAREL manufacturing facility in San Diego, California and its iovera[®] manufacturing facility in Fremont, California. These leases have remaining terms between 0.7 years and 10.7 years, some of which provide renewal options at the then-current market value. The Company also has a lease with Thermo Fisher Scientific Pharma Services, or Thermo Fisher (formerly Patheon UK Limited), for the use of their facility in Swindon, England, which is embedded in agreements the Company has with Thermo Fisher. A portion of the associated monthly base fees has been allocated to the lease component based on a relative fair value basis.

The operating lease costs for the facilities include lease and non-lease components, such as common area maintenance and other common operating expenses, along with executory costs such as insurance and real estate taxes. Total operating lease costs are as follows (in thousands):

	Year Ended December 31,	
	2019	2018
Operating Lease Costs		
Fixed lease costs	\$ 6,225	\$ 7,236
Variable lease costs	1,651	1,761
Total	\$ 7,876	\$ 8,997

Supplemental cash flow information related to operating leases is as follows (in thousands):

	Year Ended December 31, 2019	
Cash paid for operating lease liabilities, net of lease incentive	\$	7,346
Right-of-use assets recorded in exchange for lease obligations	\$	41,605

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

The Company has elected to net the amortization of the ROU asset and the reduction of the lease liability principal in accrued expenses in the condensed consolidated statement of cash flows.

The Company has measured its operating lease liabilities at an estimated discount rate in which it could borrow on a collateralized basis over the remaining term for each operating lease. The weighted average remaining lease term and the weighted average discount rate are summarized as follows:

	December 31, 2019
Weighted average remaining lease term	9.38 years
Weighted average discount rate	7.55%

Maturities of the Company's operating lease liabilities are as follows (in thousands):

Year	Aggregate Payments Due
2020	\$ 8,223
2021	6,239
2022	5,875
2023	6,013
2024	6,155
2025 through 2030	32,830
Total lease payments	65,335
Less: imputed interest	(19,462)
Total operating lease liabilities	\$ 45,873

The Company has entered into one lease agreement (not included in the table above) for which there are future obligations but the lease has not yet commenced as of December 31, 2019 (in thousands):

Year	Aggregate Payments Due
2020	\$ 2,159
2021	4,415
2022	4,548
2023	4,684
2024	4,825
2025 through 2030	29,242
Total future lease payments	\$ 49,873

As of December 31, 2018, aggregate annual minimum payments due under the Company's lease obligations were 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 2030	14,329
Total	\$ 46,345

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

NOTE 9—GOODWILL AND INTANGIBLE ASSETS**Goodwill**

In March 2007, the Company acquired from SkyePharma Holding, Inc. (now a subsidiary of Vectura Group plc), or SkyePharma, its California operating subsidiary named Pacira Pharmaceuticals, Inc. (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 the United Kingdom, France, Germany, Italy or 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 for which a valid claim existed expired on September 18, 2018 and thus, the only remaining obligations to SkyePharma are the two unmet potential 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.

There was no change in the carrying value of goodwill related to the SkyePharma Acquisition during the year ended December 31, 2019. The Company recorded goodwill related to contingent payments due under the SkyePharma Acquisition during the year ended December 31, 2018, which is not deductible for income tax purposes.

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

	Carrying Value
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
Goodwill arising from the MyoScience Acquisition	37,507
Balance at December 31, 2019	\$ 99,547

MyoScience Acquisition

In connection with the MyoScience Acquisition, the Company recorded goodwill totaling \$37.5 million. The Company subsequently made a tax election that allows the acquired goodwill and intangible assets to be tax deductible.

Intangible Assets

Intangible assets, net, consist of the developed technology and customer relationships that were acquired in the MyoScience Acquisition and are summarized as follows (in thousands):

December 31, 2019	Gross Carrying Value	Accumulated Amortization	Intangible Assets, Net	Estimated Useful Life
Developed technology	\$ 110,000	\$ (5,696)	\$ 104,304	14 Years
Customer relationships	90	(7)	83	10 Years
Total intangible assets	\$ 110,090	\$ (5,703)	\$ 104,387	

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

There were no intangible assets, net, at December 31, 2018. Amortization expense on intangible assets for the year ended December 31, 2019 was \$5.7 million. There was no amortization expense on intangible assets for the years ended December 31, 2018 and 2017.

Assuming no changes in the gross carrying amount of these intangible assets, the future amortization expense on these intangible assets will be \$7.9 million annually through 2032 and \$2.2 million in 2033.

NOTE 10—ACCRUED EXPENSES

Accrued expenses consist of the following (in thousands):

	December 31,	
	2019	2018
Accrued selling, general and administrative expenses	\$ 21,695	\$ 14,419
Accrued research and development expenses	6,562	2,432
Other accrued operating expenses	12,955	4,281
Compensation and benefits	22,258	18,861
Accrued royalties	2,883	2,286
Accrued interest	2,048	2,053
Product returns, wholesaler service fees and other	2,026	1,533
Total	<u>\$ 70,427</u>	<u>\$ 45,865</u>

NOTE 11—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 1st and October 1st 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,	
	2019	2018
2.375% convertible senior notes due 2022	\$ 345,000	\$ 345,000
Deferred financing costs	(4,143)	(5,850)
Discount on debt	(34,812)	(48,558)
Total debt, net of debt discount and deferred financing costs	<u>\$ 306,045</u>	<u>\$ 290,592</u>

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 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

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

(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, 2019, the 2022 Notes had a market price of \$1,044 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, 2019 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 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.

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

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 February 1, 2019, the Company's 3.25% convertible senior notes due 2019, or 2019 Notes, matured, and the Company paid the remaining \$0.3 million of principal in full, plus a \$0.2 million conversion premium in cash. The 2019 Notes accrued interest at a fixed rate of 3.25% per year and were payable semiannually in arrears on February 1st and August 1st of each year.

Interest Expense

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

	Year Ended December 31,		
	2019	2018	2017
Contractual interest expense	\$ 8,195	\$ 8,205	\$ 7,344
Amortization of debt issuance costs	1,707	1,634	1,381
Amortization of debt discount	13,746	12,799	10,423
Capitalized interest and other (Note 7)	(20)	(689)	(1,101)
Total	<u>\$ 23,628</u>	<u>\$ 21,949</u>	<u>\$ 18,047</u>
Effective interest rate on convertible senior notes	7.81%	7.81%	7.77%

NOTE 12—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.

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

- *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 equity investment is calculated utilizing market quotations from a major American stock exchange (Level 1). The fair value of the Company's convertible senior notes are calculated utilizing market quotations from an over-the-counter trading market for these notes (Level 2). The fair value of the Company's acquisition-related contingent consideration is reported at fair value on a recurring basis (Level 3). The carrying values and fair values of the Company's financial assets and liabilities at December 31, 2019 are as follows (in thousands):

	Carrying Value	Fair Value Measurements Using		
		Level 1	Level 2	Level 3
Financial Assets:				
Equity investment	\$ 10,024	\$ 10,024	\$ —	\$ —
Financial Liabilities:				
2.375% convertible senior notes due 2022 ^{(1) (2)}	\$ 306,045	\$ —	\$ 360,094	\$ —
Acquisition-related contingent consideration ⁽³⁾	\$ 38,142	\$ —	\$ —	\$ 38,142

(1) The closing price of the Company's common stock was \$45.30 per share at December 31, 2019 compared to a conversion price of \$66.89 per share. Therefore, at December 31, 2019, the conversion price was 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) Reported at historical cost.

(3) Reported at fair value on a recurring basis.

Financial Liabilities Measured at Fair Value on a Recurring Basis

The Company has recognized contingent consideration related to the MyoScience Acquisition in the amount of \$38.1 million as of December 31, 2019. Refer to Note 5, *MyoScience Acquisition*, for more information.

The Company's contingent consideration obligations are recorded at their estimated fair values and are revalued each reporting period if and until the related contingencies are resolved. For the year ended December 31, 2019, the Company recognized \$16.7 million of fair value adjustments related to contingent consideration, which have been included in acquisition-related charges in the consolidated statements of operations. The Company has measured the fair value of its contingent consideration using a probability-weighted discounted cash flow approach that is based on unobservable inputs and a Monte Carlo simulation. These inputs include, as applicable, estimated probabilities and the timing of achieving specified commercial and regulatory milestones, estimated forecasts of revenue and costs and the discount rate used to calculate the present value of estimated future payments. Significant changes may increase or decrease the probabilities of achieving the related commercial and regulatory events, shorten or lengthen the time required to achieve such events, or increase or decrease estimated forecasts.

The following table includes the key assumptions used in the valuation of the Company's contingent consideration:

Assumption	Ranges Utilized as of December 31, 2019
Discount rates	7.57% to 7.75%
Probabilities of payment for regulatory milestones	3% to 100%
Projected years of payment for regulatory and commercial milestones	2020 to 2023

The maximum remaining potential payments related to the contingent consideration from the MyoScience Acquisition are \$73.0 million, including a \$5.0 million and a \$10.0 million payment to be made in the first and second quarter of 2020, respectively.

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

The change in the Company's contingent consideration recorded at fair value using Level 3 measurements is as follows (in thousands):

	Contingent Consideration Fair Value
Balance at December 31, 2018	\$ —
New financial liabilities entered into on date of MyoScience Acquisition (April 9, 2019)	28,470
Fair value adjustments and accretion	16,672
Payments made	(7,000)
Balance at December 31, 2019	<u>\$ 38,142</u>

Investments

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 and losses from the Company's short-term and long-term investments are reported in other comprehensive income (loss). At December 31, 2019, all of the Company's short-term and long-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, 2019, all short-term and long-term investments had an "A" or better rating by Standard & Poor's.

The following summarizes the Company's investments at December 31, 2019 and 2018 (in thousands):

December 31, 2019 Investments:	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value (Level 2)
Short-term:				
Asset-backed securities	\$ 43,166	\$ 54	\$ —	\$ 43,220
Commercial paper	32,250	20	—	32,270
Corporate bonds	138,012	225	(5)	138,232
Subtotal	<u>213,428</u>	<u>299</u>	<u>(5)</u>	<u>213,722</u>
Long-term:				
Asset-backed securities	28,064	10	(15)	28,059
Corporate bonds	36,706	37	(4)	36,739
Subtotal	<u>64,770</u>	<u>47</u>	<u>(19)</u>	<u>64,798</u>
Total	<u>\$ 278,198</u>	<u>\$ 346</u>	<u>\$ (24)</u>	<u>\$ 278,520</u>

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

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

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.

Equity Investment

At December 31, 2019 and 2018, the Company held an equity investment in TELA Bio, Inc., or TELA Bio, in its consolidated balance sheets in the amount of \$10.0 million and \$14.1 million, respectively. During the year ended December 31, 2019, the Company made an additional cash investment of \$1.6 million in TELA Bio and received a non-cash stock dividend from TELA Bio in the amount of \$2.5 million. During the years ended December 31, 2019 and 2018, the Company recorded impairment losses in the amount of \$5.7 million and \$0.9 million, respectively, in other, net in its consolidated statements of operations. The fair value at December 31, 2019 was based on a Level 1 input and the fair value at December 31, 2018 was based on a Level 3 input.

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, 2019, three wholesalers accounted for over 10% of the Company's accounts receivable: 37%, 29% and 26%, respectively. At December 31, 2018, three wholesalers accounted for over 10% of the Company's accounts receivable: 32%, 32% and 29%, respectively. For additional information regarding the Company's wholesalers, see Note 2, *Summary of Significant Accounting Policies*. EXPAREL 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 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, 2019 and 2018, no allowances for doubtful accounts were deemed necessary by the Company on its accounts receivable.

NOTE 13—STOCKHOLDERS' EQUITY

Common Stock

The Company is authorized to issue up to 250,000,000 shares of common stock, of which 41,908,148 and 41,222,799 were issued and outstanding at December 31, 2019 and 2018, 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, 2019 or 2018.

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

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, 2017	\$ (454)
Other comprehensive income before reclassifications	174
Amounts reclassified from accumulated other comprehensive income (loss)	—
Balance at December 31, 2018	(280)
Other comprehensive income before reclassifications	602
Amounts reclassified from accumulated other comprehensive income (loss)	—
Balance at December 31, 2019	\$ 322

NOTE 14—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 both June 2016 and June 2019. The June 2019 amendment and approval by the Company's stockholders increased the number of shares of common stock authorized for issuance as equity awards under the plan by 3,000,000 shares.

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, or IRC. 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 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, 2019, 67,094 shares were purchased and issued through the ESPP.

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

The following tables contain information about the Company's stock incentive plans at December 31, 2019:

Stock Incentive Plan	Awards Reserved For Issuance	Awards Issued	Awards Available For Grant
2007 Plan	2,022,837	2,022,837	—
2011 Plan	12,931,700	10,047,564	2,884,136
2014 Inducement Plan	175,000	36,576	138,424
	<u>15,129,537</u>	<u>12,106,977</u>	<u>3,022,560</u>

Employee Stock Purchase Plan	Shares Reserved For Purchase	Shares Purchased	Shares Available For Purchase
2014 ESPP	500,000	291,981	208,019

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. 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, 2019, 2018 and 2017 as follows (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Cost of goods sold	\$ 4,665	\$ 4,478	\$ 5,467
Research and development	5,114	3,934	3,341
Selling, general and administrative	23,871	23,313	22,793
Total	<u>\$ 33,650</u>	<u>\$ 31,725</u>	<u>\$ 31,601</u>
Stock-based compensation from:			
Stock options	\$ 23,360	\$ 22,643	\$ 24,223
RSUs	9,511	8,371	6,698
ESPP	779	711	680
Total	<u>\$ 33,650</u>	<u>\$ 31,725</u>	<u>\$ 31,601</u>

The following table summarizes the Company's stock option activity and related information for the period from December 31, 2016 to December 31, 2019:

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

	Number of Options	Weighted Average Exercise Price (Per Share)	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in Thousands)
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
Granted	1,872,758	42.75		
Exercised	(425,495)	19.90		\$ 9,441
Forfeited	(286,779)	39.22		
Expired	(176,924)	63.33		
Outstanding at December 31, 2019	6,706,378	\$ 42.80	7.05	\$ 50,652
Exercisable at December 31, 2019	3,536,615	\$ 44.02	5.45	\$ 37,569
Vested and expected to vest at December 31, 2019	6,706,378	\$ 42.80	7.05	\$ 50,652

As of December 31, 2019, \$57.5 million of total unrecognized compensation cost related to non-vested stock options is expected to be recognized over a weighted average period of 2.8 years. The Company's stock options have a maximum expiration date of ten years from the date of grant.

The weighted average fair value of stock options granted for the years ended December 31, 2019, 2018 and 2017 was \$20.92, \$19.34 and \$20.78 per share, respectively. The fair values of stock options granted were estimated using the Black-Scholes model with the following weighted average assumptions:

Black-Scholes Weighted Average Assumption	Year Ended December 31,		
	2019	2018	2017
Expected dividend yield	None	None	None
Risk-free interest rate	1.33% - 2.54%	2.26% - 3.05%	1.68% - 2.42%
Expected volatility	53.9%	53.3%	51.4%
Expected term of options	5.22 years	5.14 years	5.31 years

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

The following table summarizes the Company's RSU activity and related information for the period from December 31, 2016 to December 31, 2019:

	Number of Units	Weighted Average Grant Date Fair Value (Per Share)	Aggregate Intrinsic Value (in Thousands)
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 at December 31, 2018	577,964	42.14	\$ 24,864
Granted	305,418	43.56	
Vested	(192,760)	45.55	
Forfeited	(59,481)	41.22	
Unvested and expected to vest at December 31, 2019	631,141	\$ 41.87	\$ 28,591

As of December 31, 2019, \$20.5 million of total unrecognized compensation cost related to non-vested RSUs is expected to be recognized over a weighted average period of 2.7 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:

Black-Scholes Weighted Average Assumption	Year Ended December 31,		
	2019	2018	2017
ESPP share option fair value	\$11.13 - \$11.36	\$10.40 - \$13.15	\$10.80 - \$13.85
Expected dividend yield	None	None	None
Risk-free interest rate	2.10% - 2.56%	1.53% - 2.14%	0.62% - 1.14%
Expected volatility	40.2%	52.2%	53.8%
Expected term of ESPP share options	6 months	6 months	6 months

NOTE 15—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, 2019, 2018 and 2017, no potentially dilutive securities have been included in the computation of diluted net loss per share for those periods. As discussed in Note 11, *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 and 2019, 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, 2019, 2018 and 2017 (in thousands, except per share amounts):

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

	Year Ended December 31,		
	2019	2018	2017
Numerator:			
Net loss	\$ (11,016)	\$ (471)	\$ (42,611)
Denominator:			
Weighted average shares of common stock outstanding—basic and diluted	41,513	40,911	39,806
Net loss per share:			
Basic and diluted net loss per common share	\$ (0.27)	\$ (0.01)	\$ (1.07)

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

	Year Ended December 31,		
	2019	2018	2017
Weighted average number of stock options	6,404	5,492	5,171
Weighted average number of RSUs	606	542	449
Conversion premium on the 2019 Notes	—	—	411
Weighted average ESPP purchase options	34	31	29
Total	7,044	6,065	6,060

NOTE 16—INCOME TAXES

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

	Year Ended December 31,		
	2019	2018	2017
Income (loss) before income taxes:			
Domestic	\$ (71)	\$ 5,169	\$ (39,898)
Foreign	(10,677)	(5,594)	(2,573)
Total loss before income taxes	\$ (10,748)	\$ (425)	\$ (42,471)
Current taxes:			
Federal	\$ —	\$ (96)	\$ —
State	2,096	142	140
Total current taxes	\$ 2,096	\$ 46	\$ 140
Deferred taxes:			
Federal	\$ (1,828)	\$ —	\$ —
Total deferred taxes	\$ (1,828)	\$ —	\$ —
Total income tax expense	\$ 268	\$ 46	\$ 140

Tax expense for the year ended December 31, 2019 consists primarily of state income taxes in jurisdictions where the availability of carryforward losses are either limited or fully utilized as well as state taxes on the one-time gain from the deemed sale of assets resulting from an IRC section 338(g) tax election made by the Company related to the MyoScience Acquisition. This was partially offset by a reduction in the Company's valuation allowance on its deferred tax assets due to the MyoScience Acquisition. The tax expense for each of the years ended December 31, 2018 and 2017 are principally the result of minimum state taxes.

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

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,		
	2019	2018	2017
U.S. federal statutory rate	21.00 %	21.00 %	35.00 %
State taxes	(7.33)%	(24.84)%	2.26 %
Foreign taxes	(3.95)%	(92.04)%	(1.28)%
Change in valuation allowance	19.76 %	369.27 %	4.58 %
Stock-based compensation	(10.53)%	(874.29)%	(1.21)%
Tax credits	19.93 %	700.35 %	4.96 %
Interest expense	— %	218.47 %	2.90 %
Effect of rate changes	(0.42)%	13.44 %	(130.88)%
Convertible senior notes refinancing	— %	— %	6.55 %
Effect of the adoption of ASU 2016-09	— %	— %	68.89 %
Nondeductible expenses	(13.58)%	(132.96)%	— %
Reserves	(15.41)%	(202.98)%	(2.47)%
338(g) tax election	(9.61)%	— %	— %
Other	(2.35)%	(6.15)%	10.37 %
Effective tax rate	(2.49)%	(10.73)%	(0.33)%

The Company's effective tax rates of (2.49)%, (10.73)% and (0.33)% for the years ended December 31, 2019, 2018 and 2017, respectively, differed from the expected U.S. statutory tax rate of 21.0% for 2019 and 2018 and from 35.0% for 2017. 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, 2019 and 2018 are as follows (in thousands):

	December 31,	
	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	\$ 66,638	\$ 79,446
Federal and state credits	16,895	17,730
Depreciation and amortization	16,541	2,851
Accruals and reserves	8,756	11,009
Stock based compensation	21,663	18,302
Inventory	1,542	848
Other	2,022	127
Total deferred tax assets	134,057	130,313
Deferred tax liabilities:		
Discount on convertible senior notes	(8,383)	(11,655)
Deferred tax assets, net of deferred tax liabilities	125,674	118,658
Less: valuation allowance	(125,674)	(118,658)
Net deferred tax assets	\$ —	\$ —

As of December 31, 2019, the Company's federal net operating losses, or NOLs, and federal tax credit carryforwards totaled \$288.6 million and \$11.8 million, respectively. The Company also had state NOLs and state tax credit carryforwards of \$161.9 million and \$6.4 million, respectively, which are subject to change on an annual basis due to variations in the Company's annual state apportionment factors. The Company had non-U.S. tax NOLs of \$13.6 million at December 31, 2019.

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

The existing federal NOLs will begin expiring in 2026 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 IRC 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 \$181.0 million of federal net operating losses are subject to annual limitations. At December 31, 2019, \$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 2020 through 2022, \$3.5 million in 2023, \$1.4 million in each of 2024 and 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 increase in its valuation allowance of \$7.0 million for the year ended December 31, 2019 and a net reduction of \$1.6 million for the year ended December 31, 2018. The current year net increase in the Company's valuation allowance includes a reduction of \$1.8 million as a result of the MyoScience Acquisition. 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, 2019 and 2018.

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 2019, the Company recorded a reserve of \$1.7 million related to unrecognized tax benefits, or UTBs, which relates to tax positions taken during the year. The Company's UTB liability at December 31, 2019 was \$4.5 million. The change in the Company's UTBs in 2019 is summarized as follows (in thousands):

	Unrecognized Tax Benefit
Balance at December 31, 2018	\$ 2,881
Additions for current year positions	1,656
Balance at December 31, 2019	<u>\$ 4,537</u>

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, 2019, 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, or IRS, for the years 2016 through 2019, and state tax jurisdictions for the years 2015 through 2019. However, the IRS or states

PACIRA BIOSCIENCES, INC.
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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 17—OTHER EMPLOYEE BENEFITS

The Company's 401(k) plan is a deferred salary arrangement under section 401(k) of the IRC. Under the 401(k) plan, participating U.S. employees may defer a portion of their pre-tax earnings which are eligible for a discretionary percentage match as defined in the 401(k) plan and determined by the Company's board of directors. The Company recognized \$2.6 million, \$1.6 million and \$1.3 million of related compensation expense for the years ended December 31, 2019, 2018 and 2017, respectively.

NOTE 18—ACQUISITION-RELATED CHARGES AND PRODUCT DISCONTINUATION, NET

MyoScience Acquisition

The Company recognized acquisition-related charges of \$21.6 million during the year ended December 31, 2019 related to the MyoScience Acquisition. The acquisition-related charges reflect increases in the fair value of contingent consideration in the amount of \$16.7 million during the year ended December 31, 2019. See Note 12, *Financial Instruments*, for information regarding the method and key assumptions used in the fair value measurements of contingent consideration. In addition, \$4.2 million of acquisition-related charges, representing advisory costs, including legal, financial, accounting and tax services, were incurred during the year ended December 31, 2019. The remaining \$0.7 million incurred during year ended December 31, 2019 represented separation costs, asset write-downs and other restructuring charges. The Company did not incur any acquisition-related charges in 2018 or 2017. See Note 5, *MyoScience Acquisition*, for more information.

In conjunction with the MyoScience Acquisition, the Company initiated a restructuring through a headcount reduction in the sales and administrative functions. In addition, the Company terminated a number of existing distributor agreements that were maintained by MyoScience. These eliminations resulted in the write-off of demonstration equipment held by former employees and distributors.

DepoCyt(e) Discontinuation

The Company recorded charges of \$0.2 million, \$1.6 million and \$5.4 million, in the years ended December 31, 2019, 2018 and 2017, respectively, related to the discontinuation of its DepoCyt(e) manufacturing activities. Production at the Company's DepoCyt(e) manufacturing facility ceased in June 2017. Cash payments related to the lease of the idle DepoCyt(e) manufacturing facility are expected to cease once the lease term expires in August 2020.

In April 2018, the Company received formal notice of the termination of a Supply Agreement and a Distribution Agreement (and all related agreements as subsequently amended) from Mundipharma International Corporation Limited and Mundipharma Medical Company, respectively (collectively, "Mundipharma"). In November 2019, the Company reached a settlement with Mundipharma and made a \$5.3 million payment related to the DepoCyt(e) discontinuation which had previously been accrued.

Summary of Acquisition-Related Restructuring Activities and DepoCyt(e) Discontinuation Costs

At January 1, 2019, there was a balance sheet reclassification from the lease cost reserves related to the DepoCyt(e) discontinuation to lease liabilities in the amount of \$1.5 million, recognized as part of the transition to the ASU 2016-02. See Note 2, *Summary of Significant Accounting Policies*, for more information. The Company's acquisition-related restructuring and DepoCyt(e) discontinuation costs as of December 31, 2019 are summarized below (in thousands):

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

	Severance and Related Costs	Lease Costs	Write-off of Property, Plant & Equipment and Inventory	AROs, Other Restructuring and 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
Charges incurred	429	—	193	225	847
Cash payments made	(348)	—	—	(404)	(752)
Other, including non-cash activity	—	—	(193)	—	(193)
Balance sheet reclassifications	—	(1,970)	—	455	(1,515)
Balance at December 31, 2019	\$ 81	\$ —	\$ —	\$ 558	\$ 639

NOTE 19—COMMERCIAL PARTNERS AND OTHER AGREEMENTS

Thermo Fisher Scientific Pharma Services (Formerly Patheon UK Limited)

In April 2014, the Company 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 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, trauma and cranio-maxillofacial (CMF) procedures, 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

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

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., a wholly owned subsidiary of Elanco Animal Health, 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 veterinary use. 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 certain 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 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 July 2033, 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) for veterinary use.

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 20—RELATED PARTY TRANSACTIONS

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, 2019, 2018, or 2017. 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, 2019 and 2018, there was nothing payable to Dr. Pace for consulting services.

NOTE 21—COMMITMENTS AND CONTINGENCIES

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

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

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.

In December 2019, the Company reached an agreement in principle with the Department of Justice and more than one state Attorney General's office (the "Plaintiffs") on a proposal for a global civil settlement in the amount of \$3.5 million, subject to accrual of interest on the settlement amount from the date of the agreement in principle, negotiation of a definitive settlement agreement and other contingencies. As part of the settlement, the Company will admit no wrongdoing and will explicitly deny the Plaintiffs' allegations. The Company has been given assurances that, if the parties can agree to negotiation of the settlement, this will conclude the investigation that originated from the U.S. Department of Justice subpoena in April 2015. This settlement was recorded in acquisition-related charges, product discontinuation and other in the consolidated financial statements for the year ended December 31, 2019.

Purchase Obligations

The Company has approximately \$25.5 million of minimum, non-cancelable contractual commitments for contract manufacturing services and \$0.3 million of minimum, non-cancelable contractual commitments for the purchase of certain raw materials as of December 31, 2019.

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 is conducting these pediatric trials as post-marketing requirements, as stated in the New Drug Application (NDA) approval letter for EXPAREL. In December 2019, the Company announced positive results for its extended pharmacokinetic and safety study for local analgesia in children aged 6 to 17 undergoing cardiovascular or spine surgeries. Those positive results will provide the foundation for a supplemental New Drug Application (sNDA).

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 potential 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 9, *Goodwill and Intangible Assets*, 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 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.

Refer to Note 5, *MyoScience Acquisition*, for information on potential contingent milestone payments related to the MyoScience Acquisition.

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

NOTE 22—SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

The following tables present selected quarterly financial data for the years ended December 31, 2019 and 2018. For periods where the Company reported a net loss, no potentially dilutive securities were included in the computation of diluted net loss per share. (In thousands, except per share amounts):

	Three Months Ended			
	March 31, 2019	June 30, 2019	September 30, 2019	December 31, 2019
Total revenues	\$ 91,313	\$ 102,604	\$ 104,685	\$ 122,424
Cost of goods sold	27,303	25,201	22,304	31,904
Total operating expenses	90,234	97,329	102,272	120,711
Net income (loss)	(2,771)	2,730	(6,087)	(4,888)
Basic net income (loss) per common share ⁽¹⁾	\$ (0.07)	\$ 0.07	\$ (0.15)	\$ (0.12)
Diluted net income (loss) per common share ⁽¹⁾	\$ (0.07)	\$ 0.06	\$ (0.15)	\$ (0.12)

	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 ⁽¹⁾	\$ (0.26)	\$ 0.06	\$ (0.02)	\$ 0.20

(1) Basic and diluted earnings per share are computed independently for each of the quarters presented. Therefore, the sum of the quarterly basic and diluted earnings per share amounts may not equal the full-year basic and diluted earnings per share computation.

**DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED
PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934**

Pacira BioSciences, Inc. ("we," "our," or "us") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common stock, par value \$0.001 per share.

General

The following description of our capital stock is intended as a summary only. This description is based upon our amended and restated certificate of incorporation, as amended to date, which we refer to as our certificate of incorporation, our second amended and restated bylaws, which we refer to as our bylaws, and applicable provisions of Delaware General Corporation Law, which we refer to as the DGCL. This summary is not complete, and is qualified by reference to our [certificate of incorporation](#) (including the [certificate of amendment](#) thereto) and [bylaws](#), each of which are incorporated by reference as exhibits to this Annual Report on Form 10-K. We encourage you to read our certificate of incorporation, our bylaws and the applicable provisions of the DGCL for additional information.

Authorized Capital Stock

Our authorized capital stock consists of 250,000,000 shares of common stock, par value \$0.001 per share and 5,000,000 shares of preferred stock, par value \$0.001 per share.

Common Stock

Voting Rights. Each holder of common stock is entitled to one vote per share on all matters properly submitted to a vote of the stockholders, including the election of directors. Our certificate of incorporation and bylaws do not provide for cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose. An election of directors by our stockholders is determined by a plurality of the votes cast by stockholders entitled to vote on the election.

Dividends. Subject to preferences that may be applicable to any then outstanding preferred stock, the holders of our outstanding shares of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation and Dissolution. In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

Rights and Preferences. Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Preferred Stock

We are authorized to issue "blank check" preferred stock, which may be issued in one or more series upon authorization of our board of directors. Our board of directors is authorized to fix the designation of the series, the number of authorized shares of the series, dividend rights and terms, conversion rights and terms, voting rights, redemption rights and terms, liquidation preferences, sinking fund terms and any other rights, powers, preferences and limitations applicable to each series of preferred stock, which may be greater than the rights of the holders of the common stock. The authorized shares of our preferred stock are available for issuance without further action by our stockholders, unless such action is required by applicable law or the rules of any stock exchange on which our securities may be listed. If the approval of our stockholders is not required for the issuance of shares of our preferred stock, our board may determine not to seek stockholder approval.

The purpose of authorizing our Board to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. A series of our preferred stock could, depending on the terms of such series, impede the completion of a merger, tender offer or other takeover attempt. Our board of directors will make any determination

to issue such shares based upon its judgment as to the best interests of our stockholders. Our directors, in so acting, could issue preferred stock having terms that could discourage an acquisition attempt through which an acquirer may be able to change the composition of our board of directors, including a tender offer or other transaction that some, or a majority, of our stockholders might believe to be in their best interests or in which stockholders might receive a premium for their stock over the then-current market price of the stock. Additionally, the issuance of preferred stock may adversely affect the holders of our common stock by restricting dividends on our common stock, diluting the voting power of our common stock or subordinating the liquidation rights of our common stock. As a result of these or other factors, the issuance of preferred stock could have an adverse impact on the market price of our common stock.

Provisions of Our Certificate of Incorporation and Bylaws and Delaware Law That May Have Anti-Takeover Effects

Our certificate of incorporation, bylaws and the DGCL contain certain provisions that are intended to enhance the likelihood of continuity and stability in the composition of our board of directors. These provisions are intended to avoid costly takeover battles, reduce our vulnerability to a hostile change of control and enhance the ability of our board of directors to maximize stockholder value in connection with any unsolicited offer to acquire us. However, these provisions may have an anti-takeover effect and may delay, deter or prevent a merger or acquisition of us by means of a tender offer, a proxy contest or other takeover attempt that a stockholder might consider in its best interest, including those attempts that might result in a premium over the prevailing market price for the shares of common stock held by stockholders.

Authorized but Unissued Capital Stock. The authorized but unissued shares of common stock and preferred stock are available for future issuance without shareholder approval, subject to any limitations imposed by the rules of any stock exchange on which our securities may be listed. These additional shares may be used for a variety of corporate finance transactions, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could make more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Board of Directors. Our certificate of incorporation and bylaws provide for a board of directors divided as nearly equally as possible into three classes. Each class is elected to a term expiring at the annual meeting of stockholders held in the third year following the year of such election.

Removal of Directors by Stockholders. Our certificate of incorporation and bylaws provide that members of our board of directors may only be removed for cause by the affirmative vote of the holders of at least 75% of the outstanding shares entitled to vote on the election of the directors.

Stockholder Nomination of Directors. Our bylaws provide that a stockholder must notify us in writing of any stockholder nomination of a director in the case of an election of directors at an annual meeting of stockholders, not less than 90 days nor more than 120 days prior to the first anniversary of the preceding year's annual meeting; provided, however, that in the event that the date of the annual meeting in any other year is advanced by more than 20 days, or delayed by more than 60 days, from the first anniversary of the preceding year's annual meeting, a stockholder's notice must be so received not earlier than the 120th day prior to such annual meeting and not later than the close of business on the later of (A) the 90th day prior to such annual meeting and (B) the tenth day following the day on which notice of the date of such annual meeting was mailed or public disclosure of the date of such annual meeting was made, whichever first occurs. In the case of an election of directors at a special meeting of stockholders, a stockholder must, subject to certain other requirements as set forth in the bylaws, notify us in writing of any stockholder nomination of a director not earlier than the 120th day prior to such special meeting and not later than the close of business on the later of the 90th day prior to such special meeting and the tenth day following the day on which notice of the date of such special meeting was mailed or public disclosure of the date of such special meeting was made, whichever first occurs.

No Cumulative Voting. Under Delaware law, the right to vote cumulatively does not exist unless the certificate of incorporation specifically authorizes cumulative voting. Our certificate of incorporation does not provide for cumulative voting. Accordingly, a holder or group of holders of a majority of the shares of our common stock are able to elect all of the directors.

No Action by Written Consent. Our certificate of incorporation and bylaws provide that our stockholders may not act by written consent and may only act at duly called meetings of stockholders.

Delaware Business Combination Statute. Section 203 of the DGCL is applicable to us. Section 203 of the DGCL restricts some types of transactions and business combinations between a corporation and a 15% stockholder. A 15% stockholder is generally considered by Section 203 to be a person owning 15% or more of the corporation's outstanding voting stock. Section 203 refers to a 15% stockholder as an "interested stockholder." Section 203 restricts these transactions for a period of three years from the date the stockholder acquires 15% or more of our outstanding voting stock. With some exceptions, unless the transaction is approved

by the board of directors and the holders of at least two-thirds of the outstanding voting stock of the corporation, Section 203 prohibits significant business transactions such as:

- a merger with, disposition of significant assets to or receipt of disproportionate financial benefits by the interested stockholder, and
- any other transaction that would increase the interested stockholder's proportionate ownership of any class or series of our capital stock.

The shares held by the interested stockholder are not counted as outstanding when calculating the two-thirds of the outstanding voting stock needed for approval.

The prohibition against these transactions does not apply if:

- prior to the time that any stockholder became an interested stockholder, the board of directors approved either the business combination or the transaction in which such stockholder acquired 15% or more of our outstanding voting stock, or
- the interested stockholder owns at least 85% of our outstanding voting stock as a result of a transaction in which such stockholder acquired 15% or more of our outstanding voting stock. Shares held by persons who are both directors and officers or by some types of employee stock plans are not counted as outstanding when making this calculation.

Transfer Agent and Registrar

Computershare Trust Company, N.A. is the transfer agent and registrar for our common stock.

Exchange Listing

Our common stock is traded on the Nasdaq Global Select Market under the symbol "PCRX."

SUBSIDIARIES OF THE REGISTRANT

The following is a listing of the subsidiaries of Pacira BioSciences, Inc., a Delaware corporation:

	Jurisdiction of Incorporation
Pacira Pharmaceuticals, Inc.	California
Pacira CryoTech, Inc.	Delaware
Pacira Pharmaceuticals International, Inc.	Delaware
Pacira Limited	United Kingdom
Pacira Canada, Inc.	Canada
Pacira Ireland Limited	Ireland

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Pacira BioSciences, Inc.:

We consent to the incorporation by reference in the registration statements (Nos. 333-175101, 333-181986, 333-196542, 333-212098 and 333-233141) on Form S-8 of Pacira BioSciences, Inc. of our reports dated February 20, 2020, with respect to the consolidated balance sheets of Pacira BioSciences, Inc. as of December 31, 2019 and 2018, 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, 2019, and the related notes, and the effectiveness of internal control over financial reporting as of December 31, 2019, which reports appear in the December 31, 2019 annual report on Form 10-K of Pacira BioSciences, Inc.

Our report refers to a change in the method of accounting for leases as of January 1, 2019 due to the adoption of Accounting Standards Update 2016-02, Leases (Topic 842).

Our report includes an explanatory paragraph indicating that management excluded from its assessment of the effectiveness of the Company's internal control over financial reporting as of December 31, 2019, internal control over financial reporting associated with the acquisition of MyoScience, Inc. (now Pacira CryoTech, Inc.) during 2019, associated with 1% of total assets and 2% of total revenues included in the consolidated financial statements of the Company as of and for the year ended December 31, 2019. Our audit of internal control over financial reporting of the Company also excluded an evaluation of the internal control over financial reporting of Pacira CryoTech, Inc.

/s/ **KPMG LLP**

Short Hills, NJ
February 20, 2020

CERTIFICATION

I, David Stack, certify that:

1. I have reviewed this annual report on Form 10-K of Pacira BioSciences, Inc. (the “Registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) evaluated the effectiveness of the Registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in the Registrant’s internal control over financial reporting that occurred during the Registrant’s most recent fiscal quarter (the Registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant’s internal control over financial reporting; and
5. The Registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant’s auditors and the audit committee of the Registrant’s board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant’s ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant’s internal control over financial reporting.

Date: February 20, 2020

/s/ DAVID STACK

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

CERTIFICATION

I, Charles A. Reinhart, III, certify that:

1. I have reviewed this annual report on Form 10-K of Pacira BioSciences, Inc. (the “Registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) evaluated the effectiveness of the Registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in the Registrant’s internal control over financial reporting that occurred during the Registrant’s most recent fiscal quarter (the Registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant’s internal control over financial reporting; and
5. The Registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant’s auditors and the audit committee of the Registrant’s board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant’s ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant’s internal control over financial reporting.

Date: February 20, 2020

/s/ CHARLES A. REINHART, III

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

STATEMENT PURSUANT TO 18 U.S.C. §1350

Pursuant to 18 U.S.C. §1350, the undersigned certifies that this Annual Report on Form 10-K of Pacira BioSciences, Inc. for the year ended December 31, 2019, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in this report fairly presents, in all material respects, the financial condition and results of operations of Pacira BioSciences, Inc.

Date: February 20, 2020

/s/ DAVID STACK

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

Date: February 20, 2020

/s/ CHARLES A. REINHART, III

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