

# PACIRA

BIOSCIENCES, INC.

## 2020 ANNUAL REPORT





"Our initiatives during the global pandemic translated into **record revenues** for 2020 despite COVID-related disruptions in care delivery."

David Stack | Chief Executive Officer and Chairman

### Enhancing Leadership in Non-Opioid Pain Management

I am delighted to report that during the challenging times faced in 2020, Pacira quickly adapted to our customers' needs to provide opioid-free pain relief in a virtual world. COVID-19 has further escalated our nation's opioid crisis, placing an even brighter spotlight on the tremendous need for opioid-sparing pain management. Equally important is the pain that patients endured due to COVID-related delays in necessary surgical procedures. We know that expedited recovery is more critical than ever before, and we are dedicating considerable resources to develop and implement EXPAREL-based Enhanced Recovery after Surgery (ERAS) protocols to redefine best practice and drive surgical migration to the outpatient setting.

Our initiatives during the global pandemic translated into record revenues for 2020, despite COVID-related disruptions in care delivery. This success is a testament to our steadfast commitment to providing an opioid alternative to as many patients as possible while redefining the use of opioids as a rescue medication only.

The overwhelming needs of the marketplace and transformation underway in outpatient surgical care allowed EXPAREL average daily sales to return to year-over-year growth in June. Attractive growth trends continued throughout the remainder of 2020 and into 2021.

Our strategy to transition from an inpatient, surgery-based company to an outpatient anesthesia-based company is translating elegantly into a long-term earnings growth story. The ongoing evolution of the marketplace is a direct result of EXPAREL-based low or no opioid protocols, which we expect to become permanently embedded in healthcare systems given the improved patient outcomes, satisfaction rates, and economic advantages of outpatient care. Payers including CMS and major commercial payers are driving patients to outpatient care based on significant cost savings.

Our leadership position in non-opioid pain management is underscored by growing revenue of EXPAREL, the only FDA-approved non-opioid, long-acting local analgesic for infiltration in patients aged 6 and up and in adults as a brachial

plexus nerve block for regional anesthesia. With more than 8 million patients treated since launch, EXPAREL remains well positioned for long-term market leadership given its established efficacy and excellent safety profile.

Since acquiring iovera® in 2019, we have improved the reliability of the device and launched new clinical initiatives to demonstrate its potential to improve patient care using novel cold technology to administer a nerve block for long-term, non-opioid pain control. We have great confidence in the long-term opportunity for this important product.

### Global Growth Strategies

2020 was highlighted by strong execution across two robust global growth strategies. First, expanding the use of EXPAREL and iovera® for opioid-sparing pain management while enabling the migration of large, painful, and profitable procedures to the ambulatory surgery center, or ASC, and hospital outpatient department settings. Second, pursuing innovation by investing in our internally and externally sourced portfolio of non-opioid pain management and regenerative health solutions while simultaneously advancing partnerships and education designed to revolutionize medical practice through best practice opioid-sparing ERAS protocols.

### Expanding Use of EXPAREL

We have invested significant resources to help support the market's continuing shift toward anesthesia-driven regional pain management and the migration of procedures to outpatient sites of care. We believe regional anesthesia is the most important driver of our business for 2021. In 2020, only 20% of anesthesia procedures used a regional approach. The field is poised for rapid expansion given advances in ultrasound guidance, newer techniques, and improved outcomes. We are paving the way for EXPAREL to revolutionize the practice of regional anesthesia through our expanding educational and training initiatives. This is vital to our future and the focus of our state-of-the-art training center in Tampa – the PITT.

For decades, there has been a high level of interest in regional blocks but with short-acting agents only providing hours of pain control, it was difficult to justify a time return on



investment. Today, long-acting EXPAREL-based blocks have extended the duration of pain control to several days – a significantly positive change in the paradigm of patient care.

Our customers see the strong advantages of using blocks and replacing antiquated pumps and catheters. Additionally, EXPAREL reimbursement is consistently improving in ASC settings as payers and self-insured employers continue to drive the shift from inpatient to outpatient care given the economic benefits.

Not only are these market dynamics fundamental to our growth, but also directly correlate with patient outcomes and satisfaction rates given the compelling advantages of opioid-sparing regional approaches.

Beyond on-label opportunities, we are working to further broaden the EXPAREL label with key milestones in the near-term. In March 2021, FDA approved our supplemental New Drug Application (sNDA) of EXPAREL in patients aged 6 and older and the launch is underway.

Pediatrics on label is of critical importance given the significant unmet need for non-opioid options for managing postsurgical pain in this vulnerable patient population. With approximately 1 million procedures per year, we envision this to be at least a \$100 million opportunity.

We also recently concluded enrollment in our Phase 3 STRIDE study to evaluate EXPAREL versus bupivacaine as a nerve block for lower extremity procedures. If successful, STRIDE will form the basis of an sNDA submission later this year. We believe the lower extremity opportunity to be as significant as upper extremity.

We also continue to make progress in markets outside of the U.S. We remain on track to launch EXPAREL along with iovera® in Europe later this year

### **Capitalizing on iovera®**

We remain excited about the potential for iovera® – our innovative system that delivers a non-pharmacologic nerve block using the body's natural response to cold to safely and immediately reduce pain. COVID-19 made 2020 a difficult year for iovera® and triggered clinical and commercial delays. Looking ahead, we have implemented several commercial enhancements and two opportunities that we believe will drive growth in 2021.

One is the procedural solution of iovera® plus EXPAREL to improve total knee arthroplasty (TKA) before, during and after surgery. The second is iovera® for opioid-free, surgery-free, and drug-free osteoarthritis pain control. Simply put, if a patient is not ready for surgery, iovera® can turn the pain signal off for several months with a simple

20-minute procedure, allowing for a walk on the beach or a round of golf -- things that are difficult to do with osteoarthritis pain.

On the clinical front, PREPARE is enrolling patients to evaluate iovera® and EXPAREL for opioid-sparing pain management for patients undergoing TKA. In parallel, we are launching an iovera® registry to capture real-world evidence in TKA procedures.

We are also encouraged by the excitement around iovera® in other areas. Key opinion leaders in orthopedics, spine and anesthesia are interested in replacing heat-based radiofrequency ablation with iovera® cold therapy across a wide range of treatment opportunities such as low back pain, spine, spasticity, and rib fracture. In sum, we remain highly confident in the technology behind this innovative system with sales potential approaching \$200 million in our 5-year planning horizon.

### **Business Development Opportunities**

Our team is leading a robust effort and thoughtfully pursuing opportunities of interest to the surgical and anesthesia audiences we call on today. We believe our leadership position in opioid-sparing pain control provides a significant opportunity to build a differentiated portfolio to improve the patient journey along the neural pain pathway.

We recently announced an investment in GeneQuine that provides us an opportunity to participate in developing an exciting disease-modifying gene therapy for osteoarthritis. We also made an investment in Spine BioPharma to support their advancement of a regenerative approach to treating low back pain caused by degenerative disc disease.

### **Closing Remarks**

On behalf of the board of directors and our dedicated team of professionals, thank you for your support of our company, our strategy, and the important work we are advancing.

We entered the new year in a stronger position than ever to advance our mission of providing an opioid alternative to as many patients as possible while reserving opioids for rescue use only. We expect a very exciting 2021 as we build on our progress in 2020 and further entrench EXPAREL as the leader in non-opioid postsurgical pain management, advance iovera® in orthopedic settings, and create value through additional strategic investments and collaborations.

Wishing you all the very best,



David Stack  
Chief Executive Officer and Chairman

# Milestones

## JANUARY

- EXPAREL achieves primary and key secondary endpoints in Phase 4 CHOICE study in Cesarean section patients.
- Launch of national regional anesthesia training initiative with Envision Physician Services.

## JULY

- Announced conclusion of EXPAREL agreement with DePuy Synthes.
- Issuance of \$402.5 million of 0.75% convertible senior notes due 2025.

## AUGUST

- FDA acceptance of sNDA for EXPAREL use in pediatric patients.
- Publication of Phase 4 study of EXPAREL in Cesarean Section procedures in Anesthesia & Analgesia.

## OCTOBER

- Launch of state-of-the-art training center in Tampa, the PITT, dedicated to advancing best practice regional approaches to manage acute pain.

## JANUARY

- Equity investment in GeneQuine Biotherapeutics.

2020

2021

## MAY

- Appointment of Donald C. Manning, M.D., Ph.D. as Chief Medical Officer.

## SEPTEMBER

- Collaboration formed with IPG to reduce postsurgical opioid prescribing and surgical procedure cost.
- Positive CHMP opinion for EXPAREL for the treatment of postsurgical pain.

## NOVEMBER

- European commission approves EXPAREL for the treatment of postsurgical pain.

## MARCH

- FDA approval of sNDA for EXPAREL in pediatric patients.

## APRIL

- Investment in Spine BioPharma

# Pacira Core Values



**Patient** safety and welfare are our top priorities at all times.



Our **people** are our greatest asset.



We are **passionate** about what we do.



Our **thoughts** are shared generously.



Building **trust** is essential.



**Teamwork** is the cornerstone of our business success.

**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, 2020**

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:

<b>Title of each class</b>	<b>Trading symbol</b>	<b>Name of each exchange on which registered</b>
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 ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes ☐ No ☒

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

Indicate by check mark whether the registrant has submitted electronically 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 ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management’s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☒ No ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

The aggregate market value of 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 30, 2020, the last trading day of the registrant’s most recently completed second fiscal quarter, of \$52.47 per share was approximately \$1.6 billion. Shares of common stock held by each director and executive officer (and their respective affiliates) and by each person who owns 10 percent or more of the outstanding common stock or who is otherwise believed by the registrant to be in a control position have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 21, 2021, 43,863,467 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 2021 annual meeting of stockholders to be filed with the Securities and Exchange Commission no later than 120 days after the end of the registrant’s fiscal year ended December 31, 2020.

**PACIRA BIOSCIENCES, INC.**  
**ANNUAL REPORT ON FORM 10-K**  
**FOR THE YEAR ENDED DECEMBER 31, 2020**

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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 and trends, 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 impact of the COVID-19 pandemic on elective surgeries, our manufacturing and supply chain and global and U.S. economic conditions; and our business, including our revenues, financial condition and results of operations; the cost and timing of an early termination payment to DePuy Synthes Sales, Inc.; the success of our sales and manufacturing efforts in support of the commercialization of EXPAREL<sup>®</sup> (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 success of our sales and manufacturing efforts in support of the commercialization of iovera<sup>®</sup>; the rate and degree of market acceptance of iovera<sup>®</sup>; the size and growth of the potential markets for iovera<sup>®</sup> and our ability to serve those markets; our plans to expand the use of iovera<sup>®</sup> to additional indications and opportunities, and the timing and success of any related clinical trials for iovera<sup>®</sup>; the commercial success of iovera<sup>®</sup>; 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 related timing and success of European Medicines Agency, or EMA, Marketing Authorization Applications, or MAA; our plans to evaluate, develop and pursue additional DepoFoam<sup>®</sup>-based product candidates; the approval of the commercialization of our products in other jurisdictions; clinical trials in support of an existing or potential DepoFoam-based product; our commercialization and marketing capabilities and our ability to successfully construct additional EXPAREL manufacturing suites in Swindon, England and San Diego, California; the outcome of any litigation; the recoverability of our deferred tax assets 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* and in the summary of Risk Factors appearing on the next page.



## ***Summary of Risk Factors***

This risk factor summary includes those risks most material to our business, financial condition, results of operations or prospects. A full discussion of the risks outlined in this summary, as well as those risks not outlined below, appear in Part I, Item 1A. *Risk Factors* in this Annual Report.

- A pandemic, epidemic or outbreak of a contagious disease (such as the novel coronavirus (COVID-19) pandemic), or fear of such an event, could have a material adverse effect on our business, operating results and financial condition.
- Our success depends primarily on our ability to successfully commercialize EXPAREL.
- 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.
- We face significant competition from other pharmaceutical, medical device and biotechnology companies. Our operating results will suffer if we fail to compete effectively.
- Regulatory approval for any approved product is limited 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.
- 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 additional product revenues.
- We rely on third parties to perform many essential services for EXPAREL and iovera<sup>®</sup> 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<sup>®</sup> will be significantly impacted and we may be subject to regulatory sanctions.
- We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for EXPAREL, iovera<sup>®</sup> or product candidates that we may develop and may have to limit their commercialization.
- If we fail to manufacture our products in sufficient quantities and at acceptable quality and pricing levels, or to fully comply with Current Good Manufacturing Practice regulations, we may face delays in the commercialization of these products or be unable to meet market demand, and may lose potential revenues.
- We may need to expand our manufacturing operations or outsource such operations to third parties.
- Our inability to continue manufacturing adequate supplies of our products could result in a disruption in the supply to our customers and partners, which could have a material adverse impact on our business and results of operations.
- Our co-production and other agreements with Thermo Fisher Scientific Pharma Services, or Thermo Fisher (formerly Patheon UK Limited), 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 rely on third parties for the timely supply of specified raw materials and equipment for the manufacture of EXPAREL and iovera<sup>®</sup>. 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.
- 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.
- 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.

- 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.
- Our dependence on contract research organizations could result in delays in and additional costs for our drug development efforts.
- 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.
- Our business could be materially adversely affected if a regulatory or enforcement agency determines that we are promoting or have in the past promoted the “Off-label” use of our products.
- 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) of the Federal Food, Drug, and Cosmetic Act, which would have a material adverse effect on our business and financial condition.
- For iovera<sup>®</sup> 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.
- A regulatory authority may determine that our products or any of our product candidates have undesirable side effects.
- The design, development, manufacture, supply and distribution of EXPAREL are highly regulated and technically complex.
- 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.
- If the government or third-party payers fail to provide adequate coverage and payment rates for EXPAREL, iovera<sup>®</sup> or any future products, or if hospitals or ambulatory surgical centers choose to use therapies that are less expensive, our revenue and prospects for profitability will be limited.
- Public concern regarding the safety of drug products such as EXPAREL and medical device products such as iovera<sup>®</sup> could result in the inclusion of unfavorable information in our labeling, or require us to undertake other activities that may entail additional costs.
- The patents and the patent applications that we have covering our DepoFoam 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 patents and the patent applications that we have covering our iovera<sup>®</sup> 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.
- 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.
- 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.
- We are subject to periodic litigation, which could result in losses or unexpected expense of time and resources.

## PART I

### Item 1. Business

#### References

Pacira BioSciences, Inc., a Delaware corporation, is the holding company for our California operating subsidiary named Pacira Pharmaceuticals, Inc. In March 2007, we acquired Pacira Pharmaceuticals, Inc. from SkyePharma Holdings, Inc. (now a subsidiary of Vectura Group plc), or Skyepharm (referred to herein as the “Skyepharm Acquisition”). In April 2019, we acquired MyoScience, a privately-held medical technology company (referred to herein as 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, we changed our name to Pacira BioSciences, Inc. upon the completion of the MyoScience Acquisition. Our principal executive offices are located in Parsippany, New Jersey.

#### Trademarks and Service Marks

Pacira<sup>®</sup>, EXPAREL<sup>®</sup>, iovera<sup>®</sup>, DepoFoam<sup>®</sup>, DepoCyt<sup>®</sup> (United States (U.S.) registration), DepoCyte<sup>®</sup> (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 the industry leader in our commitment to non-opioid pain management and regenerative health solutions to improve patients’ journeys along the neural pain pathway. Our corporate mission is to provide an opioid alternative to as many patients as possible using enhanced recovery after surgery (“ERAS”) multimodal protocols and opioids for rescue only. To that end, we are advancing a three-part growth strategy focusing on: (i) expanding the utilization of EXPAREL and iovera<sup>®</sup>, 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.

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 eight 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 safe and effective 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 2020 were \$413.3 million. For the years ended December 31, 2020, 2019 and 2018, net product sales of EXPAREL accounted for 96%, 97% and 98% of our total revenues, respectively. In addition to EXPAREL, DepoFoam is also the basis for future clinical candidates.

In April 2019, we completed the MyoScience Acquisition and added the iovera<sup>®</sup> system to our commercial offering. The iovera<sup>®</sup> system is an FDA-approved, non-opioid handheld cryoanalgesia device used to produce 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<sup>®</sup> system is highly complementary to EXPAREL as a non-opioid therapy that alleviates pain using a non-pharmacological nerve block to disrupt pain signals being transmitted to the brain from the site of injury or surgery. For the year ended December 31, 2020, our net product sales of iovera<sup>®</sup> were \$8.8 million.

## Product Portfolio and Product Candidate Pipeline

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:

	Preclinical	Clinical				NDA	Market	Next Expected Milestone(s)
		P1	P2	P3	P4			
EXPAREL								
Surgical infiltration	<div></div>						Geographic expansion	
Interscalene brachial plexus nerve block	<div></div>						Geographic expansion	
C-section TAP field block	<div></div>						Expand utilization and training	
Surgical infiltration/Nerve block (Ex-US)								
Europe	<div></div>						Commercial launch in target countries	
Canada	<div></div>						Regulatory submission under review	
China	<div></div>						Finalize strategy; initiate Phase 3 study	
Pediatric infiltration*	<div></div>						March 22, 2021 FDA action date	
Lower extremity nerve block	<div></div>						Complete STRIDE study; submit sNDA	
Pediatric nerve block*							Finalize study designs	
iovera°								
Total knee arthroplasty (TKA)	<div></div>						Advance PREPARE study and IGOR registry	
Other indications	<div></div>						Support investigator-initiated studies/grants	
DepoFoam								
DepoFoam-based local anesthetic	<div></div>						Complete Phase 1 study	
Other	<div></div>						Initiate clinical studies	
NOCITA								
Postsurgical analgesia in dogs and cats	<div></div>						Marketed by Aratana Therapeutics, Inc.	

\* Pediatric FDA action date of March 22, 2021 is for infiltration in patients aged 6 to 17 years old. Study designs have not been finalized for pediatric populations in infiltration or nerve block in patients aged 0 to less than 6 years old.

- TAP block is a transversus abdominis plane field block

- 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 the 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° 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. EXPAREL has become the foundation of opioid-sparing protocols for painful orthopedic procedures, including shoulder, hip fracture, joint reconstruction, and spine surgeries. We are expanding utilization through education and Phase 4 clinical evidence in key surgical settings, such as Cesarean section, or C-section, and other abdominal procedures. 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°, we are focusing on iovera° 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<sup>®</sup> 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 Phase 1 study to evaluate the epidural delivery of a DepoFoam-based local anesthetic as a potential alternative to the use of intrathecal opioids delivered by pumps and catheters and preclinical activities are underway for other DepoFoam-based clinical candidates targeting inflammation for chronic pain opportunities.

## The Opioid Epidemic

Opioid addiction in the U.S. has reached epidemic proportions, with the Centers for Disease Control and Prevention, or CDC, reporting that more than 80,000 drug overdose deaths occurred in the U.S. in the 12-months ending May 2020. This represents a worsening of the drug overdose epidemic in the U.S. and is the largest number of drug overdoses for a 12-month period ever recorded. The recent increase in drug overdose mortality began in 2019 and continued into 2020, prior to the declaration of the COVID-19 National Emergency in the U.S. in March. The increases in drug overdose deaths appear to have accelerated during the COVID-19 pandemic. Synthetic opioids are the primary driver of the increases in overdose deaths. The 12-month count of synthetic opioid overdose deaths increased 38% from the 12-months ended June 2019 compared with the 12-months ended May 2020.

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. A 2017 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, *United States for Non-Dependence: An Analysis of the Impact of Opioid Overprescribing in America*, based on an analysis of 2016 adjudicated medical and pharmacy claims data conducted by QuintilesIMS.

## EXPAREL

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 as follows:

- *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 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. In November 2020, the European Commission, or EC, approved EXPAREL as a brachial plexus block or femoral nerve block for treatment of post-operative pain in adults, and as a field block for treatment of somatic post-operative pain from small- to medium-sized surgical wounds in adults. Additionally, regulatory initiatives are advancing in global markets such as 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, 2021, CMS added total hip arthroplasty to its listing of ASC covered procedures. The final CMS rule for 2021 also includes a scheduled phase-out of the inpatient-only list over the next three years. Under this plan, by 2024, no procedures will be mandated to be conducted in the in-patient setting. 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 healthcare providers and hospital systems to support their implementation of opioid-sparing enhanced recovery protocols. 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, Shatterproof and IPG.

### **EXPAREL Clinical Benefits**

We believe EXPAREL can replace the use of bupivacaine delivered 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 a variety of 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 one opioid-free patient in the placebo arm.

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 pumps, 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 pumps 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.

### ***Key EXPAREL Markets***

#### *Orthopedics*

EXPAREL is used across multiple orthopedic procedures, including joint reconstruction, shoulder, spine, extremities and hip fractures. EXPAREL-based ERAS protocols are becoming a cornerstone of opioid-sparing postsurgical pain management and enabling the shifting of many complex, painful orthopedic procedures to the 23-hour stay environment.

EXPAREL is being adopted in an increasing number of spine surgeries as a key component of a multimodal pain management solution enabling rapid recovery after surgery and a shift to the outpatient site of care. Common applications include infiltration, erector spinae plane (ESP) blocks and TAP blocks.

EXPAREL administered as a brachial plexus nerve block is a key and growing part of our business. An EXPAREL brachial plexus block provides pain coverage for the upper quadrant for use in rotator cuff, shoulder arthroplasty, elbow, wrist and hand procedures. Our anesthesiologist customers see the strong advantages of using brachial plexus and other field blocks as a vehicle for shifting procedures to the ASC setting by replacing antiquated pumps and catheters, which often become dislodged and prevent a procedure from taking place in a 23-hour site of care. Additionally, the ASC environment is an area where EXPAREL reimbursement is consistently improving as payers and self-insured employers continue to drive the shift from inpatient to outpatient care for a variety of surgeries.

#### *Abdominal and Colorectal*

After having success with the brachial plexus block, anesthesiologists typically seek to broaden their EXPAREL use with other field blocks. TAP blocks are a significant market where EXPAREL is providing long-acting pain control in the abdominal region and supporting the migration of these procedures to the ASC setting. We expect the expanding use of EXPAREL in the estimated six million abdominal and colorectal procedures that occur annually in the U.S. to be a significant growth driver.

#### *Women's Health*

There is a significant and growing demand among women for managing pain with non-opioid options. Opioid addiction in women is growing at an alarming rate and studies have shown that women are 40% more likely than men to become newly persistent users of opioids following surgery. Women's Health continues to be an important source of growth as anesthesia-driven EXPAREL-based TAP and Pectoralis, or PEC, blocks take hold as institutional protocol for C-section, abdominoplasty, gynecologic oncology, mastectomy and breast reconstruction procedures.

#### *Cardiothoracic*

Cardiothoracic surgery is considered one of the most painful types of surgical procedures for both open and minimally invasive procedures. As a result, opioids are widely used, but are often inadequate. Poorly controlled postoperative pain leads to the development of chronic persistent pain in as many as 40% of these patients and persistent opioid use after surgery is seen in over 10% of such patients. Regional anesthesia approaches have been evolving, with EXPAREL replacing thoracic epidurals as an alternative method of producing long-lasting analgesia.

## ***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 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 and ASC 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.

## ***Third Molar (Wisdom Tooth) 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% through the utilization of EXPAREL to provide prolonged non-opioid postsurgical pain control. Aetna now includes the cost of EXPAREL as a covered expense for impacted third molar extractions performed by surgeons who have completed training on use of the product.

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

## **EXPAREL Label Expansion**

### ***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. Based on the positive data from the PLAY study, we submitted an sNDA to the FDA seeking expansion of the EXPAREL label to include single-dose infiltration to provide postsurgical analgesia in children aged six and over. In August 2020, the FDA accepted our sNDA and provided a Prescription Drug User Fee Act, or PDUFA, action date of March 22, 2021.

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 EMA has agreed that the PLAY study will meet our pediatric requirement in the E.U. for patients aged 6 to 17. The full study results will be submitted for publication in the peer-reviewed medical literature.

We are working with the FDA to identify an appropriate clinical program for EXPAREL administered as a nerve block in the pediatric setting and have an agreed upon Pediatric Investigation Plan with the EMA for EXPAREL in the E.U. We are in



negotiations with the FDA and the EMA for clarity on other pediatric study obligations and are working with both agencies to synchronize our pediatric clinical studies as much as possible between the two regions.

### *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 will support an sNDA submission seeking label expansion to include lower extremity nerve blocks. A filing strategy was agreed to with the FDA and we intend to file a variation with the EMA. 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 were granted marketing authorization by the EC in November 2020 for EXPAREL as a brachial plexus block or femoral nerve block for treatment of post-operating pain in adults and as a field block for treatment of somatic post-operative pain from small- to medium-sized surgical wounds in adults. We are planning to launch EXPAREL together with iovera<sup>®</sup> in targeted European countries beginning in the second half of 2021.

The EC approval was based on the results of four pivotal Phase 3 studies that demonstrated improvements in pain reduction and opioid use. These studies include:

- *Lower Extremity Nerve Block Study:* This study assessed the safety and efficacy of EXPAREL as a femoral nerve block in patients undergoing TKA. Results demonstrated that EXPAREL resulted in a significant reduction in cumulative pain scores over 72 hours compared to placebo. A higher percentage of patients who received EXPAREL were pain-free, consumed fewer opioids and reported higher satisfaction with their pain control compared with placebo.
- *Upper Extremity Nerve Block Study:* This study assessed the safety and efficacy of EXPAREL as an interscalene brachial plexus nerve block in patients undergoing total shoulder arthroplasty or rotator cuff repair. Results demonstrated that EXPAREL significantly improved pain control and reduced opioid consumption through 48 hours compared with placebo and a standardized pain management protocol alone.
- *Hard Tissue Surgery Infiltration Study:* This study assessed the safety and efficacy of EXPAREL administered via infiltration in patients undergoing bunionectomy. Results demonstrated that EXPAREL significantly reduced pain and opioid consumption compared with placebo over the first 24 hours following surgery than patients administered placebo.
- *Soft Tissue Surgery Infiltration Study:* This study assessed the safety and efficacy of EXPAREL administered via infiltration in patients undergoing hemorrhoidectomy. Results demonstrated that EXPAREL significantly reduced pain compared to placebo at all time points, including a 30% reduction in the cumulative pain scores at 72 hours. Patients who received EXPAREL consumed significantly fewer opioids than patients administered placebo.

The EC decision is applicable to all 27 E.U. member states plus the United Kingdom, Iceland, Norway and Liechtenstein. Despite the United Kingdom’s withdrawal from the E.U. (“Brexit”), this approval will still be recognized by the United Kingdom Medicines and Healthcare products Regulatory Agency, or MHRA, however we will need to transfer the EMA marketing authorization.

In Canada, Health Canada has validated our New Drug Submission and we remain in labeling discussions. We do not intend to pursue a commercial partnership to commercialize EXPAREL in either 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 completed a pharmacokinetic study requested by the National Medical Products Administration in China and we are planning to submit an Investigational New Drug, or IND, application in support of such a study.

## **iovera°**

The iovera° system is highly complementary to EXPAREL as a non-opioid therapy that produces cryoanalgesia via a handheld device by disrupting pain signals transmitted to the brain from the site of injury or surgery and alleviates pain. The iovera° system is 510(k) cleared in the U.S., has a CE mark in the E.U. and is cleared for marketing in Canada for the blocking of pain. It is also indicated for the relief of pain and symptoms associated with arthritis of the knee for up to 90 days.

Our commercial strategy for iovera° focuses on two broad market segments. First, iovera° and EXPAREL for opioid-sparing pain management for the TKA patient, with iovera° being administered before surgery and EXPAREL administered during surgery. We are enrolling patients into our PREPARE study that will evaluate iovera° and EXPAREL for TKA. As many as 30% 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 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 or medical 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 up to 150 days after being treated with iovera°.

Preliminary findings demonstrated reductions in opioids, including:

- The daily morphine equivalent consumption in the per protocol group analysis was significantly lower at 72 hours ( $p<0.05$ ), 6 weeks ( $p<0.05$ ) and 12 weeks ( $p<0.05$ ).
- 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 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.

## **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 preclinical and feasibility studies for these candidates, we have prioritized two programs for clinical development: (i) a DepoFoam-based

analgesic for acute and chronic pain using epidural delivery and (ii) other DepoFoam-based clinical candidates targeting inflammation for chronic pain opportunities.

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 are complementary to EXPAREL and iovera° and are of great interest to the surgical and anesthesia audiences we are already calling on today. We believe our leadership position in opioid-sparing pain control provides us with a significant opportunity to build a differentiated portfolio to improve the patient journey along the neural pain pathway.

## **Sales and Marketing**

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

## ***Pacira Innovation and Training Center of Tampa***

In October 2020, we announced the grand opening of the Pacira Innovation and Training center of Tampa (the “PITT”). We designed this facility to help advance clinician understanding of the latest local, regional and field block approaches for managing pain. The PITT provides an unparalleled training environment for healthcare providers working to reduce or eliminate patient exposure to opioids.

The PITT is a fully adaptable environment and is equipped with state-of-the-art technology and audio/visual capabilities to support a full range of educational events, such as presentations and hands-on workshops.

The PITT features several distinct training spaces including a simulation lab equipped with seven ultrasound scanning stations; a lecture hall featuring a 4½-foot-tall by 24-foot-wide liquid crystal display video wall to support live, virtual and even global presentations; and a green-screen broadcast studio designed to livestream content with single or multiple hosts.

In addition to the EXPAREL programs, we are hosting ongoing workshops to train new users on best practice techniques for iovera° administration at the PITT. Led by healthcare professionals, these labs include didactic lectures and hands-on trainings including live model nerve scanning and identification using ultrasound and peripheral nerve stimulation.

The PITT also serves as a venue for national anesthesia provider organizations to host their own workshops and training sessions.

### ***DePuy Synthes Sales Inc.***

In July 2020, we announced the conclusion of a co-promotion 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. market. The collaboration began in January 2017 and concluded in January 2021. During that time DePuy Synthes field representatives collaborated with the Pacira field teams to support EXPAREL use and education in orthopedic surgical settings. In addition to partnering with DePuy Synthes in support of orthopedic surgical procedures, Pacira field representatives remained the overall EXPAREL account managers and commercial leads for soft tissue surgeons, anesthesiologists and ASCs. Through this collaboration we significantly expanded the use of EXPAREL and solidified its role in opioid-sparing protocols across a range of orthopedic procedures. Our decision to conclude the partnership was due to the evolution of orthopedic practice from an inpatient hospital experience to the ambulatory setting with anesthesia-driven regional approaches playing an increasingly essential role. This growing market is already served by our field-based teams.

### **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 of which \$58.0 million is available at December 31, 2020. Upon the completion of the MyoScience Acquisition, we renamed MyoScience 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 investment of \$1.6 million in TELA Bio. For more information, refer to Note 12, *Financial Instruments*, to our consolidated financial statements included herein.

#### ***GeneQuine Biotherapeutics GmbH***

In December 2020, we made an equity investment in GeneQuine Biotherapeutics GmbH, or GeneQuine, a privately held biopharmaceutical company advancing a gene therapy platform for the treatment of osteoarthritis and other musculoskeletal disorders. GeneQuine's product candidates are next-generation gene transfer vehicles. These gene therapy vectors are highly efficient in entering joint cells to confer multi-year gene expression. Safety of this platform has been demonstrated in several species and is currently being evaluated in an ongoing Phase 1 study. GeneQuine's lead gene therapy product candidate, GQ-303 and its analogs are currently in preclinical development as a treatment for osteoarthritis. These helper-dependent adenoviral gene therapy vectors express proteoglycan 4 (PRG4), a protein that plays an important physiological role in regulating osteoarthritis through lubrication and decreased pain, inflammation and cartilage degeneration. After intra-articular injection, the vector enters joint cells and turns them into factories to produce sustained therapeutic levels of PRG4 to restore joint homeostasis and provide long-lasting improvement in joint function and pain relief, which has been demonstrated in several in vivo osteoarthritis models.

Under the terms of the agreement, we made an initial investment of \$1.2 million and subsequently invested \$1.2 million in the form of a convertible note in January 2021. We will make an additional \$4.9 million investment predicated upon GeneQuine achieving certain prespecified near-term milestones related to GQ-303. Up to \$3.0 million of our investment will be in the form of a convertible note. 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 Skyepharmaceutical 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 Skyepharmaceutical are the two 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 Skyepharmaceutical 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.

### ***Aratana Therapeutics, Inc.***

In December 2012, we entered into an Exclusive License, Development and Commercialization Agreement and related Supply Agreement with Aratana Therapeutics, Inc., a wholly owned subsidiary of Elanco Animal Health, 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<sup>®</sup> (bupivacaine liposome injectable suspension), as a local post-operative analgesia for cranial cruciate ligament surgery in dogs (NOCITA is a registered trademark of Aratana). In August 2018, the 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 CVM approved a 10mL vial size for NOCITA. Aratana began purchasing our bupivacaine liposome injectable suspension product in 2016.

We are eligible to receive up to \$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 certain jurisdictions 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.

## ***Nuance Biotech Co. Ltd.***

In June 2018, we 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, we agreed to be the sole supplier of EXPAREL to Nuance and granted Nuance the exclusive rights to develop and commercialize EXPAREL in China. We received an upfront payment of \$3.0 million in July 2018 and are 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 thresholds. We are also entitled to tiered royalties as a percentage of net sales.

## ***DepoCyt(e)***

DepoCyt(e) was a sustained-release liposomal formulation of the chemotherapeutic agent cytarabine that utilized our DepoFoam technology and 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.

## **Significant Customers**

We had three wholesalers each comprising 10% or more of our total revenue for the year ended December 31, 2020: Cardinal Health, Inc., McKesson Drug Company and AmerisourceBergen Health Corporation, which accounted for 31%, 31% and 25% of our total 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. We also have a mixed-use research and development, manufacturing and office facility which sits adjacent to our EXPAREL manufacturing facility, and a warehouse located within five miles of these facilities. We refer to these three buildings as the Science Center Campus, and together they consist of approximately 195,000 square feet. Our manufacturing facilities are inspected regularly and approved by the FDA, EMA, MHRA and the Environmental Protection Agency (EPA). Our iovera° facility in Fremont, California, consists of approximately 20,000 square feet of mixed-use manufacturing, research and development and office space.

We purchase raw materials and components from third-party suppliers to manufacture EXPAREL and iovera°. 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.

Our EXPAREL manufacturing facility at the Science Center Campus 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, as demand for EXPAREL increases, as explained below.

Our 90,000 square-foot mixed-use research and development, manufacturing and office facility was built in 1990 and is located adjacent to our EXPAREL manufacturing facility. This building houses our Science Center related research and development activities and general and administrative functions, as it includes both laboratories and the building infrastructure necessary to support the formulation, analytical testing, clinical and process development activities for manufacturing additional commercial product indications and new pipeline products. Our pilot plant suite for early-stage clinical product production is located in this building and there is additional space for future expansion opportunities.

We also have an approximately 21,000 square foot warehouse 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<sup>®</sup> 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. We have expanded our iovera<sup>®</sup> manufacturing capacity through a third party, Providien Device Assembly, LLC, or Providien, as explained below.

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***

#### ***Thermo Fisher Scientific Pharma Services***

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 first 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.

#### ***Providien Device Assembly***

In January 2020, we and Providien entered into a Manufacturing and Supply Agreement (the “Providien Agreement”) to collaborate in the manufacture of iovera<sup>®</sup> tips at Providien’s Tijuana, Mexico facility. The initial term of the Providien Agreement is five years. We will pay fees based on the amount of iovera<sup>®</sup> tips delivered by Providien. The Providien Agreement may be terminated by either party upon one years’ written notice without cause. We may terminate the Providien Agreement upon thirty days’ written notice in the event that iovera<sup>®</sup> is withdrawn from the market or no longer sold by us. Either party may terminate the Providien 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, 2020, there are over seven 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<sup>®</sup>. 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 2037 and the last currently issued patent for the iovera<sup>®</sup> technology expiring in 2040.

#### *Patents and Patent Applications for DepoFoam and DepoFoam Products*

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 in the Orange Book for EXPAREL and includes a patent term adjustment that equates to an expiration date of December 24, 2021. Additionally, we have filed several pending patent applications directed to other important aspects of the EXPAREL technology which, if granted, would provide additional patent protection through 2040 and beyond.

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. 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. Eight of the patent applications were issued as patents as of December 2020. 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, 2020, we have four granted patents in China, one granted patent in Europe, 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.

#### *Patents and Patent Applications for iovera<sup>®</sup>*

Issued patents in the U.S. afford us a wide range of coverage of various aspects of the iovera<sup>®</sup> 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<sup>®</sup> technology. For example, patents covering needle cladding and the probe filtration system are set to expire in 2033 and patents on the smart tip technology are set to expire between 2034 and 2037. Other patents and 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 eight new non-provisional and Patent Cooperation Treaty (PCT) applications in 2020, which if 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<sup>®</sup> products and provide protection beyond patents and regulatory exclusivity. The scale-up and commercial manufacture of DepoFoam-based and iovera<sup>®</sup> 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<sup>®</sup> 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 pumps/catheter devices intended to provide bupivacaine over several days. Avanos Medical, Inc. markets these medical devices in the U.S.

### *iovera<sup>®</sup>*

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<sup>®</sup> system, which could render the iovera<sup>®</sup> 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<sup>®</sup> 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 (including the EMA and MHRA), laws and regulations. Failure to comply with applicable regulatory requirements 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 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 National Institutes of Health (NIH)-maintained website ([www.clinicaltrials.gov](http://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 the 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 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, a 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<sup>®</sup> 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<sup>®</sup> and the subsequent growth of the iovera<sup>®</sup> 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, the FDA may not approve the 505(b)(2) application until the patent expires, plus any period of pediatric exclusivity.

In any future 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, distribution and annual reporting. Additionally, adverse events must be reported to the FDA in a timely fashion, and pharmacovigilance programs to proactively look for adverse events are mandated by the FDA.

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 U.S. indication statement in the label for EXPAREL as approved by the FDA 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 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 E.U. member states and is recognized by the MHRA. 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, EMA or MHRA approval, we may not be able to secure additional regulatory approvals 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 the United Kingdom, 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 U.S. 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. In Europe, manufacturers qualify for 8 years of data exclusivity upon marketing authorization approval and an additional two years of market exclusivity, for a total of 10 years of regulatory exclusivity.

### ***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 or medical device manufacturer from soliciting, offering, receiving, or paying any remuneration to generate business, including the purchase or prescription of a particular drug or 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.

## ***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 in February 2010. Among other things, HITECH 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.

## ***Cybersecurity***

We operate a risk-based cybersecurity program dedicated to protecting the confidentiality, integrity and availability of our information. We utilize a layered approach in protecting against, and the detection of, cyber-attacks, and leverage outside

partnerships to gain intelligence on threats and continue to adjust our protection mechanisms to be effective. We also use state-of-the-art technology to monitor systems for anomalous behavior. In the event an incident were to occur, a Security Incident Response Team would be convened that consists of members from many functions, including legal counsel. Additionally, we carry a Cyber Insurance policy to help cover investigation and mitigation expenses.

Although we have numerous controls to protect against common attacks, some attacks may still be effective. Our controls are designed to detect, triage and eradicate these attacks. Over the past three years, there have been no known material breaches, and no expenses related to the investigation of such breaches.

## **Human Capital**

### *Pacira Core Values*

We are a team of dedicated and highly talented professionals focused on driving improved patient outcomes with opioid-reducing strategies. We are an organization built on high ethical standards, an unwavering commitment to patients and transparent communications. We have a drive and a desire to improve the world around us and make a meaningful difference in the lives of patients, families, communities and society.

The six core values that underpin everything we do are:

- *Patients:* Their safety and welfare are our top priority at all times
- *People:* Our greatest asset
- *Passion:* We are passionate about what we do
- *Think:* Our thoughts are shared generously
- *Trust:* Building trust is essential
- *Teamwork:* The cornerstone of our business success

### *Total Rewards*

In order to attract and retain talent, we maintain broad-based benefits that are provided to all employees, including our 401(k) retirement plan with an employer matching contribution, employee stock purchase plan, flexible spending accounts, medical, dental and vision care plans, healthcare and dependent care savings accounts, life insurance, short- and long-term disability policies, paid vacation, paid sick time and paid company holidays. Additionally, we reward employees driving significant value creation with a variety of long-term and short-term incentives including a recognition platform, annual performance bonuses, stock options, restricted stock units and a long-term performance cash incentive. We encourage our employees to give back in their communities and offer one paid day off per year to volunteer. We regularly benchmark our rewards programs, adjusting as needed, to ensure our total rewards are competitive. We are committed to paying all our employees a fair and living wage.

### *Talent Management*

We have a desire to cultivate and develop our future leaders. We regularly assess and identify our emerging talent and support their development with programs including leadership development, executive coaching and mentoring. We track turnover and employee engagement among other metrics, and conduct stay and exit interviews to ensure our talent strategy serves our goal of attracting, developing and retaining top talent to serve as our future leaders and stewards of our vision. We offer targeted selection training for interviewers to ensure a consistent methodology applied in identifying and hiring the best candidates for open positions. We offer a number of critical skills programs including management skills training for people managers, as well as project management and communications training.

### *Employee Wellbeing, Health and Safety*

Pacira is committed to the total wellbeing of our employees and their families. We offer a range of benefits designed to meet individual needs and help employees and their families live healthy lives. This includes a variety of tools to promote total wellbeing in the areas of health, wealth, work and life to keep our employees and their families healthy, lower their healthcare costs and reduce stress. For example, we provide access to free biometric screenings, an employee assistance program, or EAP, and host in-person and webinar trainings on stress management and other EAP benefits, access to telemedicine including mental health visits, a health advocate service to help employees and their families navigate the healthcare system, activity challenges and more. Benefits that protect financial wellbeing are also provided, including but not limited to: a paid parental leave benefit, insurance to help protect assets during times of short- and long-term disability, life insurance and accidental death and dismemberment insurance, financial education seminars on savings, debt and other financial topics, access to discounts on a



variety of products and services and an incentive to engage in a new or maintain a wellbeing activity. In addition, we maintain a recognition program based on our core values, known as *Celebrate*, through which we recognize each other's commitment to making a meaningful difference for our patients and communities and create a shared culture where everyone is responsible for living up to and sustaining our core values.

We have a formal Environmental Health and Safety (EHS) Program. It is our policy that everyone is entitled to a safe and healthful place to work. We recognize that accident prevention, employee wellness and efficiency of operations are directly related to quality, production and cost. Pacira operates its facilities in a manner that protects the health of its employees and minimizes the impact of its operations on the environment.

#### *Diversity, Equity and Inclusion*

We are committed to intentionally cultivating a culture of inclusion where all feel welcomed and valued for their backgrounds, perspectives and experiences. We hold one another accountable to promote trust and transparency in support of our communities and collective purpose. In support of this diversity, equity and inclusion vision, we have developed a strategy and multi-year roadmap, prioritizing education and training. Our executive team and senior leaders have received training on Unconscious Bias and Inclusive Leadership. Additionally, we have established a project team and employee council to shape our strategy around four key areas: leadership development, diversity recruiting, culture and communications. We are committed to evaluating our people processes to ensure we are attracting, developing, promoting and retaining diverse talent.

#### *COVID-19 Pandemic*

The health and safety of our employees has always been important to us, which is why we took responsible action in response to the COVID-19 pandemic. We covered the cost of COVID-19 testing and treatment for our employees and covered family members under our benefit plans and extended our paid sick leave for COVID-related absences. We amended our 401(k) savings plan to enhance loan eligibility and repayment terms and to permit certain distributions. We implemented additional safety protocols and guidelines at our manufacturing sites and required our non-manufacturing personnel to work from home, including our field sales force and clinical education teams which continue to support our customers remotely. With the reopening of many states, the ability of our sales representatives to renew their in-person engagement efforts, in conjunction with these remote efforts, has occurred across all sites of care, with more focus on physician offices and ambulatory surgical centers. Our offices have since re-opened on a voluntary basis with strict safety and hygiene guidelines implemented, and we continue to support remote working as appropriate.

#### *Employees*

As of December 31, 2020, we had 624 employees, all of which are full-time. All of our employees are located in the U.S. except for eight 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](http://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](http://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 corporate 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 4 of this Annual Report.

### **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 first approved by the FDA on October 28, 2011 and commercially launched in April 2012. EXPAREL was approved by the European Commission on November 16, 2020. During 2020, sales of EXPAREL accounted for 96% of our total revenue, and we expect EXPAREL sales will remain of such importance 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 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 and geographic expansion 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 (“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 broader 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;
- the 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 regulatory agencies 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, our approved labels for EXPAREL do not contain claims that EXPAREL is safer or more effective than competitive products and do 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 a broader level of acceptance among physicians, patients and third-party payers, we may not generate meaningful revenues from EXPAREL, and we may not remain profitable.

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

The pharmaceutical, medical device and biotechnology industries are intensely competitive and subject to rapid and significant technological change. Our major competitors include organizations such as major multinational pharmaceutical and medical device 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<sup>®</sup> or any product candidate that we are currently developing or that we may develop, license or acquire, which could render our products obsolete and noncompetitive or significantly harm the commercial opportunity for EXPAREL, iovera<sup>®</sup> 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<sup>®</sup> 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. 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. EXPAREL also competes with elastomeric bags/catheter devices intended to provide bupivacaine over several days.

***Regulatory approval for any approved product is limited 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 marketing, labeling, advertising and promotion of prescription drugs and medical devices is strictly regulated. 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 granted is limited to those specific diseases and indications for which a product is deemed to be safe and effective by an appropriate regulatory agency. 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 regulatory 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.

As an example, in the U.S. and Europe, while physicians may choose, and are generally permitted to prescribe drugs, medical devices 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, EMA or MHRA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities 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. In the U.S., 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 additional 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 further developing our marketing and sales infrastructure, we may not be able to continue to successfully commercialize EXPAREL, including outside the U.S., which would limit our ability to generate additional 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, we previously had a co-promotion agreement with DePuy Synthes to market and promote the use of EXPAREL for orthopedic procedures in the U.S. market which we terminated effective January 2021, 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, 2020, we had 624 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 in 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 arrangements with Thermo Fisher and Provident;
- 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 both our DepoFoam delivery technology and iovera<sup>®</sup> 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 talent 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<sup>®</sup> or product candidates that we may develop and may have to limit their commercialization.***

The use of EXPAREL, iovera<sup>®</sup> 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 regulatory 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 the price of our common stock 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 may need to expand our manufacturing operations or outsource such operations to third parties.***

To successfully meet future customer demand for EXPAREL and iovera<sup>®</sup>, we may 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 or iovera<sup>®</sup> 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<sup>®</sup> or our other products, such as our manufacturing arrangements with Thermo Fisher and Providien. Entering into such arrangements requires testing and compliance inspections, regulatory agency 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 our products could result in a disruption in the supply to our customers and partners, which could have a material adverse impact on our business and results of operations.***

EXPAREL is currently manufactured at our facilities in San Diego, California and at the Thermo Fisher facility in Swindon, England, and iovera<sup>®</sup> is currently manufactured at our facility in Fremont, California. These facilities are the only currently approved sites for manufacturing EXPAREL and iovera<sup>®</sup> 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<sup>®</sup> (U.S. and Canada) and DepoCyt<sup>®</sup> (E.U.) due to persistent technical issues specific to the DepoCyt(e) manufacturing process.

Our San Diego and Fremont facilities in California, the Thermo Fisher facility in Swindon, England and the Providien facility in Tijuana, Mexico 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, England and Mexico. 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<sup>®</sup> 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 or iovera<sup>®</sup> at our facilities could result in a disruption in the supply of EXPAREL or iovera<sup>®</sup> 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 facility to receive regulatory approvals required for manufacturing to commence at the second Thermo Fisher suite.***

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 the first 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 both 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 regulatory 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<sup>®</sup>. 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<sup>®</sup> 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 network, 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 and other regulatory authorities, that each of the products are 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 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 regulatory agencies. Pre-clinical and clinical data can be interpreted in different ways.

Accordingly, regulatory authorities could interpret such data in different ways than we or our partners do, which could delay, limit or prevent regulatory approval. 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 regulatory approvals, our drug and medical device products may later exhibit adverse effects that may limit or prevent their widespread use, may cause the regulatory authority 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 Note 21, *Commitments and Contingencies*, to our consolidated financial statements included herein for information about our legal proceedings. 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**

***Our business could be materially adversely affected if a regulatory or enforcement agency determines that we are promoting or have in the past promoted the "Off-label" use of our products.***

The marketing, labeling, advertising and promotion of prescription drugs and medical devices is strictly regulated. 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, EMA, MHRA or other regulatory agency. 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 regulatory 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.

As an example, while physicians 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 a regulatory authority, our ability to promote the products is narrowly limited to those indications that are approved by the FDA or other regulatory agency. "Off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities 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, regulators may disagree. If a regulatory agency determines that our promotional activities fail to comply with their regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow rules and guidelines relating to promotion and advertising may cause a regulatory body to issue warning letters or untitled letters, bring an enforcement action against us, suspend or withdraw an approved product from the market, require a recall or institute fines or civil fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our reputation and our business.

In September 2014, we received a warning letter from the FDA's Office of Prescription Drug Promotion (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 subsequently 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.

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. In July 2020, we formally entered into settlement agreements that resolved all outstanding investigations and claims by the U.S. Department of Justice, the U.S. of Health and Human Services, various States Attorneys' General and a private plaintiff (the "Plaintiffs"). This agreement concluded a five-year investigation related to the sale and marketing of EXPAREL. Under the various settlement agreements, we paid a global settlement of \$3.5 million. As part of the settlement, we admitted to no wrongdoing and explicitly denied the Plaintiffs' allegations. We have been given assurances that this concludes the investigation that originated from the U.S. Department of Justice subpoena in April 2015.

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 warning letters in the future from the FDA or other regulatory authority 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 provided the foundation for an sNDA submitted in May 2020 that has a PDUFA action date of March 22, 2021. Additionally, we are in negotiations with the FDA and EMA for clarity on other pediatric study obligations. 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 EMA, 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<sup>®</sup> 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.

***A regulatory authority 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, a regulatory authority 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. 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<sup>®</sup> 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 regulatory authorities 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<sup>®</sup> 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.

***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 regulatory 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, EMA 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 the Thermo Fisher and Providien facilities, also require conformity with CGMP and other FDA, EMA 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, EMA, 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, EMA 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, EMA, 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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 or any other regulatory agency requires us to provide additional clinical or preclinical data for EXPAREL or iovera<sup>®</sup>, 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<sup>®</sup> may be otherwise adversely impacted.

### **Risks Related to Intellectual Property**

***The patents and the patent applications that we have covering our DepoFoam 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 instillable 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.

For instance, 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<sup>®</sup>, 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 United States Patent and Trademark Office, or 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. In Europe, manufacturers qualify for 8 years of data exclusivity upon marketing authorization approval and an additional two years of market exclusivity, for a total of 10 years of regulatory exclusivity. Our earliest patent family for iovera<sup>®</sup> is scheduled to expire in 2025. Once our patents covering EXPAREL and iovera<sup>®</sup> 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<sup>®</sup>”, “DepoFoam”, “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 or other regulatory agency 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, trade secret and/or trademark protection for EXPAREL, iovera<sup>®</sup>, 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<sup>®</sup>, 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<sup>®</sup> may infringe. There could also be existing patents of which we are not aware that EXPAREL or iovera<sup>®</sup> may inadvertently infringe.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology, biopharmaceutical and medical device 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 our Indebtedness and our Common Stock**

***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, and the 0.750% convertible senior notes due 2025, or 2025 Notes, issued in our private offering completed on July 10, 2020, each as described below, or to make cash payments in connection with any conversion of the 2022 Notes or 2025 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 July 10, 2020, we completed a private placement of \$402.5 million in aggregate principal amount of 2025 Notes, and entered into an indenture agreement, or 2025 Indenture, with respect to the 2025 Notes. The 2025 Notes accrue interest at a fixed rate of 0.750% per year, payable semiannually in arrears on February 1 and August 1 of each year. The 2025 Notes mature on August 1, 2025.

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. We used a portion of the net proceeds from the 2025 Notes to repurchase \$185.0 million in aggregate principal amount of the 2022 Notes. The 2022 Notes mature on April 1, 2022.

As of December 31, 2020, our total consolidated gross indebtedness was \$562.5 million, which consisted of \$402.5 million and \$160.0 million of principal outstanding on the 2025 Notes and 2022 Notes, respectively, 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 2025 Notes and/or 2022 Notes in cash to the extent elected or to repurchase the 2025 Notes and/or 2022 Notes upon a fundamental change, and our future indebtedness may contain limitations on our ability to pay cash upon conversion of the 2025 Notes and/or 2022 Notes or limitations on our ability to repurchase the 2025 Notes and/or 2022 Notes.***

Holders of the 2025 Notes and 2022 Notes will have the right to require us to repurchase their 2025 Notes and 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. We have the option to pay the principal in cash, shares of our common stock, or any combination thereof. While it is our intention to pay the principal in cash, upon conversion of the 2025 Notes and/or 2022 Notes we will be required to make cash payments for each \$1,000 in principal amount of 2025 Notes and/or 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 2025 Notes and/or 2022 Notes surrendered therefor or 2025 Notes and/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 2025 Notes and/or 2022 Notes. Further, our ability to repurchase the 2025 Notes and/or 2022 Notes or to pay cash upon conversions of the 2025 Notes and/or 2022 Notes may be limited by law, by regulatory authority or by agreements governing our future indebtedness. Our failure to repurchase 2025 Notes and/or 2022 Notes at a time when the repurchase is required by the indenture or to pay any cash payable on future conversions of the 2025 Notes and/or 2022 Notes as required by the 2025 Indenture and/or 2022 Indenture would constitute a default under the 2025 Indenture and/or 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 2025 Notes and/or 2022 Notes or make cash payments upon conversions thereof.

***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.

***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 24, 2021, 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<sup>®</sup>;
- 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 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.

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

We have never declared or paid any dividends on our common stock. We currently intend to retain our future earnings 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.

***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.

***Raising additional funds by issuing securities would 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.

## General Risk Factors

***A pandemic, epidemic or outbreak of a contagious disease (such as the novel coronavirus (COVID-19) pandemic), or fear of such an event, could have a material adverse effect on our business, operating results and financial condition.***

A pandemic, epidemic or outbreak of an infectious disease, including the current COVID-19 pandemic, or other public health crisis, could have a material adverse effect on our business, financial condition and operations, including but not limited to our revenue and cash flows, including potential decreases in sales, manufacturing issues, supply issues and delays in payments by our customers. For example, as a result of the COVID-19 pandemic, elective surgeries were suspended in many jurisdictions, and while elective surgery restrictions have lifted in most states beginning in April of 2020, we do not know if, and how, future restrictions may affect the surgical communities' return to, or redefining of, normal operations, whether due to governmental restrictions, institutional, patient or clinical decisions or general economic conditions. New or prolonged suspensions of elective surgeries by governmental restrictions or action would cause net sales of our products to decrease. In addition, due to health concerns from the COVID-19 pandemic or negative economic conditions, patients and clinicians could cancel or defer elective procedures or otherwise avoid medical treatment, which would result in reduced patient volumes and revenues, which could potentially continue over an extended period of time.

Business disruptions could include disruptions or restrictions to our workforce, including the ability of our sales teams to interact with our customers and healthcare professionals to educate them on the benefits of our products and perform typical sales activities. For example, the ongoing COVID-19 pandemic had significantly impacted the ability of our sales representatives to access customers and healthcare professionals through personal interactions within the healthcare setting, including hospitals and ambulatory surgical centers. With the reopening of many states, the ability of our sales representatives to renew their in-person engagement efforts, in conjunction with remote efforts, has occurred across all sites of care, with more focus on physician offices and ambulatory surgical centers. In addition, any temporary closures of our manufacturing facilities or the facilities of our suppliers and contract manufacturers (and the resulting impact on production or our products) or the workforce at such facilities, could cause delays in the shipment or production of our products. If our customers experience disruptions to their businesses and cash flows, we could experience delays or difficulties with the collection of our accounts receivable. Any sustained impacts and business disruptions to our facilities or workforce, our customers, our suppliers, or our contract manufacturers would likely adversely impact our cash flows, sales and operating results.

The significant increase in the number of our employees who are working remotely as a result of the pandemic, and an extended period of remote work arrangements and subsequent reintroduction into the workplace could introduce operational risk, strain our business continuity plans, negatively impact productivity and/or collaboration, and give rise to claims by employees or otherwise adversely affect our business. Additionally, the COVID-19 pandemic could require new or modified processes, procedures and controls to respond to changes in our business environment. We may take further actions as may be required by government authorities or that we determine are in the best interests of our employees, customers and business partners. There is no certainty that such measures will be sufficient to mitigate the risks posed by COVID-19.

Ultimately, the extent to which COVID-19 or other public health crises could continue to impact our business is difficult to predict and will depend on many factors beyond our control, including the speed of contagion, the development and implementation of effective preventative measures and possible treatments, the scope of governmental and other restrictions on elective surgeries, travel and other activity through quarantines/social distancing and other measures, the timing of effective vaccines becoming widely available and accepted by the public, public reactions to these factors and more.

The extent to which COVID-19 impacts our business, revenues and results of operations will depend on future developments, which are highly uncertain, constantly changing and cannot be predicted. This includes new information that may emerge concerning the severity of COVID-19, the spread and proliferation of COVID-19 around the world, the duration of the outbreak and the actions taken to contain COVID-19 or treat its impact, among others.

***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.

***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 recorded net income of \$145.5 million for the year ended December 31, 2020 and net losses of \$11.0 million and \$0.5 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2020, we had an accumulated deficit of \$253.9 million. Losses, among other things, have had an adverse effect on 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<sup>®</sup>. As a result, we had not been profitable prior to 2015 and were not again until 2020. Because of the numerous risks and uncertainties associated with developing pharmaceutical products and medical devices, we are unable to predict the extent of future losses, if any.

***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<sup>®</sup>;
- 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 1, 2022 and our 0.750% convertible senior notes, due August 1, 2025.

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<sup>®</sup>;
- the success of the commercialization of EXPAREL and iovera<sup>®</sup>;
- the cost and timing of manufacturing sufficient supplies of EXPAREL and iovera<sup>®</sup> to meet customer demand, including the cost of expanding our manufacturing facilities to produce EXPAREL and iovera<sup>®</sup>;
- 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 injections of bupivacaine or a cryoanalgasic device that infringes on the various patents covering iovera<sup>®</sup>.

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 sufficiently more product revenue, if ever, we expect to finance or supplement future cash needs through public or private equity offerings, debt financings, stock option exercises, 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<sup>®</sup> and end-user buying patterns;
- maintaining our existing manufacturing facilities for EXPAREL and iovera<sup>®</sup>, 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<sup>®</sup> 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, in April 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;
- risks inherent in our acquired companies' and businesses' industry 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.

***The use of our net operating loss carryforwards and research and development 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 2024 for both federal and 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. Accordingly, we have not recognized a benefit in our consolidated financial statements for the NOLs and tax credits which may expire unused. 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. We have recognized a tax benefit only for those NOLs and tax credits which are more likely than not to be utilized.

***Changes in data privacy and protection laws and regulations, particularly in Europe and the State of California, 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 total worldwide revenue.

Additionally, the California Consumer Privacy Act, or CCPA, became effective in January 2020 and imposed new responsibilities on us for the handling, disclosure and deletion of personal information for our employees and consumers who reside in California. The CCPA permits California to assess potentially significant fines for violating CCPA and creates a right for individuals to bring class action suits seeking damages for violations. In addition, we will be required to implement more stringent privacy regulations by January 1, 2023 as the California Privacy Rights Act passed in November 2020.

Furthermore, 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. Our efforts to comply with GDPR, the CCPA and other privacy and data protection laws may impose significant costs and challenges that are likely to increase over time and may require us to revise certain of our business practices. 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 substantial regulatory penalties and significant legal liability or litigation related to violation of existing or future data privacy laws and regulations.

***We face risks related to cybersecurity threats and incidents.***

We regularly face attempts by others to gain unauthorized access through the internet, or to introduce malicious software, to our Information Technology, or IT, systems. Individuals or organizations, including malicious hackers and insider threats including employees and third-party service providers, or intruders into our physical facilities, at times attempt to gain unauthorized access to our software and services. We could also be a target of malicious attackers who attempt to gain access to our network or data centers; steal proprietary information related to our business, products, employees, suppliers and customers; interrupt our systems and services or those of our suppliers, customers, or others; or demand ransom to return control of such systems and services. Such attempts, including but not limited to “phishing” attempts, are increasing in number and in technical sophistication, and if successful, expose us and any affected parties to risk of loss or misuse of proprietary or confidential information or disruptions of our business operations, including our manufacturing operations. Our IT infrastructure also includes services provided by third parties, and these providers can experience breaches of their systems and products that impact the security of our systems and our proprietary or confidential information.

***Significant changes in the global climate, extreme weather conditions and water availability could adversely affect our business or operations.***

We could experience adverse impacts to our business if climate change, other extreme weather conditions and/or water availability challenges adversely affect our operations or the operations of our suppliers, distributors and customers. There is mounting scientific evidence, as well as concern from the general public, that emissions of greenhouse gases and contributing human activities have caused and will continue to cause significant changes in global temperatures and weather patterns and increase the frequency or severity of weather events, wildfires and flooding. While such conditions cannot be predicted, if such conditions were to impact our manufacturing sites or otherwise alter production schedules, including those of our third-party suppliers of raw materials, our manufacturing equipment, or our distributors, we could experience a disruption in the supply of EXPAREL or iovera<sup>®</sup> to our customers and partners, or we could see an unfavorable impact on the cost or availability of our raw or packaging materials. Disruptions to the operations of our customers could also adversely impact the demand for our products. Regulations in response to climate change could result in increased manufacturing costs associated with increased compliance and water and energy costs.

**Item 1B. Unresolved Staff Comments**

None.

**Item 2. Properties**

We occupy three facilities totaling approximately 195,000 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 EXPAREL manufacturing facility and mixed-use research and development property leases both expire in June 2030 and our warehouse lease expires in August 2030. Our iovera<sup>®</sup> facility in Fremont, California, consists of approximately 20,000 square feet of mixed-use manufacturing, research and development and office space, and its lease currently expires in December 2021. We recently launched the *Pacira Innovation and Training center at Tampa* (known as the “PITT”) in Tampa, Florida. This approximately 10,000 square-foot facility supports a full range of educational events to advance clinician understanding of the latest local, regional and field block approaches for managing pain and reducing or eliminating exposure to opioids. We are currently in negotiations to extend the lease on the PITT which expires in September 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.

We believe that our research and development and manufacturing facilities at our Science Center Campus, Thermo Fisher, Fremont and Providien 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<sup>®</sup> 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**

For information related to Item 3. Legal Proceedings, refer to Note 21, *Commitments and Contingencies*, to our consolidated financial statements included herein.

**Item 4. Mine Safety Disclosures**

Not applicable.

## PART II

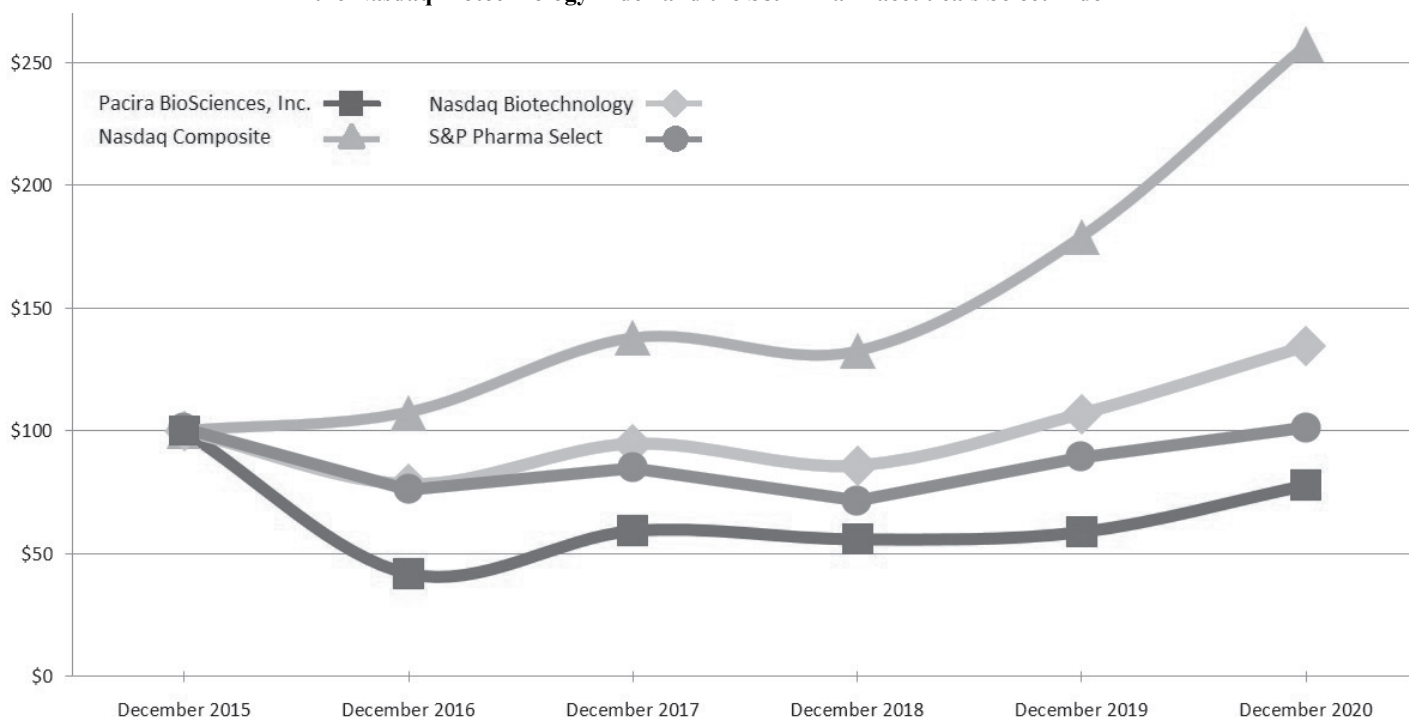
### Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock is listed and traded under the ticker symbol "PCRX" on the Nasdaq Global Select Market. As of February 21, 2021, 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, 2015, in each of Pacira BioSciences, Inc. (PCRX), the Nasdaq Composite Index (^IXIC), the Nasdaq Biotechnology Index (^NBI) and the S&P Pharmaceuticals Select Index (^SPSIPH). The three indices included are 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 31<sup>st</sup> 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,  
the Nasdaq Biotechnology Index and the S&P Pharmaceuticals Select Index**



**Cumulative Total Return as of December 31,**

	2015	2016	2017	2018	2019	2020
Pacira BioSciences, Inc. (PCRX)	\$ 100.00	\$ 42.06	\$ 59.45	\$ 56.02	\$ 58.99	\$ 77.93
Nasdaq Composite Index (^IXIC)	\$ 100.00	\$ 107.50	\$ 137.86	\$ 132.51	\$ 179.19	\$ 257.38
Nasdaq Biotechnology Index (^NBI)	\$ 100.00	\$ 78.32	\$ 94.81	\$ 85.97	\$ 106.95	\$ 134.42
S&P Pharmaceuticals Select Index (^SPSIPH)	\$ 100.00	\$ 76.25	\$ 84.87	\$ 71.54	\$ 89.24	\$ 101.37

#### Dividend Policy

We have never declared or paid any dividends on our common stock. We currently intend to retain our future earnings 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, 2020, 2019, 2018, 2017 and 2016. 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 Annual Report.

	Year Ended December 31,				
	2020	2019 <sup>B</sup>	2018	2017	2016
Consolidated Statements of Operations Data	(In thousands, except per share amounts)				
Revenues:					
Net product sales	\$ 426,614	\$ 418,926	\$ 332,427	\$ 284,342	\$ 270,073
Collaborative licensing and milestone revenue	—	—	3,000	387	3,426
Royalty revenue	3,033	2,100	1,850	1,901	2,872
Total revenues	429,647	421,026	337,277	286,630	276,371
Operating expenses:					
Cost of goods sold	117,328	106,712	86,845	87,915	110,104 <sup>F</sup>
Research and development	59,421	72,119	55,688	57,290	45,678
Selling, general and administrative	193,516	200,782	177,265	161,494	152,613 <sup>G</sup>
Amortization of acquired intangible assets	7,866	5,703	—	—	—
Acquisition-related charges, product discontinuation and other	5,166 <sup>A</sup>	25,230 <sup>C</sup>	1,564 <sup>D</sup>	4,868 <sup>E</sup>	—
Total operating expenses	383,297	410,546	321,362	311,567	308,395
Income (loss) from operations	46,350	10,480	15,915	(24,937)	(32,024)
Other (expense) income:					
Interest income	4,629	7,376	6,497	4,078	1,323
Interest expense	(25,671)	(23,628)	(21,949)	(18,047)	(7,061)
Loss on early extinguishment of debt	(8,071)	—	—	(3,732)	—
Other, net	2,852	(4,976)	(888)	167	(82)
Total other expense, net	(26,261)	(21,228)	(16,340)	(17,534)	(5,820)
Income (loss) before income taxes	20,089	(10,748)	(425)	(42,471)	(37,844)
Income tax benefit (expense)	125,434	(268)	(46)	(140)	(105)
Net income (loss)	\$ 145,523	\$ (11,016)	\$ (471)	\$ (42,611)	\$ (37,949)
Net income (loss) per share:					
Basic net income (loss) per common share	\$ 3.41	\$ (0.27)	\$ (0.01)	\$ (1.07)	\$ (1.02)
Diluted net income (loss) per common share	\$ 3.33	\$ (0.27)	\$ (0.01)	\$ (1.07)	\$ (1.02)
Weighted average common shares outstanding:					
Basic	42,671	41,513	40,911	39,806	37,236
Diluted	43,682	41,513	40,911	39,806	37,236

A - Includes charges of \$5.4 million related to the MyoScience Acquisition. Of this total, \$5.2 million represents the net change 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). For further discussion of these charges, see Note 5, *MyoScience Acquisition* and Note 18, *Acquisition-Related Charges and Product Discontinuation, Net*, to our consolidated financial statements included herein.

B - 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.

C - 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 the U.S. Department of Justice settlement agreement. 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*, respectively, to our consolidated financial statements included herein.

D - 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. These charges 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 that remained 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.

E - 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.

F - 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.

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

	December 31,				
	2020	2019 <sup>B</sup>	2018	2017	2016
Consolidated Balance Sheet Data	(In thousands)				
Cash and cash equivalents, short-term and long-term investments	\$ 617,121	\$ 356,748	\$ 409,325	\$ 371,394	\$ 172,597
Working capital	398,295	300,884	417,308	334,893	198,251
Total assets	1,274,513 <sup>A</sup>	831,065	689,353	628,371	391,466
Long-term liabilities	401,497	368,448	307,466	292,671	127,652
Accumulated deficit	(253,875)	(399,398)	(388,226)	(389,136)	(346,238)
Total stockholders' equity	619,688	354,944	321,226	279,483	218,976

A - Includes the release of a \$126.6 million domestic valuation allowance on our deferred tax assets. For further discussion, see Note 16, *Income Taxes*, to our consolidated financial statements included herein.

B - 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.



## 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. Certain defined terms have been brought forward from Part I of this Annual Report.

This section of this Annual Report discusses year-to-year comparisons between 2020 and 2019, as well as other discussions of 2020 and 2019 items. We have omitted discussion of the year ended December 31, 2018 (the earliest of the three years covered by our consolidated financial statements presented in this Annual Report) as permitted by SEC regulations. The complete Management's Discussion and Analysis of Financial Condition and Results of Operations for year-to-year comparisons between 2019 and 2018 and other discussions of 2018 items can be found within Part II, Item 7, to our Annual Report filed with the SEC on February 20, 2020.

### Overview

Pacira is the industry leader in our commitment to non-opioid pain management and regenerative health solutions to improve patients' journeys along the neural pain pathway. 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 in the U.S., and in the E.U. as a brachial plexus block or femoral nerve block for treatment of post-operative pain in adults, and as a field block for treatment of somatic post-operative pain from small- to medium-sized surgical wounds in adults. Since its initial approval in 2011 for single-dose infiltration, more than eight 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° 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 pursue the expanded use of EXPAREL and iovera° in additional procedures; progress our earlier-stage product candidate pipeline; advance regulatory activities for EXPAREL, iovera° and other product candidates; invest in sales and marketing resources for EXPAREL and iovera°; expand and enhance our manufacturing capacity for EXPAREL and iovera°; invest in products, businesses and technologies; and support legal matters.

### Recent Highlights

- In November 2020, the European Commission, or EC, granted marketing authorization for EXPAREL as a brachial plexus block or femoral nerve block for treatment of post-operative pain in adults, and as a field block for treatment of somatic post-operative pain from small- to medium-sized surgical wounds in adults. The EC decision is applicable to all 27 European Union member states plus the United Kingdom, Iceland, Norway and Liechtenstein. Commercial planning is underway, with an anticipated E.U. launch in the second half of 2021. For more information, see the subsection titled "Global Expansion" in *Part I—Item 1* above.
- In December 2020, we made a \$1.2 million (€1.0 million) initial investment in GeneQuine Biotherapeutics GmbH, or GeneQuine, a privately held biopharmaceutical company headquartered in Hamburg, Germany. GeneQuine is advancing a gene therapy platform for the treatment of osteoarthritis and other musculoskeletal disorders. GeneQuine's product candidates are next-generation gene transfer vehicles. These gene therapy vectors are highly efficient in entering joint cells to confer multi-year gene expression. Safety of this platform has been demonstrated in several species and is currently being evaluated in an ongoing Phase 1 study. In January 2021, we made a \$1.2 million (€1.0 million) investment in the form of a convertible note. We will make an additional \$4.9 million (€4.0 million) investment upon GeneQuine achieving certain prespecified near-term milestones related to its lead gene therapy product candidate, GQ-303. Up to \$3.1 million (€2.5 million) of our total investment will be in the form of a convertible note, which includes the investment made in January 2021.

## Novel Coronavirus (COVID-19) Pandemic

Our 2020 net product sales were negatively impacted by the COVID-19 pandemic, which mandated significant postponement or suspension in the scheduling of elective surgical procedures resulting from public health guidance and government directives. Elective surgery restrictions began to lift on a state-by-state basis in April 2020; however, we do not know how long it will take the surgical community to return to normal operations, or if restrictions on elective surgeries will recur. Our manufacturing sites are operational and have implemented new safety protocols and guidelines as recommended by federal, state and local governments. To date, there have been no material impacts to our supply chain. With the reopening of many states, the ability of our sales representatives to renew their in-person engagement efforts, in conjunction with remote efforts, has occurred across all sites of care, with more focus on physician offices and ambulatory surgical centers. Our offices have re-opened on a voluntary basis with strict safety and hygiene guidelines implemented, and we continue to support remote working as appropriate.

The situation remains dynamic and is subject to rapid and possibly material changes. It is not clear what the potential effects may be to our business going forward, including the impact on our revenues, results of operations or financial condition, particularly if these pandemic conditions persist or exacerbate over an extended period of time, including if states return to placing restrictions on elective surgical procedures. Additional negative impacts may also arise from the COVID-19 pandemic that we are unable to foresee. The nature and extent of such impacts will depend on future developments, which are highly uncertain and cannot be predicted, including the timing of effective vaccines becoming widely available and accepted by the public. We have also taken advantage of some of the provisions of the Coronavirus Aid, Relief and Economic Security (CARES) Act, mainly by deferring the payment of certain employer payroll taxes. For more information, see “Liquidity and Capital Resources” below.

We will continue to actively monitor the situation and implement measures recommended by federal, state or local authorities, or that we determine are in the best interests of our patients, employees, partners, suppliers, shareholders and stakeholders. For a description of risks facing the Company that relate to the COVID-19 pandemic or any other future pandemic, epidemic or outbreak of contagious disease, see Item 1A. “Risk Factors” in this Annual Report.

## Results of Operations

### *Comparison of the Years Ended December 31, 2020 and 2019*

#### *Revenues*

Net product sales consist of sales of EXPAREL in the U.S., our bupivacaine liposome injectable suspension to Aratana for veterinary use in the U.S., and sales of iovera<sup>®</sup> in the U.S. 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):

	<b>Year Ended December 31,</b>		<b>% Increase / (Decrease)</b>
	<b>2020</b>	<b>2019</b>	
Net product sales:			
EXPAREL	\$ 413,338	\$ 407,877	1 %
Bupivacaine liposome injectable suspension	4,459	3,153	41 %
Total EXPAREL / bupivacaine liposome injectable suspension	417,797	411,030	2 %
iovera <sup>®</sup>	8,817	7,896	12 %
Total net product sales	426,614	418,926	2 %
Royalty revenue	3,033	2,100	44 %
Total revenues	<u>\$ 429,647</u>	<u>\$ 421,026</u>	2 %

EXPAREL revenue grew 1% in 2020 compared to 2019, primarily due to an increase in sales volume of 1% and a 4% increase in gross selling price per unit, partially offset by the sales mix of EXPAREL vial sizes. EXPAREL revenue was impacted by the significant postponement or suspension of elective surgical procedures resulting from public health guidance and government directives due to the COVID-19 pandemic, beginning in mid-March 2020. The demand for EXPAREL has generally continued to increase as a result of ambulatory surgical centers and anesthesiologists broadening the use of long-

acting EXPAREL regional approaches as a foundation of multimodal opioid-minimization strategies that enable shifting inpatient procedures to 23-hour sites of care.

As part of the acquisition of MyoScience (the “MyoScience Acquisition”), we acquired the iovera<sup>®</sup> system and began recognizing net product sales in April 2019. Net product sales increased 12% in 2020 versus 2019. The increase in revenue largely reflects the timing of the MyoScience Acquisition in 2019 offset in part by the impact of the COVID-19 pandemic. Thus far, we have seen the greatest iovera<sup>®</sup> 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.

Any renewed government suspension of, or reluctance of patients to have, elective surgeries would impact our future sales of EXPAREL and iovera<sup>®</sup> during the ongoing COVID-19 pandemic.

Royalty revenue reflects the royalties earned on net product sales of bupivacaine liposome injectable suspension to Aratana for veterinary use, both of which increased over 40% in 2020 versus 2019 as a result of the timing of orders placed by Aratana.

### *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):

	<b>Year Ended December 31,</b>		<b>% Increase / (Decrease)</b>
	<b>2020</b>	<b>2019</b>	
Cost of goods sold	\$ 117,328	\$ 106,712	10 %
Gross margin	73 %	75 %	

Gross margin decreased two percentage points in 2020 versus 2019. One percentage point was due to unplanned downtime at our custom manufacturing suite in Swindon, England (under our partnership with Thermo Fisher), and one percentage point was due to a planned shutdown at our Science Center Campus in San Diego, California in order to prepare our manufacturing suite for a new EXPAREL capacity expansion project.

Despite shelter-in-place and other restrictive orders to combat the COVID-19 pandemic in California and England, there were no interruptions to our EXPAREL operations at either the Science Center Campus or Swindon manufacturing sites as a result of the COVID-19 pandemic as the production of EXPAREL is considered essential. Our Fremont, California facility, where we manufacture iovera<sup>®</sup>, was closed for three weeks in March 2020 to implement safety protocols and guidelines related to the COVID-19 pandemic. The Fremont facility resumed normal operations in April 2020.

### *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 iovera<sup>®</sup> 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)
	2020	2019	
Clinical and preclinical development	\$ 23,126	\$ 30,265	(24)%
Product development and manufacturing capacity expansion	23,516	29,724	(21)%
Regulatory and other	7,568	7,016	8 %
Stock-based compensation	5,211	5,114	2 %
Total research and development expense	<u>\$ 59,421</u>	<u>\$ 72,119</u>	(18)%
% of total revenue	14 %	17 %	

Total research and development expense decreased 18% in 2020 versus 2019. Clinical and preclinical development expense decreased 24% due to the completion of our Phase 3 pediatric (“PLAY”) clinical trial, our Phase 4 C-Section (“CHOICE”) trial and both our nerve block and pediatric pharmacokinetic studies. In addition, we made the strategic decision to conclude enrollment in the spine (“FUSION”) study early due to protocol feasibility given the rapid evolution of medical practice for spinal procedures. The data from approximately 65 FUSION study subjects will be analyzed with the intent to inform future studies in this patient population. These decreases were partially offset by startup activities related to our iovera<sup>o</sup> and EXPAREL (“PREPARE”) trial, our lower extremity nerve block (“STRIDE”) clinical trial, as well as the completion of our clinical trial for pectoral field block in breast augmentation. In addition, these increases included a Phase 1 intrathecal clinical trial to evaluate the safety, pharmacokinetics and sensory selective efficacy of EXPAREL. Certain clinical trials were slower than normal during 2020 as a result of the COVID-19 pandemic.

Product development and manufacturing capacity expansion expense decreased 21% in 2020 versus 2019 due to our progress in constructing the significant scale-up of our manufacturing capacity at the Thermo Fisher site in Swindon, England as the project advances from the development phase to the registration phase.

Regulatory and other expenses increased 8% in 2020 versus 2019 due to increases in the publication of clinical manuscripts and abstracts, as well as startup activities related to the iovera<sup>o</sup> clinical database registry.

Stock-based compensation increased 2% in 2020 versus 2019 primarily due to an increase in the number of equity awards granted.

#### *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<sup>o</sup>, 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)
	2020	2019	
Sales and marketing	\$ 118,682	\$ 129,663	(8)%
General and administrative	45,714	47,248	(3)%
Stock-based compensation	29,120	23,871	22 %
Total selling, general and administrative expenses	<u>\$ 193,516</u>	<u>\$ 200,782</u>	(4)%
% of total revenue	45 %	48 %	

Total selling, general and administrative expenses decreased 4% in 2020 versus 2019.

Sales and marketing expenses decreased 8% in 2020 versus 2019. The decrease was primarily driven by a decline in sales commissions, reduced marketing spend due to the cancellations of in person meetings, medical conferences, travel and increased utilization of lower cost virtual meetings due to the COVID-19 pandemic. These were partially offset by a termination fee to DePuy Synthes of up to \$9.0 million, and higher sales and marketing compensation due to an expanded sales force. We

are continuing our marketing investment in EXPAREL, which includes educational initiatives and programs related to the impact of opioids and postsurgical pain management and our national advocacy campaign designed to educate patients about non-opioid treatment options. We recently launched the *Pacira Innovation and Training center at Tampa* (the “PITT”) in Tampa, Florida. This approximately 10,000 square-foot facility will support a full range of educational events to advance clinician understanding of the latest local, regional and field block approaches for managing pain and reducing or eliminating exposure to opioids. Additionally, we have continued investing in marketing initiatives and customer outreach for iovera<sup>®</sup>.

In the near-term, we expect that sales and marketing expenditures will continue to be impacted by the COVID-19 pandemic and its resultant effects on elective surgeries, sales commissions, cancellations of in-person industry conferences and the suspension of non-essential employee travel.

General and administrative expenses decreased 3% in 2020 versus 2019. The decrease was primarily due to lower legal expenditures related to our U.S. Department of Justice subpoena received in April 2015, which was resolved in July 2020 and was partially offset by expenditures to support the expansion of the business following the MyoScience Acquisition.

Stock-based compensation increased 22% in 2020 versus 2019, primarily due to an increase in personnel and the number of equity grants awarded.

#### *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)
	2020	2019	
Amortization of acquired intangible assets	\$ 7,866	\$ 5,703	38 %

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)
	2020	2019	
Acquisition-related charges	\$ 5,354	\$ 21,571	(75)%
Product discontinuation	(188)	159	N/A
Other	—	3,500	(100)%
Total acquisition-related charges, product discontinuation and other	<u>\$ 5,166</u>	<u>\$ 25,230</u>	(80)%

In 2020, we recognized charges of \$5.4 million related to the MyoScience Acquisition primarily due to changes in the fair value of contingent consideration. In 2019, we recognized charges of \$21.6 million, which represents \$16.7 million for the changes in fair value of contingent consideration and \$4.2 million for advisory costs, including legal, financial, accounting and tax services and \$0.7 million for separation costs, asset write-downs and other restructuring activities related to the MyoScience Acquisition. For more information, see Note 18, *Acquisition-Related Charges and Product Discontinuance, Net*, to our consolidated financial statements included herein.

In 2020, we recorded a gain of \$0.2 million related to the final settlement of the lease agreement for the site of the former DepoCyt(e) manufacturing activities. In 2019, we recorded a charge of \$0.2 million primarily for the accretion of the related lease liability.

In 2019, we recorded a charge of \$3.5 million related to the U.S. Department of Justice settlement. The settlement was paid in July 2020. 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)
	2020	2019	
Interest income	\$ 4,629	\$ 7,376	(37)%
Interest expense	(25,671)	(23,628)	9 %
Loss on early extinguishment of debt	(8,071)	—	N/A
Other, net	2,852	(4,976)	N/A
Total other expense, net	<u>\$ (26,261)</u>	<u>\$ (21,228)</u>	24 %

Total other expense, net increased 24% in 2020 versus 2019, primarily due to an \$8.1 million loss on early extinguishment of debt incurred in conjunction with the retirement of \$185.0 million aggregate principal of our 2022 Notes in July 2020. In addition, there was a reduction in interest income primarily due to a decline in interest rates and an increase in interest expense due to the issuance of \$402.5 million of aggregate principal 2025 Notes in July 2020. Other, net included \$1.1 million of United Kingdom research and development tax credits and a \$1.6 million unrealized gain on our equity investment in TELA Bio in 2020 versus an unrealized loss on the equity investment of \$5.7 million in 2019.

#### *Income Tax (Benefit) Expense*

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

	Year Ended December 31,		% Increase / (Decrease)
	2020	2019	
Income tax (benefit) expense	\$ (125,434)	\$ 268	N/A
Effective tax rate	(100)% +	(2)%	

We recorded an income tax benefit of \$125.4 million for the year ended December 31, 2020 and income tax expense of \$0.3 million for the year ended December 31, 2019. A full valuation allowance had been recorded against our net deferred tax balance as of December 31, 2019 as it had been more likely than not that our net deferred tax assets would not be realizable. At each reporting date, we consider new evidence, both positive and negative, that could affect our view of the future realization of deferred tax assets. During the year ended December 31, 2020, in part because in the current year we achieved three years of cumulative pretax income in the U.S. federal and state tax jurisdictions and based on our most recent forecasts, we determined that there is sufficient positive evidence to conclude that it is more likely than not that additional deferred taxes of \$126.6 million are realizable and, therefore, we reduced the valuation allowance accordingly. For more information, see Note 16, *Income Taxes*, to our consolidated financial statements included herein.

The income tax expense for the year ended December 31, 2019 consisted 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 NOL carryforwards.

#### **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. In addition, we acquired Iovera® as part of the MyoScience Acquisition in April 2019. 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, common stock, product sales and collaborative licensing and milestone revenue. As of December 31, 2020, we had an accumulated



deficit of \$253.9 million, cash and cash equivalents, short-term and long-term investments of \$617.1 million and working capital of \$398.3 million. The net cash proceeds from the July 2020 issuance of \$402.5 million aggregate principal of the 2025 Notes was \$178.9 million, after deducting fees and offering expenses of \$12.5 million and using \$211.1 million to retire \$185.0 million in aggregate principal (including accrued interest) of our existing 2022 Notes. For more information, see Note 11, *Debt*, to our consolidated financial statements included herein.

As discussed above, we anticipate that the COVID-19 pandemic will continue to result in a reduction of certain commercial and clinical expenditures which would offset some of the revenue declines caused by the COVID-19 pandemic. We currently expect that our cash, short-term and long-term investments on hand will be adequate to cover any potential short-term liquidity needs, and that we would be able to access other sources of financing should the need arise.

On March 27, 2020, the Coronavirus Aid, Relief and Economic Security (CARES) Act was signed into law in response to the COVID-19 pandemic. The CARES Act, among other things, allows for certain measures to increase liquidity for businesses such as the deferral of employer payroll taxes, a tax credit for retaining employees and other provisions. We benefited from the provision to defer the payment of certain employer payroll taxes in the amount of \$2.8 million for the year ended December 31, 2020. One-half of these deferrals are due at each of December 31, 2021 and December 31, 2022.

### ***Summary of Cash Flows***

The following table summarizes our cash flows from operating, investing and financing activities for the years ended December 31, 2020 and 2019 (in thousands):

<b>Consolidated Statements of Cash Flows Data:</b>	<b>Year Ended December 31,</b>	
	<b>2020</b>	<b>2019</b>
Net cash provided by (used in):		
Operating activities	\$ 77,032	\$ 70,520
Investing activities	(277,607)	(128,488)
Financing activities	222,304	3,670
Net increase (decrease) in cash and cash equivalents	<u>\$ 21,729</u>	<u>\$ (54,298)</u>

#### ***Operating Activities***

In 2020, net cash provided by operating activities was \$77.0 million compared to \$70.5 million in 2019. The increase of \$6.5 million was primarily attributable to the increase in income from operations driven by the increase in revenue and reductions in research and development and selling, general and administrative expenses—reflecting reduced spending due to the COVID-19 pandemic and a decline in sales commissions. These increases were partially offset by an increase in overall working capital requirements, and contingent consideration payments made to MyoScience securityholders, \$9.4 million of which were classified as operating.

#### ***Investing Activities***

In 2020, net cash used in investing activities was \$277.6 million, which reflected \$238.6 million of short-term and long-term investment purchases (net of maturities) and purchases of fixed assets of \$37.8 million. Major fixed asset purchases included equipment for a new EXPAREL capacity expansion project at our Science Center Campus in San Diego, California and continuing expenditures for expanding our EXPAREL manufacturing capacity in Swindon, England. In addition, we made a \$1.2 million equity investment in GeneQuine.

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 England and facility upgrades at our Science Center Campus.

#### ***Financing Activities***

In 2020, net cash provided by financing activities was \$222.3 million, which consisted of gross proceeds from the issuance of the 2025 Notes of \$402.5 million, the exercise of stock options of \$45.2 million and \$2.5 million from the issuance of shares through our ESPP. In conjunction with the issuance of the 2025 Notes, we paid \$211.1 million of cash (including \$1.2 million of accrued interest classified as an operating outflow) to retire \$185.0 million of our 2022 Notes in privately-negotiated transactions and \$12.5 million in financing costs. We also made contingent consideration payments to MyoScience

securityholders, of which \$5.6 million was classified as financing activities based on their recognition at the time of the MyoScience Acquisition.

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. We also made a \$6.6 million contingent consideration payment to MyoScience securityholders and a \$0.6 million payment to retire our 3.25% convertible senior notes due 2019.

### ***Equity Financings***

From our inception through December 31, 2020, we have raised \$344.5 million of net proceeds from the sale of common stock and other equity securities via public offerings.

### ***Debt***

#### ***2025 Convertible Senior Notes***

On July 10, 2020, we completed a private placement of \$402.5 million in aggregate principal amount of our 2025 Notes and entered into the 2025 Indenture with respect to the 2025 Notes. The 2025 Notes accrue interest at a fixed rate of 0.750% per annum, payable in arrears on February 1 and August 1 of each year, beginning on February 1, 2021. The 2025 Notes mature on August 1, 2025. At December 31, 2020, the outstanding principal amount of the 2025 Notes was \$402.5 million. On or after February 3, 2025, until the close of business on the second scheduled trading day immediately preceding August 1, 2025, holders may convert their 2025 Notes at any time. Upon conversion, holders will receive the principal amount of their 2025 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 2025 Notes is 13.9324 shares of common stock per \$1,000 principal amount, which is equivalent to an initial conversion price of approximately \$71.78 per share of our common stock. The conversion rate will be subject to adjustment for certain events but will not be adjusted for any accrued and unpaid interest.

Prior to the close of business on the business day immediately preceding February 3, 2025, holders may convert the 2025 Notes under certain circumstances, including 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. None of these conditions for conversion were met during the quarter ended December 31, 2020.

While the 2025 Notes are currently classified on our consolidated balance sheet at December 31, 2020 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 2025 Notes have the right to convert the 2025 Notes at any time during the prescribed measurement period, the 2025 Notes would then be considered a current obligation and classified as such.

On or after August 1, 2023, 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 2025 Notes if the last reported sale price (as defined in the 2025 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 2025 Notes.

#### ***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 the 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. In July 2020, we used part of the net proceeds from the issuance of the 2025 Notes discussed above to repurchase \$185.0 million aggregate principal of the 2022 Notes in privately-negotiated transactions for an aggregate of approximately \$211.1 million in cash, including accrued interest. At December 31, 2020, the outstanding principal amount of the 2022 Notes was \$160.0 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 for certain 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 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.

As of 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. This condition was not met during the quarter ended December 31, 2020.

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 remaining principal on any conversions of the 2022 Notes and 2025 Notes and to service our indebtedness through at least February 26, 2022. Our future use of operating cash and capital requirements will depend on many forward-looking factors, including, but not limited to, the following:

- the impact of the COVID-19 pandemic, including the amounts and delays of suspended surgical procedures, clinical trials and general economic conditions;
- our ability to successfully continue to expand the commercialization of EXPAREL, including outside of the U.S.;
- the costs of expanding the commercialization of iovera<sup>®</sup>, including outside of the U.S.;
- 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 and an EXPAREL capacity expansion project at our Science Center Campus in San Diego, California;
- the cost and timing of potential remaining milestone payments to MyoScience security holders, which could be up to an aggregate of \$58.0 million if certain regulatory and commercial milestones are met, which includes one milestone payment of up to \$10.0 million to be paid in the first half of 2021;
- 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 cost and timing of additional strategic investments, including additional investments under existing agreements;
- the cost and timing of an early termination payment to DePuy Synthes, which we currently estimate to be up to \$9.0 million;
- the timing of and extent to which the holders of our 2022 Notes and 2025 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<sup>®</sup>;
- 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. In particular, capital market disruptions or negative economic conditions, especially in light of the COVID-19 pandemic, may hinder our access to capital.

## Contractual Obligations

The table below presents a summary of our contractual obligations as of December 31, 2020 (in thousands):

Contractual Obligations <sup>(1)</sup>	Payments Due by Period				
	Total	Less Than One Year	1-3 Years	3-5 Years	More Than 5 Years
Convertible senior notes - principal <sup>(2)</sup>	\$ 562,500	\$ —	\$ 160,000	\$ 402,500	—
Convertible senior notes - interest	20,962	6,986	7,938	6,038	—
Lease obligations <sup>(3)</sup>	106,699	12,527	21,120	22,251	50,801
Purchase obligations <sup>(4)</sup>	41,547	25,166	16,381	—	—
Achieved milestone payments <sup>(1)</sup>	10,000	10,000	—	—	—
Total	<u>\$ 741,708</u>	<u>\$ 54,679</u>	<u>\$ 205,439</u>	<u>\$ 430,789</u>	<u>50,801</u>

(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 \$48.0 million if certain regulatory and commercial milestones are met. However, the table above includes one achieved milestone payment totaling \$10.0 million scheduled to be paid in the first half of 2021. The table also does not include potential investments of \$4.9 million to be made under an investment agreement and convertible loan agreement if certain milestones are met by GeneQuine. Further, 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 cancellable nature of the services.

(2) The amounts represent the April 2022 maturity of our 2022 Notes and the August 2025 maturity of our 2025 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 and 2025 Notes, which may be settled in cash or stock at our discretion. Neither the 2022 Notes nor the 2025 Notes were convertible as of December 31, 2020.

(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 first suite (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 consolidated financial statements included herein. 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<sup>®</sup> 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. To date, there has been no revenue from the sales of EXPAREL or iovera<sup>®</sup> in the E.U. 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, namely hospitals, ambulatory surgery centers and healthcare provider offices. 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.

## **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**

We do not have any material off-balance sheet arrangements as of December 31, 2020, 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, asset-backed securities and U.S. Treasury and other government agency notes, which are reported at fair value. These securities are subject to interest rate risk and credit 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, 2020 by approximately \$2.6 million.

We have an equity investment in the common stock of TELA Bio, which is publicly traded on the Nasdaq Global Select Market. TELA Bio is measured at fair value on a recurring basis. Changes in the price of its common stock will affect the value of our investment, and we could incur realized or unrealized losses on all or a part of the value of this investment. At December 31, 2020, the value of TELA Bio was \$11.6 million, and a hypothetical 10% decrease in the market price would have caused a decrease in our carrying amount by \$1.2 million. See Note 12, *Financial Instruments*, to our consolidated financial statements included herein for additional information on our equity investments.

In July 2020, we issued \$402.5 million in aggregate principal amount of our 2025 Notes, which mature in August 2025. Holders may convert their 2025 Notes prior to maturity under certain circumstances. Upon conversion, holders will receive the principal amount of the 2025 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 2025 Notes is impacted by both the fair value of our common stock and interest rate fluctuations. As of December 31, 2020, the estimated fair value of the 2025 Notes was \$1,116 per \$1,000 principal amount. See Note 11, *Debt*, to our consolidated financial statements included herein for further discussion of the 2025 Notes. The 2025 Notes bear interest at a fixed rate. At December 31, 2020, all \$402.5 million of principal remains outstanding on the 2025 Notes.

In March 2017, we issued \$345.0 million in aggregate principal amount of our 2022 Notes, which mature in April 2022. In July 2020, we used part of the net proceeds from the issuance of the 2025 Notes discussed above to repurchase \$185.0 million aggregate principal of the 2022 Notes in privately-negotiated transactions for an aggregate of approximately \$211.1 million in cash, including accrued interest. 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. The 2022 Notes bear interest at a fixed rate. As of December 31, 2020, the estimated fair value of the 2022 Notes was \$1,144 per \$1,000 principal amount. See Note 11, *Debt*, to our consolidated financial statements included herein for additional information on the 2022 Notes. At December 31, 2020, \$160.0 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.

Based on their evaluation as of December 31, 2020, our Chief Executive Officer and Chairman and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2020.

### **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, 2020, 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, 2020.

The effectiveness of our internal control over financial reporting as of December 31, 2020 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, 2020.

### **Changes in Internal Control over Financial Reporting**

During the quarter ended December 31, 2020, our management has integrated internal controls for the acquired MyoScience acquisition into our existing controls. Other than integrating the MyoScience acquisition, there have been no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2020 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, 2020, 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, 2020, 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, 2020 and 2019, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2020, and the related notes (collectively, the consolidated financial statements), and our report dated February 26, 2021 expressed an unqualified opinion on those consolidated financial statements.

### *Basis for Opinion*

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

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

### *Definition and Limitations of Internal Control Over Financial Reporting*

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

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

/s/ **KPMG LLP**

Short Hills, New Jersey  
February 26, 2021

**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 2021 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 2021 annual stockholders' meeting and is incorporated by reference into this report.

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

Information required by this item will be included in the proxy statement for our 2021 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 2021 annual stockholders' meeting and is incorporated by reference into this report.

**Item 14. Principal Accountant Fees and Services**

Information required by this item will be included in the proxy statement for our 2021 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 Income (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 0.750% Convertible Senior Notes due 2025), dated July 10, 2020, between the Registrant and Wells Fargo Bank, National Association, as trustee.	8-K	4.1	7/10/2020
4.3	Indenture (including form of 2.375% Convertible Senior Notes due 2022), dated March 13, 2017, between the Registrant and Wells Fargo Bank, National Association, as trustee.	8-K	4.1	3/13/2017
4.4	Description of Securities.	10-K	4.3	2/21/2020
10.1	Amended and Restated 2011 Stock Incentive Plan.***	10-Q	10.1	8/8/2019
10.2	Form of Nonstatutory Stock Option Agreement under the Amended and Restated 2011 Stock Incentive Plan.***	8-K	10.3	6/4/2014
10.3	Form of Restricted Stock Unit Award Agreement (Employees) under the Amended and Restated 2011 Stock Incentive Plan.***	10-Q	10.6	7/30/2015
10.4	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
10.5	2014 Inducement Plan.***	10-Q	10.1	5/1/2014
10.6	2014 Employee Stock Purchase Plan.***	8-K	10.2	6/4/2014
10.7	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
10.8	Stock Purchase Agreement, dated January 8, 2007, between SkyePharma, Inc. and the Registrant.	S-1/A	10.5	12/3/2010
10.9	Employment Agreement between the Registrant and David Stack.***	S-1/A	10.21	12/3/2010
10.10	Amendment No. 1 to Executive Employment Agreement, dated March 13, 2013, between the Registrant and David Stack.***	8-K	99.3	3/18/2013
10.11	Amendment No. 2 to Executive Employment Agreement, dated June 30, 2015, between the Registrant and David Stack.***	10-Q	10.2	7/30/2015
10.12	Employment Agreement, dated November 29, 2012, between the Registrant and Kristen Williams.***	10-Q	10.2	4/30/2015
10.13	Amendment No. 1 to Employment Agreement, dated March 13, 2013, between the Registrant and Kristen Williams.***	10-Q	10.3	4/30/2015
10.14	Amendment No. 2 to Employment Agreement, dated June 30, 2015, between the Registrant and Kristen Williams.***	10-Q	10.5	7/30/2015
10.15	Executive Employment Agreement, dated May 2, 2016, between the Registrant and Charles A. Reinhart, III.***	10-Q	10.1	8/4/2016
10.16	Executive Employment Agreement, dated June 19, 2019, between the Registrant and Max Reinhardt.***	10-Q	10.1	5/7/2020
10.17	Executive Employment Agreement, dated April 24, 2017, between the Registrant and Roy Winston.***	10-Q	10.2	5/7/2020
10.18	Form of Indemnification Agreement between the Registrant and its directors and officers.***	S-1/A	10.32	1/13/2011
10.19	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
10.20	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

Exhibit Number	Description	Incorporation By Reference From		
		Form	Exhibit	Date Filed
10.21	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
10.22	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
10.23	Fourth through Eleventh Amendments to Commercial Outsourcing Services Agreement, between the Registrant and Integrated Commercialization Solutions, Inc.††	10-Q	10.3	5/7/2020
10.24	Pacira BioSciences, Inc. Deferred Compensation Plan.***	8-K	10.1	6/11/2020
10.25	Pacira BioSciences, Inc. Long-Term Incentive Plan.***	8-K	10.1	12/7/2020
10.26	Strategic Co-Production Agreement dated April 4, 2014, by and between the Registrant and Patheon UK Limited.†	10-Q	10.1	7/31/2014
10.27	Manufacturing and Supply Agreement dated April 4, 2014, by and between the Registrant and Patheon UK Limited.†	10-Q	10.2	7/31/2014
10.28	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
10.29	Amended and Restated Consulting Agreement, dated April 3, 2012, between the Registrant and Gary Pace.***	10-Q	10.1	5/9/2012
10.30	Second Amended and Restated Consulting Agreement, dated August 17, 2012, between the Registrant and Gary Pace.***	10-Q	10.1	11/1/2012
10.31	Third Amendment to Consulting Agreement, dated September 11, 2013, between the Registrant and Gary Pace.***	10-Q	10.3	10/31/2013
10.32	Fourth Amendment to Consulting Agreement, dated November 25, 2015, between the Registrant and Gary Pace.***	10-K	10.57	2/25/2016
10.33	Co-Promotion Agreement, dated January 24, 2017, between the Registrant and DePuy Synthes Sales, Inc.†	10-Q	10.1	5/4/2017
10.34	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
10.35	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
10.36	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 portions of the exhibit have been omitted pursuant to Rule 601(b)(10) of Regulation S-K. The omitted information is (i) not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.
- # 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.

## SIGNATURES

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

### PACIRA BIOSCIENCES, INC.

Date: February 26, 2021	By: <u>/s/ DAVID STACK</u> David Stack <i>Chief Executive Officer and Chairman</i>
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Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
<u>/s/ DAVID STACK</u> David Stack	Director, Chief Executive Officer and Chairman (Principal Executive Officer)	February 26, 2021
<u>/s/ CHARLES A. REINHART, III</u> Charles A. Reinhart, III	Chief Financial Officer (Principal Financial Officer)	February 26, 2021
<u>/s/ LAUREN RIKER</u> Lauren Riker	Vice President, Finance (Principal Accounting Officer)	February 26, 2021
<u>/s/ LAURA BREGE</u> Laura Brege	Director	February 26, 2021
<u>/s/ CHRISTOPHER J. CHRISTIE</u> Christopher J. Christie	Director	February 26, 2021
<u>/s/ MARK FROIMSON</u> Mark Froimson	Director	February 26, 2021
<u>/s/ YVONNE GREENSTREET</u> Yvonne Greenstreet	Director	February 26, 2021
<u>/s/ MARK KRONENFELD</u> Mark Kronenfeld	Director	February 26, 2021
<u>/s/ JOHN LONGENECKER</u> John Longenecker	Director	February 26, 2021
<u>/s/ GARY PACE</u> Gary Pace	Director	February 26, 2021
<u>/s/ ANDREAS WICKI</u> Andreas Wicki	Director	February 26, 2021
<u>/s/ PAUL HASTINGS</u> Paul Hastings	Lead Director	February 26, 2021

**PACIRA BIOSCIENCES, INC.**  
**ANNUAL REPORT ON FORM 10-K**  
**FOR THE YEAR ENDED DECEMBER 31, 2020**

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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, 2020 and 2019, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2020, 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, 2020, 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 26, 2021 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 Matter*

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates 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 a critical audit matter 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 matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

#### *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 fair value of the contingent consideration liabilities related to the acquisition of MyoScience, Inc. was \$28.3 million as of December 31, 2020. The contingent consideration liabilities are re-measured each reporting period, with a maximum remaining payout as of December 31, 2020 of \$58.0 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 discount rates.

We identified the evaluation of the 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 discount rates involved a high degree of subjectivity.

The following are the primary procedures we performed to address this critical audit matter. We evaluated the design and tested the operating effectiveness of certain internal controls related to the Company's ongoing fair value process for contingent consideration liabilities related to achieving commercial and regulatory milestones. This included controls related to the forecasted revenues, estimated probabilities and timing of achieving specified milestones, the volatility and the discount rates. 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 discount rates, by comparing the Company's inputs to the volatility and the discount rates, to publicly available market data for the comparable entities used by the Company and assessing the resulting volatility and discount rates. They also assisted in testing the estimate of the ongoing fair value of the contingent consideration liabilities using the Company's forecasted revenues, volatility and the discount rates, 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, New Jersey

February 26, 2021

**PACIRA BIOSCIENCES, INC.**  
**CONSOLIDATED BALANCE SHEETS**

(In thousands, except share and per share amounts)

	December 31,	
	2020	2019
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 99,957	\$ 78,228
Short-term investments	421,705	213,722
Accounts receivable, net	53,046	47,530
Inventories, net	64,650	58,296
Prepaid expenses and other current assets	12,265	10,781
Total current assets	651,623	408,557
Long-term investments	95,459	64,798
Fixed assets, net	136,688	104,681
Right-of-use assets, net	74,492	38,124
Goodwill	99,547	99,547
Intangible assets, net	96,521	104,387
Deferred tax assets	106,164	—
Equity investments and other assets	14,019	10,971
Total assets	<u>\$ 1,274,513</u>	<u>\$ 831,065</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 10,431	\$ 12,799
Accrued expenses	70,974	70,427
Lease liabilities	7,425	4,935
Convertible senior notes	149,648	—
Contingent consideration	14,736	18,179
Income taxes payable	114	1,333
Total current liabilities	253,328	107,673
Convertible senior notes	313,030	306,045
Lease liabilities	71,025	40,938
Contingent consideration	13,610	19,963
Other liabilities	3,832	1,502
Total liabilities	654,825	476,121
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, 2020 and 2019	—	—
Common stock, par value \$0.001; 250,000,000 shares authorized; 43,636,929 shares issued and outstanding at December 31, 2020; 41,908,148 shares issued and outstanding at December 31, 2019	44	42
Additional paid-in capital	873,201	753,978
Accumulated deficit	(253,875)	(399,398)
Accumulated other comprehensive income	318	322
Total stockholders' equity	619,688	354,944
Total liabilities and stockholders' equity	<u>\$ 1,274,513</u>	<u>\$ 831,065</u>

*See accompanying notes to consolidated financial statements.*



**PACIRA BIOSCIENCES, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

(In thousands, except per share amounts)

	Year Ended December 31,		
	2020	2019	2018
Revenues:			
Net product sales	\$ 426,614	\$ 418,926	\$ 332,427
Collaborative licensing and milestone revenue	—	—	3,000
Royalty revenue	3,033	2,100	1,850
Total revenues	429,647	421,026	337,277
Operating expenses:			
Cost of goods sold	117,328	106,712	86,845
Research and development	59,421	72,119	55,688
Selling, general and administrative	193,516	200,782	177,265
Amortization of acquired intangible assets	7,866	5,703	—
Acquisition-related charges, product discontinuation and other	5,166	25,230	1,564
Total operating expenses	383,297	410,546	321,362
Income from operations	46,350	10,480	15,915
Other (expense) income:			
Interest income	4,629	7,376	6,497
Interest expense	(25,671)	(23,628)	(21,949)
Loss on early extinguishment of debt	(8,071)	—	—
Other, net	2,852	(4,976)	(888)
Total other expense, net	(26,261)	(21,228)	(16,340)
Income (loss) before income taxes	20,089	(10,748)	(425)
Income tax benefit (expense)	125,434	(268)	(46)
Net income (loss)	<u>\$ 145,523</u>	<u>\$ (11,016)</u>	<u>\$ (471)</u>
Net income (loss) per share:			
Basic net income (loss) per common share	\$ 3.41	\$ (0.27)	\$ (0.01)
Diluted net income (loss) per common share	\$ 3.33	\$ (0.27)	\$ (0.01)
Weighted average common shares outstanding:			
Basic	42,671	41,513	40,911
Diluted	43,682	41,513	40,911

*See accompanying notes to consolidated financial statements.*

**PACIRA BIOSCIENCES, INC.**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)**

(In thousands)

	Year Ended December 31,		
	2020	2019	2018
Net income (loss)	\$ 145,523	\$ (11,016)	\$ (471)
Other comprehensive income (loss):			
Net unrealized gain (loss) on investments, net of tax	(3)	602	174
Foreign currency translation adjustments	(1)	—	—
Total other comprehensive income (loss)	(4)	602	174
Comprehensive income (loss)	\$ 145,519	\$ (10,414)	\$ (297)

*See accompanying notes to consolidated financial statements*

**PACIRA BIOSCIENCES, INC.**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
**FOR THE YEARS ENDED DECEMBER 31, 2020, 2019 AND 2018**

(In thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total
	Shares	Amount				
<b>Balance at December 31, 2017</b>	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
Other comprehensive income (Note 13)	—	—	—	—	174	174
Net loss	—	—	—	(471)	—	(471)
<b>Balance at December 31, 2018</b>	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 (Note 11)	—	—	(233)	—	—	(233)
Other comprehensive income (Note 13)	—	—	—	—	602	602
Net loss	—	—	—	(11,016)	—	(11,016)
<b>Balance at December 31, 2019</b>	41,908	42	753,978	(399,398)	322	354,944
Exercise of stock options	1,428	2	45,227	—	—	45,229
Vested restricted stock units	239	—	—	—	—	—
Shares issued under employee stock purchase plan	62	—	2,546	—	—	2,546
Stock-based compensation	—	—	39,920	—	—	39,920
Retirement of equity component of 2022 convertible senior notes (Note 11)	—	—	(33,089)	—	—	(33,089)
Equity component of 2025 convertible senior notes issued, net of deferred taxes of \$20,450 (Note 11)	—	—	64,619	—	—	64,619
Other comprehensive loss (Note 13)	—	—	—	—	(4)	(4)
Net income	—	—	—	145,523	—	145,523
<b>Balance at December 31, 2020</b>	<u>43,637</u>	<u>\$ 44</u>	<u>\$ 873,201</u>	<u>\$ (253,875)</u>	<u>\$ 318</u>	<u>\$ 619,688</u>

*See accompanying notes to consolidated financial statements.*

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

	Year Ended December 31,		
	2020	2019	2018
<b>Operating activities:</b>			
Net income (loss)	\$ 145,523	\$ (11,016)	\$ (471)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Deferred taxes	(126,613)	(1,828)	—
Depreciation of fixed assets and amortization of intangible assets	19,908	19,576	13,165
Amortization of unfavorable lease obligation and debt issuance costs	2,156	1,707	1,590
Amortization of debt discount	18,254	13,746	12,799
Loss on disposal and impairment of fixed assets	22	1,010	65
Loss on early extinguishment of debt	8,071	—	—
Stock-based compensation	39,920	33,650	31,725
Changes in contingent consideration (after MyoScience, Inc. acquisition)	5,204	16,672	—
(Gain) loss on investment (net of stock dividend) and other non-operating income, net	(1,618)	4,315	854
Changes in operating assets and liabilities (net of MyoScience, Inc. acquisition):			
Accounts receivable, net	(5,516)	(8,524)	(5,999)
Inventories, net	(6,353)	(8,026)	(7,157)
Prepaid expenses and other assets	(739)	(3,885)	(3,228)
Accounts payable	(3,312)	(1,822)	(573)
Accrued expenses and income taxes payable	(5,999)	22,041	5,203
Other liabilities	(2,467)	(6,726)	897
Payment of contingent consideration to MyoScience, Inc. securityholders	(9,409)	(370)	—
Net cash provided by operating activities	77,032	70,520	48,870
<b>Investing activities:</b>			
Acquisition of MyoScience, Inc. (net of cash acquired)	—	(117,691)	—
Purchases of fixed assets	(37,801)	(10,159)	(14,514)
Purchases of investments	(546,516)	(318,484)	(363,255)
Sales of investments	307,870	319,468	405,188
Payment of contingent consideration	—	—	(6,843)
Equity investment	(1,160)	(1,622)	—
Net cash (used in) provided by investing activities	(277,607)	(128,488)	20,576
<b>Financing activities:</b>			
Proceeds from exercises of stock options	45,218	8,469	7,170
Proceeds from shares issued under employee stock purchase plan	2,546	2,402	1,784
Proceeds from debt component of the 2025 convertible senior notes	314,708	—	—
Proceeds from equity component of the 2025 convertible senior notes	87,792	—	—
Repayment of 2019 convertible senior notes	—	(338)	—
Repayment of 2022 convertible senior notes	(176,793)	—	—
Retirement of equity component of the 2022 convertible senior notes	(33,089)	—	—
Conversion premium on 2019 convertible senior notes	—	(233)	—
Payment of debt issuance and financing costs	(12,487)	—	—
Payment of contingent consideration to MyoScience, Inc. securityholders	(5,591)	(6,630)	—
Net cash provided by financing activities	222,304	3,670	8,954
Net increase (decrease) in cash and cash equivalents	21,729	(54,298)	78,400
Cash and cash equivalents, beginning of year	78,228	132,526	54,126
Cash and cash equivalents, end of year	\$ 99,957	\$ 78,228	\$ 132,526

*See accompanying notes to consolidated financial statements.*

# **CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)**

(In thousands)

	Year Ended December 31,		
	2020	2019	2018
<b>Supplemental cash flow information:</b>			
Cash paid for interest	\$ 7,205	\$ 8,199	\$ 8,205
Cash paid for income taxes, net of refunds	\$ 2,417	\$ 863	\$ 128
<b>Non-cash investing and financing activities:</b>			
Fixed assets included in accounts payable and accrued liabilities	\$ 9,288	\$ 3,019	\$ 2,894
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 the industry leader in its commitment to non-opioid pain management and regenerative health solutions to improve patients’ journeys along the neural pain pathway. The Company’s long-acting, local analgesic, EXPAREL<sup>®</sup> (bupivacaine liposome injectable suspension), was commercially launched in the United States in April 2012 and approved by the European Commission in November 2020. EXPAREL utilizes DepoFoam<sup>®</sup>, 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<sup>®</sup> to its commercial offering with the acquisition of MyoScience, Inc., or MyoScience. The iovera<sup>®</sup> system is a handheld cryoanalgesia device used to deliver a precise, controlled application of cold temperature to only targeted nerves.

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.

*Novel Coronavirus (COVID-19) Pandemic*

During 2020, the Company’s net product sales were negatively impacted by the global pandemic caused by a novel strain of coronavirus (COVID-19), which mandated significant postponement or suspension in the scheduling of elective surgical procedures resulting from public health guidance and government directives. Elective surgical restrictions began to lift on a state-by-state basis in April 2020; however, the Company does not know how long it will take the surgical community to return to normal operations or if states will return to placing restrictions on elective surgical procedures. The Company’s manufacturing sites are operational and have implemented new safety protocols and guidelines as recommended by federal, state and local governments. To date, there have been no material impacts to the Company’s supply chain. The situation remains dynamic and subject to rapid and possibly material changes. Additional negative impacts may also arise from the COVID-19 pandemic that the Company is unable to foresee. The nature and extent of such impacts will depend on future developments, which are highly uncertain and cannot be predicted.

**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, stock-based compensation, inventory costs, impairments of equity investments, long-lived assets, goodwill, liabilities and accruals, including contingent consideration, convertible senior notes, 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<sup>®</sup> 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. To date, there has been no revenue from sales of EXPAREL or iovera<sup>®</sup> in the European Union, or E.U. See Note 4, *Revenue*, for further information on the Company’s accounting policies related to revenue from contracts with customers.

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

*Collaborative Licensing and Milestone Revenue*

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

Revenue recognition from milestone payments is dependent upon the facts and circumstances surrounding the milestone payments. Milestone payments based on a non-sales metric such as a development-based milestone (e.g. obtaining regulatory approval) represent variable consideration and would be 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<sup>®</sup> directly to end users. The table below includes the percentage of revenues comprised by the Company's three largest wholesalers in each period presented:

	Year Ended December 31,		
	2020	2019	2018
Largest wholesaler	31 %	34 %	34 %
Second largest wholesaler	31 %	29 %	30 %
Third largest wholesaler	25 %	26 %	26 %
Total	87 %	89 %	90 %

The Company had no revenue from outside the U.S. during the years ended December 31, 2020 and 2019. Revenue from outside the U.S. accounted for less than 1% of the Company's total revenue for the year ended December 31, 2018.

*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.

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

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

***Stock-Based Compensation***

The Company's stock-based compensation consists of 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 in addition to the closing price of the Company's common stock on the date of grant:

- 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, 2020, the carrying value of money market funds was \$51.8 million and commercial paper was \$6.5 million and as of December 31, 2019, the carrying value of money market funds was \$28.5 million, all of which are included in cash and cash equivalents. The carrying values approximate fair value as of December 31, 2020 and 2019.

***Short-Term and Long-Term Investments***

Short-term investments consist of asset-backed securities collateralized by credit card receivables, investment grade commercial paper, corporate and government bonds, and other bonds issued in the U.S. (and denominated in the U.S. dollar) by foreign entities, all with maturities of greater than three months, but less than one year. Long-term investments consist of corporate and government agency bonds with maturities greater than one year. The Company evaluates the classification of its investments at the time of purchase and re-evaluates such determination at each balance sheet date, which includes an assessment of the intent to hold the available-for-sale securities. 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 (except for credit losses) 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. The Company evaluates whether a credit loss exists, and in the event a credit loss does exist, the credit loss is recognized in the consolidated statements of operations, based on the amount that the fair value is less than the amortized cost.

***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.



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

***Fixed Assets***

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

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

<b>Asset Category</b>	<b>Useful Life</b>
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 such lease agreements. The Company records its asset retirement obligations, 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 expense to accrete the ARO to its full value. Each ARO capital asset is depreciated over the depreciable term of the associated asset.

***Leases***

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. 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 can be determined, the asset or liability is recognized; if fair value is not determinable, then 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 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 accreted to the period in which payments are expected to be made.

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

***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 testing at least annually or when a triggering event occurs that could indicate a potential impairment.

***Intangible Assets***

Intangible assets with definite useful lives are amortized on a straight-line basis over their estimated useful lives and are recorded at cost, net of accumulated amortization.

***Equity Investments***

The Company holds two separate investments in equity securities, one with a readily determined fair value and one without a readily determinable fair value. In the fourth quarter of 2019, the equity investment then held became publicly traded and thereafter, has been recognized at its fair value at each reporting period with any unrealized holding gains (losses) included in other income (expense). The equity method investment without a readily determinable fair value is recognized at its cost less any impairment, plus or minus any changes resulting from observable price changes in orderly transactions for a similar investment.

***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. 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 debt, 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 retirement 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), and the excess conversion value on the Company's convertible senior notes.

***Foreign Currency Translation***

The balance sheet accounts of foreign subsidiaries with functional currencies other than the U.S. Dollar are translated using the exchange rate at each respective balance sheet date. Revenues and expenses are translated using average exchange

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

rates for each calendar month during the year. Translation adjustments are recorded as a component of accumulated other comprehensive income (loss) in the consolidated financial statements.

***Segment Reporting***

The Company is managed and operated as a single business focused on the 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 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 financial results.

**NOTE 3—RECENT ACCOUNTING PRONOUNCEMENTS**

***Recently Adopted Accounting Pronouncements***

In June 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires entities to measure all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions and reasonable and supportable forecasts. 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 became effective for the Company beginning January 1, 2020 and there were no credit losses recognized upon adoption.

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 became effective for the Company beginning January 1, 2020 and the Company has applied these new disclosure requirements in its consolidated financial statements for the year ended December 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. 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 became effective for the Company beginning January 1, 2020. The amendments have been applied prospectively to implementation costs incurred after the date of adoption. The Company did not incur implementation costs in a hosting arrangement that were required to be capitalized during the year ended December 31, 2020.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which was adopted by the Company on January 1, 2019 using the effective date method. There were practical expedients available to the Company 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, 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.

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

In May 2014, the FASB, issued 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. The implementation of Accounting Standards Codification, or 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 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 adopted 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, 2020*

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 certain exceptions, including an exception to the use of the incremental approach for intra-period tax allocations, 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 to reflect the effects of enacted changes in tax laws or rates 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 became effective for the Company January 1, 2021 and the Company does not anticipate any material impact to its consolidated financial statements.

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)*, which limits the number of convertible instruments that require separate accounting to (i) those with embedded conversion features that are not clearly and closely related to the debt, that meet the definition of a derivative, and that do not qualify for the scope exception from derivative accounting and (ii) convertible debt instruments issued with substantial premiums for which the premiums are recorded as paid in capital. In addition, the new guidance requires diluted earnings per share calculations to be prepared using the if-converted method, instead of the treasury stock method. The guidance must be applied in fiscal years beginning after December 15, 2021, including interim periods within those fiscal years, with early adoption permitted no earlier than for fiscal years beginning after December 15, 2020. The Company has the option to adopt the new guidance using a modified retrospective method of transition, which would then be applied to transactions outstanding at the time of adoption, or the full retrospective method. The Company is evaluating the impact from the adoption of ASU 2020-06 on its consolidated financial statements.

**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<sup>®</sup> 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. To date, there has been no revenue from the sales of EXPAREL or iovera<sup>®</sup> in the E.U. 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, namely hospitals, ambulatory surgery centers and healthcare provider offices. 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.

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

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, 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, 2020, 2019 and 2018 (in thousands):

	<b>Returns Allowances</b>	<b>Prompt Payment Discounts</b>	<b>Wholesaler Service Fees</b>	<b>Volume Rebates and Chargebacks</b>	<b>Total</b>
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
Provision	794	8,541	6,437	12,345	28,117
Payments/Adjustments	(311)	(8,496)	(6,755)	(12,561)	(28,123)
Balance at December 31, 2020	<u>\$ 1,023</u>	<u>\$ 1,007</u>	<u>\$ 1,168</u>	<u>\$ 1,600</u>	<u>\$ 4,798</u>

*Accounts Receivable*

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

*Performance Obligations*

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in ASC 606. A contract's transaction price is allocated to each distinct performance obligation and recognized as revenue when, or as, the performance obligation is satisfied.

At contract inception, the Company assesses the goods promised in its contracts with customers and identifies a performance obligation for each promise to transfer to the customer a good that is distinct. When identifying individual performance obligations, the Company considers all goods promised in the contract regardless of whether explicitly stated in the customer contract or implied by customary business practices. The Company's contracts with customers require it to transfer an individual distinct product, which represents a single performance obligation. The Company's performance obligation with respect to its product sales 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):

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

	Year Ended December 31,		
	2020	2019	2018
Net product sales:			
EXPAREL / bupivacaine liposome injectable suspension	\$ 417,797	\$ 411,030	\$ 332,427
iovera <sup>o</sup>	8,817	7,896	—
Total net product sales	<u>\$ 426,614</u>	<u>\$ 418,926</u>	<u>\$ 332,427</u>

**NOTE 5—MYOSCIENCE ACQUISITION**

On April 9, 2019, the Company acquired MyoScience (the “MyoScience Acquisition”), a privately-held medical device company, in which MyoScience became a wholly-owned subsidiary of the Company and was renamed Pacira CryoTech, Inc. The total consideration was \$147.5 million, which included a cash payment of \$119.0 million and the fair value of contingent consideration in the amount of \$28.5 million. The contingent consideration consisted of contingent milestone payments up to an aggregate of \$100.0 million upon the achievement of certain regulatory and commercial milestones, of which \$58.0 million are available as of December 31, 2020. The Company’s obligation to make milestone payments is limited to those milestones achieved through December 31, 2023, and are to be paid within 60 days of the end of the fiscal quarter of achievement. During the years ended December 31, 2020 and 2019, the Company made \$15.0 million and \$7.0 million of cash payments for the achievement of certain milestones, respectively. In 2020, the Company recorded an additional charge of \$9.7 million relating to the achievement of a \$10.0 million regulatory milestone. The milestone is payable in the second quarter of 2021. See Note 12, *Financial Instruments*, for information on the measurement and amounts recognized in the Company’s consolidated financial statements for contingent consideration. See Note 21, *Commitments and Contingencies*, for information on a dispute regarding the achievement of certain milestone payments.

*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 represent what the Company’s actual results would have been 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;
- 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.

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

**NOTE 6—INVENTORIES**

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

	December 31,	
	2020	2019
Raw materials	\$ 26,886	\$ 20,019
Work-in-process	16,266	14,407
Finished goods	21,498	23,870
Total	<u>\$ 64,650</u>	<u>\$ 58,296</u>

In December 2019, the Company's contract manufacturer experienced a media fill failure, as part of its routine aseptic manufacturing requalification program, and an investigation was completed in April 2020. Based on the results of the investigation, the Company determined that no inventory reserves were required related to the media fill failure, and that all inventory in question had been determined to be sellable. The Company resumed production on this manufacturing line in May 2020.

**NOTE 7—FIXED ASSETS**

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

	December 31,	
	2020	2019
Machinery and equipment	\$ 74,966	\$ 70,078
Leasehold improvements	54,434	60,441
Computer equipment and software	12,170	8,942
Office furniture and equipment	2,387	1,882
Construction in progress	71,091	38,778
Total	215,048	180,121
Less: accumulated depreciation	(78,360)	(75,440)
Fixed assets, net	<u>\$ 136,688</u>	<u>\$ 104,681</u>

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, 2020, 2019 and 2018 was \$12.0 million, \$14.0 million and \$13.2 million, respectively. During the years ended December 31, 2020, 2019 and 2018, the Company capitalized interest of \$2.4 million, less than \$0.1 million and \$0.7 million, respectively.

As of December 31, 2020 and 2019, total fixed assets, net, includes leasehold improvements and manufacturing process equipment located in Europe in the amount of \$67.5 million and \$64.8 million, respectively.

As of December 31, 2020 and 2019, the Company had AROs of \$2.0 million and \$2.5 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 decrease of \$0.5 million for the year ended December 31, 2020 was primarily due to exiting two facilities at the Company's Science Center Campus in San Diego, California. Accretion expense was less than \$0.1 million and \$0.2 million for the years ended December 31, 2020 and 2019, respectively.

**NOTE 8—LEASES**

The Company leases all of its facilities, including its EXPAREL manufacturing facility in San Diego, California and its iovera<sup>®</sup> manufacturing facility in Fremont, California. These leases have remaining terms up to 9.7 years, some of which provide renewal options at the then-current market value. The Company also has an embedded lease with Thermo Fisher Scientific Pharma Services, or Thermo Fisher (formerly Patheon UK Limited), for the use of their manufacturing facility in Swindon, England. A portion of the associated monthly base fees has been allocated to the lease component based on a relative fair value basis.

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

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):

Operating Lease Costs	Year Ended December 31,		
	2020	2019	2018
Fixed lease costs	\$ 10,055	\$ 6,225	\$ 7,236
Variable lease costs	2,096	1,651	1,761
Total	<u>\$ 12,151</u>	<u>\$ 7,876</u>	<u>\$ 8,997</u>

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

	Year Ended December 31,	
	2020	2019
Cash paid for operating lease liabilities, net of lease incentive	\$ 14,347	\$ 7,346
Right-of-use assets recorded in exchange for lease obligations	\$ 42,191	\$ 41,605

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

The Company has measured its operating lease liabilities at an estimated discount rate at 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,	
	2020	2019
Weighted average remaining lease term	9.18 years	9.38 years
Weighted average discount rate	6.87%	7.55%

As of December 31, 2020, maturities of the Company's operating lease liabilities are as follows (in thousands):

Year	Aggregate Payments Due	
2021	\$	12,527
2022		10,423
2023		10,697
2024		10,980
2025		11,271
2026 through 2030		50,801
Total lease payments		<u>106,699</u>
Less: imputed interest		<u>(28,249)</u>
Total operating lease liabilities	\$	<u>78,450</u>



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

**NOTE 9—GOODWILL AND INTANGIBLE ASSETS**

***Goodwill***

The Company's goodwill results from the acquisition of Pacira Pharmaceuticals, Inc. from SkyePharma Holding, Inc. (now a subsidiary of Vectura Group plc), or Skyepharma in 2007 (the "Skyepharma Acquisition"), and the MyoScience Acquisition in 2019. The change in the carrying value of the Company's goodwill is summarized as follows (in thousands):

	<b>Carrying Value</b>
Balance at December 31, 2018	\$ 62,040
Goodwill arising from the MyoScience Acquisition	37,507
Balance at December 31, 2019	99,547
2020 accumulated adjustments	—
Balance at December 31, 2020	<u>\$ 99,547</u>

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 date of acquisition. In connection with the Skyepharma Acquisition, the Company agreed to certain milestone payments for DepoBupivacaine products, including EXPAREL. As of December 31, 2020, the remaining milestone payments include: \$4.0 million upon the first commercial sale in the United Kingdom, France, Germany, Italy or Spain; and \$32.0 million when annual net sales collected reach \$500.0 million (measured on a rolling quarterly basis). 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.

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 had expired on September 18, 2018.

The Company made a tax election that allows the acquired goodwill and intangible assets associated with the MyoScience Acquisition 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):

	<b>Estimated Useful Life</b>	<b>December 31,</b>	
		<b>2020</b>	<b>2019</b>
Developed technology	14 years	\$ 110,000	\$ 110,000
Customer relationships	10 years	90	90
Total intangible assets		110,090	110,090
Less: accumulated amortization		(13,569)	(5,703)
Intangible assets, net		<u>\$ 96,521</u>	<u>\$ 104,387</u>

Amortization expense on intangible assets for the years ended December 31, 2020 and 2019 were \$7.9 million and \$5.7 million, respectively.

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.

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

**NOTE 10—ACCRUED EXPENSES**

Accrued expenses consist of the following (in thousands):

	<b>December 31,</b>	
	<b>2020</b>	<b>2019</b>
Accrued selling, general and administrative expenses	\$ 23,288	\$ 21,695
Accrued research and development expenses	6,682	6,562
Other accrued operating expenses	11,196	12,955
Compensation and benefits	22,202	22,258
Accrued royalties	3,040	2,883
Accrued interest	2,376	2,048
Product returns and wholesaler service fees	2,190	2,026
Total	<u>\$ 70,974</u>	<u>\$ 70,427</u>

**NOTE 11—DEBT**

*Convertible Senior Notes Due 2025*

On July 10, 2020, the Company completed a private placement of \$402.5 million in aggregate principal amount of its 0.750% convertible senior notes due 2025, or 2025 Notes, and entered into an indenture, or 2025 Indenture, with respect to the 2025 Notes. The 2025 Notes accrue interest at a fixed rate of 0.750% per year, payable semiannually in arrears on February 1<sup>st</sup> and August 1<sup>st</sup> of each year, beginning on February 1, 2021. The 2025 Notes mature on August 1, 2025.

The total debt composition of the 2025 Notes is as follows (in thousands):

	<b>December 31,</b>
	<b>2020</b>
0.750% convertible senior notes due 2025	\$ 402,500
Deferred financing costs	(8,940)
Discount on debt	(80,530)
Total debt, net of debt discount and deferred financing costs	<u>\$ 313,030</u>

The net proceeds from the issuance of the 2025 Notes was approximately \$390.0 million, after deducting commissions and the offering expenses paid by the Company. A portion of the net proceeds from the 2025 Notes was used by the Company to repurchase \$185.0 million in aggregate principal amount of its outstanding 2.375% convertible senior notes due 2022 in privately-negotiated transactions for a total of \$211.1 million of cash (including accrued interest).

Holders may convert the 2025 Notes at any time prior to the close of business on the business day immediately preceding February 3, 2025, only under the following circumstances:

(i) during any calendar quarter (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 or equal to 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 2025 Indenture) per \$1,000 principal amount of 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 2025 Notes for redemption, until the close of business on the business day immediately preceding the redemption date.

On or after February 3, 2025, until the close of business on the second scheduled trading day immediately preceding August 1, 2025, holders may convert their 2025 Notes at any time.

None of these conditions for conversion were met during the quarter ended December 31, 2020.

Upon conversion, holders will receive the principal amount of their 2025 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 2025 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 2025 Notes is 13.9324 shares of common stock per \$1,000 principal amount, which is equivalent to an initial conversion price of \$71.78 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 2025 Notes represents a premium of approximately 32.5% to the closing sale price of \$54.17 per share of the Company's common stock on the Nasdaq Global Select Market on July 7, 2020, the date that the Company priced the private offering of the 2025 Notes.

As of December 31, 2020, the 2025 Notes had a market price of \$1,116 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 further stock price appreciation. Upon the receipt of conversion requests, the settlement of the 2025 Notes will be paid pursuant to the terms of the 2025 Indenture. In the event that all of the 2025 Notes are converted, the Company would be required to repay the \$402.5 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 August 1, 2023, the Company may not redeem the 2025 Notes. On or after August 1, 2023 (but, in the case of a redemption of less than all of the outstanding 2025 Notes, no later than the 40<sup>th</sup> scheduled trading day immediately before the maturity date), the Company may redeem for cash all or part of the 2025 Notes if the last reported sale price (as defined in the 2025 Indenture) of the Company's common stock has been at least 130% of the conversion price then in effect for (i) each of at least 20 trading days (whether or not consecutive) during any 30 consecutive trading days ending on, and including, the trading day immediately before the date the Company sends the related notice of redemption and (ii) the trading day immediately before the date the Company sends such notice. The redemption price will equal the sum of (i) 100% of the principal amount of the 2025 Notes being redeemed, plus (ii) accrued and unpaid interest, including additional interest, if any, to, but excluding, the redemption date. In addition, calling the 2025 Notes for redemption will constitute a "make-whole fundamental change" (as defined in the 2025 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 2025 Notes.

If the Company undergoes a fundamental change, as defined in the 2025 Indenture, subject to certain conditions, holders of the 2025 Notes may require the Company to repurchase for cash all or part of their 2025 Notes at a repurchase price equal to 100% of the principal amount of the 2025 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 2025 Indenture) occurs prior to August 1, 2025, 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 2025 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 2025 Notes, and equal in right of payment to the Company's unsecured indebtedness. The 2025 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 2025 Notes are currently classified on the Company's consolidated balance sheet at December 31, 2020 as long-term debt, the future convertibility and resulting balance sheet classification of this liability is monitored at each quarterly reporting date and is analyzed dependent upon market prices of the Company's common stock during the prescribed measurement periods. In the event that the holders of the 2025 Notes have the election to convert the 2025 Notes at any time during the prescribed measurement period, the 2025 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 2025 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 \$314.7 million was calculated using a 5.78% assumed borrowing rate. The equity component of \$87.8 million, representing the conversion option, was determined by deducting the fair value of the liability component from the par value of the 2025 Notes and is recorded in additional paid-in capital on the consolidated balance sheet at the issuance date. The equity component is treated as a discount on the liability component of the 2025 Notes, which is amortized over the five-year term of the 2025 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. A deferred tax liability was recognized in the amount of \$20.5 million, with the offsetting amount recorded in additional paid-in capital. See Note 16, *Income Taxes*, for information regarding the Company's deferred taxes.

The Company allocated the total transaction costs of approximately \$12.5 million related to the issuance of the 2025 Notes to the liability and equity components of the 2025 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 2025 Notes, and transaction costs attributable to the equity component totaling \$2.7 million are netted with the equity component in stockholders' equity.

The 2025 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 2025 Indenture contains customary events of default with respect to the 2025 Notes, including that upon certain events of default, 100% of the principal and accrued and unpaid interest on the 2025 Notes will automatically become due and payable.

*Convertible Senior Notes Due 2022*

On March 13, 2017, the Company completed a private placement of \$345.0 million in aggregate principal amount of 2.375% convertible senior notes due 2022, or 2022 Notes, and entered into an indenture, or 2022 Indenture, with respect to the 2022 Notes. The 2022 Notes accrue interest at a fixed rate of 2.375% per year, payable semiannually in arrears on April 1<sup>st</sup> and October 1<sup>st</sup> of each year. The 2022 Notes mature on April 1, 2022. As discussed above, in July 2020, the Company used part of the net proceeds from the issuance of the 2025 Notes to repurchase \$185.0 million aggregate principal amount of the 2022 Notes in privately-negotiated transactions for an aggregate of \$211.1 million in cash (including accrued interest). The partial repurchase of the 2022 Notes resulted in an \$8.1 million loss on early extinguishment of debt.

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

	<b>December 31,</b>	
	<b>2020</b>	<b>2019</b>
2.375% convertible senior notes due 2022	\$ 160,000	\$ 345,000
Deferred financing costs	(1,089)	(4,143)
Discount on debt	(9,263)	(34,812)
Total debt, net of debt discount and deferred financing costs	<u>\$ 149,648</u>	<u>\$ 306,045</u>

Holders may convert their 2022 Notes prior to October 1, 2021, only if certain circumstances are met, including if during the previous calendar quarter, the last reported sales price of the Company's common stock was greater than or equal to 130% of the conversion price then applicable for at least 20 out of the last 30 consecutive trading days of the quarter. During the year ended December 31, 2020, this condition for conversion was not met.

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

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

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, 2020, the 2022 Notes had a market price of \$1,144 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 settled, the Company would be required to repay the remaining \$160.0 million in principal value and any conversion premium in any combination of cash and shares of its common stock (at the Company's option).

As of 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. This condition was not met during the quarter ended December 31, 2020. 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 (trade payables) of the Company's subsidiaries.

The 2022 Notes are currently classified on the Company's consolidated balance sheet at December 31, 2020 as short-term debt. The future convertibility of this liability is monitored at each quarterly reporting date and is analyzed dependent upon market prices of the Company's common stock during the prescribed measurement periods. The holders of the 2022 Notes have the right to convert the 2022 Notes at any time on or after October 1, 2021, until the close of business on the second scheduled trading day immediately preceding April 1, 2022. Therefore, the 2022 Notes are considered a current obligation to the Company.

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

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

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.

*Interest Expense*

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

	Year Ended December 31,		
	2020	2019	2018
Contractual and other interest expense	\$ 7,650	\$ 8,195	\$ 8,205
Amortization of debt issuance costs	2,156	1,707	1,634
Amortization of debt discount	18,254	13,746	12,799
Capitalized interest (Note 7)	(2,389)	(20)	(689)
Total	<u>\$ 25,671</u>	<u>\$ 23,628</u>	<u>\$ 21,949</u>
Effective interest rate on convertible senior notes	7.15 %	7.81 %	7.81 %

**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.
- *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 with a readily determinable fair value 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 amount of the investment without a readily determinable fair value has not been adjusted for either an impairment or upward or downward adjustments based on observable transactions. The carrying values and fair values of the Company's financial assets and liabilities at December 31, 2020 are as follows (in thousands):

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

	Carrying Value	Fair Value Measurements Using			
		Level 1	Level 2	Level 3	
<i>Financial Assets and Financial Liabilities Measured at Fair Value on a Recurring Basis:</i>					
Financial Asset:					
Equity investment with readily determinable fair value	\$ 11,642	\$ 11,642	\$ —	\$ —	
Financial Liabilities:					
Acquisition-related contingent consideration	\$ 28,346	\$ —	\$ —	\$ 28,346	
<i>Financial Liabilities Measured at Amortized Cost:</i>					
2.375% convertible senior notes due 2022 <sup>(1)</sup>	\$ 149,648	\$ —	\$ 183,000	\$ —	
0.750% convertible senior notes due 2025 <sup>(1)</sup>	\$ 313,030	\$ —	\$ 449,039	\$ —	

(1) The closing price of the Company's common stock as reported on the Nasdaq Global Select Market was \$59.84 per share at December 31, 2020 compared to a conversion price of \$66.89 per share for the 2022 Notes and a conversion price of \$71.78 for the 2025 Notes. Therefore, at December 31, 2020, the conversion prices were above the stock price. The maximum conversion premium that could have been due on the 2022 Notes and 2025 Notes at December 31, 2020 was approximately 2.4 million and 5.6 million shares of the Company's common stock, respectively. These figures assume no increases in the conversion rate for certain corporate events.

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

*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 \$28.3 million and \$38.1 million as of December 31, 2020 and 2019, respectively. Refer to Note 5, *MyoScience Acquisition* and Note 18, *Acquisition-Related Charges and Product Discontinuation, Net*, 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 years ended December 31, 2020 and 2019, the Company recognized \$5.2 million and \$16.7 million of charges, respectively, as a result of revisions to the probabilities of regulatory milestones being met and revisions to future projections, 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. At December 31, 2020, the weighted average discount rate was 4.2% and the weighted average probability of success for regulatory milestones was 60.8%.

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

Assumption	Ranges Utilized as of December 31, 2020
Discount rates	4.12% to 4.22%
Probabilities of payment for regulatory milestones	2.00% to 100.00%
Projected years of payment for regulatory and commercial milestones	2021 to 2023

The maximum remaining potential payments related to the contingent consideration from the MyoScience Acquisition are \$58.0 million as of December 31, 2020.

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



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

	<b>Contingent Consideration Fair Value</b>
Balance at December 31, 2019	\$ 38,142
Fair value adjustments and accretion	5,204
Payments made	(15,000)
Balance at December 31, 2020	<u>\$ 28,346</u>

*Investments*

Short-term investments consist of asset-backed securities collateralized by credit card receivables, investment grade commercial paper and corporate and government 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 and government bonds with maturities greater than one year but less than three years. Net unrealized gains and losses (excluding credit losses, if any) from the Company's short-term and long-term investments are reported in other comprehensive income (loss). At December 31, 2020, 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 the time of purchase, 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, 2020 and 2019 (in thousands):

<b>December 31, 2020 Investments:</b>	<b>Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value (Level 2)</b>
<b>Short-term:</b>				
Asset-backed securities	\$ 34,918	\$ 98	\$ —	\$ 35,016
Commercial paper	221,494	36	(18)	221,512
Corporate bonds	120,375	179	(11)	120,543
U.S. Government bonds	44,629	7	(2)	44,634
Subtotal	421,416	320	(31)	421,705
<b>Long-term:</b>				
U.S. Government bonds	95,429	30	—	95,459
Subtotal	95,429	30	—	95,459
Total	<u>\$ 516,845</u>	<u>\$ 350</u>	<u>\$ (31)</u>	<u>\$ 517,164</u>

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

At December 31, 2020, there were no investments available for sale that were materially less than their amortized cost.



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

The Company elects to recognize its interest receivable separate from its available-for-sale investments. At December 31, 2020 and December 31, 2019, the interest receivable recognized in prepaid expenses and other current assets was \$1.6 million and \$1.4 million, respectively.

*Equity Investments*

At December 31, 2020 and 2019, the Company held an equity investment in TELA Bio, Inc., or TELA Bio, in its consolidated balance sheets in the amounts of \$11.6 million and \$10.0 million, respectively. During the year ended December 31, 2020, the fair value of this publicly traded investment increased by \$1.6 million which is recorded in other, net in the consolidated statement of operations. 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 in the amount of \$2.5 million. During 2019, the Company also recognized an impairment loss of \$5.7 million in other, net related to its investment in TELA Bio. The fair values of TELA Bio at December 31, 2020 and 2019 were based on Level 1 inputs. In 2020, the Company invested \$1.2 million in GeneQuine Biotherapeutics GmbH, or GeneQuine, a privately held biopharmaceutical company headquartered in Hamburg, Germany. This investment has no readily determinable fair value and is recorded at cost minus impairment, if any, plus or minus observable price changes of identical or similar investments. In January 2021, the Company invested an additional \$1.2 million in GeneQuine as a convertible note. The Company has the right to make an additional \$4.9 million investment predicated upon GeneQuine achieving certain prespecified near-term milestones.

*Credit Risk*

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents, short-term and 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, 2020, three wholesalers each accounted for over 10% of the Company's accounts receivable at 36%, 28% and 23%. At December 31, 2019, three wholesalers each accounted for over 10% of the Company's accounts receivable at 37%, 29% and 26%. For additional information regarding the Company's wholesalers, see Note 2, *Summary of Significant Accounting Policies*. EXPAREL revenues are primarily derived from major wholesalers that generally have significant cash resources. The Company performs ongoing credit evaluations of its customers as warranted and generally does not require collateral. Allowances for credit losses on the Company's accounts receivable are maintained based on historical payment patterns, current and estimated future economic conditions, aging of accounts receivable and its write-off history. As of December 31, 2020 and 2019, the Company did not deem any allowances for credit losses on its accounts receivable necessary.

**NOTE 13—STOCKHOLDERS' EQUITY**

*Common Stock*

The Company is authorized to issue up to 250,000,000 shares of common stock, of which 43,636,929 and 41,908,148 were issued and outstanding at December 31, 2020 and 2019, 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, 2020 or 2019.

**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):

	<b>Net Unrealized Gains (Losses)</b>
Balance at December 31, 2017	\$ (454)
Net unrealized gain on investments net of tax	174
Amounts reclassified from accumulated other comprehensive income (loss)	—
Balance at December 31, 2018	(280)
Net unrealized gain on investments net of tax	602
Amounts reclassified from accumulated other comprehensive income (loss)	—
Balance at December 31, 2019	322
Net unrealized loss on investments net of tax	(3)
Foreign currency translation adjustments	(1)
Amounts reclassified from accumulated other comprehensive income (loss)	—
Balance at December 31, 2020	<u>\$ 318</u>

**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 2011 and was amended in June 2014, 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. 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 (typically over four years from the date of grant, although the Company may occasionally grant options with different vesting terms, including grants made to its non-employee directors). The Company also grants RSUs to employees and non-employee directors generally vesting in increments over four years from the date of grant except for such grants made to non-employee directors. The Company uses authorized and unissued shares of its common stock 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, 2020, 61,585 shares were purchased and issued through the ESPP.

The following tables contain information about the Company's stock incentive plans at December 31, 2020:

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

<b>Stock Incentive Plan</b>	<b>Awards Reserved For Issuance</b>	<b>Awards Issued</b>	<b>Awards Available For Grant</b>
2011 Plan	12,931,701	11,569,813	1,361,888
2014 Inducement Plan	175,000	36,576	138,424
<b>Total</b>	<b>13,106,701</b>	<b>11,606,389</b>	<b>1,500,312</b>

<b>Employee Stock Purchase Plan</b>	<b>Shares Reserved For Purchase</b>	<b>Shares Purchased</b>	<b>Shares Available For Purchase</b>
2014 ESPP	500,000	353,566	146,434

*Stock-Based Compensation*

Compensation expense for stock options and RSUs is based on the estimated grant date fair value of an award 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, 2020, 2019 and 2018 as follows (in thousands):

	<b>Year Ended December 31,</b>		
	<b>2020</b>	<b>2019</b>	<b>2018</b>
Cost of goods sold	\$ 5,589	\$ 4,665	\$ 4,478
Research and development	5,211	5,114	3,934
Selling, general and administrative	29,120	23,871	23,313
<b>Total</b>	<b>\$ 39,920</b>	<b>\$ 33,650</b>	<b>\$ 31,725</b>
<b>Stock-based compensation from:</b>			
Stock options	\$ 26,749	\$ 23,360	\$ 22,643
RSUs	12,266	9,511	8,371
ESPP	905	779	711
<b>Total</b>	<b>\$ 39,920</b>	<b>\$ 33,650</b>	<b>\$ 31,725</b>
Related income tax benefit	\$ 8,578	\$ —	\$ —

The following table summarizes the Company's stock option activity and related information for the period from December 31, 2017 to December 31, 2020:

**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, 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
Granted	1,502,803	47.50		
Exercised	(1,428,111)	31.67		\$ 34,227
Forfeited	(426,925)	42.08		
Expired	(119,027)	71.71		
Outstanding at December 31, 2020	6,235,118	\$ 45.98	6.97	\$ 102,955
Exercisable at December 31, 2020	3,315,863	\$ 47.24	5.45	\$ 58,308
Vested and expected to vest at December 31, 2020	6,235,118	\$ 45.98	6.97	\$ 102,955

As of December 31, 2020, \$55.6 million of total unrecognized compensation cost related to non-vested stock options is expected to be recognized over a weighted average period of 2.7 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, 2020, 2019 and 2018 was \$22.40, \$20.92 and \$19.34 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,		
	2020	2019	2018
Expected dividend yield	None	None	None
Risk-free interest rate	0.22% - 1.60%	1.33% - 2.54%	2.26% - 3.05%
Expected volatility	53.5%	53.9%	53.3%
Expected term of options	5.36 years	5.22 years	5.14 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, 2017 to December 31, 2020:

	Number of Units	Weighted Average Grant Date Fair Value (Per Share)	Aggregate Intrinsic Value (in Thousands)
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 at December 31, 2019	631,141	41.87	\$ 28,591
Granted	665,476	48.70	
Vested	(239,085)	41.91	
Forfeited	(100,079)	44.43	
Unvested and expected to vest at December 31, 2020	957,453	\$ 46.34	\$ 57,294

As of December 31, 2020, \$36.2 million of total unrecognized compensation cost related to non-vested RSUs is expected to be recognized over a weighted average period of 3.1 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,		
	2020	2019	2018
ESPP share option fair value	\$11.02 - \$17.54	\$11.13 - \$11.36	\$10.40 - \$13.15
Expected dividend yield	None	None	None
Risk-free interest rate	0.14% - 1.57%	2.10% - 2.56%	1.53% - 2.14%
Expected volatility	44.9%	40.2%	52.2%
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 and 2018, 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 and 2025 Notes. Since it is the Company's intent to settle the principal amount of its 2022 Notes and 2025 Notes in cash, the potentially dilutive effect of such notes on net income (loss) per share is computed under the treasury stock method. ASU 2020-06 will require the Company to use the if-converted method upon adoption; this new accounting pronouncement has not been adopted as of December 31, 2020.

The following table sets forth the computation of basic and diluted net income (loss) per share for the years ended December 31, 2020, 2019 and 2018 (in thousands, except per share amounts):

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

	Year Ended December 31,		
	2020	2019	2018
<b>Numerator:</b>			
Net income (loss)	\$ 145,523	\$ (11,016)	\$ (471)
<b>Denominator:</b>			
Weighted average shares of common stock outstanding—basic	42,671	41,513	40,911
Computation of diluted securities:			
Dilutive effect of stock options	783	—	—
Dilutive effect of RSUs	227	—	—
Dilutive effect of ESPP purchase options	1	—	—
Weighted average shares of common stock outstanding—diluted	<u>43,682</u>	<u>41,513</u>	<u>40,911</u>
<b>Net income (loss) per share:</b>			
Basic net income (loss) per common share	\$ 3.41	\$ (0.27)	\$ (0.01)
Diluted net income (loss) per common share	\$ 3.33	\$ (0.27)	\$ (0.01)

The following outstanding stock options, RSUs, and ESPP purchase options are antidilutive in the periods presented (in thousands):

	Year Ended December 31,		
	2020	2019	2018
Weighted average number of stock options	4,237	6,404	5,492
Weighted average number of RSUs	99	606	542
Weighted average ESPP purchase options	16	34	31
Total	<u>4,352</u>	<u>7,044</u>	<u>6,065</u>

**NOTE 16—INCOME TAXES**

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

	Year Ended December 31,		
	2020	2019	2018
Income (loss) before income taxes:			
Domestic	\$ 17,000	\$ (7,026)	\$ 5,169
Foreign	3,089	(3,722)	(5,594)
Total income (loss) before income taxes	<u>\$ 20,089</u>	<u>\$ (10,748)</u>	<u>\$ (425)</u>
Current taxes:			
Federal	\$ (6)	\$ —	\$ (96)
State	1,185	2,096	142
Total current taxes	<u>\$ 1,179</u>	<u>\$ 2,096</u>	<u>\$ 46</u>
Deferred taxes:			
Federal	\$ (99,164)	\$ (1,828)	\$ —
State	(27,449)	—	—
Total deferred taxes	<u>\$ (126,613)</u>	<u>\$ (1,828)</u>	<u>\$ —</u>
Total income tax (benefit) expense	<u>\$ (125,434)</u>	<u>\$ 268</u>	<u>\$ 46</u>

For the year ended December 31, 2020, the Company had an income tax benefit of \$125.4 million primarily related to the release of a valuation allowance on its domestic net deferred assets. The income tax expense for the year ended December 31,

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

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. Income tax expense for the year ended December 31, 2018 is principally the result of minimum state taxes.

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,		
	2020	2019	2018
U.S. federal statutory rate	21.00 %	21.00 %	21.00 %
State taxes	3.15 %	(7.33)%	(24.84)%
Foreign taxes	3.18 %	(3.95)%	(92.04)%
Change in valuation allowance	(647.87)%	19.76 %	369.27 %
Stock-based compensation	(1.08)%	(10.53)%	(874.29)%
Tax credits	(7.92)%	19.93 %	700.35 %
Interest expense	— %	— %	218.47 %
Effect of rate changes	— %	(0.42)%	13.44 %
Convertible senior notes refinancing	(5.22)%	— %	— %
Nondeductible expenses	4.55 %	(13.58)%	(132.96)%
Reserves	7.66 %	(15.41)%	(202.98)%
338(g) tax election	— %	(9.61)%	— %
Other	(1.84)%	(2.35)%	(6.15)%
Effective tax rate	<u>(624.39)%</u>	<u>(2.49)%</u>	<u>(10.73)%</u>

The Company's effective tax rates of (624.39)%, (2.49)% and (10.73)% for the years ended December 31, 2020, 2019 and 2018, respectively, differed from the expected U.S. statutory tax rate of 21.0%. This difference for the year ended December 31, 2020 was primarily due to the release of the domestic valuation allowance of \$126.6 million as discussed below. The difference for the years ended December 31, 2019 and 2018 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. A full valuation allowance had been recorded against the Company's net deferred tax balance as of December 31, 2019 because at that time it was more likely than not that its net deferred tax assets would not be realizable. At each reporting date, the Company considers new evidence, both positive and negative, that could affect its view of the future realization of deferred tax assets. During the year ended December 31, 2020, in part because in the current year the Company achieved three years of cumulative pretax income in the U.S. federal and state tax jurisdictions, and based on its most recent forecasts, the Company determined that there is sufficient positive evidence to conclude that it is more likely than not that additional domestic deferred taxes of \$126.6 million are realizable and, therefore, reduced the valuation allowance accordingly.

During the year ended December 31, 2020, the Company established a deferred tax liability of \$20.5 million with an offset to additional paid-in capital resulting from the conversion feature of the 2025 Notes. The initial difference between the book value of convertible debt issued with a beneficial conversion feature and its tax basis is a temporary difference.

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

Significant components of the Company's deferred tax assets and liabilities at December 31, 2020 and 2019 are as follows (in thousands):

	<b>December 31,</b>	
	<b>2020</b>	<b>2019</b>
Deferred tax assets:		
Net operating loss carryforwards	\$ 66,123	\$ 68,921
Federal and state credits	17,335	16,895
Depreciation and amortization	13,473	15,778
Accruals and reserves	7,254	8,767
Stock based compensation	21,862	23,187
Inventory	1,345	1,646
Other	2,138	2,022
Total deferred tax assets	129,530	137,216
Deferred tax liabilities:		
Discount on convertible senior notes	(20,851)	(8,125)
Deferred tax assets, net of deferred tax liabilities	108,679	129,091
Less: valuation allowance	(2,515)	(129,091)
Net deferred tax assets	<u>\$ 106,164</u>	<u>\$ —</u>

As of December 31, 2020, the Company's federal net operating losses, or NOLs, and federal tax credit carryforwards totaled \$243.5 million and \$12.4 million, respectively. The Company also had state NOLs and state tax credit carryforwards of \$165.8 million and \$6.3 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 \$18.7 million at December 31, 2020. The existing federal and state NOLs will 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 \$88.4 million of federal net operating losses are subject to annual limitations. At December 31, 2020, \$61.5 million of these federal net operating losses were available. The Company estimates that an additional \$10.3 million will come available in each of 2021 and 2022, \$3.5 million in 2023 and \$1.4 million in each of 2024 and 2025. 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 are appropriate. The Company had a net decrease in its valuation allowance of \$126.6 million and an increase of \$7.0 million for the years ended December 31, 2020 and December 31, 2019, respectively. During the year ended December 31, 2020, the Company determined that there is sufficient positive evidence to conclude that it is more likely than not that additional domestic deferred taxes of \$126.6 million are realizable and, therefore, reduced the valuation allowance accordingly. The net increase in the Company's valuation allowance for the year ended December 31, 2019 included a reduction of \$1.8 million as a result of the MyoScience Acquisition.

In 2020, the Company recorded a reserve of \$1.5 million related to unrecognized tax benefits, or UTBs, which relate to tax positions taken during the year. The Company's UTB liability at December 31, 2020 was \$6.1 million. The change in the Company's UTBs in 2020 is summarized as follows (in thousands):



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

	<b>Unrecognized Tax Benefit</b>
Balance at December 31, 2019	\$ 4,537
Additions for current year positions	1,539
Balance at December 31, 2020	\$ 6,076

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, 2020, 2019 and 2018.

The Company is currently subject to audit by the U.S. Internal Revenue Service, or IRS, for the years 2017 through 2020, and state tax jurisdictions for the years 2016 through 2020. However, the IRS or states may still examine and adjust an NOL arising from a closed year to the extent it is utilized in a year that remains subject to audit. The Company's previously filed income tax returns are not presently under audit by the IRS or state tax authorities.

**NOTE 17—EMPLOYEE BENEFIT PLANS**

*401(k) Plan*

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 (up to the maximum amount permitted by the IRC). The Company recognized \$2.9 million, \$2.6 million and \$1.6 million of related compensation expense for its 401(k) discretionary match for the years ended December 31, 2020, 2019 and 2018, respectively.

*Deferred Compensation Plan*

In June 2020, the Company's board of directors adopted the Company's Deferred Compensation Plan, or DCP. The Company intends that the DCP constitute, and be construed and administered as, an unfunded plan of deferred compensation within the meaning of the Employee Retirement Income Security Act of 1974, as amended, and the IRC of 1986, as amended, under which eligible participants may elect to defer the receipt of current compensation. Eligible participants include select management and highly compensated employees of the Company, including the Company's named executive officers. Pursuant to the DCP, subject to any minimum and maximum deferral requirements that the administrator of the DCP may establish, participants may elect to defer their base salary and annual incentive awards. In addition to elective deferrals, the DCP permits the Company to make matching and certain other discretionary contributions to the participants. The Company recognized \$0.2 million of related compensation expense for its DCP discretionary match for the year ended December 31, 2020.

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

*MyoScience Acquisition*

The Company recognized acquisition-related charges of \$5.4 million and \$21.6 million during the years ended December 31, 2020 and 2019, respectively, related to the MyoScience Acquisition. The acquisition-related charges reflect increases in the fair value of contingent consideration in the amount of \$5.2 million and \$16.7 million during the years ended December 31, 2020 and 2019, respectively. See Note 12, *Financial Instruments*, for information regarding the method and key assumptions used in the fair value measurements of contingent consideration. In addition, \$0.2 million and \$4.2 million of other acquisition-related charges for the years ended December 31, 2020 and 2019, which included advisory costs, including legal, financial, accounting and tax services, were incurred during the year ended December 31, 2019. During the year ended December 31, 2019, the Company incurred \$0.7 million of separation costs, asset write-downs and other restructuring charges. The Company did not incur any acquisition-related charges in 2018. 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.

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

*DepoCyt(e) Discontinuation*

The Company recorded a gain of \$0.2 million during the year ended December 31, 2020, and charges of \$0.2 million and \$1.6 million in the years ended December 31, 2019 and 2018, respectively, related to the discontinuation of its DepoCyt(e) manufacturing activities in June 2017 due to persistent technical issues specific to the DepoCyt(e) manufacturing process. The lease of the idle DepoCyt(e) manufacturing facility expired 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*

The Company’s acquisition-related restructuring activities and DepoCyt(e) discontinuation costs as of December 31, 2020 are summarized below (in thousands):

	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, 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
Charges and other adjustments	—	—	—	(38)	(38)
Cash payments made	(81)	—	—	(501)	(582)
Balance at December 31, 2020	\$ —	\$ —	\$ —	\$ 19	\$ 19

**NOTE 19—COMMERCIAL PARTNERS AND OTHER AGREEMENTS**

*Thermo Fisher Scientific Pharma Services*

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 first suite, 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.

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

*DePuy Synthes Sales, Inc.*

In January 2017, the Company announced a Co-Promotion 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.

In July 2020, the Company notified DePuy Synthes that the Co-Promotion Agreement would terminate on January 2, 2021. The Company has estimated termination-related costs of up to \$9.0 million which have been recorded in selling, general and administrative expense during the year ended December 31, 2020.

*Aratana Therapeutics, Inc.*

In December 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. The Company is eligible to receive from Aratana up to an aggregate of \$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 certain jurisdictions 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<sup>®</sup> (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 thresholds. 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. 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. No services were provided under the consulting agreement in the years ended December 31, 2020, 2019, or 2018, and as of December 31, 2020 and 2019, there was nothing payable to Dr. Pace for consulting services.

**NOTE 21—COMMITMENTS AND CONTINGENCIES**

***Legal Proceedings***

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 that 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.

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

*MyoScience Milestone Litigation*

In August 2020, the Company and its subsidiary, Pacira CryoTech, Inc. (“Pacira CryoTech”), filed a lawsuit in the Court of Chancery of the State of Delaware (the “Delaware Court”) against Fortis Advisors LLC (“Fortis”), solely in its capacity as representative for the former securityholders of MyoScience, and certain other defendants, seeking declaratory judgment with respect to certain terms of the merger agreement for the MyoScience Acquisition (the “Merger Agreement”), specifically related to the achievement of certain milestone payments under the Merger Agreement. In addition, the Company and Pacira CryoTech sought general, special and compensatory damages against the other defendants related to breach of fiduciary duties in connection with the purported achievement of milestone payments under the Merger Agreement, and breach of the Merger Agreement and certain other agreements with the defendants. In October 2020, Fortis filed an answer and counterclaim against the Company and Pacira CryoTech seeking to recover certain milestone payments under the Merger Agreement totaling \$40.0 million, and attorneys’ fees. The Company believes that the counterclaim from Fortis is without merit and intends to vigorously defend against all claims. The Company is unable to predict the outcome of this action at this time.

*Department of Justice Inquiry Settlement*

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 pertaining to marketing and promotional practices related to EXPAREL. In July 2020, the Company formally entered into settlement agreements that resolved all outstanding investigations and claims by the United States Department of Justice, the United States Department of Health and Human Services, various States Attorneys’ General and a private plaintiff. This agreement concluded a five-year investigation related to the sale and marketing of EXPAREL. Under the various settlement agreements, the Company paid a global settlement of \$3.5 million, which was recorded in acquisition-related charges, product discontinuation and other in the consolidated financial statements for the year ended December 31, 2019. The Company expressly denies all allegations and contentions and has admitted no wrongdoing in connection with the settlement agreements. The Company has been given assurances that this concludes the investigation that originated from the U.S. Department of Justice subpoena in April 2015.

***Purchase Obligations***

The Company has approximately \$24.5 million of minimum, non-cancelable contractual commitments for contract manufacturing services and \$17.1 million of minimum, non-cancelable contractual commitments for the purchase of certain raw materials as of December 31, 2020.

***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 provided the foundation for a supplemental New Drug Application, or sNDA. The sNDA was accepted by the FDA in August 2020 with a Prescription Drug User Fee Act (PDUFA) action date of March 22, 2021. Additionally, the Company is in negotiations with the FDA and the European Medicines Agency (EMA) for clarity on other pediatric study obligations.

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.

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

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

**NOTE 22—SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)**

The following tables present selected quarterly financial data for the years ended December 31, 2020 and 2019. 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, 2020	June 30, 2020	September 30, 2020	December 31, 2020
Total revenues	\$ 105,684	\$ 75,505	\$ 117,484	\$ 130,974
Cost of goods sold	29,732	22,305	29,993	35,298
Total operating expenses	88,590	82,652	99,864	112,191
Net income (loss)	8,159	(7,269)	130,119	14,514
Basic net income (loss) per common share <sup>(1)</sup>	\$ 0.19	\$ (0.17)	\$ 3.03	\$ 0.33
Diluted net income (loss) per common share <sup>(1)</sup>	\$ 0.19	\$ (0.17)	\$ 2.94	\$ 0.32

	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 <sup>(1)</sup>	\$ (0.07)	\$ 0.07	\$ (0.15)	\$ (0.12)
Diluted net income (loss) per common share <sup>(1)</sup>	\$ (0.07)	\$ 0.06	\$ (0.15)	\$ (0.12)

(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.

**SUBSIDIARIES OF THE REGISTRANT**

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

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

**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 26, 2021, with respect to the consolidated balance sheets of Pacira BioSciences, Inc. as of December 31, 2020 and 2019, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2020, and the related notes, and the effectiveness of internal control over financial reporting as of December 31, 2020, which reports appear in the December 31, 2020 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).

**/s/ KPMG LLP**

Short Hills, New Jersey  
February 26, 2021

## 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 26, 2021

/s/ DAVID STACK

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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 26, 2021

/s/ CHARLES A. REINHART, III

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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, 2020, 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 26, 2021

/s/ DAVID STACK

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

Date: February 26, 2021

/s/ CHARLES A. REINHART, III

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

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# Corporate Information

## Board of Directors

**David Stack**

**Paul Hastings**

**Laura Brege**

**Chris Christie**

**Mark Froimson, MD**

**Yvonne Greenstreet, MBChB, MBA**

**Mark Kronenfeld, MD**

**John Longenecker, PhD**

**Gary Pace, PhD**

**Andreas Wicki, PhD**

## Executive Officers

**David Stack**

Chief Executive Officer and Chairman

**Charles Laranjeira**

Chief Technical Officer

**Max Reinhardt**

President, Rest of World

**Charles A. Reinhart, III**

Chief Financial Officer

**Donald C. Manning, MD, PhD**

Chief Medical Officer

**Dennis McLoughlin**

Chief Customer Officer

**Kristen Williams, JD**

Chief Administrative Officer and Secretary

**Roy Winston, MD**

Chief Clinical Officer

## Corporate Headquarters

**Pacira BioSciences, Inc.**

5 Sylvan Way, Suite 300

Parsippany, New Jersey 07054

973.254.3560

## Common Stock

The common stock of Pacira is traded on the Nasdaq Global Select Market under the symbol **PCR.X**.

*This annual report contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Reference is made in particular to statements regarding the description of the plans, objectives, and other forwardlooking statements included in the Letter to Stockholders and Annual Report on Form 10-K for the fiscal year ended December 31, 2020, which is included herein. Such statements are based on management's current expectations and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. In particular, careful consideration should be given to cautionary statements made in the company's filings with the SEC, specifically those statements found in its Annual Report on Form 10-K under the caption "Risk Factors" in Item 1A.*

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## Independent Registered Public Accounting Firm

**KPMG LLP**

51 John F. Kennedy Parkway

Short Hills, NJ 07078

## Investor Relations

Information about Pacira is available by accessing the company's website at [www.pacira.com](http://www.pacira.com). The Pacira website includes press releases and filings with the U.S. Securities and Exchange Commission (SEC). Interested parties may also subscribe to email alerts through the investor relations section. Email alerts are delivered to subscribers when new and relevant company information is posted to the site. Copies of current press releases and SEC filings can also be obtained by calling Pacira investor relations at 973.451.4030.

## Annual Meeting of Stockholders

Due to the public health impact of the COVID-19 pandemic and our effort to help support a safe and healthy environment for everyone, the annual stockholders' meeting will be held entirely online via a live audio webcast on June 8, 2021 at 2:00PM ET at [www.virtualshareholdermeeting.com/PCR.X2021](http://www.virtualshareholdermeeting.com/PCR.X2021).

## Registrar and Transfer Agent

The transfer agent is responsible for handling inquiries relating to stock transfer or lost certificates and notifications of changes in address. These requests may be directed to the transfer agent using the following information:

**Computershare**

462 South 4th Street Suite 1600

Louisville, KY 40202

800.962.4284

[www.computershare.com](http://www.computershare.com)

## Code of Ethics

Pacira has adopted a corporate code of business conduct and ethics that applies to all of its directors, officers and employees. The company requires that all of its directors, officers, employees and agents certify compliance with the code on an annual basis. A copy of the Code of Business Conduct and Ethics is accessible through the corporate governance section of the Pacira website at [www.pacira.com](http://www.pacira.com).



**Pacira BioSciences, Inc.**

5 Sylvan Way, Suite 300, Parsippany, New Jersey 07054 | 973.254.3560