Recro Pharma, Inc.
Form 10-K
February 19, 2019

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018

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: 001-36329

Recro Pharma, Inc.

(Exact name of registrant as specified in its charter)

Pennsylvania	26-1523233
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
490 Lapp Road, Malvern, Pennsylvania	19355
(Address of principal executive offices)	(Zip Code)

(484) 395-2470

(Registrant’s telephone number, including area code)

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

Title of Each Class	Name of Exchange on Which Registered
Common Stock, par value $0.01	Nasdaq Capital 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of registrant’s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	Accelerated filer
Non-accelerated filer	Smaller reporting company
	Emerging growth company

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 provided pursuant to Section 13(a) of the Exchange Act.

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

On the last business day of the most recently completed second fiscal quarter, the aggregate market value (based on the closing sale price of its common stock on that date) of the voting stock held by non-affiliates of the registrant was $88.0 million.

As of February 15, 2019, there were 21,872,803 shares of common stock outstanding, par value $0.01 per share.

DOCUMENTS INCORPORATED BY REFERENCE

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

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K and the documents incorporated by reference herein contain forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this Annual Report on Form 10-K or the documents incorporated by reference herein regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “pla “predict,” “project,” “will,” “would” or the negative of such terms and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements are based on assumptions and expectations that may not be realized and are inherently subject to risks, uncertainties and other factors, many of which cannot be predicted with accuracy and some of which might not even be anticipated.

The forward-looking statements in this Annual Report on Form 10-K and the documents incorporated herein by reference include, among other things, statements about:

- our estimates regarding expenses, future revenue, capital requirements and timing and availability of and the need for additional financing;
- our ability to resolve the deficiencies identified by the Food and Drug Administration, or FDA, in the complete response letter, or CRL, for intravenous, or IV, meloxicam;
- whether the FDA will approve our amended New Drug Application, or NDA for IV meloxicam and, if approved, the labeling under any such approval that we may obtain;
- if the FDA does not approve our amended NDA, the time frame otherwise associated with resolving the deficiencies identified by the FDA in the CRL and whether the FDA will require additional clinical studies to support the approval of IV meloxicam and the time and cost of such studies;
- our ability to successfully commercialize IV meloxicam or our other product candidates, upon regulatory approval;
- our ability to generate sales and other revenues from IV meloxicam or any of our other product candidates, once approved, including setting an acceptable price for and obtaining adequate coverage and reimbursement of such products;
- the results, timing and outcome of our clinical trials of IV meloxicam or our other product candidates, and any future clinical and preclinical studies;
- our ability to raise future financing and attain profitability for continued development of our business and our product candidates and to meet required debt payments, and any milestone payments owing to Alkermes plc, or Alkermes, or our other licensing and collaboration partners;
- our ability to comply with the regulatory schemes applicable to our business and other regulatory developments in the United States and foreign countries;
- our ability to operate under increased leverage and associated lending covenants;
- the performance of third-parties upon which we depend, including third-party contract research organizations, or CRO’s, and third-party suppliers, manufacturers, group purchasing organizations, distributors and logistics providers;
- our ability to obtain and maintain patent protection and defend our intellectual property rights against third-parties;
- our ability to maintain our relationships, profitability and contracts with our key commercial partners;
- our ability to defend the securities class action lawsuit filed against us, or any future material litigation filed against us;
- our ability to recruit or retain key scientific, technical, commercial, and management personnel or to retain our executive officers;
- our ability to comply with stringent U.S. and foreign government regulation in the manufacture of pharmaceutical products, including Good Manufacturing Practice, or cGMP, compliance and U.S. Drug Enforcement Agency, or DEA, compliance and other relevant regulatory authorities; and
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the effects of changes in our effective tax rate due to changes in the mix of earnings in countries with differing statutory tax rates, changes in tax strategy, changes in the valuation of deferred tax assets and liabilities and changes in the tax laws.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly under “Risk Factors,” that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, collaborations or investments we may make.

You should read this Annual Report on Form 10-K and the documents that we incorporate by reference herein completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements.

Solely for convenience, tradenames referred to in this Annual Report on Form 10-K appear without the ® symbol, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these tradenames. All trademarks, service marks and tradenames included or incorporated by reference in this Annual Report on Form 10-K are the property of their respective owners, including, without limitation, the NanoCrystal® mark owned by Alkermes and/or its affiliates.

PART I

Item 1. Business

Overview

We are a specialty pharmaceutical company that operates through two business segments: an Acute Care segment and a revenue-generating contract development and manufacturing, or CDMO segment, through which we operate a revenue generating manufacturing business in Gainesville, Georgia. We believe that we can bring valuable therapeutic options for patients, prescribers and payers, such as our lead product candidate, injectable meloxicam, to the hospital and related acute care markets. We believe we can create value for our shareholders through the development, registration and commercialization of injectable meloxicam and our other pipeline product candidates, as well as through the ongoing contributions of our cash-flow positive CDMO segment. In addition to our pipeline, we continue to evaluate acquisition, out-licensing and in-licensing opportunities.

Acute Care

Our Acute Care segment is primarily focused on developing and commercializing innovative products for hospital and related acute care settings. Our lead product candidate is a proprietary injectable form of meloxicam, a long-acting preferential COX-2 inhibitor. IV meloxicam has successfully completed three Phase III clinical trials, including two pivotal efficacy trials, a large double-blind Phase III safety trial and other safety studies for the management of moderate to severe pain. Overall, the total new drug application, or NDA, program included over 1,400 patients. In July 2017, we submitted an NDA to the Food and Drug Administration, or FDA, for IV meloxicam for the management of moderate to severe pain. In May 2018, we received a Complete Response Letter, or CRL, from the FDA regarding our NDA for IV meloxicam. In July 2018, we participated in a Type A End-of-Review meeting with the FDA to discuss the topics covered in the CRL. In September 2018, we resubmitted the NDA for IV meloxicam and the FDA has set a date for decision on the NDA under the Prescription Drug User Fee Act, or PDUFA, of March 24, 2019. We believe that IV meloxicam compares favorably to competitive therapies in onset of pain relief, duration of pain relief, extent of pain relief and time to peak analgesic effect as well as that it has been well tolerated. We believe injectable meloxicam, as a non-opioid product, will overcome many of the issues associated with commonly prescribed opioid therapeutics, including respiratory depression, excessive nausea and vomiting, constipation, as well having no addiction potential, while maintaining analgesic, or pain relieving, effects. We are pursuing a Section 505(b)(2) regulatory strategy for IV meloxicam.

Our pipeline also includes other early-stage product candidates, including two novel neuromuscular blocking agents, or NMBAs, and a related proprietary chemical reversal agent and Dex-IN, a proprietary intranasal formulation of dexmedetomidine, or Dex, an alpha-2 adrenergic agonist that we are evaluating for possible partnering.

Pipeline

CDMO

Our CDMO segment leverages formulation expertise to develop and manufacture pharmaceutical products using proprietary delivery technologies and know-how for partners who plan to develop and commercialize these products. These collaborations result in revenue streams including manufacturing, royalties, profit sharing, and research and development, which support continued operations for our CDMO segment and have contributed excess cash flow to be used for activities in our Acute Care segment. We operate a 97,000 square foot, DEA-licensed manufacturing facility and a 24,000 square foot development and high potency facility, each in Gainesville, Georgia. We currently manufacture the following key products with our commercial partners: Ritalin LA®, Focalin XR®, Verelan PM®, Verelan SR®, Verapamil PM, Verapamil SR and Zohydro ER®, as well as supporting multiple development stage products.

Our Strategy

We believe that we can bring valuable therapeutic options for patients, prescribers and payers, such as injectable meloxicam, to the hospital and acute care markets. We believe we can create value for our shareholders through the development, registration and commercialization of injectable meloxicam and our other pipeline product candidates as well as through the ongoing contributions of our cash-flow positive CDMO segment. In addition to our pipeline, we evaluate acquisition and in-licensing opportunities, especially those that can contribute additional revenue and cash flow. Our near-term goals include:

Complete regulatory approval of IV meloxicam. Our key 2019 goal is to receive FDA approval of IV meloxicam for the management of moderate to severe pain. In September 2018, we resubmitted our NDA to the FDA for IV meloxicam for the management of moderate to severe pain. The FDA accepted the resubmission for review and set a PDUFA date of March 24, 2019.

Expand data supporting benefits of IV meloxicam. We are currently evaluating IV meloxicam in a Phase IIIb program that includes clinical trials in colorectal surgery patients and orthopedic surgery patients. We anticipate continuing the Phase IIIb program in 2019.

Commercialize IV meloxicam in the United States independently or with third-parties. We believe IV meloxicam targets a group of specialists which would allow for successful marketing and commercialization by a company of our size. Assuming approval, we are currently preparing for a U.S. commercial launch of IV meloxicam and are establishing sales management, marketing and reimbursement functions to commercialize IV meloxicam in the United States.

Enter into strategic partnerships to maximize the potential of IV meloxicam and other product candidates outside of the United States. We intend to pursue strategic collaborations with other pharmaceutical companies to develop and commercialize IV meloxicam outside of the United States. We believe that our development expertise and unique product candidates make us an attractive partner to potential strategic collaborators.

Leverage our development experience to progress our other pipeline product candidates. Our early-stage product pipeline includes proprietary product candidates for use in anesthesia (neuromuscular blockade and reversal). Our goal is to leverage our drug development expertise to develop these product candidates for use in hospital and acute care settings.

Expand our contract development and manufacturing business (CDMO). We are focused on the growth of our CDMO services. We intend to seek additional product and related development partnerships through ongoing business development efforts, as well as possibly through expansion of our proprietary drug delivery technologies, and current

and new manufacturing service offerings.

Acute Care

Our Acute Care segment is primarily focused on developing innovative products for hospital and related acute care settings.

Our Lead Product Candidate - IV Meloxicam

Meloxicam is a long-acting, preferential COX-2 inhibitor that possesses analgesic, anti-inflammatory, and antipyretic activities. Our proprietary injectable form of the drug, which utilizes NanoCrystal® technology, increases overall drug solubility which provides a faster onset of action of meloxicam and provides a rapid treatment of acute pain, which lasts for approximately 24 hours.

Post-Operative Pain Market

Based upon information from the National Center for Health Statistics, it is estimated that there are over 100 million surgeries performed in the United States each year. Of these surgeries, we believe at least 50 million procedures require post-operative pain medication. Additionally, despite efforts to improve the provision of perioperative analgesia, the proportion of patients reporting moderate to severe pain after surgery has remained constant over the past decade.

While opioids provide effective analgesia for post-operative pain, their use is increasingly limited due to the known side effects of nausea, vomiting, constipation, respiratory depression, the development of tolerance and the potential for impact on addiction, misuse and abuse. Due to the potential for abuse, opioids are regulated as controlled substances and are listed on Schedule II and III by the DEA. According to a January 2016 article in the New England Journal of Medicine, overdose deaths from prescription painkillers (defined to mean opioid or narcotic pain relievers) increased significantly over the past 14 years and emergency department visits involved with misusing or abusing prescription opioid painkillers increased 153% between 2004 and 2011. In the acute care setting, and according to the Joint Commission Sentinel Event Alert on the Safe Use of Opioids in Hospitals, opioid analgesics rank among the drugs most frequently associated with adverse drug events. As a result of the addictive potential and side effects, pain sufferers tend to limit their use of opioids, resulting in as many as 40% of post-operative patients reporting inadequate pain relief. This can reduce the quality of life for individuals and, according to an August 2012 article in the Journal of Pain, creates an economic burden estimated to be at least $560 to $635 billion a year in medical costs and lost productivity.

Efforts to improve pain control with multimodal analgesia are being recommended by many medical societies as a way to decrease opioid-related morbidity and mortality. Multimodal analgesia, or MMA, refers to the use of two or more drugs or nonpharmacologic interventions with differing mechanisms. Its use has been demonstrated to limit the amount of opioids consumed and provide more effective pain control than opioids alone. Effective MMA may further lessen the cost burden and personal toll of opioid-centric regimens. According to an April 2013 article in Pharmacotherapy, opioid-related adverse events negatively impact patients and the healthcare system and cause a 55% longer length of hospital stay, 47% higher cost of care, 36% higher 30-day readmission rates and a 3.4% higher risk of inpatient mortality.

We believe that IV meloxicam offers an attractive alternative for relief of moderate to severe pain without the risks associated with opioids. We also believe it can be an important part of an MMA approach for patients in the post-operative setting. Accordingly, we believe that physicians, hospitals and third-party payers, including Integrated Delivery Systems (IDNs), Medicare and Medicaid, are interested in new non-opioid pain therapies that provide effective post-operative pain relief without the adverse issues associated with opioids.

IV Meloxicam Advantages

We believe IV meloxicam has a number of advantages over existing analgesics, including the following:

Does not cause respiratory depression. Meloxicam does not cause respiratory depression. Besides the addictive nature of opioids, we believe that medical practitioners are highly concerned with respiratory depression, which is a well-documented side effect of opioid use (all opioids, including morphine, fentanyl and oxycodone). Respiratory depression, which is defined by inadequate ventilation leading to increased carbon dioxide levels and respiratory acidosis, is an established outcome of opioid use and requires significant patient monitoring in the acute care setting. One of the more concerning adverse effects of chronic opioid use, for which tolerance does not develop, is respiratory depression during sleep, which can be life threatening. IV meloxicam has demonstrated through multiple clinical trials and patient use that it does not cause respiratory depression.

Not a controlled substance. Meloxicam is not an opioid and not a controlled substance. Opioid therapeutics are currently controlled by the DEA under the Controlled Substances Act. Under this act, opioids have been scheduled based on their potential for abuse and/or addiction. For those opioids placed in Schedule II, federal law prohibits the refilling of prescriptions, thus requiring patients to request, and physicians to write, additional prescriptions for each refill. Examples of Schedule II opioids include morphine, fentanyl, sufentanil, hydrocodone and oxycodone.

Duration of pain relief. IV meloxicam has demonstrated the potential to be an effective analgesic for up to 24 hours after a single dose in clinical trials. IV forms of ketorolac, ibuprofen and acetaminophen provide effective pain relief up to four to six hours, resulting in the need for four to six doses per day.

Administration. We believe that IV meloxicam has an administration advantage in terms of being administered by bolus injection, whereas ibuprofen and acetaminophen can take up to 15 to 30 minutes to be infused.

GI Tolerability. Unlike opioids, the mechanism of action of meloxicam provides analgesic activity with limited impact on gastrointestinal motility thus limiting the common unwanted side effects of opioids, referred to as Opioid Induced Bowel Dysfunction, or OIBD. OIBD comprises several symptoms including constipation, anorexia, nausea and vomiting, gastroesophageal reflux, delayed digestion, abdominal pain, flatulence, bloating, hard stool, straining during bowel movement and incomplete evacuation.

Reduction of Opioid Consumption. Reducing opioid use inside and outside the hospital is becoming more of a priority for physicians and hospital administrators. IV meloxicam has demonstrated the potential to relieve serious pain while reducing overall opioid consumption. IV meloxicam also demonstrated a potential greater reduction in opioid use in patients over 65 years old with mild renal impairment in clinical trials.

Commercial Strategy

If IV meloxicam is approved by the FDA, we believe that it may have a positive value proposition based on our current clinical data. Based on our market research, a new analgesic would be perceived to have a strong value proposition if it can: (1) reduce opioid consumption, (2) allow ambulatory surgical centers to perform more complex procedures and discharge patients on the same day, and (3) allow hospitals to safely speed up patient discharge, reduce inpatient admission and/or length of stay.

If IV meloxicam is approved by the FDA, we are hoping to generate early commercial experience with IV meloxicam at settings that have lower barriers to new product adoption and have an appetite for use of newer therapies. To accomplish this goal, we believe it is important to educate surgeons (e.g., orthopedic, colorectal and general) and anesthesiologists that practice at multiple settings of care within the acute care market, including ambulatory surgical centers, or ASCs, hospital outpatient departments, and hospitals (often referred to as the "hospital inpatient setting"). We believe that ASCs may have lower barriers to adoption and be willing to consider newer therapies during our launch phase, based on our market research in this sector. We also believe early success in commercializing IV meloxicam with ASC's could lead to increased adoption of IV meloxicam in hospital outpatient settings, and ultimately hospital inpatient settings.

Overall, we plan to initially target approximately 1,500 hospitals and associated hospital outpatient departments, or HOPDs, and 600 ASCs, which together represent approximately 12.6 million patients across all settings of care. If IV meloxicam is approved by the FDA, we plan to build a sales force with approximately 80 to 100 representatives who would market IV meloxicam to health care professionals at our called-on institutions. In addition, we have medical, account-based and reimbursement teams. We believe this focused approach will help educate health care professionals, support formulary review processes and generate early adoption after launch with surgeons and anesthesiologists.

Clinical Development

Multiple clinical trials have been conducted to evaluate the safety, pharmacokinetics and analgesic effect of IV meloxicam. Based on the results of these trials, we believe IV meloxicam has the potential to be a potent analgesic used in the management of moderate to severe pain. IV meloxicam has successfully completed two pivotal Phase III clinical trials, a large double-blind Phase III safety trial as well as four Phase II trials and additional pharmacokinetics/safety studies. Overall, we enrolled a total of approximately 1,400 patients in our Phase II/III programs. In addition, we are currently evaluating IV meloxicam in Phase IIIb clinical trials in colorectal surgery patients and orthopedic surgery patients. Per the Pediatric Study Plan Agreement with FDA, two clinical trials will be conducted in the pediatric population. These trials will be initiated following NDA approval of IV meloxicam and after appropriate regulatory and institutional review board, or IRB, review.

At the end of July 2017, we submitted an NDA to the FDA for IV meloxicam 30mg for the management of moderate to severe pain. In May 2018, we received a Complete Response Letter, or CRL, from the FDA regarding our NDA for IV meloxicam, which stated that the FDA determined it could not approve the NDA in its present form. The CRL stated that data from ad hoc analyses and selective secondary endpoints suggest that the analgesic effect did not meet the expectations of the FDA. In addition, the CRL identified certain CMC related questions on extractable and leachable data provided in the NDA. The CRL did not identify any issues relating to the safety of IV meloxicam. In July 2018, we participated in a Type A End-of-Review meeting with the FDA to discuss the topics covered in the CRL, and we resubmitted the NDA for IV meloxicam in September 2018. The FDA has set a PDUFA date of March 24, 2019.

Phase IIIb Clinical Trials

We are currently evaluating IV meloxicam in a Phase IIIb program that includes clinical trials in colorectal surgery patients and orthopedic surgery patients to assess opioid consumption, pain intensity and length of hospital stay with associated pharmacoeconomic parameters. We anticipate continuing the Phase IIIb program in 2019.

Phase III Clinical Trials

Study REC-15-016

In this pivotal clinical trial, evaluating pain relief over a 48-hour period in a hard tissue, post-operative pain model (bunionectomy), IV meloxicam achieved the primary endpoint of a statistically significant difference in Summed Pain Intensity Difference, or SPID, over the first 48 hours, or SPID48, compared to placebo. This was a Phase III, randomized, multicenter, multi-dose, double-blind, placebo-controlled study evaluating IV meloxicam in the management of post-operative pain following bunionectomy surgery. Two hundred and one patients who met the eligibility criteria were randomized to receive either IV meloxicam (30 mg) or placebo once daily for up to three days. Following the beginning of treatment, patients remained under observation for 48 hours at study centers. Patients were followed for 28 days after the initial dose of study medication. There was an oral opioid rescue treatment available to all patients, if required. The primary objective of the trial was to evaluate pain relief over a 48-hour period of IV meloxicam when administered as a bolus injection.

The primary efficacy endpoint of the trial was SPID48, utilizing a windowed 2-hour last observation carried forward, or W2LOCF, analysis method. Secondary efficacy endpoints included use of opioid rescue medication, SPIDs over various time intervals, and patient global assessment, or PGA, of pain control. The IV meloxicam treatment arm demonstrated a statistically significant reduction in SPID48 (p=0.0034) compared to the placebo arm (Figure 1).

Figure 1: SPID48

The study also achieved the majority of secondary endpoints, including statistically significant differences in SPID6 (p=0.0153), SPID12 (p=0.0053), SPID24 (p=0.0084), SPID24-48 (p=0.0050), time to first use of rescue medication (p=0.0076), and several other rescue use and pain relief metrics during the first 48 hours, compared to placebo. Times to Perceptible and Meaningful Pain Relief, % Subjects with >50% Improvement within 6 Hours, and PGA of Pain Control at 24 hours were not significantly different between treatment groups.

The safety results demonstrated that IV meloxicam was well tolerated with no serious adverse events, or SAEs, or bleeding events in the IV meloxicam-treated patients. The most common adverse events, or AEs, occurring in at least 3% of IV meloxicam-treated patients, were nausea, headache, pruritus, constipation, vomiting, dizziness, flushing and somnolence, and the incidence of these AEs was generally comparable to the placebo group. The IV meloxicam-treated patients experienced injection site pain and injection site erythema at a rate comparable to placebo. The majority of treatment emergent AEs, or TEAEs, were mild in nature and there were no discontinuations due to AEs. There were no meaningful differences between treatment groups in vital signs, electrocardiogram, or ECGs, or clinical lab assessments.

Study REC-15-015

In the second of our two Phase III pivotal clinical trials, evaluating pain relief over a 24-hour period in a soft tissue, post-operative pain model (abdominoplasty), IV meloxicam achieved the primary endpoint of a statistically significant difference in SPID over the first 24 hours, or SPID24, compared to placebo. This was a Phase III, randomized, multicenter, multi-dose, double-blind, placebo-controlled study evaluating IV meloxicam in the management of post-operative pain following abdominoplasty surgery. Two hundred nineteen patients who met the eligibility criteria were randomized to receive either IV meloxicam (30 mg) or placebo once daily for up to three days. Following the beginning of treatment, patients remained under observation for 48 hours at study centers. Patients were followed for 28 days after the initial dose of study medication. There was an oral opioid rescue treatment available to all patients, if required. The primary objective of the trial was to evaluate pain relief over a 24-hour period of IV meloxicam when administered as a bolus injection (over 15-30 seconds).

The primary efficacy endpoint of the trial was SPID24 (0-24), utilizing a W2LOCF analysis method. Secondary efficacy endpoints included use of opioid rescue medication, SPIDs over various time intervals, time to pain relief and PGA of pain control. The IV meloxicam treatment arm demonstrated a statistically significant reduction in SPID24 (p=0.0145) compared to the placebo arm (Figure 2).

Figure 2: SPID24

The study also achieved statistical significance for 10 of the secondary endpoints, including statistically significant differences in SPID12 (p=0.0434), time to perceptible pain relief (p=0.0050), subjects with ≥30% improvement at 24 hours (p=0.0178), number of times patients required rescue in the first 24 hours after randomization (p=0.0275), as well as number of times rescued from 24 to 48 hours (p=0.0009), and several other pain relief metrics, compared to placebo.

SPID6, Times to Meaningful Pain Relief and First Rescue, Number of Subjects rescued 0-24 and 0-48 hours, % Subjects with ≥30 and ≥50% Improvement within 6 Hours and ≥50% within 24 hours, and PGA of Pain Control at 24 hours were not significantly different between treatment groups.

The safety results demonstrated that IV meloxicam was well tolerated with no difference in SAEs related to bleeding for IV meloxicam treated patients versus placebo (1 each). There were two additional SAEs observed in the placebo group. The most common (at least 3% in the IV meloxicam group) AEs were nausea, headache, vomiting, and dizziness. The incidence of these events was lower than those observed in the placebo group. The majority of AEs were mild in nature and one patient in the placebo group discontinued treatment due to an adverse event of post-procedural bleeding. There were no meaningful differences between treatment groups in vital signs, ECGs or clinical lab assessments.

Safety Study

IV meloxicam has also successfully completed a double-blind, randomized Phase III safety study evaluating IV meloxicam (30mg bolus injection) or placebo following major surgery. The primary objective of the study was to evaluate the safety and tolerability of IV meloxicam 30mg vs. placebo through Day 28 following treatment. The clinical trial demonstrated that the adverse event profile of IV meloxicam 30mg was consistent with previously completed clinical trials and was similar to placebo reported events.

This was a multicenter, randomized, double-blind, placebo-controlled Phase III clinical trial and included patients who had undergone major elective surgical procedures which were expected to result in hospitalization for at least 24-48 hours. Major surgical procedures included total hip and knee replacements, spinal, GI, hernia repair, and gynecologic surgeries, as well as a range of other surgeries. Patient demographics were balanced across treatment groups and included 40% male patients and about 23% of patients who were over age 65. Unlike the pivotal efficacy trials, minimum pain scores were not required for treatment. Sites were permitted to use opioids and other pain management modes according to their “standard of care” and meloxicam or placebo was added to this regimen in a randomized, double-blind manner. Patients were randomized in a 3:1 ratio to receive either IV meloxicam 30mg or IV placebo daily for up to 7 doses. A total of 721 patients received at least one dose of study medication.

The most common (≥3%) AEs observed in the IV meloxicam 30mg treatment group (n=538) are listed in the table below:

	IV Meloxicam 30 mg		Placebo	
Preferred Term	N = 538		N = 183	
Subjects with ≥1 AE	339	(63.0)	119	(65.0)
Nausea	123	(22.9)	51	(27.9)
Constipation	51	(9.5)	17	(9.3)
Vomiting	27	(5.0)	14	(7.7)
Pruritis	21	(3.9)	10	(5.5)
Gamma-glutamyl transferase (GGT) increased	21	(3.9)	5	(2.7)
Headache	20	(3.7)	12	(6.6)
Anemia	18	(3.3)	4	(2.2)

In patients age 65 and over, the percentage of patients reporting at least one AE was approximately 7% less in the IV meloxicam 30mg treatment arm compared to the placebo arm. The total occurrence of patients with at least one SAE was observed to be lower in the IV meloxicam 30mg group, 2.6%, than in the placebo group, 5.5%. In this safety study only two SAE events were listed as possibly related to study treatment. Both of these SAEs occurred in one placebo treated patient. No deaths were reported in either treatment group. Approximately 3% of patients in each study group discontinued.

There were no meaningful clinical differences between treatment groups in vital signs, ECGs, clinical lab assessments and surgeon satisfaction with wound healing. Overall there was low incidence of clinically significant wound healing abnormalities, as scored by the primary investigator, in both treatment groups (~2%). The meloxicam group had 4/538 patients with more than one attribute scored “clinically significant”, while in placebo, 1/183 patients were scored “clinically significant” for only one attribute.

In addition, mean opioid consumption for the total population was lower in the IV meloxicam 30mg group compared with placebo at all evaluated intervals; Hour 0-24, Hour 24-48, Hour 48-72 and Hour 0-72 intervals, or the full treatment period. There was also a significant increase in time to first use of opioids in the IV meloxicam 30mg treatment arm, compared to placebo. Mean opioid consumption in the IV meloxicam group was lower than the placebo group at all evaluated intervals in the subgroups of Orthopedic Surgeries, Total Knee Replacements, and subjects >65 years with Mild Renal Impairment, as depicted in the table below.

Population	% reduction in Opioid Use			
	Hour 0-24	Hour 24-48	Hour 48-72	Treatment Period
Total Population	23.2%*	23.0%	33.9%	23.6%
Orthopedic Surgeries	28.9%*	25.5%*	38.4%	26.8%*
Total Knee Replacement Surgeries	41.0%**	35.2%**	58.9%	40.8%**
>65 years & Mild Renal Impairment Population	42.8%*	41.9%*	56.9%	40.7%*

*reaching statistical significance ($p<0.05$)

**reaching statistical significance (p<0.01)

Our Other Pipeline Candidates

While our current priority is the commercialization of IV meloxicam, our pipeline also includes other earlier stage product candidates including intermediate and short-acting NMBAs, and accompanying reversal agents, DEX-IN, along with other product candidates that we may choose to develop for use in hospital or related settings.

NMBAs

Neuromuscular blocking agents are used as muscle paralyzing agents to facilitate intubation and surgery. We are developing an intermediate-acting NMBA, RP1000, an ultrashort-acting NMBA, RP2000, and a reversal agent specific to our NMBAs. The table below summarizes the predicted onset and duration of activity for each NMBA based on currently available data, as well as the development status of each NMBA:

Compound	Onset Time	Duration of Activity	Status
RP1000	Rapid	Intermediate acting	Phase I
RP2000	Rapid	Ultra-short acting	Pre-clinical

In animal models, the proprietary reversal agent acts quickly by chemical reaction to reverse the neuromuscular blockade. We believe that the NMBAs can reduce the time required for induction of anesthesia and the reversal agent can reduce the time needed to recover from NMBA dosing post-procedure, while potentially enhancing patient safety and resulting in cost savings for the hospital or other provider. RP1000, the intermediate-acting NMBA, and the reversal agent were subject to a clinical hold imposed by the FDA due to need for additional toxicity data at higher dose exposures. We have met with the FDA and the clinical hold has been lifted with respect to RP1000. We continue to work with the FDA regarding a path forward for the reversal agent. We expect to submit a new IND for RP1000 in 2019.

We have a worldwide, exclusive license to the NMBAs and the related reversal agent from Cornell University.

Dex-IN

Dex (dexmedetomidine) is a selective alpha-2 adrenergic agonist that has demonstrated sedative, analgesic and anxiolytic properties. Dex has an extensive commercial history of safe IV use. We have formulated Dex-IN, a proprietary intranasal formulation of Dex, at a significantly lower dose (approximately as low as $1/10^{th}$) than the currently recommended IV dosage levels used for clinical sedation. Based upon our lower dose, we have seen minimal sedation to date in our clinical trials while still demonstrating an analgesic effect.

We continue to explore possible uses of Dex-IN in other indications in the Acute Care space as well as pursue possible partnering opportunities.

CDMO Segment

Through our contract development and manufacturing, CDMO, segment, we leverage our formulation and development expertise to develop and manufacture pharmaceutical products using proprietary delivery technologies and know-how for commercial partners who commercialize or plan to commercialize these products. Our manufacturing and development capabilities include formulation, product development from formulation through commercial manufacturing, and specialized capabilities for solid oral dosage forms, extended release and controlled substance manufacturing, as well as high potency development and manufacturing. In a typical collaboration, we work with our commercial partners to develop product candidates, or new formulations of existing product candidates, and may license certain intellectual property to such commercial partners. We also typically exclusively manufacture and supply clinical and commercial supplies of these proprietary products and product candidates. These collaborations may result in revenue streams including from manufacturing, royalties, profit sharing, and research and development, which support continued operations for our CDMO segment as well as provide free cash flow to support research and development of proprietary product candidates in our Acute Care segment.

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The table below details the key products developed and/or manufactured with our key commercial partners:

Product	Indication	Territory	Revenue Source	Commercial Partner	Agreement term
Ritalin LA®	Attention Deficit Hyperactivity Disorder	Worldwide	Manufacturing	Novartis Pharma AG	Through December 31, 2023
Focalin XR®	Attention Deficit Hyperactivity Disorder	Worldwide, except Canada	Manufacturing	Novartis Pharma AG	Through December 31, 2023
Verelan PM®, SR & Verapamil PM	Hypertension	United States	Profit Sharing / Manufacturing	Lannett Company, Inc.	Through December 31, 2021
Verapamil SR	Hypertension	United States	Profit Sharing / Manufacturing	Teva Pharmaceutical Industries Ltd.	Annual renewals on a calendar year basis
Zohydro ER®	Severe Pain	United States	Royalty / Manufacturing	Pernix Therapeutics, Inc.	Through March 2029

In addition to these key products, we also develop and manufacture other development stage products. The manufacture of these products for clinical trials and commercial use is subject to cGMPs and other regulatory agency regulations. We own and operate a 97,000 square foot, DEA-licensed manufacturing facility in Gainesville, Georgia, which has been inspected by U.S., EU, Turkish and Brazilian regulatory authorities for compliance with required cGMP standards for continued commercial manufacturing and lease a 24,000 square foot development and high potency facility, also in Gainesville, Georgia.

With each product, we either purchase active drug substance from third parties or receive it from our partners to formulate product using our technologies. Although some materials for our products are currently available from a single source or a limited number of qualified sources, we attempt to acquire an adequate inventory of such materials, establish alternative sources and/or negotiate long-term supply arrangements. We do not currently have any significant issues finding suppliers. However, there is no certainty that we will be able to obtain long-term supplies of our manufacturing materials in the future.

On February 8, 2019, we entered into new five-year manufacturing and supply agreement with Novartis Pharma AG, referred to as the 2019 Novartis Agreement. Under the terms of the 2019 Novartis Agreement, we will continue to be the exclusive supplier to Novartis of Ritalin LA and Focalin XR through December 31, 2023. We previously supplied Ritalin LA and Focalin XR through two separate supply agreements, which included two revenue components, product manufacturing revenue and royalty revenue; the 2019 Novartis Agreement combines the supply of Ritalin LA and Focalin XR into one agreement, which provides product manufacturing revenue that is expected to provide similar total revenue per capsule economics as did the two prior revenue components combined.

Permits and Regulatory Approvals

We hold various licenses for our CDMO segment manufacturing activities. The primary licenses held are FDA Registrations of Drug Establishments and DEA Controlled Substance Registration. Due to certain U.S. state law requirements, we also hold certain state licenses for distribution activities throughout certain states. We also hold

cGMP certifications for EU importation of products made in Gainesville for sale in the EU and an ANVISA certification for sale in Brazil.

In certain of our commercial partnerships, our commercial partner is the product authorization holder for products that have been developed on behalf of the commercial partner. In other commercial partnerships, we are the authorization holder. When our commercial partner holds the relevant authorization from the FDA or other national regulator, we support this authorization by furnishing a letter of reference to the Drug Master File, or the chemistry, manufacturing and related data to the relevant regulator or sponsor to provide adequate manufacturing support in respect of the product. We generally update this information annually with the relevant regulator.

We hold the approved NDAs for Verelan and Verapamil, which we license to Lanett Company, Inc. and Teva Pharmaceutical Industries, Inc., respectively.

Customer Agreements

We are party to agreements with each of our commercial partners governing the development, formulation and/or supply services we provide, as well as any applicable intellectual property licenses. Each commercial partner generally remains responsible for distributing, marketing and promoting their respective products. These collaborations result in revenue streams including royalties, profit sharing, etc., which support continued operations for our CDMO segment and have contributed funds to be used in our research and development and pre-commercialization activities in our Acute Care segment. We are dependent on a small number of commercial partners, with our four largest customers (Novartis Pharma AG, Teva Pharmaceutical Industries, Inc., Pernix Therapeutics, Inc., or Pernix, and Lannett Company, Inc.) having generated 99% of our revenues for the twelve months ended December 31, 2018, of which Teva Pharmaceutical Industries, Inc. generated 48% of our revenue under one customer agreement, and Novartis Pharma AG, generated 38% of our revenue combined under two separate customer agreements, which effective January 1, 2019 is combined into one agreement.

Intellectual Property

Acute Care

We own patents and patent applications for injectable meloxicam, that cover compositions, including compositions produced using NanoCrystal® technology, method of making and method of treating. These issued patents expire in 2022 in the United States. We also in-license from Alkermes, on a perpetual, royalty-free basis, composition and methods of making patents, one of which we anticipate to be Orange-Book listable, and patent applications (specifically directed to the prevention of flake like aggregates), which expire in 2030.

We license the patents and other intellectual property covering the NMBAs and the related reversal agent under a worldwide, exclusive, sublicensable, royalty-bearing license from Cornell University. Under the license agreement, we are obligated to pay Cornell University (i) an annual license maintenance fee payment until the first commercial sale of a licensed compound; (ii) milestone payments upon the achievement of certain milestones, up to a maximum, for each NMBA, of $5 million for U.S. regulatory approval and commercialization milestones and $3 million for European regulatory approval and commercialization milestones; and (iii) royalties on net sales of the NMBAs and the related reversal agent at rates ranging from low to mid-single digits, depending on the applicable licensed compound and whether there is a valid patent claim in the applicable country, subject to an annual minimum royalty amount. In addition, we will reimburse Cornell University for past and ongoing patent costs related to prosecution and maintenance of the patents related to the licensed compounds. The license agreement is terminable by us at any time upon 90 days' written notice and by Cornell University upon our material breach, subject to a cure period, and upon our filing any claim asserting the invalidity of any of Cornell University's licensed patent rights. The royalty term for each licensed compound expires, on a country-by-country basis, on the later of (i) the expiration date of the longest-lived licensed patent, (ii) the expiration of any granted statutory period of marketing exclusivity, or (iii) the first commercial sale of a generic equivalent of the applicable licensed compound. On the last to expire royalty term the license agreement will automatically convert to a royalty-free nonexclusive license.

We hold patent applications directed to the analgesia indication, formulations and intranasal and transmucosal methods of use of Dex, and we are progressing through the patent application process globally, including the United States. Several patent applications have issued as patents outside the United States for transmucosal methods, and the resulting patent protection will last into 2030, subject to any disclaimers or extensions. In addition, a patent related to intranasal methods has issued in the United States, and the resulting patent protection will last into 2032, subject to any disclaimers or extensions.

We are party to an exclusive license with Orion for the development and commercialization of Dex for use in the treatment of pain in humans in any dosage form for transdermal, transmucosal (including sublingual and intranasal), topical, enteral or pulmonary (inhalational) delivery, but specifically excluding delivery vehicles for administration by injection or infusion, worldwide, except for Europe, Turkey, and the CIS (currently includes Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine and Uzbekistan), referred to herein as the Territory. We have the right to sublicense the rights under such license at any time. We are required to pay Orion lump sum payments on the achievement of certain developmental milestones and upon the achievement of certain commercial milestones, as well as a royalty on net sales during the term, which varies from 10% to 20% depending on annual sales levels.

CDMO Segment

We own various controlled release formulation patents, including patents in the United States, Canada, Europe, and Brazil, related to our proprietary delivery technologies that we utilize in our drug development, formulation and manufacturing business through our CDMO segment. These patents are scheduled to expire between 2019 and 2026. We own patents and patent applications in the United States and Canada directed to the composition of, manufacturing of, and formulations of Zohydro ER®. We license our U.S. patents and patent applications to our commercial partner Pernix in the United States. We also own Canadian patents and patent applications

relating to the same technology. The patent protection for Zohydro ER® formulation provides for protection of Zohydro ER® through 2019, subject to any extensions or disclaimers. In addition, we own several issued patents in the United States and several foreign patent applications for abuse resistant pharmaceutical compositions and methods of use related to Zohydro ER®, which provide patent protection through 2034, subject to any extensions or disclaimers. Although certain patents may have expired or may expire in the future, we believe there are other barriers to entry for our commercial partners and competition, including ownership of regulatory filings, NDAs, abbreviated new drug applications or ANDAs, and drug master files or DMF's, manufacturing trade secrets, proprietary dosage strengths, pricing limitations in various geographies, costs to revalidate with another supplier, maturity and life-cycle stage of products.

Intellectual Property Protection Strategy

We intend to rely on a combination of patents and trade secrets, as well as confidentiality agreements and license agreements, to protect our product candidates. Our patent strategy is designed to facilitate commercialization of our current product candidates and future product candidates, as well as create barriers to entry for third parties. One focus of our claim strategy is on formulation claims and other related claims.

We are seeking patent protection in the United States and internationally for our product candidates. Our policy is to pursue, maintain and defend patent rights and to protect the technology, inventions and improvements that are commercially important to the development of our business. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents granted to us in the future will be commercially useful in protecting our technology. We also intend to rely on trade secrets to protect our product candidates. Our commercial success also depends in part on our non-infringement of the patents or proprietary rights of third parties.

Our success will depend significantly on our ability to:

- obtain and maintain patent and other proprietary protection for our product candidates;
- defend our patents;
- develop trade secrets as needed and preserve the confidentiality of our trade secrets; and
- operate our business without infringing the patents and proprietary rights of third parties.

We have taken steps to build and will continue to build proprietary positions for our product candidates and related technology in the United States and abroad. We note that the patent laws of foreign countries differ from those in the United States, and the degree of protection afforded by foreign patents may be different from the protection offered by United States patents.

Sales and Marketing

Our current intent is to develop and commercialize our product candidates in the United States while out-licensing development and commercialization rights for other territories outside the United States, for which we own the territorial rights. We believe the initial target audience for our product candidates will be specialty physicians, including surgeons, anesthesiologists and pain specialists. Our management team has experience building and launching therapeutics to specialty physicians, including hospital and related settings. As this target audience is only a portion of all physicians, we believe we have the capabilities to build a sales and marketing infrastructure and effectively market our product candidates after FDA approval. We are establishing sales infrastructure, marketing and reimbursement functions to commercialize IV meloxicam, if approved, in the United States. While we plan to develop and commercialize our product candidates in the United States, we will consider potential strategic collaborations that could accelerate or enhance development and, upon approval, commercial success of our product candidates.

Manufacturing and Supply of our Acute Care Product Candidates

We currently rely on contract manufacturers to produce drug product for our clinical studies under cGMPs, with oversight by our internal managers. We plan to continue to rely on contract manufacturers to manufacture development quantities of our product candidates, as well as commercial quantities of our product candidates, if and when approved for marketing by the FDA. We currently rely on a single manufacturer for the clinical supplies of our drug product for each of our product candidates and do not currently have agreements in place for redundant supply or a second source for any of our product candidates. We have identified other potential drug product manufacturers that could satisfy our clinical and commercial requirements, but this would require significant expense and could produce a significant delay in setting up the facility and moving equipment. Additionally, should a supplier or a manufacturer on whom we rely to produce a product candidate provide us with a faulty product or a product that is later recalled, we would likely experience significant delays and additional costs.

Injectable Meloxicam

Alkermes is currently our exclusive supplier of bulk injectable meloxicam. Pursuant to a Development, Manufacturing and Supply Agreement, or Supply Agreement, Alkermes (through a subsidiary), provides clinical and commercial bulk supplies of injectable meloxicam formulation. During the term of the Supply Agreement, we will purchase our clinical and commercial supplies of bulk injectable meloxicam formulation exclusively from Alkermes. If the first commercial sale of injectable meloxicam occurs on or prior to December 31, 2020, the Supply Agreement will have an initial term expiring ten years following the date of such first commercial sale. The Supply Agreement will then automatically renew for successive one-year terms unless terminated by either party upon written notice at least 180 days prior to the expiration of the applicable term. If the first commercial sale of injectable meloxicam has not occurred by December 31, 2020, the Supply Agreement will expire on that date.

Patheon UK Limited, or Patheon, provides sterile fill-finish of injectable meloxicam drug product pursuant to a Master Manufacturing Services Agreement and Product Agreement, collectively the Patheon Agreements, at its Monza, Italy manufacturing site. We have agreed to purchase a certain percentage of our annual requirements of finished injectable meloxicam from Patheon during the term of the Patheon Agreements. The Patheon Agreements expire on December 31, 2020 and will automatically renew thereafter for successive two-year periods unless terminated by either party upon prior written notice.

NMBAs

We have successfully sourced the manufacturing of the NMBAs and reversing agent at a contract manufacturer for use in pre-clinical studies and early clinical trials for these product candidates.

Dex-IN

We are party to an API supply agreement with Orion, whereby Orion provides us with API for the development and, if approved, commercialization of Dex-IN. Prior to obtaining regulatory approval, subject to advance notice to Orion, Orion will provide API without charge for agreed upon amounts. Any amounts ordered by us that are greater than the planned supply will be charged at 50% of the supply price for commercial product. The single unit dose intranasal sprayer for Dex-IN is manufactured by a supplier of proprietary components and devices. Suppliers of components, subassemblies and other materials are located in Europe, Asia and the United States.

Competition

The pharmaceutical and biotechnology industries are intensely competitive and subject to rapid and significant technological change. Our current and future competitors include pharmaceutical, biotechnology and specialty pharmaceutical 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 to obtain 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 technologies and drug products that are more effective or less costly than our product candidates or any other products that we may develop which could render our products obsolete and noncompetitive. We expect any products that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price and the availability of

reimbursement from government and other third-party payers. We also expect to face competition in our efforts to identify appropriate collaborators or partners to help commercialize our product candidates in our target commercial markets.

In the post-operative pain relief setting, we believe patients are prescribed injectable acetaminophen, nonsteroidal anti-inflammatory drugs, or NSAIDs, sodium channel blockers and opioids, depending on the severity of pain. Specifically, acetaminophen, NSAIDs and sodium channel blockers, we believe, are prescribed for mild to moderate pain relief, whereas we believe opioids are prescribed for moderate to severe pain relief. While we will compete with all of these compounds in the post-operative pain setting, we believe injectable meloxicam will be used to manage moderate to severe pain, competing with opioids and predominantly systemic non-opioid pain treatments. There are a number of pharmaceutical companies that currently market and or manufacture therapeutics in the pain relief area, including Johnson & Johnson, Purdue Pharma, L.P., Mallinckrodt plc, Teva Pharmaceutical Industries, Inc., Pacira Pharmaceuticals, Inc. and AcelRx Pharmaceuticals, Inc. Mallinckrodt commercializes an injectable formulation of acetaminophen. Pacira commercializes an intraoperative formulation of bupivacaine, a sodium channel blocker, that is injected or instilled at the surgical site. Additionally, companies such as Adynxx, Inc., Durect Corporation, Heron Therapeutics, Inc., Innocoll Holdings plc, Sandoz AG, Trevena, Inc., Avenue Therapeutics, Inc., Neumentum Inc. and Cara Therapeutics, Inc. are currently developing post-operative pain therapeutics that could compete with IV meloxicam in the future.

The CDMO segment competes with contract pharmaceutical formulation and manufacturing companies such as Alcami Corporation, Cambrex Corporation, Mylan N.V., Catalent, Inc., Patheon, a part of Thermo Fischer Scientific, Mikart, LLC, Quotient Sciences, and other formulation, development and manufacture-related service providers.

Information about Segment Revenue

Information about segment revenue is set forth in Note 17 to the Consolidated Financial Statements included in this Form 10-K.

Government Regulation

Governmental authorities in the United States at the federal, state and local level, and the equivalent regulatory authorities in other countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, export and import of products such as those we are developing. Our product candidates, including our formulations of injectable meloxicam, must be approved by the FDA before they may legally be marketed in the United States. In addition, to the extent we choose to clinically evaluate or market any products in other countries or develop these products for future licensing to third parties, we are subject to a variety of regulatory requirements and to the authority of the competent regulatory authorities of those other countries.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations. The process of obtaining regulatory approvals and ensuring compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process, or after approval, may subject an applicant to administrative enforcement or judicial sanctions. This enforcement could include, without limitation, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, corrective actions, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies, some of which must be conducted according to Good Laboratory Practices regulations;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to the FDA's current Good Clinical Practices, or cGCPs, to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA for a new drug;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities identified in the NDA; and
- FDA review and approval of the NDA.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

Once a pharmaceutical product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND. The sponsor must also include a protocol detailing, among other things, the objectives of the initial clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated if the initial clinical trial lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during trials due to safety concerns regarding the product candidate or non-compliance with applicable requirements.

All clinical trials of a product candidate must be conducted under the supervision of one or more qualified investigators, in accordance with cGCP regulations. These regulations include the requirement that all research subjects provide informed consent. Further, an IRB, must review and approve the plan for any clinical trial before it commences at any institution. The IRB's role is to protect the rights and welfare of human subjects involved in clinical studies by evaluating, among other things, the potential risks and benefits to subjects, processes for obtaining informed consent, monitoring of data to ensure subject safety, and provisions to protect the subjects' privacy. The IRB approves the information regarding the clinical trial and the consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

Once an IND is in effect, each new clinical protocol, and any amendments to the protocol, must be submitted to the IND for FDA review and to the IRBs for approval. Protocols detail, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase I. The product is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case 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 may be conducted in patients.
- Phase II. Phase II trials involve investigations in a limited patient population to identify possible AEs and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted indications and to determine dosage tolerance and optimal dosage and schedule.
- Phase III. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for regulatory approval and product labeling.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA, and safety reports must be submitted to the FDA and the investigators for serious and unexpected side effects. Phase I, Phase II and Phase III testing may not be completed successfully within any specified period, if at all. Results from earlier trials are not necessarily predictive of results from later trials. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the drug, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA for a new drug, requesting approval to market the product.

The submission of an NDA generally is subject to the payment of a substantial user fee for a human drug application. A waiver of such fee may be obtained under certain limited circumstances. For example, an applicant is eligible for waiver of the application fee if the applicant is a small business submitting its first human drug application and does not have another product approved under a human drug application and introduced and delivered for introduction into interstate commerce. However, we did not qualify due to prior NDA approvals received by our CDMO segment.

In addition, under the Pediatric Research Equity Act of 2003, an NDA or supplement to an NDA for a new indication, dosage form, dosing regimen, route of administration, or active ingredient, must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may waive or defer pediatric studies under certain circumstances.

Section 505(b)(2) New Drug Applications. As an alternate path to FDA approval, particularly for modifications to drug products previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA, or a Section 505(b)(2) NDA. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments, and it permits approval of applications other than those for duplicate products and

permits reliance for such approvals on literature or on the FDA's findings of safety and effectiveness of an approved drug product. A Section 505(b)(2) NDA is an application where at least some of the information required for approval comes from clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA requires submission of information needed to support any changes relative to a previously approved drug, known as the reference product, such as published data or new studies conducted by the applicant, including bioavailability or bioequivalence studies, or clinical trials demonstrating safety and effectiveness. The FDA may then approve the Section 505(b)(2) NDA for all or some of the labeled indications for which the reference product has been approved, as well as for any new indication sought by the applicant, unless such indications or uses are protected by patent or exclusivity provisions covering the reference product. To the extent that a Section 505(b)(2) NDA relies on clinical trials conducted for a previously approved drug product or the FDA's prior findings of safety and effectiveness for a previously approved drug product, the Section 505(b)(2) applicant must submit patent certifications in its application with respect to any patents for the reference product that are listed in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book. Specifically, the applicant must certify for each listed patent that, in relevant part, (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is not sought until after patent expiration; or (4) the listed patent is invalid, unenforceable or will not be infringed by the proposed new product. A certification that the new product will not infringe the previously approved product's listed patent or that such patent is invalid or unenforceable is known as a Paragraph IV certification. If the applicant does not challenge one or more listed patents through a Paragraph IV certification, the FDA will not approve the Section 505(b)(2) NDA until all the listed patents claiming the referenced product have expired.

Further, the FDA will also not approve a Section 505(b)(2) NDA until any non-patent exclusivity, such as, for example, five-year exclusivity for obtaining approval of a new chemical entity, three-year exclusivity for an approval based on new clinical trials, or pediatric exclusivity, listed in the Orange Book for the reference product, has expired.

If the Section 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the owner of the reference product and relevant patent holders within 20 days after the Section 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement suit against the Section 505(b)(2) applicant. Under the FDCA, the filing of a patent infringement lawsuit within 45 days of receipt of the notification regarding a Paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA for 30 months, beginning on the date the patent holder receives notice, or until the patent expires or a court deems the patent unenforceable, invalid or not infringed, whichever is earlier. Even if a patent infringement claim is not brought within the 45-day period, a patent infringement claim may be brought under traditional patent law, but it does not invoke the 30-month stay. Moreover, in cases where a Section 505(b)(2) application containing a Paragraph IV certification is submitted after the fourth year of a previously approved drug's five-year exclusivity period, and the patent holder brings suit within 45 days of notice of certification, the 30-month period is automatically extended to prevent approval of the Section 505(b)(2) application until the date that is seven and one-half years after approval of the previously approved reference product. The court also has the ability to shorten or lengthen either the 30-month or the seven and one-half year period if either party is found not to be reasonably cooperating in expediting the litigation. Thus, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its product only to be subject to significant delay and patent litigation before its product may be commercialized. Alternatively, if the NDA applicant or relevant patent holder does not file a patent infringement lawsuit within the specified 45-day period, the FDA may approve the Section 505(b)(2) application at any time, assuming the application is otherwise approvable.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, some pharmaceutical companies and other stakeholders have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in

court, this could delay or even prevent the FDA from approving any Section 505(b)(2) NDA that we submit.

FDA Review of New Drug Applications. The FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. If the FDA does not find an NDA to be sufficiently complete for filing, it may request additional information rather than accepting the NDA for filing. In this event, the sponsor must resubmit the NDA with the additional information. The re-submitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether clinical data demonstrates that a product is safe and effective for its intended use and whether its manufacturing process can assure the product's identity, strength, quality and purity. 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 adequate to assure consistent production of the product within required specifications. The FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. An advisory committee is a panel of independent experts who provide advice and recommendations when requested by the FDA. The FDA is not bound by the recommendation of an advisory committee.

The approval process is lengthy and difficult, and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA will issue a complete response letter if the agency decides not to approve the NDA in its present form. The complete response letter usually describes all the specific deficiencies that the FDA identified in the NDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all the deficiencies identified in the letter, withdraw the application or request an opportunity for a hearing.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages, or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling, and the agency also may require a Risk Evaluation and Mitigation Strategy, or REMS, if it determines that a REMS is necessary to assure that the benefits of a drug outweigh its risks. In addition, the FDA may require Phase IV testing, which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA approval, and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specific circumstances of FDA marketing approval of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. Subject to certain limitations, the patent term restoration period is generally equal to one-half of the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. However, each phase of the regulatory review period may be reduced by any time that the FDA finds the applicant did act not act with due diligence. Only one patent applicable to an approved drug is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent and within sixty days of approval of the drug. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for patents that issue from some of our currently owned or licensed patents or patent applications to add patent life beyond their current expiration dates, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to NDAs for products containing chemical entities never previously approved by the FDA alone or in combination. A new chemical entity means a drug that contains no active moiety that has been approved by the FDA in any application submitted under Section 505(b) of the FDCA. An active moiety is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a Section 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. This exclusivity provision does not prevent the submission or approval of another full Section 505(b)(1) NDA, but such an NDA applicant would be required to conduct its own preclinical and adequate, well-controlled clinical trials to demonstrate safety and effectiveness. The FDCA also provides three years of marketing exclusivity for an NDA,

Section 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. Such clinical trials may, for example, support new indications, dosages, routes of administration or strengths of an existing drug, or for a new use. This exclusivity, which is sometimes referred to as clinical investigation exclusivity, prevents the FDA from approving an application under a Section 505(b)(2) NDA or an ANDA for the same conditions of use associated with the new clinical investigations before the expiration of three years from the date of approval. Such three-year exclusivity, however, would not prevent the approval of another application if the applicant submits a Section 505(b)(1) NDA and has conducted its own adequate, well-controlled clinical trials demonstrating safety and efficacy, nor would it prevent approval of an ANDA or a Section 505(b)(2) NDA product that did not incorporate the exclusivity-protected aspects of the approved drug product.

Pediatric exclusivity is another type of exclusivity in the United States. Pediatric exclusivity, if granted, provides an additional six months of exclusivity to any existing exclusivity (e.g., three- or five-year exclusivity) or patent protection for a drug. This six-month exclusivity, which runs from the end of other exclusivity or patent protection, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued “Written Request” for such a trial.

Post-Approval Requirements

Any drugs for which we receive FDA approval will be subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other government agencies enforce the laws and regulations prohibiting the false or misleading promotion of drugs. The FDA also limits the promotion of product candidates prior to their approval. With limited exceptions, pre-approval promotion is prohibited under the FDA's regulations.

Further, manufacturers of drugs must continue to comply with cGMP requirements, which are extensive and require considerable time, resources and ongoing investment to ensure compliance. In addition, changes to the manufacturing process may require prior FDA approval before being implemented, and other types of changes to the approved product, such as adding new indications and additional labeling claims, are subject to further FDA review and approval. Drug manufacturers and other entities involved in the manufacturing and distribution of approved drugs are required to list their products and to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the drug. Manufacturers must establish validated systems to ensure that products meet specifications and regulatory standards and test each product batch or lot prior to its release. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our product candidates for the Acute Care segment. FDA and state inspections may identify compliance issues at our CDMO sites or at the facilities of our contract manufacturers that may disrupt production or distribution or may require substantial resources to correct.

The FDA may withdraw a product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Further, the failure to maintain compliance with regulatory requirements may result in administrative or judicial actions, such as fines, untitled and warning letters, holds on clinical trials, product recalls or seizures, product detention or refusal to permit the import or export of products, refusal to approve pending applications or supplements, restrictions on marketing or manufacturing, consent decrees, injunctions or the imposition of civil or criminal penalties.

From time to time, legislation is drafted, introduced and passed in the U.S. Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, the FDA regulations and policies are often revised or reinterpreted by the agency in ways that may significantly affect our business and our product candidates. It is impossible to predict whether further legislative or FDA regulation or policy changes will be enacted or implemented and what the impact of such changes, if any, may be. For example, in December 2016, the 21st Century Cures Act, or the Cures Act, became law. The Cures Act contains numerous provisions, including provisions designed to speed development of innovative therapies and encourage greater use of real-world evidence to support regulatory decision making for drugs.

The U.S. Drug Enforcement Administration and other Governmental Actions

Certain products that we manufacture are regulated as a "controlled substance" as defined in the Controlled Substances Act of 1970, or CSA, which establishes registration, security, recordkeeping, reporting, storage, distribution and other

requirements administered and enforced by the DEA. The DEA is concerned with the control and handling of controlled substances, and with the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce.

The DEA regulates controlled substances by controlling them in five schedules. Schedule I and II controlled substances have a high potential for abuse, whereas Schedule III-V controlled substances have relatively decreasing potential for abuse. Therefore, the DEA imposes more stringent controls on Schedule I and II substances than Schedule III-V substances, including stricter security controls, quotas, and increased recordkeeping and reporting requirements. Certain of the products we manufacture and/or develop are regulated as Schedule II controlled substances. The DEA establishes annually an aggregate quota for how much certain controlled substances that we manufacture may be produced in total in the United States, based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. This limited aggregate amount that the DEA allows to be produced in the United States each year is allocated among individual companies, who must submit applications annually to the DEA for individual production and procurement quotas. We must receive an annual quota from the DEA in order to produce any Schedule II substance. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. In April 2018, the DEA proposed new guidelines aimed at strengthening the process for setting controls over diversion of controlled substances and making other improvements in the quota managements regulatory system for the production, manufacturing and procurement of controlled substances. Following a public comment period, the DEA published the final guidelines, which were substantially similar to the proposed guidelines, in July 2018. For 2019, the DEA has proposed decreased manufacturing quotas for the six most frequently misused opioids, including hydrocodone

which we use in the manufacture of certain products in our CDMO division, by an average of 10% as compared to the 2018 quotas. Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule.

The DEA requires facilities that manufacture controlled substances to adhere to certain security requirements. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Required security measures include background checks on employees and physical control of inventory through measures such as cages, surveillance cameras and inventory reconciliations. Records must be maintained for the handling of all controlled substances and periodic reports must be made to the DEA, for example, distribution, acquisition, and inventory reports for Schedule I and II controlled substances, Schedule III substances that are narcotics and other designated substances. Reports must also be made for thefts or losses of any controlled substance and suspicious orders. In addition, special authorization and notification requirements apply to imports and exports.

The DEA requires drug manufacturers to design and implement a system that identifies suspicious orders of controlled substances, such as those of unusual size, those that deviate substantially from a normal pattern and those of unusual frequency, prior to completion of the sale. A compliant suspicious order monitoring, or SOM, system includes well-defined due diligence, “know your customer” efforts and order monitoring.

To enforce these requirements, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Individual states also independently regulate controlled substances. We are subject to state regulation of distribution for these products. Failure to maintain compliance with applicable requirements, particularly where noncompliance results in loss or diversion, can result in enforcement action that could have a material adverse effect on our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations, or take other enforcement action. In certain circumstances, violations could result in criminal prosecution.

In addition to DEA regulations, the U.S. government and state legislatures have enacted legislation and regulations intended to fight the opioid epidemic. In February 2016, the FDA released an action plan to address the opioid epidemic, which is part of a broader initiative led by the Department of Health and Human Services, which includes the release of a new Guideline for Prescribing Opioids for Chronic Pain, FDA’s requirement of enhanced warnings and safety labeling, and institution of a class-wide REMs as a condition of approval. Further, the Comprehensive Addiction and Recovery Act, or CARA, was passed in 2016. CARA provides resources to improve state monitoring of controlled substances, including opioids. A Senate bill introduced in February 2018, known as CARA 2.0, would further limit initial prescriptions for opioids to three days, while exempting initial prescriptions for chronic care, cancer care, hospice or end of life care, and palliative care. CARA 2.0 would also increase civil and criminal penalties for opioid manufacturers that fail to report suspicious orders for opioids or fail to maintain effective controls against diversion of opioids. More recently, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, or Support Act, has been enacted. It provides for further regulation as well as funding for research and development of non-addictive painkillers. State legislatures have followed in the footsteps of the federal government in passing similar laws intended to limit prescription sales and quantities as well as increase the ability to monitor and regulate the manufacture and sale of opioids. These efforts may result in a reduction of demand for opioid products manufactured by our CDMO segment or government action against us if we fail to comply, both of which could have a material adverse effect on our business.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our product candidates to the extent we choose to clinically evaluate or sell any products outside of the United States. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. As in the United States, post-approval regulatory requirements, such as those regarding product manufacture, marketing or distribution, would apply to any product that is approved outside the United States.

For example, in the European Union, we may submit applications for marketing authorizations either under a centralized, decentralized, or mutual recognition marketing authorization procedure. The centralized procedure provides for the grant of a single marketing authorization for a medicinal product by the European Commission on the basis of a positive opinion by the European Medicines Agency, or the EMA. A centralized marketing authorization is valid for all European Union member states and three of the four European Free Trade Association (EFTA) States (Iceland, Liechtenstein and Norway). The decentralized procedure and the mutual recognition procedure apply between European Union member states. The decentralized marketing authorization procedure involves the submission of an application for marketing authorization to the competent authority of all European Union member states in which the product is to be marketed. One national competent authority, selected by the applicant, assesses the application for marketing authorization. The competent authorities of the other European Union member states are subsequently required to grant marketing authorization for their territory on the basis of this assessment, except where grounds of potential serious risk to public

health require this authorization to be refused. The mutual recognition procedure provides for mutual recognition of marketing authorizations delivered by the national competent authorities of European Union member states by the competent authorities of other European Union member states. The holder of a national marketing authorization may submit an application to the competent authority of a European Union member state requesting that this authority recognize the marketing authorization delivered by the competent authority of another European Union member state for the same medicinal product.

We are also subject to the U.K. Bribery Act, and other third country anti-corruption laws and regulations pertaining to our financial relationships with foreign government officials. The U.K. Bribery Act, which applies to any company incorporated or doing business in the UK, prohibits giving, offering, or promising bribes in the public and private sectors, bribing a foreign public official or private person, and failing to have adequate procedures to prevent bribery amongst employees and other agents. Penalties under the Bribery Act include potentially unlimited fines for companies and criminal sanctions for corporate officers under certain circumstances. Liability in relation to breaches of the U.K. Bribery Act is strict. This means that it is not necessary to demonstrate elements of a corrupt state of mind. However, a defense of having in place adequate procedures designed to prevent bribery is available.

Formulary Approvals and Third-Party Payer Coverage and Reimbursement

In both the United States and foreign markets, our ability to commercialize our Acute Care segment product candidates successfully, and to attract commercialization partners for our product candidates, depends in significant part on the availability of institutional formulary approvals and on adequate financial coverage and reimbursement from third-party payers, including, in the United States. These payers include the Centers for Medicare and Medicaid Services, or CMS, the federal program that runs the Medicare program and monitors the Medicaid programs offered by each state, as well as national and regional commercial plans. Medicare is a federally funded program managed by CMS through local Medicare Administrative Contractors that administer coverage and reimbursement for certain healthcare items and services furnished to the elderly, disabled and other individuals with certain conditions. Medicaid is an insurance program for certain categories of patients whose income and assets fall below state defined levels that is both federally and state funded and managed by each state. The federal government sets general guidelines for Medicaid and each state creates specific regulations that govern its individual program. Each government or commercial plan has its own process and standards for determining whether it will cover and reimburse a procedure or particular product and how much it will pay for that procedure or product. Commercial plans often rely on the lead of the governmental payers in rendering coverage and reimbursement determinations. Therefore, achieving favorable Medicare coverage and reimbursement is usually an essential component of successfully launching a new product. The competitive position of some of our products will depend, in part, upon the extent of coverage and adequate reimbursement for such products and for the procedures in which such products are used. Reimbursement for our product candidates can be subject to challenge, reduction or denial by government and other commercial plans.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government healthcare programs and other third-party payers are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy, and have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payers are challenging the prices charged for medical products and requiring that drug companies provide them with predetermined discounts from list prices.

Payers also are increasingly changing the metrics for reimbursement rates, such as basing payment on average sales price, or ASP, average manufacturer price, or AMP, and wholesale acquisition cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. CMS surveys and publishes retail community pharmacy acquisition cost information in the form of National Average Drug Acquisition Cost files to provide state

Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates. It may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payers to cover any products for which we receive regulatory approval.

If we successfully commercialize any of our products, we may participate in the Medicaid Drug Rebate Program. Participation is required for federal funds to be available for our products under Medicaid and Medicare Part B. Under the Medicaid Drug Rebate Program, we would be required to pay a quarterly rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Part B of the Medicare program.

Federal law requires that any company that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B drug pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients.

Additionally, in order to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, a manufacturer also must participate in the Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program, established by Section 603 of the Veterans Health Care Act of 1992, or VHCA. Under this program, the manufacturer is obligated to make its innovator and single source products available for procurement on an FSS contract and charge a price to four federal agencies, Department of Veterans Affairs, Department of Defense, or DoD, Public Health Service, and Coast Guard, that is no higher than the statutory Federal Ceiling Price. Moreover, pursuant to regulations issued by the DoD's TRICARE Management Activity, now the Defense Health Agency, to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008, manufacturers are required to provide rebates on utilization of their innovator and single source products that are dispensed to TRICARE beneficiaries by TRICARE network retail pharmacies. The formula for determining the rebate is established in the regulations and is based on the difference between the annual non-federal average manufacturer price and the Federal Ceiling Price (these price points are required to be calculated by us under the VHCA). The requirements under the 340B, FSS, and TRICARE programs could reduce the revenue we may generate from any products that are commercialized in the future.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers costs, including research, development, manufacturing, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover costs and may only be temporary. Reimbursement rates vary according to the use of the drug and the clinical setting in which it is used. Product reimbursement may also be incorporated into existing bundled payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or commercial payers and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Limited coverage may impact the demand for, or the price of, any product candidate for which marketing approval is obtained. Third-party payers also may seek additional clinical evidence, including expensive pharmacoeconomic studies, beyond the data required to obtain marketing approval, demonstrating clinical benefits and value in specific patient populations, before covering our products for those patients. If reimbursement is available only for limited indications, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and commercial payers for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. Moreover, the requirements governing drug pricing and reimbursement vary widely from country to country. For example, in the European Union the sole legal instrument at the European Union level governing the pricing and reimbursement of medicinal products is Council Directive 89/105/EEC, or the Price Transparency Directive. The aim of the Price Transparency Directive is to ensure that pricing and reimbursement mechanisms established in European Union member states are transparent and objective, do not hinder the free movement and trade of medicinal products in the European Union and do not hinder, prevent or distort competition on the market. The Price Transparency Directive does not, however, provide any guidance concerning the specific criteria on the basis of which pricing and reimbursement decisions are to be made in individual European Union member states. Neither does it have any direct consequence for pricing or levels of reimbursement in individual European Union member states. The national authorities of the individual European Union member states are free to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices and/or reimbursement of medicinal products for human use. Some individual European Union member states adopt policies according to which a specific price or level of reimbursement is approved for the medicinal product. Other European Union member states adopt a system of reference pricing, basing the price or reimbursement level in

their territory either, on the pricing and reimbursement levels in other countries, or on the pricing and reimbursement levels of medicinal products intended for the same therapeutic indication. Furthermore, some European Union member states impose direct or indirect controls on the profitability of the company placing the medicinal product on the market.

Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some European Union member states. These countries include the United Kingdom, France, Germany and Sweden. The HTA process in the European Union member states is governed by the national laws of these countries. HTA is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of the use of a given medicinal product in the national healthcare systems of the individual country is conducted. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost, and cost-effectiveness of individual medicinal products as well as their potential implications for the national healthcare system. Those elements of medicinal products are compared with other treatment options available on the market.

The outcome of HTA may influence the pricing and reimbursement status for specific medicinal products within individual European Union member states. The extent to which pricing and reimbursement decisions are influenced by the HTA of a specific medicinal product vary between the European Union member states.

In 2011, Directive 2011/24/EU was adopted at European Union level. This Directive concerns the application of patients' rights in cross-border healthcare. The Directive is intended to establish rules for facilitating access to safe and high-quality cross-border healthcare in the European Union. Pursuant to Directive 2011/24/EU, a voluntary network of national authorities or bodies responsible for HTA in the individual European Union member states was established. The purpose of the network is to facilitate and support the exchange of scientific information concerning HTAs. This could lead to harmonization between European Union member states of the criteria taken into account in the conduct of HTA in pricing and reimbursement decisions and negatively impact price in at least some European Union member states.

United States Healthcare Reform

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system. The United States government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs.

In recent years, Congress has considered reductions in Medicare reimbursement levels for drugs administered by physicians. CMS, the agency that administers the Medicare and Medicaid programs, also has authority to revise reimbursement rates and to implement coverage restrictions for some drugs. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products. While Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payers.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the Affordable Care Act, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Affordable Care Act is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms. Among other things, the Affordable Care Act expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum Medicaid rebate for both branded and generic drugs, expanded the 340B program, and revised the definition of AMP, which could increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The legislation also extended Medicaid drug rebates, previously due only on fee-for-service Medicaid utilization, to include the utilization of Medicaid managed care organizations as well and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the amount of rebates due on those drugs. On February 1, 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate program under the Affordable Care Act. These regulations became effective on April 1, 2016. There have been significant ongoing efforts to modify or eliminate the Affordable Care Act. For example, the Tax Cuts and Jobs Act, or the Tax Act, enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code, commonly referred to as the individual mandate, beginning in 2019. Further legislative changes to and regulatory changes under the Affordable Care Act remain possible. It is unknown what form any such changes or any law proposed to replace the Affordable Care Act would take, and how or whether it may affect our business in the future. We expect that changes to the Affordable Care Act, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug prices and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual

states, could have a material adverse effect on the healthcare industry generally.

The Affordable Care Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee of $4.0 billion in 2017, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. Furthermore, the law requires manufacturers to provide a 50% discount off the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the “donut hole.”

The Affordable Care Act also expanded the Public Health Service’s 340B drug pricing program. As noted above, the 340B drug pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B “ceiling price” for the manufacturer’s covered outpatient drugs. The Affordable Care Act expanded the 340B program to include additional types of covered entities: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the Affordable Care Act. Because the 340B ceiling price is determined based on AMP and Medicaid drug rebate data, revisions to the Medicaid rebate formula and AMP definition could cause the required 340B discounts to increase.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologics, were reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Subsequent legislation extended the 2% reduction, on average, to 2025. Continuation of sequestration or enactment of other reductions in Medicare reimbursement for drugs could affect our ability to achieve a profit on any candidate products that are approved for marketing.

Other Healthcare Laws and Compliance Requirements

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our activities may become subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil False Claims Act, and laws and regulations pertaining to limitations on and reporting of healthcare provider payments (physician sunshine laws). These laws and regulations are interpreted and enforced by various federal, state and local authorities including CMS, the Office of Inspector General for the U.S. Department of Health and Human Services, the U.S. Department of Justice, individual U.S. Attorney offices within the Department of Justice, and state and local governments. These laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, or arranging for or recommending the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
    - the U.S. civil False Claims Act (which can be enforced through “qui tam,” or whistleblower actions, by private citizens on behalf of the federal government), prohibits any person from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the U.S. federal government;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for healthcare benefits, items or services by a healthcare benefit program, which includes both government and privately funded benefits programs; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.
- state laws and regulations, including state anti-kickback and false claims laws, that may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payer, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and
- the Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children’s Health Insurance Program to report annually to CMS information related to certain payments made in the preceding calendar year and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

Violations of any of these laws or any other governmental regulations that may apply to us, may subject us to significant civil, criminal and administrative sanctions including penalties, damages, fines, imprisonment, and exclusion from government funded healthcare programs, such as Medicare and Medicaid, and/or adverse publicity.

Moreover, government entities and private litigants have asserted claims under state consumer protection statutes against pharmaceutical and medical device companies for alleged false or misleading statements in connection with the marketing, promotion and/or sale of pharmaceutical and medical device products, including state investigations and litigation by certain government entities regarding the marketing of opioid products.

In addition to regulations in the United States, to the extent we choose to clinically evaluate or sell any products outside of the United States, we will be subject to a variety of foreign healthcare laws and compliance requirements. For example, in the European Union, the EU Data Protection Directive imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. Switzerland has adopted similar restrictions. Data protection authorities from the different European Union member states may interpret the applicable laws differently, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data in the European Union.

Although there are legal mechanisms to allow for the transfer of personal data from the European Union to the U.S., the decision of the European Court of Justice in the Schrems case (Case C-362/14 Maximillian Schrems v. Data Protection Commissioner) invalidated the Safe Harbor framework and increased uncertainty around compliance with European Union restrictions on cross-border data transfers. As a result of the decision, it was no longer possible to rely on Safe Harbor certification as a legal basis for the transfer of personal data from the European Union to entities in the U.S. On February 29, 2016, however, the European Commission announced an agreement with the United States Department of Commerce, or DoC, to replace the invalidated Safe Harbor framework with a new EU-U.S. “Privacy Shield.” On July 12, 2016, the European Commission adopted a decision on the adequacy of the protection provided by the Privacy Shield. The Privacy Shield is intended to address the requirements set out by the European Court of Justice in its ruling by imposing more stringent obligations on companies, providing stronger monitoring and enforcement by the DoC and Federal Trade Commission, and making commitments on the part of public authorities regarding access to information. U.S. companies have been able to certify to the DoC their compliance with the privacy principles of the Privacy Shield since August 1, 2016.

On September 16, 2016, the Irish privacy advocacy group Digital Rights Ireland brought an action for annulment of the European Commission decision on the adequacy of the Privacy Shield before the European Court of Justice (Case T-670/16). In October 2016, a further action for annulment was brought by three French digital rights advocacy groups (Case T-738/16). Case T-670/16 and Case T-738/16 are still pending before the European Court of Justice. If, however, the European Court of Justice invalidates the Privacy Shield, it will no longer be possible to rely on the Privacy Shield certification to support transfer of personal data from the European Union to entities in the US. Adherence to the Privacy Shield is not, however, mandatory. U.S.-based companies are permitted to rely either on their adherence to the EU-US Privacy Shield or on the other authorized means and procedures to transfer personal data provided by the EU Data Protection Directive.

In December 2015, a proposal for an EU General Data Protection Regulation, intended to replace the current EU Data Protection Directive, introducing new data protection requirements in the EU, as well as substantial fines for breaches of the data protection rules, was agreed between the European Parliament, the Council of the European Union and the European Commission. The EU General Data Protection Regulation has applied since May 25, 2018. The EU Data Protection Regulation increased the responsibility and liability in relation to personal data processed in the European Union and also introduced substantial fines for breaches of the data protection rules. Furthermore, there is a growth towards the public disclosure of clinical trial data in the European Union which adds to the complexity of processing health data from clinical trials. During 2018, we implemented policies and controls to adhere to the EU General Data Protection Regulation.

Corporate Information

We were incorporated under the laws of the Commonwealth of Pennsylvania in November 2007. Our principal executive offices are located at 490 Lapp Road, Malvern, PA 19355, and our telephone number is (484) 395-2470.

Employees

We currently have 255 full-time employees and 5 temporary employees. None of our employees are covered by collective bargaining agreements, and we consider relations with our employees to be good.

Available Information

Our website address is www.recropharma.com. Our Annual Report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, any amendments to those reports, proxy and registration statements filed or furnished with the Securities and Exchange Commission, or SEC, are available free of charge through our website. We make these materials available through our website as soon as reasonably practicable after we electronically file such materials with, or furnish such materials to, the SEC. The reports filed with the SEC by our executive officers and directors pursuant to Section 16 under the Exchange Act are also made available, free of charge on our website, as soon as reasonably practicable after copies of those filings are provided to us by those persons. These materials can be accessed through the “Investor Relations” section of our website. The information contained in, or that can be accessed through, our website is not part of this Report.

Item 1A. Risk Factors

The following risk factors and other information included in this Annual Report on Form 10-K should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Please see page 4 of this Annual Report on Form 10-K for a discussion of some of the forward-looking statements that are qualified by these risk factors. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. All references and risks related to the launch, commercialization or sale of injectable meloxicam or any of our other product candidates are predicated on such product candidates receiving the requisite marketing and regulatory approval in the United States and applicable foreign jurisdictions.

Risks Related to Our Finances and Capital Requirements

We have incurred net losses since inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

To date, we have focused primarily on developing our proprietary product candidates. We have incurred significant pre-tax losses in each year since our inception in November 2007, including pre-tax losses of approximately $62.3 million and $52.0 million for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, we had an accumulated deficit of $188.3 million.

We have financed our operations through the sale of debt and equity securities, term loans made under our previous and existing credit facilities, including our current $100.0 million credit facility with Athyrium Opportunities III Acquisition LP, or Athyrium, and revenue generated by our CDMO segment. We have used revenue generated by our CDMO segment primarily to fund the operations of our CDMO segment, to make payments under our credit facility and to partially fund our research and development and pre-commercialization activities. We believe that our CDMO segment revenue will continue to contribute cash for general corporate purposes that may, to some extent, reduce the amount of external capital needed to fund development and commercialization operations.

The size of our future net losses and our ability to achieve profitability will depend, in part, on the rate of future expenditures and our ability to successfully resolve the issues raised by the FDA with regard to our NDA for IV meloxicam and obtain regulatory approval of IV meloxicam, successfully commercialize IV meloxicam, if approved, and successfully commercialize our other current or future product candidates, if approved. To date, none of our

product candidates have been commercialized, and revenues generated by our CDMO segment do not cover our costs and may never be sufficient to achieve profitability. Our ability to generate future revenues from product sales depends heavily on our success in:

- adequately addressing the concerns raised by the FDA in the CRL for IV meloxicam and obtaining regulatory approval for IV meloxicam;
- obtaining the labeling we requested for IV meloxicam, if approved;
- launching and commercializing IV meloxicam;
- developing a sufficient commercial organization capable of sales, marketing and distribution for IV meloxicam;
- establishing a commercially viable price for IV meloxicam;

- manufacturing commercial quantities of IV meloxicam at acceptable cost levels;
- effectively managing the levels of production, distribution and delivery of IV meloxicam through our supply chain and adequately adjusting such production and delivery to correspond to market demand;
- obtaining coverage and adequate reimbursement from third-parties, including government payers;
- obtaining and maintaining patent protection for IV meloxicam and our other product candidates;
- completing the clinical development of our other product candidates; and
- generating increased revenue from our CDMO segment.

As a result of the CRL we received in May 2018 with respect to IV meloxicam, we have incurred additional expenses, including increased legal and consulting fees associated with addressing the CRL, and we expect to continue to incur substantial and increased expenses as we continue our launch preparation and commercialization activities for IV meloxicam, and expand our research and development activities and advance our clinical programs for our other product candidates. Because of the numerous risks and uncertainties associated with pharmaceutical product development and commercialization, we are unable to predict the timing or amount of increased expenses, and when, or if, we will be able to achieve or maintain profitability.

If IV meloxicam or our other product candidates are not successfully developed or commercialized, or if revenues are insufficient following marketing approval, we will not achieve profitability and our business may fail. Even if we successfully obtain regulatory approval for IV meloxicam in the United States, our revenues are also dependent upon the size of the markets outside of the United States, as well as our ability to obtain market approval and achieve commercial success outside of the United States on our own or with a collaboration partner.

As a result of the foregoing, we expect to continue to incur significant and increasing losses from operations for the foreseeable future. Even if we are able to generate revenues from the sale of our products, we may not become profitable and may need to obtain additional funding to continue operations.

If we fail to obtain sufficient additional financing, we would be forced to delay, reduce or eliminate our product development and related commercialization programs or to significantly scale back, re-leverage or monetize our manufacturing business.

Developing and commercializing pharmaceutical products, including conducting preclinical studies and clinical trials and ramping up commercial manufacturing activities, is expensive. We expect our research and development expenses to increase as we continue our ongoing clinical and pre-commercialization activities in anticipation of a potential commercial launch of IV meloxicam, advance our other clinical programs and, if IV meloxicam is approved, scale up our commercialization activities. If we obtain regulatory approval for IV meloxicam, we anticipate incurring significant costs of sales and general and commercialization expenses in connection with its launch and commercialization. In addition, maintaining our cGMP pharmaceutical manufacturing facilities is expensive. While our CDMO segment generates revenue and profit, that revenue and profit alone is not sufficient to support the development and commercialization of our product candidates. We will need to raise additional funds to support our future product development operations. In addition, we may also need to obtain additional financing if the capital requirements for operating and maintaining our manufacturing facilities exceed our current expectations. Such financing may not be available to us on acceptable terms, or at all.

We expect our existing cash and cash equivalents and other expected financing sources will be sufficient to fund our operations over the next 12 months. If the FDA requires us to conduct additional clinical trials, preclinical studies or additional chemistry, manufacturing and controls, or CMC, work to resolve issues raised by the FDA in the CRL for IV meloxicam, we will need to raise additional funding for the costs of conducting such clinical trials, preclinical studies and CMC work. Further, if IV meloxicam is ultimately approved by the FDA, we will need to raise additional funding to implement our commercial launch plans for IV meloxicam and to satisfy the milestone payments due to

Alkermes following FDA approval of IV meloxicam. In addition, changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. For example, our pre-commercialization and commercialization activities for IV meloxicam may lead to additional, unexpected costs related to the commercial manufacture of IV meloxicam or the build-out of our commercial sales organization. We may also encounter technical, enrollment or other difficulties that could increase our development costs more than we expect for our other product candidates. Additional funding will be needed to develop our other product candidates.

Securing additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates or to develop and maintain customer relationships. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- significantly delay, scale back or discontinue the development or commercialization of IV meloxicam or curtail the development programs for our other product candidates;
- seek collaboration partners for the development or commercialization of IV meloxicam or our other product candidates at an earlier stage than otherwise would be desirable, on terms that are less favorable than might otherwise be available or for product candidates that we would otherwise plan to develop and commercialize on our own;
- relinquish or license, on unfavorable terms, our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves; or
- significantly scale back, re-leverage or monetize our CDMO segment.

Any of the above could have a material adverse effect on our business, operating results and prospects.

We may sell additional equity or debt securities or incur additional indebtedness to fund our operations, which would result in dilution to our shareholders and may impose restrictions on our business.

We may seek additional capital through a combination of private and public equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. On December 29, 2017, we entered into a Sales Agreement, or the Sales Agreement, with Cowen and Company, LLC, or Cowen, pursuant to which we may sell from time to time, at our option, up to $40.0 million of shares of our common stock through Cowen, as our placement agent. Through December 31, 2018, we have not sold any shares of common stock under the Sales Agreement. On March 2, 2018, we entered into a common stock purchase agreement, or the 2018 Purchase Agreement, with Aspire Capital Fund, LLC, or Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth in the 2018 Purchase Agreement, Aspire Capital is committed to purchase, at our sole election, up to an aggregate of $20.0 million of our shares of common stock over the approximately 30-month term of the 2018 Purchase Agreement. Through December 31, 2018, we have sold $17.0 million in shares of our common stock under the 2018 Purchase Agreement. On February 19, 2019, we entered into a second common stock purchase agreement, or the 2019 Purchase Agreement, with Aspire Capital which provides that, upon the terms and subject to the conditions and limitations set forth in the 2019 Purchase Agreement, Aspire Capital is committed to purchase, at our sole election, up to an aggregate of an additional $20.0 million of our shares of common stock over the approximately 30-month term of the 2019 Purchase Agreement. To the extent that we raise additional capital through sales of common stock under the Sales Agreement or additional shares of common stock under the 2018 and 2019 Purchase Agreements or through the sale of equity or convertible debt securities by any other means, existing ownership interests will be diluted, and the terms of such financings may include liquidation or other preferences that adversely affect the rights of existing shareholders. Debt financings may be coupled with an equity component, such as warrants to purchase shares, or repayment of the debt, which could also result in dilution of our existing shareholders' ownership and could include additional negative covenants that restrict our business operations. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us.

Our operating results may fluctuate significantly.

Our operating results may be subject to quarterly and annual fluctuations. Our operating results will be affected by numerous factors, including:

- the nature and scope of any activities required to adequately address the concerns raised by the FDA in the CRL for IV meloxicam, which may include the completion of additional clinical trials, preclinical studies and/or CMC work;
- any additional delays in regulatory review and approval of IV meloxicam or our other product candidates in clinical development;
- the timing and amount of development and net sales milestones, royalties and earn-out payments payable by us under our existing license agreements and acquisition agreements;

- fluctuations in the revenues generated by our CDMO segment, including the loss of a major customer or product;
- variations in the level of expenses related to our development programs;
- the success of our clinical trials through all phases of clinical development;
    - any newly identified side effects of IV meloxicam or our other product candidates that could delay or prevent commercialization or cause an approved drug to be taken off the market;
- changes in the fair values of our warrants and contingent consideration liabilities;
- any intellectual property infringement lawsuit in which we may become involved;
- our ability to obtain and maintain patent protection;
- the success of our commercial launch preparations activities;
- our ability to establish an effective sales and marketing infrastructure;
- our dependence on third parties to supply and manufacture our product candidates and delivery devices;
    - the level of market acceptance for IV meloxicam or any of our other product candidates, once approved, and underlying demand for that product and wholesalers' buying patterns;
- the amount of sales and other revenues from IV meloxicam or any of our other product candidates, once approved, including the selling prices for such potential products and the availability of adequate third-party coverage and reimbursement;
- competition from existing products or new products that may emerge;
- regulatory developments affecting our product candidates, which are not limited to but could include the imposition of a REMS program as a condition of approval;
- our execution of any additional collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements;
- our acquisition, divestiture or in-licensing of new products, product candidates or business units; and
- the discontinuance, licensing or sale of any asset or segment of our business.

Due to the various factors mentioned above, and others, the results of any prior quarterly period should not be relied upon as an indication of our future operating performance. If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

We have incurred significant indebtedness, which could adversely affect our business.

As of December 31, 2018, we had an outstanding balance under our credit agreement with Athyrium of $70 million. Upon entry into the credit agreement with Athyrium, we drew upon an initial $60 million term loan. In December 2018 we amended the credit agreement and drew upon a $10 million term B-1 loan. We have the ability to draw upon two additional tranches of terms loans, each in the aggregate original principal amount of $15 million, subject to certain timing and milestone restrictions, including that we receive regulatory approval of IV meloxicam by September 30, 2019.

Our indebtedness could have important consequences to our shareholders. For example, it:

- increases our vulnerability to adverse general economic or industry conditions;
- limits our flexibility in planning for, or reacting to, changes in our business or the industries in which we operate;

- reduces proceeds we may receive as a result of any sale of our CDMO segment;
- makes us more vulnerable to increases in interest rates, as borrowings under our credit agreement with Athyrium are at variable rates;
- limits our ability to obtain additional financing in the future for working capital or other purposes; and
- places us at a competitive disadvantage compared to our competitors that have less indebtedness.

Any of the above-listed factors could materially adversely affect our business, financial condition, results of operations and cash flows. Our credit agreement with Athyrium also contains certain financial and other covenants, including a minimum liquidity requirement and a trailing four-quarter revenue requirement, maximum leverage ratios and includes limitations on, among other things, additional indebtedness, paying dividends in certain circumstances, acquisitions and certain investments. The credit agreement provides for certain mandatory prepayment events, including with respect to the proceeds of asset sales, extraordinary receipts, debt issuances and other specified events, based on the terms of the credit agreement with Athyrium. Any failure to comply with the terms, covenants and conditions of the credit agreement may limit our ability to draw upon additional tranches of term loans and may result in an event of default under such agreement, which could have a material adverse effect on our business, financial condition and results of operation.

Uncertainties in the interpretation and application of the Tax Cuts and Jobs Act of 2017 could adversely affect our business and financial condition.

The Tax Cuts and Jobs Act of 2017, or the Tax Act, enacted in December 2017, significantly changed the Internal Revenue Code of 1986, as amended. These changes included, among other things, significant changes to corporate taxation, including a permanent reduction to the corporate income tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Any federal net operating loss carryovers created in 2018 and thereafter will be carried forward indefinitely. As a result of the Tax Act, in 2017 we incurred a one-time net expense of $7.9 million related to the remeasurement of our deferred tax balances to the new statutory rate. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain, and our business and financial condition could be adversely affected.

Changes in tax laws and unanticipated tax liabilities could adversely affect our effective income tax rate and ability to achieve profitability.

We are subject to income taxes in the United States and Ireland. Our effective income tax rate in the future could be adversely affected by a number of factors including changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities, reversal of established valuation allowances, changes to our operations including the discontinuance, licensing or sale of any asset or segment of our business, changes to tax strategy, changes in transfer pricing and changes in tax laws.

We regularly assess these matters to determine the adequacy of our tax provision, which is subject to discretion. If our assessments are incorrect, it could have an adverse effect on our business and financial condition. There can be no assurance that income tax laws and administrative policies with respect to the income tax consequences generally applicable to our subsidiaries or to us will not be changed in a manner which adversely affects our shareholders. Changes in tax laws and unanticipated tax liabilities could adversely affect our effective income tax rate and ability to achieve profitability, which could have a material adverse effect on our business, financial condition and results of operation.

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Risks Related to Clinical Development and Regulatory Approval

Considering our receipt of a CRL from the FDA regarding our NDA for IV meloxicam, the U.S. regulatory pathway for IV meloxicam is uncertain, and we will need to successfully address deficiencies raised by the FDA in order to obtain regulatory approval.

In July 2017 we submitted an NDA for IV meloxicam for the management of moderate to severe pain to the FDA. On May 23, 2018, we received a CRL from the FDA regarding the NDA, which stated that the FDA determined it could not approve the NDA in its present form. The CRL stated that data from ad hoc analyses and selective secondary endpoints suggest that the analgesic effect did not meet the expectations of the FDA. In addition, the CRL identified certain CMC related questions on extractable and leachable data provided in the NDA. The CRL did not identify any issues relating to the safety of IV meloxicam. In July 2018, we participated in a Type A End-of-Review meeting with the FDA to discuss the topics covered in the CRL. Upon receipt and review of the meeting minutes, we resubmitted the NDA for IV meloxicam in September 2018. The FDA has set a date of decision on the NDA, or PDUFA date, of March 24, 2019.

Our anticipated commercialization of IV meloxicam has been delayed by the CRL and we have incurred additional costs, including increased legal and consulting fees, and devoted additional resources to address the FDA's concerns raised in the CRL. Our receipt of the CRL and delay in the commercialization of IV meloxicam has adversely affected our business and caused our stock price to decline. While we believe that our amended NDA addresses the concerns raised by the FDA in the CRL, the FDA may not approve the amended NDA, may require additional information, may require the completion of additional clinical trials, preclinical studies and/or CMC work or may raise additional issues with regard to regulatory approval of IV meloxicam. Any of these items could further delay or prevent the approval of or limit the product labeling claims for IV meloxicam.

In addition, either the substance of the items identified by the FDA in the CRL, or the CRL itself, could have an adverse impact on future efforts to obtain marketing authorization for IV meloxicam from the EMA and other foreign regulatory authorities, or on our future efforts to commercialize IV meloxicam and gain acceptance of IV meloxicam from third-party payors.

Should we fail to obtain regulatory approval of IV meloxicam, we may be forced to rely on our other product candidates, which are at an earlier development stage and will require significant additional time and resources to obtain regulatory approval and proceed with commercialization, which could have a material adverse effect on our business, financial condition and results of operations.

Regulatory approval of IV meloxicam may be delayed by the U.S. government shutdown.

Beginning on December 22, 2018, a shutdown of the U.S. federal government went into effect, which resulted in many government agencies, including the FDA, drastically reducing or ceasing operations. While the FDA was not accepting new regulatory approval applications during the shutdown, it was continuing to review NDAs that were submitted prior to the shutdown using funds from the user fees paid by applicants in connection with NDA submissions. The commissioner of the FDA had indicated in public statements, however, that user fees would only fund review of drug product NDAs until mid-February. On January 25, 2019, President Trump signed a bill to provide funding to temporarily re-open the U.S. government for three weeks, and on February 15, 2019 President Trump signed a bill ending the government shutdown. It is uncertain what impact the government shutdown may have of the FDA's timing of review of pending NDAs, despite the re-opening of the government.

This government shutdown, and any other subsequent full or partial government shutdowns, may impact the FDA's ability to reach a timely decision on our resubmitted NDA for IV meloxicam by the PDUFA date of March 24,

2019. If approval of the NDA is significantly delayed, our anticipated commercial launch of IV meloxicam could be materially impacted, which could adversely affect our business and cause our stock price to decline.

We are substantially dependent on the success of our lead product candidate IV meloxicam, which is in a later stage of development than our other product candidates. To the extent regulatory approval of IV meloxicam is delayed or not granted, our business, financial condition and results of operations may be materially adversely affected, and the price of our common stock may decline.

We currently have no product candidates approved for sale, and we may never be able to develop marketable products. We are focusing a significant portion of our activities and resources on our lead product candidate, IV meloxicam, and we believe our prospects are highly dependent on, and a significant portion of the value of our company relates to, our ability to successfully obtain regulatory approval for, and successfully commercialize, IV meloxicam. The regulatory approval of IV meloxicam is subject to many risks, including the risks discussed in other risk factors, and IV meloxicam may not receive marketing approval from any regulatory agency. If the results or timing of regulatory filings, the regulatory process, regulatory developments, clinical trials or preclinical studies, or other activities, actions or decisions related to IV meloxicam do not meet our or others' expectations, the market price of our common stock could decline significantly.

We have resubmitted the NDA for IV meloxicam and the FDA has set a PDUFA date of March 24, 2019. If the FDA requires us to conduct additional clinical trials, preclinical studies or CMC work in connection with our resubmitted NDA, our timeline for commercialization of IV meloxicam will be further delayed and we will incur additional costs. Further, there can be no assurance that we will complete any additional required clinical and non-clinical studies in a manner that is acceptable to the FDA. In addition, we are conducting Phase IIIb clinical trials for IV meloxicam in colorectal surgery patients and orthopedic surgery patients, and those clinical trials could fail or produce results that are adverse or inconclusive, which could have a negative impact on regulatory approval.

Any further delay or setback in the development or regulatory approval of IV meloxicam could adversely affect our business and cause our stock price to decline. We cannot assure you that we will be able to obtain approval for IV meloxicam from the FDA. Should we fail to obtain regulatory approval of IV meloxicam, we may be forced to rely on our other product candidates, which are at an earlier development stage and will require significant additional time and resources to obtain regulatory approval and proceed with commercialization, which could have a material adverse effect on our business, financial condition and results of operations.

If we fail to obtain approval for the product labeling requested in our NDA for IV meloxicam, our ability to successfully market IV meloxicam may be adversely affected.

The FDA raised certain concerns in the CRL that could ultimately lead the FDA to conclude that information in our NDA is not sufficient to support a product label with claims covering management of moderate to severe pain or 24-hour dosing intervals. We have made changes to our dosage and administration section of the product label to address the FDA's concerns regarding onset and duration of analgesic effect and these changes were included in our September 2018 resubmission of our NDA. If the approval of IV meloxicam is for a more limited indication or different dosing interval, our ability to market to our full target market may be reduced. We could need to significantly revise our launch and commercialization strategy, which could delay commercial launch of IV meloxicam, if approved, and could significantly limit our ability to realize the full market potential of IV meloxicam. The approved labeling could decrease the target market to a point where we would be unable to achieve profitability from IV meloxicam, in which case we may be forced to limit or discontinue the commercialization of IV meloxicam, or seek a collaboration partner for the commercialization of IV meloxicam, all of which would have an adverse impact on our business.

In addition, the labeling approved by the FDA could also significantly limit the approved indications for use, require that precautions, contraindications or warnings be included on the product labeling, including black box warnings, require expensive and time-consuming post-approval clinical trials, REMS or surveillance as conditions of approval, or, through product labeling limit the claims that we may make, any of which may also impede the successful commercialization of IV meloxicam, which would have an adverse impact on our business.

Our development of IV meloxicam depends, in part, on published scientific literature and the FDA's prior findings regarding the safety and efficacy of approved products containing meloxicam based on data not developed by us, but upon which the FDA may rely in reviewing our NDA.

Section 505(b)(2) of the FDCA permits the filing of an NDA where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. The FDA interprets Section 505(b)(2) of the FDCA, for purposes of approving an NDA, to permit the applicant to rely, in part, upon published literature or the FDA's previous findings of safety and efficacy for an already-approved reference product. The FDA may also require companies to perform additional clinical trials or measurements to support any deviation from the reference product. The FDA may then approve the new product candidate for all or some of the label indications for which the reference product has been approved, as well as for any new indication sought by the

Section 505(b)(2) applicant. The label, however, may require all or some of the limitations, contraindications, warnings or precautions included in the reference product's label, including a black box warning, or may require additional limitations, contraindications, warnings or precautions. Our NDA for IV meloxicam was submitted under Section 505(b)(2) and as such the NDA relies, in part, on the FDA's previous findings of safety and efficacy from investigations for approved products containing meloxicam and published scientific literature for which we have not received a right of reference. Even though we may be able to take advantage of Section 505(b)(2) to support potential U.S. approval for IV meloxicam, the FDA may require us to perform additional clinical trials or measurements to support approval. In addition, notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), if the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving our NDA for IV meloxicam or any other Section 505(b)(2) NDAs that we submit. Such a result could require us to conduct additional testing and costly clinical trials, which could substantially delay or prevent the approval and launch of IV meloxicam, which could have a material adverse effect on our business, financial condition and results of operations.

IV meloxicam and our other product candidates may cause adverse events or other safety concerns or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

AEs caused by IV meloxicam and our other product candidates could cause us, other reviewing entities, clinical study sites or regulatory authorities to interrupt, delay or halt clinical studies and could result in the denial of regulatory approval. Clinical studies conducted with IV meloxicam and our other product candidates have generated some AEs, and in some cases SAEs, as those terms are defined by the FDA in its regulations, and AEs or SAEs could be generated during our on-going Phase IIIb clinical trials for IV meloxicam. Our ability to obtain regulatory approval for IV meloxicam and our other product candidates may be adversely impacted by these AEs, SAEs or other safety concerns. Further, if our products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution in a form of a modified REMS;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical studies;
- we could be sued and held liable for harm caused to patients; and/or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates, which could have a material adverse effect on our business, financial condition and results of operations.

IV meloxicam or any of our other product candidates, if approved, may require REMS, which may significantly increase our costs.

IV meloxicam or any of our other product candidates, if approved, may require REMS. The REMS may include requirements for special labeling or medication guides for patients, special communication plans to health care professionals and restrictions on distribution and use. We cannot predict the specific scope or magnitude of REMS that may be required as part of the FDA's approval of IV meloxicam or our other product candidates. Depending on the extent of the REMS requirements, our costs to commercialize IV meloxicam or our other product candidates may increase significantly and distribution restrictions could limit sales, which could have a material adverse effect on our business, financial condition and results of operations. Similar obstacles may arise in countries outside of the United States.

We will need to obtain approval for any proposed names for IV meloxicam, and any delay associated with doing so could delay commercialization of IV meloxicam, and adversely impact our business.

The proprietary name we propose to use with IV meloxicam in the United States must be reviewed and accepted by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA reviews any proposed product name, including an evaluation of the potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims or contributes to an overstatement of efficacy. Although the FDA has conditionally accepted our proposed proprietary product name for IV meloxicam, it may still object to the proposed proprietary product name at the time of any NDA approval, which would require us to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable laws, not infringe the existing rights of third parties and be acceptable to the FDA, all of which could delay commercialization of IV meloxicam, and adversely impact our business.

Even if we obtain regulatory approval for our product candidates, we will still face extensive regulatory requirements and our products may face future regulatory difficulties.

Even if we obtain regulatory approval in the United States or other countries, the FDA and state regulatory authorities and the equivalent regulatory authorities in other countries may still impose significant restrictions on the indicated uses or marketing of our product candidates, or impose ongoing requirements for potentially costly post-approval studies or post-marketing surveillance. Any approved products will also be subject to ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping and reporting of safety and other post-marketing information. The holder of an

approved NDA is obligated to monitor and report AEs and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. The applicable regulations in countries outside the United States grant similar powers to the competent authorities and impose similar obligations on companies.

In addition, manufacturers of drug products and their facilities are subject to payment of substantial user fees and continual review and periodic inspections by the FDA and other regulatory authorities, including equivalent regulatory authorities in other countries, for compliance with cGMP regulations and adherence to commitments made in the NDA or the application for marketing authorization. If we, or a regulatory authority, discover previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with a facility where the product is manufactured, a regulatory authority may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market, suspension of manufacturing, or other FDA action or other action by the equivalent regulatory authorities in other countries.

If we fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory authority may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend, modify or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or supplements to an NDA submitted by us;
- seize our product candidate; and/or
- refuse to allow us to enter into supply contracts, including government contracts.

If any of the above were to occur, our ability to successfully commercialize any approved product candidates and achieve profitability could be negatively impacted, which could have a material adverse effect on our business, financial condition and results of operations.

Even if we obtain FDA approval for IV meloxicam or our other product candidates in the United States, we may never obtain approval for or commercialize our products outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding quality, safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional non-clinical studies or clinical trials, which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. While our management has experience in obtaining foreign regulatory approvals, we do not have any product candidates approved for sale in any jurisdiction, including international markets, and we, as a company, do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, our target market will be reduced, and our ability to realize the full market potential of our products will be adversely affected.

For example, in the European Union, similar to the United States regulation scheme, both marketing authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA and the competent authorities of the individual European Union member states both before and after grant of the manufacturing and Marketing Authorizations. This includes control of compliance with cGMP rules, which govern quality control of the manufacturing process and require documentation policies and procedures. We and our third-party manufacturers are required to ensure that all of our processes, methods, and equipment are compliant with cGMP. Failure by us or by any of our third-party partners, including suppliers,

manufacturers, and distributors to comply with European Union laws and the related national laws of individual European Union member states governing the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products, both before and after grant of marketing authorization, and marketing of such products following grant of authorization may result in administrative, civil, or criminal penalties. These penalties could include delays in or refusal to authorize the conduct of clinical trials or to grant Marketing Authorization, product withdrawals and recalls, product seizures, suspension, or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing, or clinical trials, operating restrictions, injunctions, suspension of licenses, fines, and criminal penalties, which could have a material adverse effect on our business, financial condition and results of operations.

The regulatory approval processes of the FDA are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA may not accept our NDA filing;
- the FDA may disagree with the design, scope or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA that a product candidate is safe and effective for its proposed indication;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA;
- the FDA may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA may change significantly in a manner rendering our clinical data insufficient for approval.

For example, we have received a CRL from the FDA with regard to our NDA for IV meloxicam and have resubmitted our NDA. We cannot be certain that any of our product candidates will receive regulatory approval. If we do not receive regulatory approval or any of our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market one of our product candidates, our revenue will be dependent, to a significant extent, upon the size of the markets in the territories for which we gain regulatory approval. If the markets for patients or indications that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such products, if approved, which could have a material adverse effect on our business, financial condition and results of operations.

Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Clinical failure can occur at any stage of clinical development.

Clinical trials are expensive, can take many years to complete and have highly uncertain outcomes. Failure can occur at any time during the clinical trial process as a result of inadequate study design, inadequate performance of a drug,

inadequate adherence by patients or investigators to clinical trial protocols, or other factors. New drugs in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through earlier clinical trials. Some of our pipeline product candidates are in early stages of development, and positive preclinical and Phase I clinical trials for those product candidates may not necessarily be predictive of the results of later stage clinical trials. A number of companies in the biopharmaceutical industry have suffered

significant setbacks in advanced clinical trials as a result of a lack of efficacy or adverse safety profiles, despite promising results in earlier trials. Our clinical trials may not be successful or may be more expensive or time-consuming than we currently expect. If clinical trials for any of our product candidates fail to demonstrate safety or efficacy to the satisfaction of the FDA or the equivalent regulatory authorities in other countries, the FDA or the equivalent regulatory authorities in other countries will not approve that drug and we would not be able to commercialize it, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.

We may experience delays in clinical trials of our product candidates or the time required to complete clinical trials for our product candidates may be longer than anticipated. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients, or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including, but not limited to:

- inability to raise funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching an agreement with the FDA or the equivalent regulatory authorities in other countries on final trial design or the scope of the development program;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or the equivalent regulatory authorities in other countries;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- delays in obtaining required IRB approval at each site;
- delays in recruiting suitable patients to participate in a trial;
- delays in having subjects complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new clinical sites; or
- delays by our contract manufacturers to produce and deliver a sufficient supply of clinical trial materials.

For example, the FDA had imposed a clinical hold on two of our early-stage product candidates, RP1000 and the reversal agent. While the clinical hold on RP1000 has been lifted, the reversal agent remains under clinical hold and we will be unable to proceed with clinical development on that product candidates until the clinical hold is resolved. If we are unable to resolve these issues with the FDA, or if clinical trials for any of our other product candidates are delayed for any of the above reasons or other reasons, our development costs may increase, our approval process could be delayed and our ability to commercialize our product candidates could be materially harmed, which could have a material adverse effect on our business, financial condition or results of operations.

Risks Related to Commercialization of Our Product Candidates

We have no history of commercializing drugs, which may make it difficult to predict our future performance or evaluate our business and prospects.

Although we commenced operations in 2007, our operations have been primarily limited to developing our technology and undertaking non-clinical studies and clinical trials for our product candidates. We have not yet obtained regulatory approval for any of our product candidates. To date, we have not yet demonstrated our ability to successfully manufacture at commercial scale or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Because our success is dependent on our ability to commercialize IV meloxicam, any predictions about our future success or viability may not be as accurate as they could be if we had a longer history of successfully developing and commercializing drugs.

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Our anticipated commercial launch of IV meloxicam has been significantly delayed, which has changed our commercialization strategy and could adversely impact our ability to successfully commercialize IV meloxicam.

Due to receipt of the CRL from the FDA regarding IV meloxicam, our anticipated commercial launch of IV meloxicam has been delayed from summer of 2018 to 2019, if approved. Our initial commercial launch plans have changed. We now intend to launch with a sales team of approximately 80 to 100 sales representatives. This will require us to hire more sales force members, which will increase our costs. In addition, we may face challenges when recruiting a sufficient number of sales representatives. If we are unable to hire the planned sales team for the commercial launch of IV meloxicam, our commercialization of IV meloxicam may be adversely impacted, which could have a material adverse effect on our business, financial condition and results of operations.

If we are unable to successfully commercialize IV meloxicam, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.

Even if we receive regulatory approval from the FDA for the labeling that we request, our ability to successfully commercialize IV meloxicam will depend on many factors, including but not limited to:

- our ability to create sufficient capital (through debt, equity or both) to support the product launch;
- any negative perception of IV meloxicam as a result of receipt of the CRL from the FDA, even if ultimately resolved;
- the results of our ongoing Phase IIIb clinical trials for IV meloxicam;
- our ability to consistently manufacture commercial quantities of IV meloxicam at a reasonable cost and with sufficient speed to meet commercial demand, which may be higher or lower than expected demand on which our manufacturing forecasts have been based;
- our ability to build a sales and marketing organization to market IV meloxicam;
- our success in educating physicians, patients and caregivers about the benefits, administration and use of injectable meloxicam;
- our share of promotional “voice” during launch versus other existing or new products in our market segment;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of competing products;
- our ability to successfully defend any challenges to our intellectual property relating to IV meloxicam;
- our ability to set an acceptable price for IV meloxicam and to obtain adequate coverage and adequate reimbursement for IV meloxicam;
- our ability to contract with pharmaceutical wholesalers and specialty distributors on acceptable term;
- the effectiveness of our marketing campaigns;
- our effective use of promotional resources;
- our success in obtaining formulary approvals; and
- a continued acceptable profile for IV meloxicam.

Many of these matters are beyond our control and are subject to other risks described elsewhere in this “Risk Factors” section. Accordingly, we cannot assure that we will be able to successfully commercialize or generate revenue from IV meloxicam, even if we receive regulatory approval for the labeling that we have requested. If we cannot do so or are significantly delayed in doing so, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.

If we fail to supply IV meloxicam in sufficient quantities and at acceptable quality levels, we may face delays in the commercialization of IV meloxicam, if approved, or be unable to meet market demand, and may lose potential revenues.

Our ability to supply sufficient quantities of IV meloxicam is substantially dependent on the performance of third-party manufacturers. We do not own facilities with capabilities for clinical-scale or commercial manufacturing of injectable meloxicam and we rely, and expect to continue to rely, on third-party suppliers and contract manufacturers to manufacture injectable meloxicam. Alkermes is currently our sole supplier of bulk injectable meloxicam formulation and is the only established supplier of bulk injectable meloxicam formulation. We have committed to purchase our current requirements of injectable meloxicam formulation from Alkermes, and we have commissioned dedicated space in Alkermes' manufacturing facility for the production of bulk injectable meloxicam. Patheon provides sterile fill and finish services for injectable meloxicam.

Although our supply agreement and manufacturing agreements for injectable meloxicam allow us to qualify and purchase from an alternative supplier or manufacturer in certain circumstances, it would be time-consuming and expensive for us to do so, and there can be no assurance that an alternative supplier could be found on terms that are acceptable to us or at all. The number of potential manufacturers that have the necessary equipment, expertise and governmental licenses to produce IV meloxicam is limited. If we encounter any issues with our contract manufacturers or choose to engage a new supplier or contract manufacturer for IV meloxicam, we would need to qualify and obtain FDA approval for another contract manufacturer or supplier as an alternative source, which could be costly and cause significant delays.

Our reliance on a limited number of vendors to manufacture IV meloxicam exposes us to risks, any of which could delay commercialization of our products, result in higher costs, or deprive us of potential revenues. Our contract manufacturers may encounter difficulties in achieving the volume of production needed to satisfy our demand for commercial launch and ongoing commercial demand (even after accounting for the increased capacity to be provided by the dedicated space at the Alkermes facility), may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, may be affected by natural disasters that interrupt or prevent manufacturing of our products, may experience shortages of qualified personnel to adequately staff production operations, may experience shortages of raw materials and may have difficulties finding replacement parts or equipment. In addition, our contract manufacturers could default on their agreement with us to meet our requirements for commercial supplies of IV meloxicam and/or Alkermes could fail to deliver the dedicated space according to the currently agreed timeline.

We and our contract manufacturers must comply with federal, state and foreign regulations, including FDA's regulations governing current 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. Our contract manufacturers are subject to ongoing periodic unannounced inspection by the FDA to ensure compliance with these regulations. Any failure to comply with applicable regulations may result in fines and civil penalties, suspension of production, product seizure or recall, imposition of a consent decree, or withdrawal of product approval, and would limit the availability of IV meloxicam. Any manufacturing defect or error discovered after IV meloxicam has 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.

While we have scaled up our commercial manufacturing of IV meloxicam in anticipation of a potential commercial launch, due to the delay in our anticipated commercial launch of IV meloxicam as a result of the CRL, we have launch

stock of IV meloxicam that, depending on the approved expiration date, could be unable to be sold or could be sold but returned by our wholesalers if expired prior to final sale. A significant amount of expired product or returned product could impact the success of our commercial launch of IV meloxicam, if approved.

If, as a result of any of these issues, we are unable to supply the required commercial quantities of IV meloxicam to support commercial launch and meet market demand for IV meloxicam, if approved, on a timely basis or at all, we may suffer damage to our reputation and commercial prospects and we will lose potential revenues.

The commercial success of IV meloxicam and our other product candidates will depend upon the acceptance of these products by the medical community, including physicians, patients, health care payers and hospital formularies.

Physicians may not prescribe IV meloxicam or any of our other product candidates if approved by the FDA, in which case we would not generate the revenues we anticipate. The degree of market acceptance of any of our product candidates will depend on a number of factors, including:

- demonstration of clinical safety and efficacy;
- the prevalence and severity of any AEs;
- the indications for which each of our product candidates are approved, including any dosing instructions and potential additional restrictions placed on each product candidate in connection with its approval;
- limitations or warnings contained in the FDA-approved label for each product candidate;
- the results of our ongoing Phase IIIb clinical trials for IV meloxicam;
- relative convenience and ease of administration of our product candidates;
- prevalence of the condition for which each product candidate is approved;
- availability of alternative treatments and perceived advantages of our product candidates over such alternative treatments;
- the proposed sales price and cost-effectiveness of IV meloxicam and the availability of adequate third-party coverage and reimbursement;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- our ability to convince hospitals to include IV meloxicam and our other product candidates on their list of authorized products, referred to as formulary approval;
- consolidation among healthcare providers, which increases the impact of the loss of any relationship;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

In addition, market acceptance of IV meloxicam could be negatively impacted by any negative perception physicians may have of IV meloxicam following announcement of the CRL received from the FDA for IV meloxicam, even if subsequently resolved. If IV meloxicam or any of our other product candidates are approved but do not achieve an adequate level of acceptance by physicians, patients and healthcare payers, we may not generate sufficient revenue and we may not become or remain profitable.

If third-party payers do not reimburse physicians or patients for IV meloxicam or our other product candidates or if reimbursement levels are, or pricing pressures cause the sales price to be, set too low for us to sell IV meloxicam or our other product candidates at a profit, our ability to successfully commercialize IV meloxicam or our other product candidates and our results of operations will be harmed.

Our ability to commercialize IV meloxicam or our other product candidates successfully will depend in part on the extent to which coverage and adequate reimbursement for such products, once approved, will be available in a timely manner from third-party payers, including governmental healthcare programs such as Medicare and Medicaid, commercial health insurers and managed care organizations and other pricing limitations such as mandatory rebates or discounts. Reimbursement and pricing limitations may hinder our ability to recoup our investment in IV meloxicam and our other product candidates, even if approved.

Government authorities and other third-party payers, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. Reimbursement decisions by particular third-party payers depend upon a number of factors, including each third-party payer's determination that use of a product is:

- a covered benefit under its health plan;
- appropriate and medically necessary for the specific condition or disease;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for IV meloxicam or our other product candidates from government authorities or other third-party payers may be a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data, including expensive pharmacoeconomic studies beyond the data required to obtain marketing approval, for the use of IV meloxicam or our other product candidates to each government authority or other third-party payer. For example, if our ongoing Phase IIIb clinical trials for IV meloxicam in colorectal surgery patients and orthopedic surgery patients do not show improved outcomes relative to the current standard of care, obtaining payer coverage could be more difficult. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. In addition, acceptance by third-party payers could be negatively impacted by any negative perception third-party payers may have of IV meloxicam following announcement of the CRL received from the FDA for IV meloxicam, despite subsequent FDA approval.

Third-party payers may deny reimbursement for covered products if they determine that a medical product was used for an unapproved indication. Third-party payers may also limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. Failure to obtain timely hospital formulary approval will limit our commercial success, and obtaining such approval can be an expensive and time-consuming process. We cannot be certain if and when we will obtain the formulary approvals to allow us to sell our products into our target markets, nor, if formulary approval is obtained, at what price our products will be accepted for sale and reimbursement.

Increasingly, third-party payers are also requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. These third-party payers could also impose price controls restricting the prices at which the products will be reimbursed and other conditions that must be met by patients prior to providing coverage for the use of IV meloxicam or our other product candidates.

Third-party payers are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for medical products and services, which can impact the demand for, or the price of, such products and services. The process for determining whether a payer will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payer will pay for the product once coverage is approved. Levels of reimbursement may also decrease in the future, due to the availability of numerous generic pain medications available at lower costs or future legislation, regulation or reimbursement policies of third-party payers which may adversely affect the demand for and reimbursement available for IV meloxicam or our other product candidates, which in turn, could negatively impact pricing. If patients are not adequately reimbursed for IV meloxicam or our other product candidates, they may reduce or discontinue purchases of it.

Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government

healthcare programs or private payers and by any future relaxation of laws that presently restrict imports of drugs from policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payers for IV meloxicam and our other product candidates, if approved, could result in a significant shortfall in achieving revenue expectations, prevent us from achieving profitability and negatively impact our business, prospects and financial condition

Legislative or regulatory programs that may influence prices of prescription drugs could have a material adverse effect on our ability to successfully commercialize IV meloxicam and our other product candidates.

Current or future federal or state laws and regulations may influence the prices of drugs and, therefore, could adversely affect the prices that we receive for IV meloxicam or our other product candidates, if approved. Programs in existence in certain states seek to set prices of all drugs sold within those states through the regulation and administration of the sale of prescription drugs. Expansion of these programs, in particular, state Medicaid programs, or changes required in the way in which Medicaid rebates are calculated under such programs, could adversely affect the price we receive for IV meloxicam or our other product candidates, if approved, and could have a material adverse effect on our business, results of operations and financial condition.

Further, the pharmaceutical industry has in recent years been the subject of significant publicity regarding the pricing of pharmaceutical products, including publicity and pressure resulting from prices charged by pharmaceutical companies for new products as well as price increases by pharmaceutical companies on older products that the public has deemed excessive. Any downward pricing pressure on the price of IV meloxicam or our other product candidates, if approved, arising from social or political pressure to lower the cost of pharmaceutical products could have a material adverse impact on our business, results of operations and financial condition. As a result, pharmaceutical product prices have been the focus of increased scrutiny by the government, including certain state attorneys general, members of congress and the United States Department of Justice. Decreases in health care reimbursements or prices of IV meloxicam or our other product candidates, if approved, could limit our ability to sell our IV meloxicam or our other product candidates, if approved, or decrease our revenues, which could have a material adverse effect on our business, results of operations and financial condition.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell IV meloxicam or our other product candidates, we may be unable to generate any revenue for IV meloxicam or our other product candidates.

In anticipation of the approval and commercialization of IV meloxicam, we have begun to build out our sales, marketing and distribution capabilities, and will need to continue to do so. Our sales force expansion was negatively impacted by our receipt of a CRL with respect to IV meloxicam and the delay in potential commercialization of IV meloxicam to 2019. We were forced to withdraw many of the offers of employment we had made to sale force representatives in anticipation of a 2018 commercial launch. We will need to hire additional sales personnel, and, due to the CRL and other market dynamics, this recruitment and hiring may be more difficult.

In addition, we may discover that the cost of continuing to establish, expand and maintain such sales force may exceed the cost-effectiveness of doing so. In order to market IV meloxicam, if approved, we must continue to build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. We intend to enter into strategic partnerships with third parties to commercialize our product candidates outside of the United States. We will also consider the option to enter into strategic partnerships for certain product candidates in the United States.

To date, we have not entered into any strategic partnerships for any of our product candidates. We face significant competition in seeking appropriate strategic partners, and these strategic partnerships can be intricate and time-consuming to negotiate and document. We may not be able to negotiate strategic partnerships on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any strategic partnerships because of the numerous risks and uncertainties associated with establishing strategic partnerships.

Our strategy for IV meloxicam is to develop a specialty sales force and/or collaborate with third parties to promote the product to healthcare professionals and third-party payers in the United States. Our future collaboration partners, if any, may not dedicate sufficient resources to the commercialization of our product candidates or may otherwise fail in their commercialization due to factors beyond our control. If we are unable to establish effective collaborations to enable the sale of our product candidates to healthcare professionals and in geographic regions, including the United States, that will not be covered by our own marketing and sales force, or if our potential future collaboration partners do not successfully commercialize our product candidates, our ability to generate revenues from product sales will be adversely affected.

If we are unable to negotiate a strategic partnership or obtain additional financial resources for our other product candidates, we may be forced to curtail the development of them, delay potential commercialization, reduce the scope

of our sales or marketing activities or undertake development or commercialization activities at our own expense. In addition, without a partnership, we will bear all the risk related to the development of these other product candidates. If we elect to increase our expenditures to fund development or commercialization activities ourselves, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring our other product candidates to market or generate product revenue from them, which could have a material adverse effect on our business, financial condition and results of operations.

We are subject to intense competition and, if we are unable to compete effectively, IV meloxicam or any of our other product candidates may not reach their commercial potential.

The market for our product candidates is characterized by intense competition and rapid technological advances. If our product candidates obtain FDA approval, they will compete with a number of existing and future pharmaceuticals and drug delivery devices developed, manufactured and marketed by others. We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations.

In the post-operative pain relief setting, we believe patients are prescribed injectable acetaminophen, NSAIDs, sodium channel blockers and opioids, depending on the severity of pain. Specifically, acetaminophen, NSAIDs and sodium channel blockers, we believe, are prescribed for mild to moderate pain relief, whereas we believe opioids are prescribed for moderate to severe pain relief. While we will compete with all of these compounds in the post-operative pain setting, we believe IV meloxicam will be prescribed for moderate to severe pain, competing with opioids and other non-opioid pain treatments. There are a number of pharmaceutical companies that currently market and/or manufacture therapeutics in the pain relief area, including Johnson & Johnson, Purdue Pharma, L.P., Mallinckrodt plc, Teva Pharmaceutical Industries, Inc. and Pacira Pharmaceuticals, Inc. and AcelRx Pharmaceuticals, Inc. Purdue is the primary competitor in the manufacture of opioid therapeutics. Mallinckrodt commercializes an injectable formulation of acetaminophen. Pacira commercializes an intraoperative formulation of bupivacaine, a sodium channel blocker. Additionally, companies such as Adynxx, Inc., Durect Corporation, Heron Therapeutics, Inc., Innocoll Holdings plc, Sandoz AG, Trevena, Inc. and Cara Therapeutics, Inc. are currently developing post-operative pain therapeutics that could compete with us in the future.

More established companies may have a competitive advantage over us due to their greater size, cash flows and institutional experience. Compared to us, many of our competitors may have significantly greater financial, technical and human resources. As a result of these factors, our competitors may have an advantage in marketing their approved products and may obtain regulatory approval of their product candidates before we are able to do so, which may limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are safer, more effective, more widely used and less expensive than ours, and our competitors may also be more successful than we are in manufacturing and marketing their products. These advantages could materially impact our ability to develop and commercialize IV meloxicam and our other product candidates successfully.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We anticipate that we will face intense and increasing competition as new drugs enter the market and additional technologies become available in the pain management and relief space. Finally, the development of different methods for the treatment of acute pain following surgery could render injectable meloxicam non-competitive or obsolete. These and other risks may materially adversely affect our ability to attain or sustain profitable operations.

If we obtain approval to commercialize our products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If our product candidates are approved for commercialization, we may enter into agreements with third parties to market IV meloxicam or other product candidates outside the United States. We expect that we will be subject to

additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- lower pricing of products in our market segment or in general; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

The realization of any of these risks would negatively affect our ability to attain or sustain profitability.

Our relationships with physicians, patients and payers in the U.S. are subject to applicable anti-kickback, fraud and abuse laws and regulations. Our failure to comply with these laws could expose us to criminal, civil and administrative sanctions, reputational harm, and could harm our results of operations and financial conditions.

Our current and future operations with respect to the commercialization of IV meloxicam and our other product candidates are subject to various U.S. federal and state healthcare laws and regulations. These laws impact, among other things, our proposed sales, marketing, support and education programs and constrain our business and financial arrangements and relationships with third-party payers, healthcare professionals and others who may prescribe, recommend, purchase or provide IV meloxicam or our other product candidates, and other parties through which we market, sell and distribute IV meloxicam or our other product candidates. Finally, our current and future operations are subject to additional healthcare-related statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws are described in greater detail in the section below under "Business Government Regulation — Other Healthcare Laws and Compliance Requirements," and include, but are not limited to:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, or arranging for or recommending the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
    - the U.S. civil False Claims Act (which can be enforced through "qui tam," or whistleblower actions, by private citizens on behalf of the federal government), prohibits any person from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the U.S. federal government;
- HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for healthcare benefits, items or services by a healthcare benefit program, which includes both government and privately funded benefits programs; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.
- state laws and regulations, including state anti-kickback and false claims laws, that may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payer, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may

be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and

- the Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS information related to certain payments made in the preceding calendar year and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance or reporting requirements in multiple jurisdictions increases the possibility that a healthcare or pharmaceutical company may fail to comply fully with one or more of these requirements. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with applicable fraud and abuse or other healthcare laws and regulations or guidance. In addition, the complex framework of laws and regulations at the federal and state law are subject to change, which could lead to non-compliance or additional costs in updating our compliance mechanism to reflect these changes. For example, several states have enacted laws or regulations affecting or restricting payments that pharmaceutical manufacturers or distributors can make to physicians and other drug prescribers. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional oversight and reporting requirements if we become subject to a corporate integrity agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to the same criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our financial condition and divert resources and the attention of our management from operating our business.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity in addition to the aforementioned potential regulatory actions. The occurrence of any event or penalty described above may inhibit our ability to commercialize IV meloxicam or our other product candidates and generate revenues which would have a material adverse effect on our business, financial condition and results of operations.

If we are able to successfully commercialize IV meloxicam or our other product candidates and if we participate in but fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program, or other governmental pricing programs, we could be subject to additional pricing pressures and controls, reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

If we participate in the Medicaid Drug Rebate Program, and other governmental pricing programs, we will be obligated to pay certain specified rebates and report pricing information with respect to IV meloxicam or our other product candidates. Pricing and rebate calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies and the courts. We cannot assure you that our submissions will not be found by the CMS to be incomplete or incorrect. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. The Medicaid rebate amount is computed each quarter based on our submission to CMS of our current AMP and best price for the quarter. If we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for a period not to exceed twelve quarters from the quarter in which the data originally were due, and CMS may request or require restatements for earlier periods as well. Such restatements and recalculations increase our costs for complying with

the laws and regulations governing the Medicaid Drug Rebate Program. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. Price recalculations also may affect the ceiling price at which we are required to offer our products to certain covered entities, such as safety-net providers, under the 340B program, and other similar government pricing programs. These programs are described in greater detail in the section below under "Business — Government Regulation — Third-Party Payer Coverage and Reimbursement."

We will also be liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted false AMP, or best price information to the government, we may be liable for civil monetary penalties in the amount of $181,071 per item of false information. If we are found to have made a misrepresentation in the reporting of our average sales price, we may be liable for civil monetary penalties of up to $13,066 for each misrepresentation for each day in which the misrepresentation was applied. Our failure to submit monthly/quarterly AMP and best price data on a timely basis could result in a civil monetary penalty of $18,107 per day for each day the information is

late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, federal payments may not be available under Medicaid for IV meloxicam or our other product candidates. A final regulation imposes a civil monetary penalty of up to $5,000 for each instance of knowingly and intentionally charging a 340B covered entity more than the 340B ceiling price.

Federal law requires that a company must participate in the FSS pricing program to be eligible to have its products paid for with federal funds. As part of this program, we would be obligated to make IV meloxicam or our other product candidates available for procurement on an FSS contract, under which we must comply with standard government terms and conditions and charge a price that is no higher than the statutory Federal Ceiling Price to four federal agencies (VA, DOD, Public Health Service, and U.S. Coast Guard). The Federal Ceiling Price is based on the Non-Federal Average Manufacturer Price, which we calculate and report to the VA on a quarterly and annual basis. If we overcharge the government in connection with our FSS contract or Section 703 Agreement, whether due to a misstated Federal Ceiling Price or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the U.S. civil False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The Affordable Care Act and any changes in healthcare law may increase the difficulty and cost for us to commercialize IV meloxicam or our other product candidates and affect the prices we may obtain.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of IV meloxicam or our other product candidates or restrict or regulate post-approval activities and affect our ability to profitably sell IV meloxicam or our other product candidates for which we obtain marketing approval. The United States government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs.

The Affordable Care Act was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. These intended reforms are described in greater detail in the section below under “Business — Government Regulation — United States Healthcare Reform.”

Among the provisions of the Affordable Care Act that have been implemented since enactment and are of importance to the commercialization of IV meloxicam or our other product candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs or biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the U.S. civil False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer’s outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers’ Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- requirements to report certain financial arrangements with physicians and teaching hospitals;

- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There have been significant ongoing efforts to modify or eliminate the Affordable Care Act. For example, the Tax Act enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code, commonly referred to as the individual mandate. Further legislative changes to and regulatory changes under the Affordable Care Act remain possible. It is unknown what form any such changes or any law proposed to replace the Affordable Care Act would take, and how or whether it may affect our business in the future.

We expect that the Affordable Care Act, as well as other healthcare reform measures that have and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved products and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

Our business, financial condition, and results of operations are subject to risks arising from the international scope of our manufacturing and supply relationships.

Some of the contract manufacturers of product candidates manufacture and source raw materials outside the United States and we may, in the future, use manufacturers outside the United States for our other product candidates. As such, we are subject to risks associated with such international manufacturing relationships, including:

- unexpected changes in regulatory requirements;
- problems related to markets with different cultural biases or political systems;
- possible difficulties in enforcing agreements in multiple jurisdictions;
- longer payment cycles and shipping lead-times;
- increased risk relating to the transport of products internationally, including damage to our product, shipment delays relating to the import or export of our products or the delivery of our products by means of additional third-party vendors;
- difficulties obtaining export or import licenses for our products;
- compliance with the U.S. Foreign Corrupt Practices Act and other laws and regulations governing international trade;
- fluctuations in foreign currency exchange rates;
- changes to U.S. and foreign trade policies, including the enactment of tariffs on goods imported into the United States.; and
- imposition of domestic and international customs and tariffs, withholding or other taxes, including any value added taxes.

Additionally, we are subject to periodic reviews and audits by governmental authorities responsible for administering import/export regulations. To the extent that we are unable to successfully defend against an audit or review, we may be required to pay assessments, penalties, and increased duties on products imported into the United States.

Risks Related to Our Reliance on Third Parties

Relying on third-parties to manufacture our product candidates exposes us to risks that may delay testing, development, regulatory approval, commercialization and overall manufacturing of our product candidates.

We currently lack the internal resources to manufacture injectable meloxicam and our other product candidates and we rely on third-party suppliers and contract manufacturers to manufacture injectable meloxicam. For example, Alkermes is currently our sole supplier of bulk injectable meloxicam formulation and is the only established supplier of bulk injectable meloxicam formulation. We have committed to purchase our current requirements of injectable meloxicam formulation from Alkermes, and we have commissioned dedicated space in Alkermes' manufacturing facility for the production of bulk injectable meloxicam. Patheon provides sterile fill and finish services, and we have committed to purchase a certain percentage of our annual requirements of sterile fill and finish services from Patheon. Our agreement with Patheon also obligates us to a minimum annual order quantity, which, if higher than the commercial demand for IV meloxicam, if approved, could expose us to increased costs. Although our supply agreement and manufacturing agreements for injectable meloxicam and our other product candidates allow us to qualify and purchase from an alternative supplier or manufacturer in certain circumstances, it would be time-consuming and expensive for us to do so, and there can be no assurance that an alternative supplier could be found. The number of potential manufacturers that have the necessary equipment, expertise and governmental licenses to produce our product candidates is limited. If we encounter any issues with our contract manufacturers or choose to engage a new supplier or contract manufacturer for any of our product candidates, we would need to qualify and obtain FDA approval for another contract manufacturer or supplier as an alternative source for these products and services, which could be costly and cause significant delays.

Our reliance on a limited number of third-party manufacturers also exposes us to the following risks:

- third-party manufacturers might be unable to manufacture our products in the volume and of the quality required to meet our clinical and commercial needs, if any;
- contract manufacturers may not perform as agreed, and operate their business independently from us. Contract manufacturers are directly responsible for their own FDA cGMP interactions and we may not be privy to all ongoing discussions and information concerning products or process unrelated to us. Additionally, contract manufacturers may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute our products;
- product manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the DEA, and corresponding state agencies to ensure strict compliance with cGMP and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards and our manufacturers may be found to be in noncompliance with certain regulations, which may impact our ability to manufacture our drug product candidates and may impact the regulatory status of our product candidates; and
- if any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation.

Each of these risks could delay our preclinical studies and clinical trials, the submission of regulatory applications or the approval, if any, of our product candidates by the FDA, or the commercialization of our product candidates or could result in higher costs or deprive us of potential product revenues. If we do not successfully navigate each of these risks in a timely manner or at all, we could experience significant delays or an inability to successfully develop and commercialize our product candidates, which would materially harm our business.

If third-party service providers, including carriers, logistics providers and distributors, fail to devote sufficient time and resources to IV meloxicam or their performance is substandard, our product launch may be delayed and our costs may be higher than expected.

Our reliance on third-party service providers, including carriers, logistics providers and distributors, exposes us to risks which could delay or impair the commercialization of IV meloxicam or our other product candidates, result in higher costs, or deprive us of potential product revenues. Our carriers may experience technical issues relating to the timing and shipment of our products, may encounter issues in connection with transporting our products internationally, or may become subject to other transit difficulties that could cause loss or damage to our products, some of which may not be adequately covered under our insurance policies. Our third-party logistic providers may experience difficulty in providing key services relating to customer service, warehousing, inventory management, distribution services, contract management, chargeback processing, accounts receivable management, cash application

and financial management. Our distributors could become unable to sell and deliver IV meloxicam or our other product candidates for regulatory, compliance and other reasons. Our carriers, logistics providers, distributors and other third-party service providers may not perform as agreed or may not remain in business for the time required to successfully ship, store, deliver, sell and distribute our products and we may incur additional cost. Any of our vendors could also default on or terminate their agreements with us, which could delay or impair the commercialization of IV meloxicam or our other product candidates, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Issues with product quality could have a material adverse effect upon our business, subject us to regulatory actions and cause a loss of customer confidence in us or our products.

Our success depends upon the quality of our products. Quality management plays an essential role in meeting customer requirements, preventing defects, improving our product candidates and services and assuring the safety and efficacy of our product candidates. Our future success depends on our ability to maintain and continuously improve our quality management program. A quality or safety issue may result in adverse inspection reports, warning letters, product recalls or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, costly litigation, refusal of a government to grant approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses. An inability to address a quality or safety issue in an effective and timely manner may also cause negative publicity, a loss of customer confidence in us or our future products, which may result in difficulty in successfully launching product candidates and the loss of sales, which could have a material adverse effect on our business, financial condition, and results of operations.

Manufacturing issues may arise that could increase product and regulatory approval costs or delay commercialization.

As we scale up manufacturing of IV meloxicam or our other product candidates and conduct required stability testing, issues may arise involving product-packaging and third-party equipment malfunctions. These issues may require refinement or resolution in order to proceed with commercial marketing of IV meloxicam or our other product candidates. In addition, quality issues may arise during scale-up and validation of commercial manufacturing processes. Any issues in our product or delivery devices could result in increased scrutiny by regulatory authorities, delays in our regulatory approval process, increases in our operating expenses, or failure to obtain or maintain approval for our products, which could have a material adverse effect on our business, financial condition, and results of operations.

We use third parties to assist with conducting, supervising and monitoring portions of our nonclinical and clinical studies, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We use third parties to provide certain manufacturing and operational support and for assistance with clinical trials, data management and statistical support. While we have agreements governing their activities, we have limited influence over certain of these third parties' actual performance. We have previously relied upon such third parties and plan to continue to use third parties to assist with monitoring and managing data for our ongoing clinical programs for IV meloxicam and our other product candidates, as well as the execution of nonclinical studies. We control only certain aspects of our third parties' activities.

We and our contractors are required to comply with GLPs and cGCPs, which are regulations and guidelines enforced by the FDA and equivalent regulatory authorities in other countries for all of our product candidates in development. The FDA and the equivalent regulatory authorities in other countries enforce these GLPs and cGCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our contractors fail to comply with applicable GLPs and cGCPs, the data generated in our nonclinical studies and clinical trials may be deemed unreliable and the FDA may require us to perform additional studies or clinical trials before approving our

marketing applications. In addition, our clinical trials for our product candidates will require a sufficiently large number of test subjects to evaluate the safety and effectiveness of each product candidate. Accordingly, if our contractors fail to comply with these regulations or fail to recruit a sufficient number of patients, we may be required to repeat the clinical trials, which would delay the regulatory approval process.

These contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities that could harm our competitive position. While we take steps to protect our intellectual property, we face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by our contractors, which may allow our potential competitors to access our proprietary technology. If our contractors do not successfully carry out their contractual duties or obligations or fail to meet expected deadlines for items within their purview, or if the quality or accuracy of the clinical data they oversee is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize IV meloxicam or our other product candidates. As a result, our financial results and the commercial prospects for IV meloxicam and any future product candidates that we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

Risks Related to Our CDMO Segment

Revenues from our development, formulation and manufacturing business are dependent on a small number of commercial partners, and the loss of any one of these partners, or a decline in their orders, may adversely affect our business.

Our CDMO segment is dependent on our relationships with a small number of commercial partners, with our four largest customers (Novartis AG, Teva Pharmaceutical Industries, Inc., Pernix and Lannett Company, Inc.) having generated 99% of our revenues for the year ended December 31, 2018, of which Teva Pharmaceutical Industries, Inc. generated 48% of our revenue under one customer agreement and Novartis Pharma AG generated 38% of our revenue combined under two separate customer agreements (combined into one agreement effective January 1, 2019). The Teva contact renews on an annual basis. Other contracts range from three to five years. If any one or more of these commercial partners fails to renew their contract, faces increasing or new competition in their market, adjusts pricing, significantly reduces their purchasing volume or experiences financial difficulties such as bankruptcy, our revenues could be adversely affected. We are actively seeking to develop new customer relationships; but there can be no guarantee that we will be able to expand our customer base.

Our royalty, profit sharing and manufacturing revenues from this business also depend on the ability of our commercial partners to effectively market and sell their products to their customers. A commercial partner may choose to devote its efforts to its other products or reduce or fail to devote the necessary resources to provide effective sales and marketing support for the products we manufacture and supply. Our commercial partners face competition from other pharmaceutical companies for sales of products to end users. Competition from sellers of generic drugs is a major challenge for our commercial partners, and the loss or expiration of intellectual property rights for the products we manufacture can have a significant adverse effect on their sales volume. This and any other significant reduction, delay or cancellation of orders from our commercial partners could adversely affect our revenues.

In addition, the financial covenants in our credit agreement with Athyrium include minimum revenue targets for our CDMO segment, and any significant reduction, delay or cancellation of orders from our commercial partners may cause us to fail to meet such targets, which may result in an event of default under the credit agreement with Athyrium and could have a material adverse effect on our business, financial condition and results of operation.

We are subject to risks related to large-scale commercial manufacturing.

Manufacturing pharmaceuticals, especially in large quantities, is complex. The products we manufacture for our commercial partners require several manufacturing steps and may involve complex techniques to assure quality and sufficient quantity. Our manufactured products must be made consistently and in compliance with a clearly defined manufacturing process. Slight deviations anywhere in the manufacturing process, including obtaining materials, equipment malfunctions, filling, labeling, packaging, storage, shipping, regulatory compliance, quality control and testing, some of which all pharmaceutical manufacturing companies experience from time to time, may result in lot failures, delay in the release of lots, product recalls or spoilage. Success rates can vary dramatically at different stages of the manufacturing process, which can lower yields and increase costs.

In addition, some of the raw materials needed for the manufacture of our products are currently available from a single source or a limited number of qualified sources of these products. Although we attempt to acquire an adequate inventory of such materials, establish alternative sources and/or negotiate long-term supply arrangements, there is no certainty that we will be able to obtain long-term supplies of our manufacturing materials in the future. We may also experience deviations in the manufacturing process or interruptions in our supply chain that may take significant time and resources to resolve and, if unresolved, may affect manufacturing output and/or cause us to fail to satisfy customer orders or contractual commitments or result in litigation or regulatory action.

Our manufacturing facilities also require specialized personnel and are expensive to operate and maintain. Any suspension of the sale of products of our commercial partners to be manufactured in our facilities may cause operating losses as we continue to operate the facilities and retain specialized personnel. In addition, any interruption in manufacturing could result in delays in meeting our contractual obligations and could damage our relationships with our commercial partners, including the loss of manufacturing and supply rights, which could have a material adverse effect on our business, financial condition, and results of operations.

Our CDMO segment is highly-leveraged.

As of December 31, 2018, we had an outstanding balance under our credit agreement with Athyrium of $70 million, which is secured primarily by the assets of our CDMO segment. Our credit agreement with Athyrium contains certain financial and other covenants, including a minimum liquidity requirement and a trailing four-quarter revenue requirement and maximum leverage ratios. In addition, it includes limitations on, among other things, additional indebtedness, acquisitions and certain investments. The credit agreement provides for certain mandatory prepayment events, including with respect to the proceeds of asset sales, extraordinary receipts, debt issuances and other specified events, based on the terms of the credit agreement with Athyrium. Any failure to comply

with the terms, covenants and conditions may result in an event of default under such agreement, which could allow Athyrium to foreclose on the assets of the CDMO segment, which could have a material adverse effect on our business, financial condition and results of operation. In addition, any sale of our CDMO segment would require repayment of the Athyrium credit facility, including and prepayment penalties applicable, which could significantly decrease the proceeds of any such sale, which could have a material adverse effect on our financial condition.

Our development and formulation services projects are typically for a shorter term than our manufacturing projects, and any failure by us to maintain an adequate volume of development and formulation services projects, including due to lower than expected success rates of the products for which we provide services, could have a material adverse effect on our business, results of operations and financial condition.

Our pharmaceutical development services business contracts are generally shorter in term than our manufacturing contracts and typically require us to provide development services within a designated scope. Since our development and formulation services focus on products that are still in developmental stages, their viability depends on the ability of such products to reach their respective subsequent development phases. In many cases, such products do not reach subsequent development phases and, as a result, the profitability of the related pharmaceutical development service project may be limited. Even if a customer wishes to proceed with a project, the product we are developing on such customer's behalf may fail to receive necessary regulatory approval or may have its development hindered by other factors, such as the development of a competing product.

If we are unable to continue to obtain new projects from existing and new customers, our development and formulation services business could be adversely affected. Furthermore, although our development and formulation services business may act as a pipeline for our manufacturing services business, we cannot predict the conversion rate of our development and formulation services projects to commercial manufacturing services projects, or how successful we will be in winning new projects that lead to a viable product. As such, an increase in the turnover rate of our development and formulation services projects may not benefit our manufacturing services business at a later time. In addition, the discontinuation of a project as a result of our failure to satisfy a customer's requirements may also affect our ability to obtain future projects from such customer, as well as from new customers. Any failure by us to maintain a high volume of development and formulation services projects could have a material adverse effect on our business, results of operations and financial condition.

If we fail to meet the stringent requirements of governmental regulation in the manufacture of pharmaceutical products, we could incur substantial costs and a reduction in revenues.

We are required to maintain compliance with cGMP, and our manufacturing facilities are subject to inspections by the FDA and other global regulators to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application(s) to the FDA and acceptance of the change by the FDA prior to release of our manufactured products. Because we produce multiple products at our manufacturing facilities, there are increased risks associated with cGMP compliance. On January 24, 2018, following a six-day inspection of our primary manufacturing facility, the FDA issued a Form 483 containing four observations relating to good documentation practices and data integrity. We have promptly responded to these observations as a part of our ongoing obligations under the FDA's quality system regulation and have implemented corrective and preventative actions to ensure these type of observations do not occur in the future. While we remain committed to continuous improvement and strengthening our quality system and ensuring that all aspects of the system are in full compliance, we can provide no assurance that we will not encounter future inspections resulting in observations not acceptable by the FDA.

Our inability to demonstrate ongoing cGMP compliance could require us to engage in additional lengthy and expensive remediation efforts, withdraw or recall products and/or interrupt commercial supply of any products. Any

delay, interruption or other issue that arises in the manufacture, fill/finish, packaging, or storage of any drug product as a result of a failure of our facilities to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our relationships with our commercial partners, which would substantially harm our business, prospects, operating results and financial condition. Any ongoing or additional findings of non-compliance could also increase our costs and cause us to lose revenue from manufactured products, which could be seriously detrimental to our business, prospects, operating results and financial condition.

Additionally, our manufacturing activities are subject to the Controlled Substances Act and the regulations of the DEA. Accordingly, we must adhere to a number of requirements with respect to controlled substances, including registration, recordkeeping and reporting requirements; labeling and packaging requirements; security controls, procurement and manufacturing quotas; and certain restrictions on refills. Failure to maintain compliance with applicable requirements can result in an enforcement action that could have a material adverse effect on our business, financial condition, operating results and cash flows. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In certain circumstances, violations could result in criminal proceedings.

We manufacture opioid products, which are subject to additional regulation by state and federal law enforcement and other regulatory agencies.

We manufacture opioid products, including Zohydro ER, an extended-release opioid treatment, containing hydrocodone. The U.S. government and state legislatures have prioritized combatting the growing misuse and addiction to opioids such as hydrocodone and have enacted legislation and regulations as well as other measures intended to fight the opioid epidemic. Addressing prescription drug abuse is a priority for the current U.S. administration and the FDA and is part of a broader initiative led by the Department of Health and Human Services. Overall, there is greater scrutiny of entities involved in the manufacture, sale and distribution of opioids. These initiatives, existing regulations, and any negative publicity related to opioids may have a material impact on our business and our ability to manufacture opioid products.

Opioids are controlled substance regulated by the DEA. The amount of Schedule II substances that can be obtained is limited by the CSA and DEA regulations. For 2019, the DEA has proposed decreased manufacturing quotas for the six most frequently misused opioids, including hydrocodone, by an average of 10% as compared to the 2018 quotas. If limited supply of opioids impacts demand for products of our partners, our revenues may be adversely impacted. In addition to DEA regulations, the U.S. government and states have enacted other laws that seek to promote improved monitoring of opioids and to increase funding for research and development of non-addictive painkillers. Legislation has also been proposed that would further limit the ability to sell and prescribe opioids. These efforts may result in an additional reduction of demand for opioid products or government action against us if we fail to comply with these laws and could have a material adverse effect on our business.

We may not be able to successfully offer new services.

In order to successfully compete, we will need to offer and develop new services. Without the timely introduction of enhanced or new services, our services and capabilities may become obsolete over time, in which case, our revenues and operating results would suffer. The related development costs may require a substantial investment before we can determine their commercial viability, and we may not have the financial resources to fund such initiatives.

In addition, the success of enhanced or new services will depend on several factors, including but not limited to our ability to:

- properly anticipate and satisfy customer needs, including increasing demand for lower cost services;
- enhance, innovate, develop and manufacture new offerings in an economical and timely manner;
- differentiate our deliverables from competitors' offerings;
- meet quality requirements, authorization requirements, and other regulatory requirements of government agencies;
- obtain valid and enforceable intellectual property rights; and
- avoid infringing the proprietary rights of third parties.

Even if we were to succeed in creating enhanced or new services, those services may not result in commercially successful offerings or may not produce revenues in excess of the costs of development and capital investment and may be quickly rendered obsolete by changing customer preferences or by technologies or features offered by our competitors. In addition, innovations may not be accepted quickly in the marketplace due to, among other things, entrenched patterns of clinical practice, the need for regulatory clearance and uncertainty over market access or government or third-party reimbursement. If we are not able to offer new services and effectively compete, our business, financial condition, and results of operations could be negatively impacted.

Technological change may cause our offerings to become obsolete over time. A decrease in our customers' purchases of our offerings could have a material adverse effect on our business, results of operations and financial condition.

The healthcare industry is characterized by rapid technological change. Demand for our services may change in ways that we may not anticipate because of evolving industry standards or as a result of evolving customer needs that are increasingly sophisticated and varied or because of the introduction by competitors of new services and technologies. In addition, we require capital and resources to support the maintenance and improvement of our facilities, including replacing or repairing aging production equipment and updating overall facility master plans. If we are unable to maintain and improve our facilities, we may experience unscheduled equipment downtime and unpredicted machinery failure and become unable to supply our customers with products or services which may affect business continuity. Any such incident or disruption in business continuity could have a material adverse effect on our business, results of operations and financial condition.

We may be adversely affected by natural disasters or other events that disrupt our business operations, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our manufacturing facilities are located in Gainesville, Georgia, where natural disasters or similar events, like hurricanes, blizzards, tornadoes, fires, floods, earthquakes or explosions or large-scale accidents or power outages, could severely disrupt our operations and have a material adverse effect on our business, prospects, results of operations and financial condition. If a disaster, power outage or other event occurred that prevented us from using all or a significant portion of our Gainesville facilities, damaged critical infrastructures, such as manufacturing resource planning and enterprise quality systems, or otherwise disrupted operations at that location, it may be difficult or, in certain cases, impossible for us to continue our development, formulation and manufacturing business for a substantial period of time, which could have a material adverse effect on our business, financial condition, and results of operations.

Currently, we maintain insurance coverage against damage to our property and equipment, and to cover business interruption expenses, in an amount we believe is sufficient for our development, formulation and manufacturing operations. However, there can be no assurance that such insurance will continue to be available on acceptable terms or that such insurance will provide adequate protection against actual losses. Even if we maintain adequate insurance coverage, claims could have a material adverse effect on our financial condition, liquidity and results of operations and on our ability to obtain suitable, adequate or cost-effective insurance in the future.

We must comply with environmental and health and safety laws and regulations, which can be expensive and restrict how we do business.

In connection with our CDMO segment, we are subject to federal, state and local laws, rules, regulations and policies concerning the environment and the health and safety of our employees. Although we believe that we have complied with the applicable laws, regulations and policies in all material respects and have not been required to correct any material noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions, which could have a material adverse effect on our business, financial condition, and results of operations.

In addition, our business conducted by our CDMO segment involves the use, generation and disposal of hazardous materials, including chemicals, solvents, agents and biohazardous materials. As a result, we are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. Although we believe that our safety procedures for storing, handling and disposing of such materials comply with the standards prescribed by those regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. We currently contract with third parties to dispose of these substances that we generate, and we rely on these third parties to properly dispose of these substances in compliance with applicable laws and regulations. If these third parties do not properly dispose of these substances in compliance with applicable laws and regulations, we may be subject to legal action by governmental agencies or private parties for improper disposal of these substances. The costs of defending such actions and the potential liability resulting from such actions are often very large. In the event we are subject to such legal action or we otherwise fail to comply with applicable laws and regulations governing the use, generation and disposal of hazardous materials and chemicals, we could be held liable for any damages that result, and any such liability could exceed our resources. In addition, although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, including those resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. If we become subject to any of the foregoing liabilities, our business, financial condition, and results of operations could

be materially adversely impacted.

Risks Related to Our Business Operations and Industry

We are subject to securities class action litigation, which is expensive, can divert management attention, and, if resolved unfavorably, could expose us to significant liabilities.

On May 24, 2018, we announced the receipt from the FDA of a CRL for our NDA for IV meloxicam. The announcement was followed by a substantial decrease in the trading price of our common stock on the Nasdaq Capital Market. On May 31, 2018, a securities class action lawsuit was filed against us and certain of our officers and directors for alleged violations of Section 10(b) and 20(a) of the Exchange Act and Rule 10(b)(5) promulgated thereunder, based on statements made by us concerning the NDA for IV meloxicam. The complaint seeks unspecified damages, interest, attorneys' fees and other costs. On December 10, 2018, lead plaintiff filed an amended complaint that asserted the same claims and sought the same relief but included new allegations and named additional officers and directors as defendants. On February 8, 2019, we filed a motion to dismiss the amended complaint in its

entirety. We believe that the lawsuit is without merit and intend to vigorously defend against it. The lawsuit is in the early stages and, at this time, no assessment can be made as to its likely outcome or whether the outcome will be material to us. This litigation could result in substantial costs and a diversion of management's resources and attention. In addition, any adverse determination could expose us to significant liabilities, which could have a material adverse effect on our business, financial condition, and results of operations.

We may be subject to additional litigation or government investigations for a variety of claims, which could adversely affect our operating results, harm our reputation or otherwise negatively impact our business.

In addition to our ongoing securities class action litigation, we may be subject to other litigation or government investigations. These may include claims, lawsuits, and proceedings involving product liability, labor and employment, wage and hour, commercial and other matters. The outcome of any litigation or government investigation, regardless of its merits, is inherently uncertain. Any lawsuits or government investigations, and the disposition of such lawsuits and government investigations, could be time-consuming and expensive to resolve and divert management attention and resources. Any adverse determination related to litigation or government investigations could adversely affect our operating results, harm our reputation or otherwise negatively impact our business. In addition, depending on the nature and timing of any such dispute, a resolution of a legal matter or government investigation could materially affect our future operating results, our cash flows or both.

Our future success depends on our ability to retain and have the full attention of our key executives as well as to attract, retain and motivate other qualified personnel.

We are highly dependent on the principal members of our executive team and, in particular, the services of Gerri A. Henwood, our President and Chief Executive Officer, the loss of whose services would adversely impact the achievement of our objectives. We have entered into employment agreements with each of our executive officers. Recruiting and retaining qualified employees for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. In addition, failure to succeed in clinical studies may make it more challenging to recruit and retain qualified personnel. The inability to recruit or loss of the services of any executive or key employee could impede the progress of our research, development and commercialization objectives.

We will need to continue to grow the size of our organization, and we may experience difficulties in managing this growth.

We have begun to grow the size of our managerial, operational, sales, marketing, financial and other resources as we prepare for the potential approval and commercialization of IV meloxicam and the ongoing development of our other product candidates. However, our management, personnel and systems currently in place may not be adequate to support this growth or assist us with the potential growth into a commercial stage pharmaceutical company. As we continue to expand, we may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Additional future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. Future growth would impose significant added responsibilities on members of management, including:

- managing the commercialization of any FDA approved product candidates;
- overseeing our ongoing clinical trials effectively;

- identifying, recruiting, maintaining, motivating and integrating additional employees, including any additional sales and marketing personnel engaged in connection with the commercialization of any approved product, on terms that are favorable to us if at all;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- improving our managerial, development, operational and financial systems and procedures; and
- expanding our facilities.

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As our operations expand, we will need to manage additional relationships with various collaboration partners, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

We may acquire other assets or businesses, or form collaborations or make investments in other companies or technologies, that could have a material adverse effect on our operating results, dilute our shareholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of assets, including preclinical, clinical or commercial stage products or product candidates, businesses or strategic alliances and collaborations, to expand our existing technologies and operations. We may not identify or complete these transactions in a timely manner, on a cost effective basis, or at all, and we may not realize the anticipated benefits of any such transaction, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. We may not be able to find suitable acquisition candidates, and if we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business and we may incur additional debt or assume unknown or contingent liabilities in connection therewith. Integration of an acquired company or assets may also disrupt ongoing operations, require the hiring of additional personnel and the implementation of additional internal systems and infrastructure, especially the acquisition of commercial assets, and require management resources that would otherwise focus on developing our existing business. On April 10, 2015, we completed the acquisition from Alkermes of certain assets, including the worldwide rights to injectable meloxicam and the development, formulation and manufacturing business that comprised our CDMO segment, which we refer to as the Gainesville Transaction. While we have successfully integrated the assets that we purchased in the Gainesville Transaction into our infrastructure, we cannot assure that the experience would be the same for future acquisitions. We may not be able to find suitable strategic alliances or collaborators or identify other investment opportunities, and we may experience losses related to any such investments.

To finance any acquisitions or collaborations, we may choose to issue debt or shares of our common or preferred stock as consideration. Any such issuance of shares would dilute the ownership of our shareholders. If the price of our common stock is low or volatile, we may not be able to acquire other assets or companies or fund a transaction using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

Our employees, partners, independent contractors, principal investigators, consultants, vendors and contract research organizations may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, partners, independent contractors, principal investigators, consultants, vendors and CROs may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these employees could include intentional, reckless and/or negligent conduct or unauthorized activity that violates: (1) FDA or DEA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA; (2) manufacturing standards; (3) federal and state healthcare fraud and abuse laws and regulations; or (4) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. Any incidents or any other conduct that leads to an employee receiving an FDA debarment could result in a loss of business from our partners and severe reputational harm. We have adopted a Code of Business Conduct and Ethics, but it is not always

possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business, operating results and financial condition.

We face potential product liability claims, and, if successful claims are brought against us, we may incur substantial liability.

The use of our product candidates in clinical studies and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. In addition, our CDMO segment exposes us to potential toxic tort and other types of product liability claims that are inherent in the manufacture of pharmaceutical products. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and negative media attention;
- withdrawal of clinical study participants;
- termination of clinical trial sites;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- decreased demand for our manufacturing services or loss of any of our commercial partners;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates;
- decreased demand for our product candidates, if approved for commercial sale; and/or
- increased scrutiny and potential investigation by, among others, the FDA, the Department of Justice, the Office of Inspector General of the U.S. Department of Health and Human Services, State Attorneys General, members of Congress and the public.

Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for our product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts.

On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated AEs. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

We incur increased costs and demands upon our management as a result of complying with the laws and regulations affecting public companies, which could harm our operating results.

We are a public company and, as such, we incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. We incur costs associated with current corporate governance requirements, including certain of the requirements under Section 404 and other provisions of the Sarbanes-Oxley Act of 2002, as well as rules implemented by the SEC and the NASDAQ Capital Market, the stock exchange on which our common stock is listed. If we fail to comply with current corporate governance requirements, our business may be negatively affected, including by having our common stock delisted from the NASDAQ Capital Market.

The expenses incurred by public companies for reporting and corporate governance purposes have increased dramatically in recent years. We expect these rules and regulations to continue to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. We are unable to currently estimate these costs with any degree of certainty. We also expect that these rules and regulations may make it difficult and expensive for us to continue to maintain director and officer liability insurance, and if we are able to maintain

such insurance, we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage available to privately-held companies. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors, or the board, or as our executive officers, which could have a material adverse effect on our business.

The security of our information technology systems may be compromised in the event of system failures, unauthorized access, cyberattacks or a deficiency in our cybersecurity, and confidential information, including non-public personal information that we maintain, could be improperly disclosed.

We rely extensively on information technology and systems including internet sites, data hosting, physical security, and software applications and platforms. Despite our security measures, our information technology systems, some of which are managed by third parties, may be susceptible to damage, disruptions or shutdowns due to computer viruses, attacks by computer hackers, failures during the process of upgrading or replacing software, power outages, user errors or catastrophic events. A significant breakdown, invasion, corruption, destruction or interruption of critical information technology systems, by our employees, others with authorized access to our systems or unauthorized persons could negatively impact or interrupt operations. For example, the loss of data from completed or ongoing clinical trials for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. The use of technology, including cloud-based computing, creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in our systems or our third-party systems. We could also experience a business interruption, theft of confidential information or reputational damage from malware or other cyberattacks, which may compromise our systems or lead to data leakage, either internally or at our third-party providers.

As part of our business, we maintain large amounts of confidential information, including non-public personal information on patients and our employees. The maintenance of such information is governed by various rules and regulations in the jurisdictions in which we conduct our business, including by the General Data Privacy Regulation, or GDPR, in the European Union. Breaches in security, either internally or at our third-party providers, could result in the loss or misuse of this information, which could, in turn, result in potential regulatory actions or litigation, including material claims for damages, interruption to our operations, damage to our reputation or otherwise have a material adverse effect on our business, financial condition and operating results. Although we believe we have appropriate information security policies and systems in place in order to prevent unauthorized use or disclosure of confidential information, including non-public personal information, there can be no assurance that such use or disclosure will not occur.

Any such business interruption, theft of confidential information or reputational damage from malware or other cyberattacks, or violation of personal information laws, could have a material adverse effect on our business, financial condition, and results of operations.

If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity, which could negatively affect our operating results and business.

We are subject to laws and regulations that address privacy and data security of patients who use our product candidates in the United States and in states in which we conduct our business. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act) govern the collection, use, disclosure, and protection of health-related and other personal information. For instance, HIPAA imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information and imposes notification obligations in the event of a breach of the privacy or security of individually identifiable health information on entities subject to HIPAA and their business associates that perform certain activities that involve the use or disclosure of protected health information on their behalf. Certain of these laws and regulations are described in greater detail in the section below under “Business — Government Regulation — Other Healthcare Laws and Compliance Requirements.” Failure to comply with applicable data protection laws and regulations could result in government enforcement actions and create liability for us, which

could include civil and/or criminal penalties, as well as private litigation and/or adverse publicity that could negatively affect our operating results and business.

Risks Related to Our Intellectual Property

We own or license numerous pending patent applications and issued patents in the United States. If our pending patent applications fail to issue or if our issued patents expire or are successfully opposed, invalidated, or rendered unenforceable, our business will be adversely affected.

Our commercial success will depend in part on obtaining and maintaining patent protection for our product candidates, as well as successfully defending our current and future patents against third-party challenges. To protect our proprietary technology, we intend to rely on patents, and we may also rely on other intellectual property protections, including trade secrets, nondisclosure agreements and confidentiality provisions.

There can be no assurance that our pending patent applications will result in issued patents. As of December 31, 2018, we own patents and patent applications for injectable meloxicam that cover compositions, including compositions produced using NanoCrystal® technology, a method of making and method of treating. These issued patents expire in 2022 in the United States. We also in-license from Alkermes, on a perpetual royalty-free basis, composition and methods of making patents, one of which we anticipate to be Orange-Book listable, and patent applications (specifically directed to the prevention of flake like substances) which expire in 2030. As of December 31, 2018, we own or license a total of eight issued U.S. patents and nine U.S. pending patent applications, and 59 issued foreign patents (including European validation countries) and six pending foreign applications related to meloxicam. As of December 31, 2018, we own seven issued U.S. patents relating to Zohydro-ER®, two of which expire on November 1, 2019, and five of which expire on September 12, 2034. We also own Canadian patent applications that are pending relating to the same technology, which we license to our commercial partner, Paladin Labs Inc., in Canada. As of December 31, 2018, we are the owner of record of one issued U.S. patent and 25 issued foreign patents, including European validation countries, to Dex. In addition, we have licensed four patent families containing several U.S. and foreign issued patents and pending applications related to neuromuscular blocking agents from Cornell University. The patent applications that we have filed and have not yet been granted may fail to result in issued patents in the United States or foreign countries. Even if the patents do successfully issue, third parties may challenge the patents or the inventorship thereof, which can lead to an issued patent being found invalid, unenforceable or can otherwise alter the ownership of the patents.

The issuance of any patent is not a certainty. Unless and until our pending applications issue, their protective scope is impossible to determine. It is impossible to predict whether or how many of these applications will result in issued patents and patents that issue may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of patent exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which may limit our ability to prevent others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, upon expiration of a patent, we may be limited in our ability to prevent others from using or commercializing subject matter covered by the expired patents. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

The patent position of biotechnology and pharmaceutical companies, including us, generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after the first filing, or in some case at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. In addition, we may not be aware of particular prior art publications that may have an impact on patentability or enforceability. Further, the examination process may require us or our licensors to narrow the claims for our pending patent applications due to, for example, such prior art publications, which may limit the scope of patent protection that may be obtained if these applications issue. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Furthermore, our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or have licensed from third parties may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges

may result in the loss of patent protection, the narrowing of claims in such patents, and/or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection for our technology and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of patents or narrow the scope of patent protection.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. The Leahy Smith America Invents Act, or the Leahy Smith Act, enacted in September 2011, brought significant changes to the U.S. patent system. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent Office continues to develop and implement new regulations and procedures to govern administration of the Leahy Smith Act, and many of the substantive changes to patent law associated with the Leahy Smith Act became effective on March 16, 2013. The Leahy Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patent, all of which could have a material adverse effect on our business and financial condition.

Litigation involving patents, patent applications and other proprietary rights is expensive and time-consuming. If we are involved in such litigation, it could cause delays in bringing our product candidates to market and interfere with our business.

Our commercial success depends in part on not infringing patents and proprietary rights of third parties. Although we are not currently aware of litigation or other proceedings or third-party claims of intellectual property infringement related to our product candidates, the pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights.

As we enter our target markets, it is possible that competitors or other third parties will claim that our products and/or processes infringe their intellectual property rights. These third parties may have obtained and may in the future obtain patents covering products or processes that are similar to, or may include compositions or methods that encompass our technology, allowing them to claim that the use of our technologies infringes these patents. If such third-party patent is listed in the Orange Book, we would be required to file a certification, known as a Paragraph IV certification, that we are not infringing the patent, or that the patent is invalid. The third-party would then have 45 days to file a patent infringement lawsuit against us, and if so brought, we could be subject to a stay of up to 30 months (unless before that time the patent expires or is judged to be invalid or not infringed), in which we would be unable to have our 505(b)(2) application approved.

In a patent infringement claim against us, we may assert, as a defense, that we do not infringe the relevant patent claims, that the patent is invalid or both. The strength of our defenses will depend on the patents asserted, the interpretation of these patents and/or our ability to invalidate the asserted patents. However, we could be unsuccessful in advancing non-infringement and/or invalidity arguments in our defense. In the United States, issued patents enjoy a presumption of validity, and the party challenging the validity of a patent claim must present clear and convincing evidence of invalidity, which is a high burden of proof. Conversely, the patent owner need only prove infringement by a preponderance of the evidence, which is a low burden of proof.

If we were found by a court to have infringed a valid patent claim, we could be prevented from using the patented technology or be required to pay the owner of the patent for the right to license the patented technology. If we decide to pursue a license to one or more of these patents, we may not be able to obtain a license on commercially reasonable terms, if at all, or the license we obtain may require us to pay substantial royalties or grant cross licenses to our patent rights. For example, if the relevant patent is owned by a competitor, that competitor may choose not to license patent rights to us. If we decide to develop alternative technology, we may not be able to do so in a timely or cost-effective manner, if at all.

In addition, because patent applications can take years to issue and are often afforded confidentiality for some period of time, there may currently be pending applications, unknown to us, that later result in issued patents that could cover one or more of our products.

It is possible that we may in the future receive, particularly as a public company, communications from competitors and other companies alleging that we may be infringing their patents, trade secrets or other intellectual property rights, offering licenses to such intellectual property or threatening litigation. In addition to patent infringement claims, third parties may assert copyright, trademark or other proprietary rights against us. We may need to expend considerable resources to counter such claims and may not be able to be successful in our defense. Our business may suffer if a finding of infringement is established.

Generic competitors can challenge the U.S. patents protecting our product candidates by filing an ANDA or an NDA for a generic or a modified version of our product candidates and negatively affect our competitive position.

Separate and apart from the protection provided under the U.S. patent laws, drug candidates may be subject to the provisions of the Hatch- Waxman Act, which may provide drug candidates with either a three- or five-year period of marketing exclusivity following receipt of FDA approval. The Hatch-Waxman Act prohibits the FDA from accepting the filing of an ANDA application (for a generic product) or a 505(b)(2) NDA (for a modified version of the product) for three years for active drug ingredients previously approved by the FDA or for five years for active drug ingredients not previously approved by the FDA.

There is an exception, however, for newly approved molecules that allows competitors to challenge a patent beginning four years into the five-year exclusivity period by alleging that one or more of the patents listed in the FDA's list of approved drug products are invalid, unenforceable and/or not infringed and submitting an ANDA for a generic version of a drug candidate. This patent challenge is commonly known as a Paragraph IV certification. Within the past several years, the generic industry has aggressively pursued approvals of generic versions of innovator drugs at the earliest possible point in time.

If a generic company is able to successfully challenge the patents covering drug candidates by obtaining FDA approval for an ANDA, the generic company may choose to launch a generic version of a drug candidate. Any launch of a generic version of our drug candidates prior to the expiration of patent protection will have a material adverse effect on our revenues and our results of operations.

We and our commercial partners have been involved in Paragraph IV litigation in the United States involving some of our patents in respect of Zohydro ER®. These litigations have been, and any other Paragraph IV litigation may be, expensive, distracting to management and protracted. Although we and our commercial partners have successfully settled our Paragraph IV litigation, any future Paragraph IV litigation could result in new or additional generic competition to Zohydro ER®. The introduction of a generic version of Zohydro ER® could cause a reduction in revenue for our CDMO segment, which could have a material adverse effect on our business, results of operations, financial condition and prospects. In addition, we were previously involved in an interference in front of the United States Patent and Trademark Office with another party, which involved a patent application relating to Zohydro ER®, for which we ultimately were successful on appeal. However, any future interference claims could arise, and if successful, result in the issuance of a patent that could limit our freedom to operate in respect to Zohydro ER®, which could also cause a reduction in revenue for our CDMO segment and have a material adverse effect on our business, prospects, results of operations and financial condition.

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.

The patent positions of pharmaceutical 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 patents has emerged in the United States to date. The pharmaceutical patent situation outside of the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents that may be issued from the applications we currently or may in the future own or license from third parties. Further, if any patent license we obtain is deemed invalid and/or unenforceable, it could impact our ability to commercialize or partner our technology.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- we were the first to make the inventions covered by each of our pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- an individual or party will not challenge inventorship, that if successful, could have an adverse effect on our business;
- any patents issued to us or our collaborators will provide a basis for commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties; or
- the patents of others will not have an adverse effect on our business.

If we do not adequately protect our proprietary rights, competitors may be able to use our technologies and erode or negate any competitive advantage we may possess, which could materially harm our business, negatively affect our position in the marketplace, limit our ability to commercialize our product candidates and delay or render impossible our achievement of profitability.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

In the future, we may rely on trade secrets to protect our proprietary know-how and technological advances, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection could

enable competitors to use our proprietary information to develop products that compete with our products or cause additional, material adverse effects on our competitive business position.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the United States Patent and Trademark Office and various foreign governmental patent agencies in several stages over the lifetime of the patents and/or applications.

We have systems in place to remind us to pay periodic maintenance fees, renewal fees, annuity fees and various other patent and application fees, and we employ an outside law firm to pay these fees. The U.S. Patent and Trademark Office and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ an outside law firm and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If this occurs, our competitors may be able to enter the market, which would have a material adverse effect on our business.

We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property. If we are unable to adequately enforce our intellectual property rights throughout the world, our business, financial condition, and results of operations could be adversely impacted.

Our ability to manufacture products for our commercial partners may be impaired if any of our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain, are found to infringe patents of others.

Our ability to continue to manufacture Ritalin LA®, Focalin XR®, Verelan PM®, Verelan SR®, Verapamil PM, Verapamil SR and Zohydro ER® for our commercial partners, to utilize third parties to supply raw materials or other products, or to perform fill/finish services or other steps in our manufacture and supply chain, depends on our and their ability to operate without infringing the patents and other intellectual property rights of others. Other parties may allege that our manufacturing activities, or the activities of third parties involved in our manufacturing and supply chain, infringe patents or other intellectual property rights. A judicial decision in favor of one or more parties making such allegations could preclude the manufacture of the products to which those intellectual property rights apply, which could materially harm our business, operating results and financial condition.

Risks Relating to Our Securities

The market price and trading volume of our common stock have been and may continue to be volatile, which could result in rapid and substantial losses for our shareholders.

The market price for our common stock has been volatile and may continue to fluctuate or may decline significantly in the future. An active, liquid and orderly market for our common stock may not be sustained, which could depress the trading price of our common stock or cause it to continue to be highly volatile or subject to wide fluctuations. Some of the factors that could negatively affect our share price or result in fluctuations in the price or trading volume of our common stock include, among other things:

- our ability to resolve the deficiencies identified by the FDA in the CRL for IV meloxicam and obtain regulatory approval of IV meloxicam;
- the approved labeling for IV meloxicam, if any;

- our ability to successfully commercialize IV meloxicam, if approved;
- FDA, state or international regulatory actions, including actions on regulatory applications for any of our product candidates;
- legislative or regulatory changes;
- judicial pronouncements interpreting laws and regulations;
- changes in government programs;
- announcements of new products, services or technologies, commercial relationships, acquisitions or other events by us or our competitors;
- market conditions in the pharmaceutical and biotechnology sectors;
- fluctuations in stock market prices and trading volumes of similar companies;
- changes in accounting principles;
- litigation or public concern about the safety of our product candidates or similar product candidates;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant shareholders
- our announcement of financing transactions, including debt, convertible notes, etc.;
- actions by institutional or activist shareholders; and
- our discontinuance, licensing or sale of any asset or segment of our business.

These broad market and industry factors may decrease the market price of our common stock, regardless of our actual operating performance. For example, on May 24, 2018, we announced the receipt from the FDA of a CRL for our NDA for IV meloxicam. The announcement was followed by a substantial decrease in the trading price of our common stock on the Nasdaq Capital Market. In addition, in the past, following periods of volatility in the overall market and decreases in the market price of a company's securities, securities class action litigation has often been instituted against these companies. Following the decrease in our trading price in May 2018, a securities class action lawsuit was filed against us and certain of our officers and directors for alleged violations of Section 10(b) and 20(a) of the Exchange Act and Rule 10(b)(5) promulgated thereunder. The complaint seeks unspecified damages, interest, attorneys' fees and other costs. On December 10, 2018, lead plaintiff filed an amended complaint that asserted the same claims and sought the same relief but included new allegations and named additional officers and directors as defendants. On February 8, 2019, we filed a motion to dismiss the amended complaint in its entirety. While we believe that the lawsuit is without merit and intend to vigorously defend against it, the lawsuit is in the early stages and, at this time, no assessment can be made as to its likely outcome or whether the outcome will be material to us. This litigation, and any other securities class actions that may be brought against us, could result in substantial costs and a diversion of our management's attention and resources.

The JOBS Act allows us to postpone the date by which we must comply with certain laws and regulations and reduce the amount of information provided in reports filed with the SEC. We cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. We will remain an emerging growth company until the earliest of (1) December 31, 2019, (2) the beginning of the first fiscal year after our annual gross revenue is $1.07 billion or more, (3) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt securities and (4) as of the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded $700 million as of the end of the second quarter of that fiscal year.

For as long as we remain an "emerging growth company," we may take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation and financial statements in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote to approve executive compensation and shareholder approval of any golden parachute payments not previously approved. In addition, Section 102(b)(1) of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we have chosen to "opt out" of such extended transition period and, as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 102(b)(1) of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

We cannot predict if investors will find our common stock less attractive because we may rely on some of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. Our reduced disclosure may make it more difficult for investors and securities analysts to evaluate us and may result in less investor confidence, which could have a material adverse effect on the trading price of our common stock.

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

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

Certain holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act. Any sales of shares by these shareholders could have a material adverse effect on the trading price of our common stock.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that will need to be frequently evaluated. Section 404 of the Sarbanes-Oxley Act requires public companies to conduct an annual review and evaluation of their internal controls and attestations of the effectiveness of internal controls by independent auditors (the latter requirement does not apply to smaller reporting companies-we qualify as a smaller reporting company). Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of the Sarbanes-Oxley Act could have a material adverse effect on our business. We could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on the price of our common stock.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

If securities or industry analysts do not continue to publish research or reports, or if they publish unfavorable research or reports, about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. We currently have limited research coverage by securities and industry analysts. If additional securities or industry analysts do not commence coverage of our company, the trading price for our stock could be negatively impacted. In the event we obtain securities or industry analyst coverage, if one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

We have never paid dividends on our common stock and do not intend to do so for the foreseeable future.

We have never paid dividends on our common stock and we do not anticipate that we will pay any dividends on our common stock for the foreseeable future. Accordingly, any return on an investment in our common stock will be realized, if at all, only when shareholders sell their shares. In addition, our failure to pay dividends may make our stock less attractive to investors, adversely impacting trading volume and price.

The concentration of our capital stock ownership with our directors and their affiliated entities and our executive officers will limit shareholders' abilities to influence certain corporate matters.

Our directors and their affiliated entities, and our executive officers, beneficially own, in the aggregate, approximately 14% of our outstanding common stock as of December 31, 2018. As a result, these shareholders are collectively able to influence matters requiring approval of our shareholders, including the election of directors and approval of significant corporate transactions, such as mergers, consolidations or the sale of all or substantially all of our assets. Such influence may delay, prevent or deter a change in control of our company, even when such a change may be in the best interests of some shareholders, impede a merger, consolidation, takeover or other business combination involving us, or could deprive our shareholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might adversely affect the prevailing market price of our common stock.

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

Provisions in our articles of incorporation and amended and restated bylaws 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 shareholders, or remove our current management. These include provisions that:

- divide our board of directors into three classes with staggered three-year terms;
- provide that a special meeting of shareholders may be called only by a majority of our board of directors;
- establish advance notice procedures with respect to shareholder proposals to be brought before a shareholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of director;
- provide that shareholders may only act at a duly organized meeting; and
- provide that members of our board of directors may be removed from office by our shareholders only for cause by the affirmative vote of 75% of the total voting power of all shares entitled to vote generally in the election of directors.

These provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it more difficult for shareholders to replace members of our board of directors, who are responsible for appointing the members of our management. Because we are incorporated in Pennsylvania, we are governed by the provisions of the Pennsylvania Business Corporation Law of 1988, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our shareholders. Under Pennsylvania law, a corporation may not, in general, engage in a business combination with any holder of 20% or more of its capital stock unless the holder has held the stock for five years or, among other things, the board of directors has approved the transaction. Any provision of our articles of incorporation or bylaws or Pennsylvania law that has the effect of delaying or deterring a change in control could limit the opportunity for our shareholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Item 1B. Unresolved Staff Comments
None.

Item 2. Properties
Our principal executive offices, primarily used by our Acute Care Segment are located at 490 Lapp Road, Malvern, PA 19355, where we occupy approximately 22,313 square feet of leased laboratory and office space pursuant to a six-year lease, which expires on December 31, 2022. The Acute Care Segment also leases a 4,145 square foot office space in Dublin, Ireland, which expires April 16, 2020. Our CDMO segment currently operates our owned 97,000 square foot, DEA-licensed facility in Gainesville, Georgia and leased 24,000 square foot development and high potency product services facility, also in Gainesville, GA, which expires on June 30, 2025.

Item 3. Legal Proceedings
On May 31, 2018, a securities class action lawsuit was filed against us and certain of our officers and directors in the U.S. District Court for the Eastern District of Pennsylvania (Case No. 2:18-cv-02279-MMB) that purported to state a claim for alleged violations of Section 10(b) and 20(a) of the Exchange Act and Rule 10(b)(5) promulgated thereunder, based on statements made by us concerning the NDA for IV meloxicam. The complaint seeks unspecified damages, interest, attorneys' fees and other costs. On December 10, 2018, lead plaintiff filed an amended complaint that asserted the same claims and sought the same relief but included new allegations and named additional officers and directors as defendants. On February 8, 2019, we filed a motion to dismiss the amended complaint in its entirety. We believe that the lawsuit is without merit and intend to vigorously defend against it. The lawsuit is in the early stages and, at this time, no assessment can be made as to its likely outcome or whether the outcome will be material to us.

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

Market Information

Our common stock is traded on the NASDAQ Capital Market under the symbol "REPH."

Holders of Common Stock

As of February 15, 2019, there were 9 holders of record of our common stock. We believe that the number of beneficial owners of our common stock at that date was substantially greater.

Dividend Policy

We have never declared or paid any cash dividends on our common stock and our ability to pay cash dividends is currently prohibited by the terms of our credit facility with Athyrium. We do not anticipate paying cash dividends on our common stock in the foreseeable future. Payment of future dividends, if any, on our common stock will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, anticipated cash needs and plans for expansion.

Issuer Repurchases of Equity Securities

None.

Securities Authorized for Issuance Under Equity Compensation Plans

Other information about our equity compensation plans is incorporated herein by reference to Part III, Item 12 of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities

None.

Performance Graph

This performance graph shall not be deemed “soliciting material” or to be “filed” with the SEC for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act or the Exchange Act.

The following graph illustrates a comparison of the total cumulative stockholder return for our common stock since March 7, 2014, which is the first trading day for our stock, to two indices: the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph assumes an initial investment of $100 on March 7, 2014, in our common stock, the stocks comprising the NASDAQ Composite Index, and the stocks comprising the NASDAQ Biotechnology Index. Historical stockholder return is not necessarily indicative of the performance to be expected for any future periods.

Item 6. Selected Financial Data

The following tables present our selected financial data for the periods indicated. The consolidated statements of operations data for the years ended December 31, 2018, 2017 and 2016 and the selected consolidated balance sheet data as of December 31, 2018 and 2017 have been derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K. The consolidated statements of operations data for the years ended December 31, 2015 and 2014 and the consolidated balance sheet data as of December 31, 2016, 2015 and 2014 have been derived from audited financial statements not included in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of the results that may be expected in the future. The selected financial data below should be read in conjunction with the information contained in "Management's Discussion and Analysis of Financial Condition and Results of Operations," the consolidated financial statements and notes thereto, and other financial information included elsewhere in this Annual Report on Form 10-K.

	Year ended December 31,				
	2018	2017	2016	2015	2014
	(in thousands, except share and per share data)				
Consolidated Statements of Operations Data:					
Revenue	$77,347	$71,834	$69,337	$51,952	$—
Operating expenses:					
Cost of sales (excluding amortization of intangible assets)	43,160	38,193	37,152	28,054	—
Research and development	39,985	33,095	33,278	12,281	7,874
General and administrative	36,879	25,426	12,742	13,017	3,998
Amortization of intangible assets	2,583	2,583	2,583	1,884	—
Change in warrant valuation	284	9	(373)	(1,560)	—
Change in contingent consideration valuation	8,499	12,839	9,728	5,246	—
Total operating expenses	131,390	112,145	95,110	58,922	11,872
Operating loss	(54,043)	(40,311)	(25,773)	(6,970)	(11,872)
Other income (expense):					
Interest income	512	385	49	12	11
Interest expense	(8,756)	(12,034)	(5,588)	(5,560)	(4,273)
Loss before income taxes	(62,287)	(51,960)	(31,312)	(12,518)	(16,134)
Income tax benefit	(17,436)	1,880	1,107	15,551	—
Net income (loss)	(79,723)	(50,080)	(30,205)	3,033	(16,134)
Accretion of redeemable convertible preferred stock and deemed dividend	—	—	—	—	(1,270)
Net income (loss) applicable to common shareholders	$(79,723)	$(50,080)	$(30,205)	$3,033	$(17,404)
Basic net income (loss) per common share	$(3.90)	$(2.63)	$(2.82)	$0.36	$(2.79)
Diluted net income (loss) per common share	$(3.90)	$(2.63)	$(2.82)	$0.21	$(2.79)
Weighted average basic common shares outstanding	20,465,106	19,070,983	10,721,928	8,491,025	6,238,581
Weighted average diluted common shares outstanding	20,465,106	19,070,983	10,721,928	8,749,234	6,238,581

	As of December 31,				
	2018	2017	2016	2015	2014
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$38,514	$64,482	$64,483	$19,779	$19,682
Working capital	42,112	37,379	68,497	29,189	18,928
Total assets	155,493	186,226	182,997	138,697	20,374
Debt, net	64,243	53,598	24,388	29,760	—
Total liabilities	174,993	157,378	111,384	98,347	1,446
Total shareholders' equity (deficit)	(19,500)	28,848	71,613	40,350	18,928

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes appearing elsewhere. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included in Part I, Item 1A of this Annual Report on Form 10-K.

Overview

We are a specialty pharmaceutical company that operates through two business segments: an Acute Care segment and a revenue-generating CDMO segment. Each of these segments are deemed to be reportable segments for financial reporting purposes.

Our Acute Care segment is primarily focused on developing and commercializing innovative products for hospital and other acute care settings. Our lead product candidate is a proprietary injectable form of meloxicam, a long-acting preferential COX-2 inhibitor. IV meloxicam has successfully completed three Phase III clinical trials for the management of moderate to severe pain, consisting of two pivotal efficacy trials and a large double-blind Phase III safety trial, as well as other safety studies. Overall, the total new drug application, or NDA, program included over 1,400 patients. In July 2017, we submitted an NDA to the U.S. Food and Drug Administration, or FDA, for IV meloxicam for the management of moderate to severe pain. In May 2018, we received a Complete Response Letter, or CRL, from the FDA regarding our NDA for IV meloxicam. In July 2018, we participated in a Type A End-of-Review meeting with the FDA to discuss the topics covered in the CRL. In September 2018 we resubmitted the NDA for IV meloxicam and the FDA has set a date for decision on the NDA under the Prescription Drug User Fee Act, or PDUFA, of March 24, 2019. Our Acute Care segment has no revenue and our costs consist primarily of expenses incurred in conducting our manufacturing scale-up, clinical trials and preclinical studies, regulatory activities, pre-commercialization of meloxicam and personnel costs.

Our CDMO segment leverages formulation expertise to develop and manufacture pharmaceutical products using proprietary delivery technologies for commercial partners who commercialize or plan to commercialize these products. These collaborations result in revenue streams including manufacturing, royalties or profit sharing, and research and development, which support continued operations for our CDMO segment and have contributed excess cash flow to be used for activities in our Acute Care segment. We operate a 97,000 square foot, DEA-licensed manufacturing facility in Gainesville, Georgia and we currently develop and/or manufacture the following key products with our commercial partners: Ritalin LA®, Focalin XR®, Verelan PM®, Verelan SR®, Verapamil PM, Verapamil SR and Zohydro ER®, as well as supporting development stage products. In October 2018, we opened a 24,000 square foot GMP development and high potency product services facility, also in Gainesville, GA. Our CDMO segment's revenue streams are primarily derived from manufacturing, and royalty revenues, as well as research and development services performed for commercial partners.

We have incurred losses and generated negative cash flows from operations since inception and expect to continue to incur significant and increasing operating losses for the foreseeable future. Substantially all of our operating losses resulted from costs incurred in connection with our development programs, including our non-clinical and formulation development activities, manufacturing, clinical trials and pre-commercialization activities. We have used cash flow generated by our CDMO segment primarily to fund operations at our Gainesville, Georgia manufacturing facilities, to make payments under our credit facility and to partially fund our development and pre-commercialization activities of our Acute Care segment. We believe our CDMO segment will continue to contribute cash for general corporate purposes that may reduce the amount of external capital needed to fund development and commercial operations. Our expenses over the next several years are expected to relate to obtaining regulatory approval for IV meloxicam,

successfully commercializing IV meloxicam, if approved, and continuing to develop our other current and future product candidates.

On April 10, 2015, we completed the acquisition from Alkermes of certain assets, including the worldwide rights to injectable meloxicam and the development, formulation and manufacturing business that comprised our CDMO segment, which we refer to as the Gainesville Transaction. The consideration paid consisted of $50.0 million cash, a $4.0 million working capital adjustment and a seven-year warrant to purchase 350,000 shares of our common stock at an exercise price of $19.46 per share. In addition, according to the agreement, as amended, we were required to pay up to an additional $140.0 million in milestone payments, including regulatory and net sales milestones, and a royalty percentage of future product net sales related to IV meloxicam. In December 2018, we entered into an Amendment to the Purchase and Sale Agreement with Alkermes which restructured the $45 million milestone originally due upon FDA approval of IV meloxicam to (i) a $5 million payment made within 30 days of the amendment; (ii) a $5 million payment due by April 23, 2019; (iii) a $5 million payment due within 180 days following approval of an NDA for IV meloxicam; and (iv) an additional $45 million following approval of an NDA for injectable meloxicam, payable over a seven year period. In addition, we amended our warrant held by Alkermes to decrease the exercise price to $8.26 per share.

Financial Overview

Revenues

During the twelve months ended December 31, 2018, 2017 and 2016, we recognized revenues from three revenue streams: manufacturing revenue, royalty revenue and research and development revenue. All revenue is generated from our CDMO segment.

Manufacturing revenue

We recognize manufacturing revenue from the sale of products we manufacture for our commercial partners. Manufacturing revenues are recognized upon transfer of control of a product to a customer, generally upon shipment, based on a transaction price that reflects the consideration we expect to be entitled to as specified in the agreement with the commercial partner, which could include pricing and volume-based adjustments.

Royalty revenue

We recognize royalty or profit sharing revenue, collectively referred to as royalty revenue, related to the sale of products by our commercial partners that incorporate our technologies. Royalty revenues are generally recognized under the terms of the applicable license, development and/or supply agreement. For arrangements that include sales-based royalties and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue when the related sales occur by the commercial partner. For arrangements that include sales-based royalties and the license is not deemed to be the predominant item to which the royalties relate, we recognize revenue when the performance obligation to which the royalty has been allocated has been satisfied, which is upon transfer of control of a product to a customer. In this case, significant judgment is used in the estimation of these royalties based on historical customer pricing and deductions and is partially constrained due to items that are outside of our control including the uncertainty of the timing of future commercial partner sales, mix of volume, customer stocking and ordering patterns, as well as unforeseen price adjustments made by our commercial partners.

Research and development revenue

Research and development revenue consists of revenue that compensates us for services performed at our CDMO, such as formulation, process development, and preparation of pre-clinical and clinical drug product materials prepared by our CDMO segment under research and development arrangements with partners. Revenues related to research and development are generally recognized as the related services or activities are performed using the output method and in accordance with the contract terms. To the extent that the agreements specify services are to be performed on a fixed basis, revenues are recognized consistent with the pattern of the work performed. In agreements which specify milestones, we evaluate whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone is recognized at a point in time. Non-refundable milestone payments related to arrangements under which we have continuing performance obligations would be deferred and recognized over the period of performance. Milestone payments that are not within our control, such as submission for approval to regulators by a partner or approvals from regulators, are not considered probable of being achieved until those submissions are submitted by the customer or approvals are received.

Research and Development Expenses

Research and development expenses currently consist primarily of costs incurred by our Acute Care segment in connection with the development of injectable meloxicam and other pipeline activities. These expenses consist primarily of:

- expenses incurred under agreements with contract services organizations, investigative sites and consultants that conduct our clinical trials and a substantial portion of our preclinical studies;
- the cost of acquiring and manufacturing clinical trial drug supply and related manufacturing services and pre-commercial product validation and inventory manufacturing expenses;
- costs related to facilities, depreciation and other allocated expenses;
- acquired in-process research and development;
- costs associated with non-clinical and regulatory activities; and
- salaries and related costs for personnel in research and development and regulatory functions.

The majority of our external research and development costs relate to clinical trials, manufacturing of drug supply for pre-commercial products, analysis and testing of product candidates and patent costs. Costs related to facilities, depreciation and support are not charged to specific programs.

The successful development of IV meloxicam and our other product candidates is highly uncertain and subject to a number of risks, including, but not limited to:

- the costs, timing and outcome of regulatory review of a product candidate, including, with respect to IV meloxicam, the nature and scope of any activities required to resolve the CRL issued by the FDA in response to our NDA for IV meloxicam, which may include the completion of additional studies;
- the duration of clinical trials, which varies substantially according to the type, complexity and novelty of the product candidate;
- substantial requirements on the introduction of pharmaceutical products imposed by the FDA and comparable agencies in foreign countries, which require lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures;
- the possibility that data obtained from pre-clinical and clinical activities at any step in the testing process may be adverse and lead to discontinuation or redirection of development activity or may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval;
- risk involved with development of manufacturing processes, FDA pre-approval inspection practices and successful completion of manufacturing batches for clinical development and other regulatory purposes;
- the emergence of competing technologies and products and other adverse market developments, which could impede our commercial efforts; and
- the other risks disclosed in the section titled “Risk Factors” of this Annual Report on Form 10-K for the fiscal year ended December 31, 2018.

Development timelines, probability of success and development costs vary widely. As a result of the uncertainties discussed above, we anticipate that we will make determinations as to which additional programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical data of each product candidate, additional information as we progress through our discussions with the FDA around the CRL regarding our NDA for IV meloxicam, as well as ongoing assessments of such product candidate’s commercial potential and available capital resources. Accordingly, we cannot currently estimate with any degree of certainty the amount of time or costs that we will be required to expend in the future on our product candidates to complete current or future clinical or pre-commercial stages prior to their regulatory approval, if such approval is ever granted. As a result of these uncertainties surrounding the timing and outcome of any approvals, we are currently unable to estimate precisely when, if ever, any of our product candidates will generate revenues and cash flows.

We expect our research and development costs to relate to IV meloxicam as we seek to obtain regulatory approval for IV meloxicam, and if successful in obtaining regulatory approval, advance IV meloxicam through the commercialization scale-up, clinical and other activities. We also expect to have expenses as we initiate clinical trials and related work for our other product candidates. We may elect to seek collaborative relationships in order to provide us with a diversified revenue stream and to help facilitate the development and commercialization of our product candidate pipeline. We expect our research and development costs to continue to increase as we continue clinical and pre-commercialization manufacturing activities for IV meloxicam and engage in pipeline development activities.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, pre-commercial and finance and information technology functions. General and administrative expenses also include professional fees for legal, including patent-related expenses, consulting, auditing and tax services and CDMO business development activities.

Our general and administrative expenses were lower for the second half of 2018 as we progressed through our discussions with the FDA regarding the CRL as compared to the first half of 2018 when we were preparing for a potential commercial launch of IV meloxicam. We expect these expenses to increase in 2019 depending on the timing

of the regulatory approval process and subsequent commercialization of IV meloxicam. In addition, we will continue to incur costs relating to our operations as a public company, including salary, consulting, legal, patent and compliance, accounting, insurance and investor relations costs.

Amortization of Intangible Assets

We recognize amortization expense related to the intangible asset for our contract manufacturing relationships on a straight-line basis over an estimated useful life of six years. The intangible asset related to injectable meloxicam represents in process research and development, or IPR&D, which is considered an indefinite-lived intangible asset that is assessed for impairment annually or more frequently if impairment indicators exist. If the associated research and development effort is abandoned, the related assets will be written-off, and we will record a noncash impairment loss on our Consolidated Statements of Operations and Comprehensive Loss. For those compounds that reach commercialization, the IPR&D assets will be amortized over their estimated useful lives.

Change in Fair Value of Contingent Consideration

Pursuant to the Purchase and Sale Agreement for the Gainesville Transaction, as amended in December 2018, we are required to pay up to an additional $140.0 million in milestone payments, including $10.0 million during the first half of 2019, another $5.0 million due within 180 days of approval of IV meloxicam and $45.0 million over seven years beginning one year after approval, as well as net sales milestones and a royalty percentage of future product net sales related to IV meloxicam between 10% and 12% (subject to a 30% reduction when no longer covered by patent). The estimated fair value of the initial $54.6 million payment obligation was recorded as part of the purchase price for the Gainesville Transaction. We have continued to reevaluate the fair value each subsequent period and as of December 31, 2018 had recorded a $90.9 payment obligation, representing the estimated probability adjusted fair value. We expect, at a minimum, contingent consideration will further increase by approximately $25 million to $30 million as we approach the PDUFA date for the IV meloxicam NDA and potential approval of IV meloxicam. Each reporting period, we revalue this estimated obligation with changes in fair value recognized as a non-cash operating expense or gain.

Change in Fair Value of Warrants

We have classified as liabilities certain warrants outstanding that contain a contingent net cash settlement feature, upon a change in control. The fair value of these warrants are remeasured through settlement or expiration with changes in fair value recognized as a period charge within the Consolidated Statements of Operations and Comprehensive Loss.

Interest Expense, net

Interest expense, net for the twelve months ended December 31, 2018 was a result of interest expense incurred on our Athyrium senior secured term loan and the amortization of the related financing costs. Interest expense for the twelve months ended December 31, 2017 was a result of interest expense incurred on our OrbiMed and Athyrium senior secured term loans and the amortization of the related financing costs. In addition, due to the November 2017 refinancing of our debt, in 2017 we incurred one-time charges for fees related to early extinguishment of the OrbiMed debt and the non-cash write-off of OrbiMed deferred financing costs. Interest expense, net for the twelve months ended December 31, 2016 was a result of interest expense incurred on our OrbiMed senior secured term loan and the amortization of the related financing costs.

Net Operating Losses and Tax Carryforwards

As of December 31, 2018, we had approximately $21.3 million of federal net operating loss carryforwards. We also had federal and state research and development tax credit carryforwards of $4.3 million available to offset future taxable income. U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. With the exception of the 2018 federal net operating loss which has an indefinite carry forward period, these federal

and state net operating loss and federal and state tax credit carryforwards will begin to expire at various dates beginning in 2028, if not utilized. We have also generated foreign net operating loss carryforwards in Ireland. We currently do not believe it is more likely than not we will use any of these federal, state or foreign net operating losses and as a result have recorded a full valuation allowance against the deferred tax asset related to the losses.

Under the Tax Reform Act of 1986, or the Act, the utilization of a corporation's net operating loss and research and development tax credit carryforwards is limited following a greater than 50% change in ownership during a three-year period. Any unused annual limitation may be carried forward to future years for the balance of the carryforward period. We determined that we have experienced ownership changes, as defined by the Act, during the 2008, 2014 and 2016 tax years as a result of past financings; accordingly, our ability to utilize the aforementioned carryforwards will be limited. In addition, state net operating loss carryforwards may be further limited, including in Pennsylvania, which has a limitation of 30%, 35% or 40% of taxable income after modifications and apportionment on state net operating losses utilized in any one year during tax years beginning during 2017, 2018 or 2019 going forward respectively. In addition, since we will need to raise substantial additional funding to finance our operations, we may undergo further ownership changes in the future, including changes to our organizational structure relating to foreign operations, purchases, sales and licenses, which could further limit our ability to use net operating loss carryforwards. As a result, if we generate taxable income, our ability to use some of our net operating loss carryforwards to offset U.S. federal and state taxable income may be subject to limitations, which could result in increased future tax liabilities to us.

As discussed in Note 19 to the Consolidated Financial Statements included in this Form 10-K, in December 2017, the federal government enacted numerous amendments to the Internal Revenue Code of 1986 pursuant to the Tax Act. The Tax Act has and will impact our income tax expense/(benefit) from operations in the current and in future periods. The Tax Act resulted in the following impacts to us:

- Our federal statutory income tax rate was reduced from 34% to 21% for 2018 and tax years following.

- Our results for the fourth quarter of 2017 included a one-time net expense of $7.9 million, as a result of remeasuring our deferred tax balances to the new statutory rate.

- We will be able to claim an immediate deduction for investments in qualified fixed assets acquired and placed in service beginning September 27, 2017 through 2022. This provision phases out through 2026.

- Given our taxable losses in the U.S., we will be limited in our ability to deduct interest expense, and any disallowed interest expense for 2018 and tax years following will result in an indefinite carry forward until such time as we meet the taxable income thresholds required to deduct interest expense.

Results of Operations

Comparison of the Twelve Months Ended December 31, 2018 and 2017

	Year ended December 31,	
	2018	2017
	(amounts in thousands)	
Revenue	$77,347	$71,834
Operating expenses:		
Cost of sales (excluding amortization of intangible assets)	43,160	38,193
Research and development	39,985	33,095
General and administrative	36,879	25,426
Amortization of intangible assets	2,583	2,583
Change in warrant valuation	284	9
Change in contingent consideration valuation	8,499	12,839
Total operating expenses	131,390	112,145
Operating loss	(54,043)	(40,311)
Other income (expense):		
Interest expense, net	(8,244)	(11,649)
Loss before income taxes	(62,287)	(51,960)
Income tax (expense)/benefit	(17,436)	1,880
Net loss	$(79,723)	$(50,080)

Revenue and costs of sales. Our revenues were $77.3 million and $71.8 million and cost of sales were $43.2 million and $38.2 million for the twelve months ended December 31, 2018 and 2017, respectively. The increase of $5.5 million in revenue includes the impact from the new standard Accounting Standards Update, or ASU, No. 2014-09, “Revenue from Contracts with Customers,” or ASU 2014-09, and was primarily due to increased profit sharing royalties

recognized from one of our commercial partners and an increase in product sales to various commercial partners. The increase in cost of sales of $5.0 million was primarily due to product mix and expanded service and development capabilities as well as growth in manufacturing demand.

Research and Development. Our research and development expenses were $40.0 million and $33.1 million for the twelve months ended December 31, 2018 and 2017, respectively. The increase of $6.9 million in 2018 was primarily due to an increase in pre-commercialization manufacturing costs for IV meloxicam, an increase in development costs for other pipeline products, an increase in Phase IIIb clinical trial costs, and an increase in salaries and benefits expense. These increases were partially offset by a decrease in Phase III clinical trial costs and NDA costs due to the prior year NDA filing fee.

General and Administrative. Our general and administrative expenses were $36.9 million and $25.4 million for the twelve months ended December 31, 2018 and 2017, respectively. The increase of $11.5 million was primarily due to commercial team personnel and pre-commercial consulting costs in the first half of the year in preparation of the anticipated launch of IV meloxicam, public company costs including legal fees, business development costs in our CDMO segment as well as increased professional fees associated with addressing the CRL issued by the FDA regarding our NDA for IV meloxicam.

Amortization of Intangible Assets. Amortization expense was $2.6 million for the twelve months ended December 31, 2018 and 2017, which was exclusively related to the amortization of our royalties and contract manufacturing relationships intangible asset over its estimated useful life.

Interest Expense, net. Interest expense, net was $8.2 million and $11.6 million during the twelve months ended December 31, 2018 and 2017, respectively. The decrease in interest expense, net, was due to the refinancing of our prior credit agreement with OrbiMed in 2017, which resulted in a one-time charge of approximately $6.8 million for fees related to early extinguishment of debt and the non-cash write-off of related deferred financing costs. Excluding the one-time charges in 2017 for the debt refinancing, interest expense, net, increased year over year due to the higher principal balance on our Athyrium senior secured term loan and amortization of the related financing costs.

Income Tax (Expense)/Benefit. Income tax (expense)/benefit was ($17.4) million and $1.9 million for the twelve months ended December 31, 2018 and 2017, respectively. The increase in income tax expense was primarily due to the recognition of a full valuation allowance against our federal and state net deferred tax assets and the increase to the valuation allowance against our foreign net deferred tax assets. As a result of the Tax Cuts and Jobs Act of 2017, included within income tax benefit for the year ended December 31, 2017 was a non-cash adjustment of $7.9 million for the remeasurement of the net deferred tax items using the recently enacted 21% statutory tax rate. As discussed in Note 19 to the Consolidated Financial Statements included in this Form 10-K, we believe that it is more likely than not that the deferred income tax assets associated with our U.S. and foreign operations will not be realized, and as such, there is a full valuation allowance against our U.S. and foreign deferred tax assets.

Operating Income (Loss) per Segment.

CDMO Segment-

Our CDMO segment’s revenues were $77.3 million and $71.8 million and cost of sales were $43.2 million and $38.2 million for the twelve months ended December 31, 2018 and 2017, respectively. The increase of $5.5 million in revenue was primarily due to increased profit sharing royalties recognized from one of our commercial partners including the impact from the new accounting standard ASU 2014-09 and an increase in product sales to various commercial partners.

Our CDMO segment’s operating expenses (including cost of sales) increased by $6.0 million, from $46.4 million in the twelve months ended December 31, 2017 to $52.4 million in the twelve months ended December 31, 2018. Costs of sales were $43.2 million and $38.2 million, for the twelve months ended December 31, 2018 and 2017, respectively. The increase in cost of sales of $5.0 was primarily due to product mix and expanded service and development capabilities attributed to the anticipated rise in manufacturing and research and development services demand. Research and development expenses decreased by $0.1 million and general and administrative expenses increased by $1.1 million. All of the above contributed to our CDMO segment’s operating income of $24.9 million for the twelve months ended December 31, 2018, which included non-cash charges of $7.5 million for depreciation and amortization and $1.3 million for stock-based compensation.

Acute Care Segment-

Our Acute Care segment’s operating expenses (excluding non-cash charges for contingent consideration and warrants) increased $17.3 million from $52.9 million in the twelve months ended December 31, 2017 to $70.2 million in the twelve months ended December 31, 2018. Research and development expenses increased $7.0 million as a result of increased IV meloxicam pre-commercialization manufacturing costs, salaries and benefits and Phase IIIb clinical trial costs. The increase was partially offset by a decrease in Phase III clinical trial costs and NDA costs due to the prior year NDA filing fee. General and administrative costs increased by $10.4 million as a result of increased salaries and

benefits and increased pre-commercialization consulting expenses as well as costs due to the CRL including severance and increased professional fees associated with delay in potential commercial launch of IV meloxicam and addressing the CRL issued by the FDA regarding our NDA for IV meloxicam. The non-cash charge for contingent consideration decreased by $4.3 million due to the change in estimated timing of approval of IV meloxicam and the amendment of the development milestones due to Alkermes. All of the above, as well as the non-cash charges for warrants and contingent consideration, contributed to our Acute Care segment's operating loss of $79.0 million for the twelve months ended December 31, 2018, which also included non-cash charges of $6.3 million for stock-based compensation, depreciation and amortization.

Comparison of the Years Ended December 31, 2017 and 2016

	Year ended December 31,	
	2017	2016
	(amounts in thousands)	
Revenue	$71,834	$69,337
Operating expenses:		
Cost of sales (excluding amortization of intangible assets)	38,193	37,152
Research and development	33,095	33,278
General and administrative	25,426	12,742
Amortization of intangible assets	2,583	2,583
Change in warrant valuation	9	(373)
Change in contingent consideration valuation	12,839	9,728
Total operating expenses	112,145	95,110
Operating loss	(40,311)	(25,773)
Other income (expense):		
Interest expense, net	(11,649)	(5,539)
Loss before income taxes	(51,960)	(31,312)
Income tax benefit	1,880	1,107
Net loss	$(50,080)	$(30,205)

Revenue and costs of sales. Our revenues were $71.8 million and $69.3 million and cost of sales were $38.2 million and $37.2 million for the twelve months ended December 31, 2017 and 2016, respectively. Excluding the $2.3 million, one-time, contractually based manufacturing revenue amount from one of our commercial partners in the twelve months ended December 31, 2016, the $4.8 million increase in 2017 revenue versus 2016 was primarily due to higher profit share royalties as a result of stronger sales volumes and pricing of one of our products as well as increased manufacturing revenue. These increases were partially offset by decreased royalty revenue due to a change in the mix of generic and brand sales by another of our commercial partners. Costs of sales were $38.2 million and $37.2 million for the twelve months ended December 31, 2017 and 2016, respectively. The increase in cost of sales of $1.0 million was primarily due to changes in the product mix.

Research and Development. Our research and development expenses were $33.1 million and $33.3 million for the twelve months ended December 31, 2017 and 2016, respectively. The decrease of $0.2 million in 2017 was primarily due to lower IV meloxicam clinical trial expenses offset by increases in pre-commercialization IV meloxicam product validation, manufacturing and support costs, NDA filing fees and development costs for our other pipeline products.

General and Administrative. Our general and administrative expenses were $25.4 million and $12.7 million for the twelve months ended December 31, 2017 and 2016, respectively. The increase of $12.7 million was primarily due to building of the commercial team and its related infrastructure, and pre-commercial activities for IV meloxicam.

Amortization of Intangible Assets. Amortization expense was $2.6 million for the twelve months ended December 31, 2017 and 2016 which was exclusively related to the amortization of our royalties and contract manufacturing relationships intangible asset over its estimated useful life.

Interest Expense, net. Interest expense, net was $11.6 million and $5.5 million during the twelve months ended December 31, 2017 and 2016, respectively. The increase in interest expense, net, was due to the refinancing of our

prior credit agreement with OrbiMed in 2017 which resulted in a one-time charge totaling approximately $6.8 million for fees related to early extinguishment of debt and the non-cash write-off of related deferred financing costs. Additionally, the higher principal balance on our Athyrium senior secured term loan and amortization of the related financing costs contributed to an increase in interest expense, net.

Income Tax Benefit. Income tax benefit was $1.9 million and $1.1 million for the twelve months ended December 31, 2017 and 2016, respectively. The increase in income tax benefit was primarily due to the increase in net loss before income. As a result of the Tax Cuts and Jobs Act of 2017, included within income tax benefit for the year ended December 31, 2017 was a non-cash adjustment of $7.9 million for the remeasurement of the net deferred tax items using the recently enacted 21% statutory tax rate. We believe that it is more likely than not that the deferred income tax assets associated with our foreign operations will not be realized, and as such, there is a full valuation allowance against our foreign deferred tax assets.

Operating Income (Loss) per Segment.

CDMO Segment-

Our CDMO segment's revenues were $71.8 million and $69.3 million and cost of sales were $38.2 million and $37.2 million for the twelve months ended December 31, 2017 and 2016, respectively. Excluding the $2.3 million, one-time, contractually based manufacturing revenue amount from one of our commercial partners in the twelve months ended December 31, 2016, the $4.8 million increase in revenue versus prior year was primarily due to increased profit share royalties as a result of increased sales volumes and pricing by one of our commercial partners as well as increased manufacturing revenue. These increases were partially offset by decreased royalty revenue due to a change in the mix of generic and brand sales by one of our commercial partners.

Our CDMO segment's operating expenses (including cost of sales) increased by $1.3 million, from $45.1 million in the twelve months ended December 31, 2016 to $46.4 million in the twelve months ended December 31, 2017. Costs of sales were $38.2 million and $37.2 million, for the twelve months ended December 31, 2017 and 2016, respectively. The increase in cost of sales of $1.0 million was primarily due to changes in the product mix. Research and development expenses decreased by $0.3 million due to expanded investment in our formulation and development capabilities and general and administrative expenses increased by $0.6 million. All of the above contributed to our CDMO segment's operating income of $25.4 million for the twelve months ended December 31, 2017, which included non-cash charges of $7.4 million for depreciation and amortization and $1.0 million for stock-based compensation.

Acute Care Segment-

Our Acute Care segment's operating expenses (excluding non-cash charges for contingent consideration and warrants) increased $12.2 million from $40.7 million in the twelve months ended December 31, 2016 to $52.9 million in the twelve months ended December 31, 2017. Research and development expenses increased $0.1 million as a result of increased IV meloxicam pre-commercialization manufacturing costs, NDA filing fees and increased headcount, which was partially offset by a decrease in our IV meloxicam clinical trial expenses. General and administrative costs increased by $12.1 million as a result of increased headcount and increased pre-commercialization marketing expenses. The non-cash charge for contingent consideration increased by $3.1 million. All of the above, as well as the non-cash charges for warrants and contingent consideration, contributed to our Acute Care segment's operating loss of $65.7 million for the twelve months ended December 31, 2017, which also included non-cash charges of $4.6 million for stock-based compensation, depreciation and amortization.

Liquidity and Capital Resources

As of December 31, 2018, we had $38.5 million in cash and cash equivalents and short-term investments.

Since inception through December 31, 2018, we have financed our product development, operations and capital expenditures primarily from sales of equity and debt securities, including sales of our common stock with net proceeds of $133.5 million, and term loans made under our previous and existing credit facilities, including our credit facility with Athyrium with an outstanding balance of $70.0 million and contributions of excess cash flow from our CDMO segment. During the twelve months ended December 31, 2018, our capital expenditures were $10.5 million, which increased primarily related to expansion of the CDMO capabilities to support anticipated new business activities.

We will need to raise substantial additional funds in order to fund the payments which may become due, including milestone payments owed to Alkermes or other licensing partners, to commercialize IV meloxicam, if approved, to continue our Phase IIIb program for IV meloxicam, to commence our clinical trial programs of our other product

candidates, to commercialize any of our other product candidates or technologies that receive regulatory approval and to enhance our sales and marketing efforts for additional products we may acquire. Insufficient funds may cause us to delay, reduce the scope of or eliminate one or more of our development, commercialization or expansion activities. Our future capital needs and the adequacy of our available funds will depend on many factors, including our ability to timely and adequately resolve the CRL issued by the FDA regarding our NDA for IV meloxicam, the cost of studies and other actions that may be needed to obtain regulatory approval for IV meloxicam, the timing of approval of IV meloxicam, the level of market acceptance of IV meloxicam and the costs of commercialization activities for IV meloxicam, if approved, the continued profitability of our CDMO segment, and our ability to access additional tranches under our Credit Agreement with Athyrium. We may raise such additional funds through debt refinancing, bank or other loans, through strategic research and development, licensing, including out-licensing activities, sale of assets and/or marketing arrangements or through public or private sales of equity or debt securities from time to time. Financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could materially adversely impact our growth plans and our financial condition or results of operations. Additional debt or equity financing, if available, may be dilutive to the holders of our common stock and may involve significant cash payment obligations and covenants that restrict our ability to operate our business or access to capital.

On March 7, 2015, in connection with the Gainesville Transaction, we, through a wholly owned subsidiary, entered into a credit agreement with OrbiMed. Pursuant to the credit agreement, OrbiMed provided us with a term loan in the original principal amount of $50.0 million on April 10, 2015, which amount was used to fund the Gainesville Transaction. On November 17, 2017, we entered into our credit agreement with Athyrium, pursuant to which we drew upon an initial $60.0 million term loan. We used the proceeds from the initial term loan to (i) repay in full all outstanding indebtedness under our credit facility with OrbiMed of approximately $31.7 million, which included the remaining debt principal balance of $27.3 million and early termination charges of $4.4 million and (ii) pay transaction fees associated with the credit facility with Athyrium of approximately $4.2 million. In December 2018 we amended the credit agreement with Athyrium and drew upon a $10 million term B-1 loan. We have the ability to draw upon two additional tranches of term loans, each in the aggregate original principal amount of $15 million, subject to certain timing and milestone restrictions, including that we receive regulatory approval of IV meloxicam by September 30, 2019. As of December 31, 2018, we had $70 million outstanding principal under our credit agreement with Athyrium.

Sources and Uses of Cash

Cash used in operations was $43.1 million, $17.0 million and $3.2 million for the twelve months ended December 31, 2018, 2017 and 2016, respectively, which represents our operating losses less our stock-based compensation, depreciation, non-cash interest expense, loss on early extinguishment of debt, acquired IPR&D, changes in fair value of warrants and contingent consideration and amortization of intangibles, as well as changes in operating assets and liabilities.

Cash used in investing activities was $7.1 million, $10.3 million and $3.8 million for the twelve months ended December 31, 2018 and 2017 and 2016, respectively, and reflected cash used for the purchase of short-term investments offset by maturities/redemption of investments and for the purchase of property and equipment. Our short-term investments were classified as available for sales securities with maturities of less than one year.

There was $27.7 million of cash provided by financing activities in the twelve months ended December 31, 2018 from proceeds from issuance of long-term debt from Athyrium of $10.0 million, net proceeds of $17.0 million from the sale of shares of common stock through our Common Stock Purchase Agreement with Aspire Capital and proceeds of $1.8 million from exercise of options, which was partially offset by deferred financing costs of $1.0 million from the Athyrium transaction and $0.1 million of payments of withholdings on shares withheld for income taxes. Cash provided by financing activities was $23.9 million for the twelve months ended December 31, 2017, from proceeds from issuance of long-term debt from Athyrium of $60.0 million, offset by repayment of long term debt for the payoff of the OrbiMed debt of $27.3 million, fees related to early extinguishment of debt paid to OrbiMed of $4.4 million and deferred financing costs from the Athyrium transaction of $4.2 million. Cash provided by financing activities was $51.7 million for the twelve months ended December 31, 2016, primarily as a result of the sale of common stock raising net proceeds of $58.1 million, partially offset by payments of $6.3 million on long-term debt.

Our future use of operating cash and capital requirements will depend on many forward-looking factors, including the following:

- our ability to resolve the deficiencies identified by the FDA in the complete response letter, or CRL, for intravenous, or IV, meloxicam;
- whether the FDA will approve our amended NDA for IV meloxicam and, if approved, the labeling under any such approval that we may obtain;
- if the FDA does not approve our amended NDA, the time frame otherwise associated with resolving the deficiencies identified by the FDA in the CRL and whether the FDA will require additional clinical studies to support the approval of IV meloxicam and the time and cost of such studies;

- the timing and outcome of our Phase IIIb clinical trials for IV meloxicam;
- the timing of the Gainesville Transaction regulatory milestone payments and other contingent consideration;
- the costs of manufacturing scale-up and commercialization activities, for IV meloxicam, if approved;
- the level of market acceptance of IV meloxicam, if approved;
- the scope, progress, results and costs of development for our other product candidates;
- the cost, timing and outcome of regulatory review of our other product candidates;
- the cost of manufacturing scale-up, acquiring drug product and other capital equipment for our other product candidates;

- the extent to which we in-license, acquire or invest in products, businesses and technologies;

- the timing and extent of our manufacturing and capital expenditures related to our CDMO segment;
- our ability to maintain our relationships and contracts with our commercial partners;
- our ability to continue profitability in our CDMO segment;
- our ability to comply with stringent U.S. & foreign government regulation in the manufacture of pharmaceutical products, including cGMP and U.S. DEA requirements;
- the extent to which we choose to establish collaboration, co-promotion, distribution or other similar agreements for product candidates;
- our ability to access additional tranches of term loans under our credit agreement with Athyrium;
- our ability to raise additional funds through equity or debt financings or sale of certain assets;
- the costs of preparing, submitting and prosecuting patent applications and maintaining, enforcing and defending intellectual property claims; and
- the effect of any changes in our effective tax rate due to changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities and changes in tax laws.

We might use existing cash and cash equivalents on hand, additional debt, equity financing, sale of assets or out-licensing revenue or a combination thereof to fund our operations or product acquisitions. If we increase our debt levels, we might be restricted in our ability to raise additional capital and might be subject to financial and restrictive covenants. Our shareholders may experience dilution as a result of the issuance of additional equity or debt securities. This dilution may be significant depending upon the amount of equity or debt securities that we issue and the prices at which we issue any securities.

Contractual Commitments

The table below reflects our contractual commitments as of December 31, 2018:

	Payments Due by Period (in 000s)				
Contractual Obligations	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Long-Term Debt Obligations (1):					
Athyrium Debt	$70,700	$—	$—	$70,700	$—
Interest on Debt	$34,589	8,916	17,856	7,817	—
Purchase Obligations (2):	$26,763	21,374	2,335	28	—
Operating Leases (3)	$2,849	781	1,136	685	247
Other Long-Term Liabilities:					
Other License Commitments and Milestone payments (4), (5)	$54,010	25	100	150	315
Alkermes Payments (6)	$140,000	—	—	—	—
Employment Agreements (7)	$461	461	—	—	—
Other Non-Current Liabilities (8)	$62	—	34	19	9
Total Contractual Obligations	$329,434	$31,557	$21,461	$79,399	$571

(1) The long-term debt obligations consist of principal, an exit fee of 1% of the principal, and interest on the outstanding balance of $70.0 million of our $100 million credit facility with Athyrium as of December 31, 2018. The debt bears interest at a rate of LIBOR plus 9.75% per annum. Due to fluctuations of the future LIBOR interest rate, it has been set at the rate as of December 31, 2018 to calculate the obligation. In accordance with U.S. GAAP, the future interest obligations are not recorded on our Consolidated Balance Sheet. See Note 12 to the

Consolidated Financial Statements included in this Form 10-K.

(2) These obligations consist of cancelable and non-cancelable purchase commitments related to inventory, capital expenditures and other goods or services. In accordance with U.S. GAAP, these obligations are not recorded on our Consolidated Balance Sheets. See Note 13 to the Consolidated Financial Statements included in this Form 10-K.

(3) We have become party to certain operating leases, for the leased space in Malvern, Pennsylvania, Gainesville, Georgia and Dublin, Ireland, as well as for residential and office equipment, for which the minimum lease payments are presented. See Note 13(d) to the Consolidated Financial Statements included in this Form 10-K.

(4) We are party to exclusive licenses with Orion for the development and commercialization of certain pipeline product candidates, under which we may be required to make certain milestone and royalty payments to Orion. See Note 5 and Note 13(a) to the Consolidated Financial Statements included in the Form 10-K. The amount reflects only payment obligations that are fixed and determinable. We are unable to reliably estimate the timing of these payments because they are dependent on the type and complexity of the clinical studies and intended uses of the products, which have not been established. In accordance with U.S. GAAP, these obligations are not recorded on our Consolidated Balance Sheets.

(5) We license the NMBAs from Cornell University pursuant to a license agreement under which we are obligated to make annual license maintenance fee payments, milestone payments and patent cost payments and to pay royalties on net sales of the NMBAs. The amount reflects only payment obligations that are fixed and determinable. We are unable to reliably estimate the timing of certain of these payments because they are dependent on the type and complexity of the clinical studies and intended uses of the products, which have not been established. In accordance with U.S. GAAP, certain of these obligations are not recorded on our Consolidated Balance Sheets. See Note 5 and 13(a) to the Consolidated Financial Statements included in this Form 10-K.

(6) Pursuant to the purchase and sale agreement governing the Gainesville Transaction, we agreed to pay to Alkermes milestone and royalty payments. The amount reflects only payment obligations that are fixed and determinable. We are unable to reliably estimate the timing of these payments because they are in some instances, events that are not in our control and dependent on the commercial success of the product. In accordance with U.S. GAAP, the fair value of these obligations are recorded as contingent consideration on our Consolidated Balance Sheets. See Note 4 and Note 13(b) to the Consolidated Financial Statements included in this Form 10-K.

(7) We have entered into employment agreements with certain of our named executive officers. As of December 31, 2018, these employment agreements provided for, among other things, annual base salaries in an aggregate amount of not less than this amount, from that date through calendar year 2019. In accordance with U.S. GAAP, these obligations are not recorded on our Consolidated Balance Sheets. See Note 13 (f) to the Consolidated Financial Statements included in this Form 10-K.

(8) This value represents the deferred rent. In accordance with U.S. GAAP, these liabilities are recorded on our Consolidated Balance Sheets. See Note 13(a) to the Consolidated Financial Statements included in this Form 10-K.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K.

Critical Accounting Policies and Estimates

This management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, revenue recognition, stock-based compensation and contingent consideration. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Impairment of Goodwill and Indefinite-lived Intangible Assets – We are required to review, on an annual basis, the carrying value of goodwill and indefinite-lived intangible assets, to determine whether impairment may exist. For goodwill, the impairment model prescribes a one-step method for determining impairment. The one-step quantitative test calculates the amount of goodwill impairment as the excess of a reporting unit's carrying amount over its fair value, not to exceed the total amount of goodwill allocated to the reporting unit. The impairment test for indefinite-lived intangible assets is a one-step test, which compares the fair value of the intangible asset to its carrying value. If the carrying value exceeds its fair value, an impairment loss is recognized in an amount equal to the excess. Based on accounting standards, it is required that these assets be assessed at least annually for impairment unless a triggering event occurs between annual assessments which would then require an assessment in the period which a triggering event occurred.

Impairment of Long-lived Assets—We are required to review the carrying value of long-lived fixed and amortizing intangible assets for recoverability whenever events occur or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. The impairment test is a two-step test. Under step one we assess the recoverability of an asset (or asset group). The carrying amount of an asset (or asset group) is not recoverable if it exceeds the sum of the undiscounted cash flows expected from the use and eventual disposition of the asset (or asset group). The impairment loss is measured in step two as the difference between the carrying value of the asset (or asset group) and its fair value. Assumptions and estimates used in the evaluation of impairment are subjective and changes in these assumptions may negatively impact projected undiscounted cash flows, which could result in impairment charges in future periods. On an ongoing periodic basis, we evaluate the useful life of our long-lived assets and determine if any economic, governmental or regulatory event has modified their estimated useful lives.

Contingent Consideration — We revalue our contingent consideration on a quarterly basis using a discounted cash flow valuation model. The model uses significant unobservable inputs, including the probability and timing of FDA approval and successful product launch. We estimate IV meloxicam net revenues based on estimated market share, pricing and customary trade discounts, taking into consideration variables such as, market acceptance of the product and the expected number of product competitors in the market.

Revenue Recognition— We generate revenues from manufacturing, packaging, research and development, and related services for multiple pharmaceutical companies through our CDMO segment. Our agreements with our commercial partners provide for manufacturing revenues, sales-based royalties and/or profit sharing components. Our revenue policies listed below are reflective of ASU 2014-09, which we adopted effective January 1, 2018. See Note 18 to the Consolidated Financial Statements included in this Form 10-K for additional information regarding our adoption of ASU 2014-09 and its impact on our financial statements.

Manufacturing and other related services revenue is recognized upon transfer of control of a product to a customer, generally upon shipment, based on a transaction price that reflects the consideration we expect to be entitled to as specified in the agreement with the commercial partner.

In addition to manufacturing and packaging revenue, certain customer agreements may have intellectual property sales-based royalties and/or profit sharing consideration, collectively referred to as royalties, computed on the net product sales of the commercial partner. Royalty revenues are generally recognized under the terms of the applicable license, development and/or supply agreement. For arrangements that include sales-based royalties where the license for intellectual property is deemed to be the predominant item to which the royalties relate, we recognize revenue when the related sales occur by the commercial partner. For arrangements that include sales-based royalties where the license for intellectual property is not deemed to be the predominant item to which the royalties relate, we recognize revenue upon transfer of control of the manufactured product. In these cases, significant judgment is required to calculate this estimated variable consideration using the most-likely amount method based on historical customer pricing and deductions and is partially constrained due to items that are outside of our control including the

uncertainty of the timing of future commercial partner sales, mix of volume, customer stocking and ordering patterns, as well as unforeseen price adjustments made by our commercial partners.

Revenues related to research and development are generally recognized over-time as the related services or activities are performed using the output method and in accordance with the contract terms. In agreements which specify milestones, we evaluate whether the milestones are considered probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. Milestone payments related to arrangements under which we have continuing performance obligations would be deferred and recognized over the period of performance. Milestone payments that are not within our control, such as submission for approval to regulators by a commercial partner or approvals from regulators, are not considered probable of being achieved until those submissions are submitted by the customer or approvals are received.

Income taxes - We use the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between the financial statement carrying amount and the tax basis of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. We provide a valuation allowance when it is more-likely-than-not that deferred tax assets will not be realized.

On a periodic basis, we evaluate the realizability of our deferred tax assets and adjust such amounts in light of changing facts and circumstances, including but not limited to projections of future taxable income, the reversal of deferred tax liabilities, tax legislation, rulings by relevant tax authorities, tax planning strategies and the progress of ongoing tax examinations. As part of this evaluation, we consider whether it is more likely than not that all or some portion of the deferred tax asset will not be realized. The ultimate realization of a deferred tax asset is dependent upon the generation of future taxable income during the period in which the related temporary difference becomes deductible or the net operating loss, or NOL, and credit carryforwards can be utilized.

We maintain a full valuation allowance against our deferred tax assets where realizability is not certain. We periodically evaluate the likelihood of the realization of deferred tax assets and adjust the carrying amount of these deferred tax assets by a valuation allowance based on the anticipated realizability. The valuation allowance can be reversed if objective negative evidence in the form of cumulative losses is no longer present and additional weight is given to subjective evidence, such as our projection of future growth. This determination depends on a variety of factors, some of which are subjective, including our current year taxable income in the United States, expectations of future taxable income, impact of tax reform, achievement of milestones, carryforward periods available to us for tax reporting purposes, various income tax strategies and other relevant factors. If we determine that the deferred tax assets realizability is impacted, we would record material changes to income tax expense in that period.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business. These market risks are principally limited to interest rate fluctuations. At December 31, 2018, we had approximately $29.7 million invested in money market instruments and government and agency bonds. We believe our policy of investing in highly-rated securities, whose liquidities are, at December 31, 2018, all less than two months, minimizes such risks. Due to the short-term duration of our investment portfolio and the low-risk profile of our investments, an immediate 10.0% change in interest rates would not have a material effect on the fair market value of our portfolio. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our investment portfolio. We do not enter into investments for trading or speculative purposes. Our Athyrium secured term loan interest expense is based on the current committed rate of three-month LIBOR plus 9.75% with a 1.0% LIBOR floor. A fluctuation in LIBOR of 0.25% would result in a charge of $0.2 million of interest expense over a twelve-month period.

We have license agreements with Orion for certain product pipeline candidates which require the payment of milestones upon the achievement of certain regulatory and commercialization events and royalties on product sales, which are required to be made in Euros. As of December 31, 2018, no milestones or royalties were due under these agreements, and we do not anticipate incurring milestone or royalty costs under these agreements until we advance our development of certain product pipeline candidates. We do not believe foreign currency exchange rate risk is a material risk at this time; however, these agreements could, in the future, give rise to foreign currency transaction gains or losses. As a result, our results of operations and financial position could be exposed to changing currency exchange rates. In the future, we may periodically use forward contracts to hedge certain transactions or to neutralize exposures.

Item 8. Financial Statements and Supplementary Data

Our consolidated financial statements and the report of our independent registered public accounting firm are included in this Annual Report on Form 10-K on the pages indicated in Part IV, Item 15.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of December 31, 2018. We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure.

A control system, no matter how well conceived and operated, can provide only reasonable, and not absolute, assurance that the objectives of the control system will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. However, our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives. Based on the evaluation of our disclosure controls and procedures as of December 31, 2018, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance of the reliability of financial reporting and of the preparation of financial statements for external reporting purposes, in accordance with U.S. generally accepted accounting principles.

Internal control over financial reporting includes policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and disposition of assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with the authorization of its management and directors; and (3) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on its financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of the 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 and procedures included in such controls may deteriorate.

Our management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. In making this assessment, management used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control – Integrated Framework (2013). These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and monitoring. Management's assessment included extensive documentation, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

Based on the Management's processes and assessment, as described above, management has concluded that, as of December 31, 2018, our internal control over financial reporting was effective.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

On February 19, 2019, we entered into the Purchase Agreement with Aspire Capital, pursuant to which we have the right to sell to Aspire Capital from time to time in our sole discretion up to $20.0 million in shares of our common stock over the next 30 months, subject to certain limitations and conditions set forth in the Purchase Agreement. In consideration for entering into the Purchase Agreement, we have agreed to issue to Aspire Capital 34,762 shares of our common stock, or the Commitment Shares, on February 19, 2019.

Concurrently with entering into the Purchase Agreement, we also entered into a registration rights agreement, or the Registration Rights Agreement, with Aspire Capital, pursuant to which we agreed to file with the SEC a prospectus supplement to our effective shelf registration statement on Form S-3 (File No. 333-218487), registering all of the shares of common stock that may be offered to Aspire Capital from time to time, including the Commitment Shares.

Under the Purchase Agreement, on any trading day we select, following the filing of the prospectus supplement and the satisfaction of other closing conditions, we have the right, in our sole discretion, to present Aspire Capital with a purchase notice, or a Purchase Notice, directing Aspire Capital (as principal) to purchase up to 75,000 shares of common stock per trading day, up to an aggregate of $20.0 million of common stock, at a per share price, or the Purchase Price, equal to the lesser of:

•the lowest sale price of the common stock on the purchase date; or

•the arithmetic average of the three lowest closing sale prices for our common stock during the 10 consecutive trading days ending on the trading day immediately preceding the purchase date.

The aggregate purchase price payable by Aspire Capital on any one purchase date may not exceed $500,000, unless otherwise mutually agreed, and upon mutual agreement we may issue up to 2,000,000 shares of common stock under a purchase notice.

In addition, on any date on which we submit a purchase notice to Aspire Capital, we also have the right, in our sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice, or a VWAP Purchase Notice, directing Aspire Capital to purchase an amount of common stock equal to up to 30% of the aggregate shares of common stock traded on our principal market on the next trading day, or the VWAP Purchase Date, as we determine. The purchase price per share pursuant to such VWAP Purchase Notice is generally 97% of the volume-weighted average price for the common stock traded on our principal market on the VWAP Purchase Date.

We may deliver multiple Purchase Notices and VWAP Purchase Notices to Aspire Capital from time to time during the term of the Purchase Agreement, so long as the most recent purchase has been completed.

The Purchase Agreement provides that we and Aspire Capital will not affect any sales under the Purchase Agreement on any purchase date where the closing sale price of our common stock is less than $0.50. There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of sales of common stock to Aspire Capital.

The Purchase Agreement provides that the number of shares that may be sold pursuant to the Purchase Agreement will be limited to 4,372,373 shares, including the Commitment Shares, or the Exchange Cap, which represents 19.99% of our outstanding shares of common stock as of February 19, 2019, unless stockholder approval or an exception pursuant to the rules of the NASDAQ Capital Market is obtained to issue more than 19.99%. This limitation will not apply if, at any time the Exchange Cap is reached and at all times thereafter, the average price paid for all shares issued under the Purchase Agreement is equal to or greater than $8.63, which was the average of the five closing sale prices of our common stock immediately preceding the execution of the Purchase Agreement. We are not required or

permitted to issue any shares of common stock under the Purchase Agreement if such issuance would breach our obligations under the rules or regulations of the NASDAQ Capital Market.

The Purchase Agreement may be terminated by us at any time, at our discretion, without any cost to us. Aspire Capital has agreed that neither it nor any of its agents, representatives and affiliates shall engage in any direct or indirect short-selling or hedging of our common stock during any time prior to the termination of the Purchase Agreement. Aspire Capital has no right to require any sales by us, but is obligated to make purchases from us as directed by us in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future fundings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement.

Any proceeds we receive under the Purchase Agreement are expected to be used for commercial activities for IV meloxicam, pipeline development activities, the payment of Alkermes milestones, and general corporate purposes.

The foregoing descriptions of the Purchase Agreement and the Registration Rights Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of the Purchase Agreement and the Registration Rights Agreement, which are attached hereto as Exhibits 10.34 and 4.8, respectively, and incorporated by reference herein.

Pepper Hamilton LLP, counsel to the Company, has issued an opinion to the Company, dated February 19, 2019, regarding the validity of the shares of common stock to be issued and sold pursuant to the Purchase Agreement. A copy of the opinion is filed as Exhibit 5.1 to this Annual Report on Form 10-K.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information with respect to this item will be set forth in the Proxy Statement for the 2018 Annual Meeting of Shareholders, or the Proxy Statement, under the headings “Board of Directors,” “Executive Officers,” “Section 16(a) Beneficial Ownership Reporting Compliance,” and “Corporate Governance and Risk Management” and is incorporated herein by reference. The Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

Our board of directors has adopted a Code of Business Conduct and Ethics, or Code of Conduct, applicable to all of our employees, executive officers and directors. The Code of Conduct is available on our website at www.recropharma.com. Our board of directors is responsible for overseeing compliance with the Code of Conduct, and our board of directors or an appropriate committee thereof must approve any waivers of the Code of Conduct for employees, executive officers or directors. Disclosure regarding any amendments to the Code of Conduct, or any waivers of its requirements, will be made on our website.

Item 11. Executive Compensation

Information with respect to this item will be set forth in the Proxy Statement under the headings “Director Compensation,” “Executive Compensation,” and “Corporate Governance and Risk Management” is incorporated herein by reference. The Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

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

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options and other rights		Weighted-average exercise price of outstanding options and other rights(1)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))	
Equity compensation plans approved by security Holders	4,095,461	(2)	$ 7.46	3,777,352	
Equity compensation plans not approved by security Holders	783,000	(3)	$ 8.24	—	(4)
Total	4,878,461		$ 7.62	3,777,352	

(1) Represents the weighted-average exercise price of outstanding stock options and does not include restricted stock units.
(2) Consists of outstanding (i) options to purchase 3,026,315 shares of common stock and (ii) restricted stock units covering an aggregate of 1,069,146 shares of common stock. Shares in settlement of vested restricted stock units are deliverable within 30 days of the vesting date.
(3) Reflects grants of stock options and restricted stock units that were "inducement grants" as defined under NASDAQ Listing Rule 5635(c)(4). The terms and conditions of each inducement grant are subject to the terms and conditions of the Form of Award Agreement for Option Inducement Awards Form of Award Agreement for Restricted Stock Unit Inducement Awards, included as Exhibits 10.13 and 10.14, respectively, of this Annual Report on Form 10-K.
(4) Our board of directors has not established any specific number of shares that could be issued without shareholder approval. Inducement grants to new key employees are determined on a case-by-case basis. Other than possible inducement grants, we expect that all equity awards will be made under shareholder-approved plans.

Other information with respect to this item will be set forth in the Proxy Statement under the headings "Security Ownership of Directors, Certain Beneficial Owners and Management," "Executive Compensation," and "Director Compensation," and is incorporated herein by reference. The Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

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

Information with respect to this item will be set forth in the Proxy Statement under the headings “Certain Relationships and Related Party Transactions” and “Corporate Governance and Risk Management” and is incorporated herein by reference. The Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

Item 14. Principal Accounting Fees and Services

Information with respect to this item will be set forth in the Proxy Statement under the heading “Independent Registered Public Accounting Firm,” and is incorporated herein by reference. The Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

PART IV

Item 15. Exhibits, Consolidated Financial Statement Schedules
(a)(1) Consolidated Financial Statements.

The following consolidated financial statements are filed as a part of this Annual Report on Form 10-K:

Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2018 and 2017

Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2018, 2017 and 2016

Consolidated Statements of Shareholders' Equity for the years ended December 31, 2018, 2017 and 2016

Consolidated Statements of Cash Flows for the years ended December 31, 2018, 2017 and 2016

(a)(2) Consolidated Financial Statement Schedules.

Not applicable.

(a)(3); (b) Exhibits:

Exhibit No.	Description	Method of Filing
2.1†	Purchase and Sale Agreement, dated March 7, 2015, by and among Recro Pharma, Inc., Recro Pharma LLC, Daravita Limited, Alkermes Pharma Ireland Limited and Eagle Holdings USA, Inc.	Incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on March 11, 2015 (File No. 001-36329).
2.2	First Amendment, dated December 8, 2016 to Purchase and Sale Agreement, dated March 7, 2015, by and among Recro Pharma, Inc., Recro Pharma LLC, Daravita Limited, Alkermes Pharma Ireland Limited and Eagle Holdings USA, Inc.	Incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on December 8, 2016 (File No. 001-36329).
2.3	Second Amendment, dated December 20, 2018 to Purchase and Sale Agreement, dated March 7, 2015, by and among Recro Pharma, Inc., Recro Pharma LLC, Daravita Limited, Alkermes Pharma Ireland Limited and Eagle Holdings USA, Inc.	Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 28, 2018 (File No. 001-36329).
3.1		

	Second Amended and Restated Articles of Incorporation of Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on March 13, 2014 (File No. 001-36329).
3.2	Third Amended and Restated Bylaws of Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on March 13, 2014 (File No. 001-36329).
4.1	Specimen certificate evidencing shares of common stock.	Incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1/A filed on December 20, 2013 (File No. 333-191879).
4.2	Form of Alkermes Warrant.	Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on March 11, 2015 (File No. 001-36329).
4.3	First Amendment, dated December 20, 2018 to Warrant to Purchase Stock, dated April 10, 2015, by and between Recro Pharma, Inc. and Alkermes Pharma Ireland Limited.	Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on December 28, 2018 (File No. 001-36329)

Exhibit

No.	Description	Method of Filing
4.4	Form of IPO Warrant.	Incorporated herein by reference to Exhibit A of Exhibit 1.1 to the Company's Registration Statement on Form S-1/A filed on February 11, 2014 (File No. 333-191879).
4.5†	Common Stock Purchase Warrant, dated November 17, 2017, in favor of Athyrium Opportunities III Acquisition LP	Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on November 20, 2017 (File No. 001-36329).
4.6†	Common Stock Purchase Warrant, dated November 17, 2017, in favor of Athyrium Opportunities II Acquisition LP	Incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on November 20, 2017 (File No. 001-36329).
4.7	Registration Rights Agreement, dated March 2, 2018, by and between Recro Pharma, Inc. and Aspire Capital Fund, LLC.	Incorporated herein by reference to Exhibit 4.8 to the Company's Annual Report on Form 10-K filed on March 2, 2018 (File No. 001-36329).
4.8	Registration Rights Agreement, dated February 19, 2019, by and between Recro Pharma, Inc. and Aspire Capital Fund, LLC.	Filed herewith.
5.1	Opinion of Pepper Hamilton LLP.	Filed herewith.
10.1†	Dexmedetomidine License Agreement, dated August 22, 2008, by and among Recro Pharma, Inc. and Orion Corporation.	Incorporated herein by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1/A filed on November 29, 2013 (File No. 333-191879).
10.2†	First Amendment to Dexmedetomidine License Agreement, dated January 17, 2009, by and between Recro Pharma, Inc., and Orion Corporation.	Incorporated herein by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1/A filed on November 29, 2013 (File No. 333-191879).
10.3†	Dexmedetomidine API Supply Agreement, dated August 22, 2008, by and among Recro Pharma, Inc., and Orion Corporation.	Incorporated herein by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1/A filed on November 29, 2013 (File No. 333-191879).
10.4•	Employment Agreement, dated October 8, 2013, between Recro Pharma, Inc. and Gerri Henwood.	Incorporated herein by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1/A filed on November 29, 2013 (File No. 333-191879).
10.5•	Employment Agreement, dated July 1, 2016, between Recro Pharma, Inc. and Michael Celano.	Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 5, 2016 (File No. 001-36329).
10.6•	Employment Agreement, dated June 5, 2017, between Recro Pharma, Inc. and Ryan D. Lake.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 9,

		2017 (File No. 001-36329).
10.7•	Form of Amendment to the Employment Agreement of Gerri Henwood.	Incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on December 19, 2014 (File No. 001-36329).
10.8•	Recro Pharma Inc. 2018 Amended and Restated Equity Incentive Plan.	Incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on May 9, 2018 (File No. 001-36329).
10.9•	2008 Stock Option Plan.	Incorporated herein by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1/A filed on November 29, 2013 (File No. 333-191879).
10.10•	Form of 2008 Stock Option Plan Award Agreement.	Incorporated herein by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1/A filed on November 29, 2013 (File No. 333-191879).

Exhibit

No.	Description	Method of Filing
10.11•	Form of Equity Incentive Plan Award Agreement.	Incorporated herein by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-K filed on March 25, 2015 (File No. 001-36329).
10.12•	Form of Recro Pharma, Inc. Amended and Restated Equity Incentive Plan Award Agreement for Restricted Stock Units.	Incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K on December 22, 2015 (File No. 001-36329).
10.13•	Form of Award Agreement for Option Inducement Awards	Incorporated herein by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-8 filed on December 23, 2015 (File No. 333-208750).
10.14•	Form of Award Agreement for Restricted Stock Unit Inducement Awards	Incorporated herein by reference to Exhibit 10.20 to the Company's Annual Report on Form 10-K filed on March 2, 2018 (File No. 001-36329).
10.15†	Asset Transfer and License Agreement, dated as of April 10, 2015, between Alkermes Pharma Ireland Limited and DV Technology LLC.	Incorporated herein by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on May 12, 2015 (File No. 001-36329).
10.16	Amendment to Asset Transfer and License Agreement, dated December 23, 2015, between Alkermes Pharma Ireland Limited and Recro Gainesville LLC	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 23, 2015 (File No. 001-36329).
10.17	Second Amendment to Asset Transfer and License Agreement, dated December 20, 2018, between Alkermes Pharma Ireland Limited and Recro Gainesville LLC	Incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on December 28, 2018 (File No. 001-36329).
10.18†	Development, Manufacturing and Supply Agreement, dated July 10, 2015, by and between Alkermes Pharma Ireland Limited and Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2015 (File No. 001-36329).
10.19†	First Amendment to the Development, Manufacturing and Supply Agreement, dated October 19, 2016, by and between Alkermes Pharma Ireland Limited and Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 10.35 to the Company's Annual Report on Form 10-K filed on March 9, 2017 (File No. 001-36329).

10.20†	Second Amendment to the Development, Manufacturing and Supply Agreement, dated February 1, 2017, by and between Alkermes Pharma Ireland Limited and Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 10.36 to the Company's Annual Report on Form 10-K filed on March 9, 2017 (File No. 001-36329).
10.21†	Third Amendment to the Development, Manufacturing and Supply Agreement, dated June 15, 2017, by and between Alkermes Pharma Ireland Limited and Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 11, 2017 (File No. 001-36329).
10.22†	Amended and Restated License and Supply Agreement, dated June 26, 2003, by and among Elan Corporation, plc (predecessor-in-interest to Recro Gainesville LLC) and Watson Laboratories, Inc.	Incorporated herein by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2015 (File No. 001-36329).
10.23	Supplemental Agreement, dated December 8, 2004, to Amended and Restated License and Supply Agreement, dated June 26, 2003, by and among Elan Corporation, plc (predecessor-in-interest to Recro Gainesville LLC) and Watson Laboratories, Inc.	Incorporated herein by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2015 (File No. 001-36329).
10.24	Supplemental Agreement No. 2, dated January 17, 2014, to Amended and Restated License and Supply Agreement, dated June 26, 2003, by and among Elan Corporation, plc (predecessor-in-interest to Recro Gainesville LLC) and Watson Laboratories, Inc.	Incorporated herein by reference to Exhibit 10.8 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2015 (File No. 001-36329).
10.25†	License Agreement, dated June 30, 2017, by and between Cornell University and Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 11, 2017 (File No. 001-36329).

Exhibit No.	Description	Method of Filing
10.26†	Amendment to License Agreement, dated October 31, 2018, by and between Cornell University and Recro Pharma, Inc.	Filed herewith.
10.27†	Master Manufacturing Services Agreement, dated July 14, 2017, by and between Patheon UK Limited and Recro Ireland Limited	Incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on August 11, 2017 (File No. 001-36329).
10.28†	Product Agreement, dated July 14, 2017, by and between Patheon UK Limited and Recro Ireland Limited	Incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on August 11, 2017 (File No. 001-36329).
10.29†	Credit Agreement, dated as of November 17, 2017, by and between Recro Pharma, Inc. and Athyrium Opportunities III Acquisition LP. *	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 20, 2017 (File No. 001-36329).
10.30†	First Amendment to Credit Agreement and Investment Documents, dated as of December 28, 2018, by and between Recro Pharma, Inc. and Athyrium Opportunities III Acquisition LP. *	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 4, 2019 (File No. 001-36329).
10.31†	Security Agreement, dated as of November 17, 2017, by Recro Pharma, Inc. in favor of Athyrium Opportunities III Acquisition LP.	Incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on November 20, 2017 (File No. 001-36329).
10.32	Sales Agreement, dated as of December 29, 2017, by and between Recro Pharma, Inc. and Cowen and Company, LLC.	Incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed on December 29, 2017 (File No. 001-36329).
10.33	Common Stock Purchase Agreement, dated March 2, 2018, by and between Recro Pharma, Inc. and Aspire Capital Fund, LLC.	Incorporated herein by reference to Exhibit 10.38 to the Company's Annual Report on Form 10-K filed on March 2, 2018 (File No. 001-36329).
10.34	Common Stock Purchase Agreement, dated February 19, 2019, by and between Recro Pharma, Inc. and Aspire Capital Fund, LLC.	Filed herewith.
21.1	Subsidiaries of Recro Pharma, Inc.	Filed herewith.
23.1	Consent of KPMG LLP, Independent Registered Public Accounting Firm.	Filed herewith.

23.2	Consent of Pepper Hamilton LLP.	Included in Exhibit 5.1.
31.1	Rule 13a-14(a)/15d-14(a) certification of Principal Executive Officer	Filed herewith.
31.2	Rule 13a-14(a)/15d-14(a) certification of Principal Financial Officer	Filed herewith.
32.1	Section 1350 certification, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
101 INS	XBRL Instance Document	Filed herewith.
101 SCH	XBRL Taxonomy Extension Schema	Filed herewith.
101 CAL	XBRL Taxonomy Extension Calculation Linkbase	Filed herewith.
101 DEF	XBRL Taxonomy Extension Definition Linkbase	Filed herewith.
101 LAB	XBRL Taxonomy Extension Label Linkbase	Filed herewith.

• Management contract or compensatory plan or arrangement.
† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 406 under the Securities Act of 1933.
(c) Not applicable

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.

Date: February 19, 2019

RECRO PHARMA, INC.

By: /s/ Gerri A. Henwood
Gerri A. Henwood
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, Annual Report on Form 10-K has been signed by the following persons in the capacities held on the dates indicated.

Signature	Title	Date
/s/ Gerri A. Henwood	President, Chief Executive Officer and Director	February 19, 2019
Gerri A. Henwood	(Principal Executive Officer)	
/s/ Ryan D. Lake Ryan D. Lake	Chief Financial Officer	February 19, 2019
	(Principal Financial Officer and Principal Accounting Officer)	
/s/ Alfred Altomari Alfred Altomari	Director	February 19, 2019
/s/ William L. Ashton William L. Ashton	Director	February 19, 2019
/s/ Michael Berelowitz Michael Berelowitz	Director	February 19, 2019
/s/ Winston J. Churchill Winston J. Churchill	Director	February 19, 2019
/s/ Karen Flynn Karen Flynn	Director	February 19, 2019
/s/ Bryan M. Reasons Bryan M. Reasons	Director	February 19, 2019

/s/ Wayne B. Weisman Wayne B. Weisman	Director	February 19, 2019

RECRO PHARMA, INC. AND SUBSIDIARIES

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors

Recro Pharma, Inc.:

Opinion on the Consolidated Financial Statements

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

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 Public Company Accounting Oversight Board (United States) (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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2009.

Philadelphia, Pennsylvania

February 19, 2019

RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

(amounts in thousands, except share and per share data)	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 38,514	$ 60,984
Short-term investments	—	3,498
Accounts receivable	12,866	9,686
Inventory	10,699	9,839
Contract asset	5,201	—
Prepaid expenses and other current assets	3,861	3,276
Total current assets	71,141	87,283
Property, plant and equipment, net	45,640	39,074
Deferred income taxes	—	18,573
Intangible assets, net	32,266	34,850
Goodwill	6,446	6,446
Total assets	$ 155,493	$ 186,226
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 4,510	$ 7,954
Accrued expenses and other current liabilities	14,165	9,897
Current portion of contingent consideration	10,354	32,053
Total current liabilities	29,029	49,904
Long-term debt, net	64,243	53,598
Warrants and other long-term liabilities	1,163	3,516
Long-term portion of contingent consideration	80,558	50,360
Total liabilities	174,993	157,378
Commitments and contingencies (Note 13)		
Shareholders' equity:		
Preferred stock, $0.01 par value. Authorized, 10,000,000 shares; none issued and outstanding	—	—
Common stock, $0.01 par value. Authorized, 50,000,000 shares; issued and outstanding, 21,799,961 shares at December 31, 2018 and 19,127,435 shares at December 31, 2017	218	191
Additional paid-in capital	168,535	140,006
Accumulated deficit	(188,253)	(111,348)
Accumulated other comprehensive loss	—	(1)
Total shareholders' equity (deficit)	(19,500)	28,848
Total liabilities and shareholders' equity	$ 155,493	$ 186,226

See accompanying notes to consolidated financial statements.

RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss

	For the Year ended December 31,		
(amounts in thousands, except share and per share data)	2018	2017	2016
Revenue	$77,347	$71,834	$69,337
Operating expenses:			
Cost of sales (excluding amortization of intangible assets)	43,160	38,193	37,152
Research and development	39,985	33,095	33,278
General and administrative	36,879	25,426	12,742
Amortization of intangible assets	2,583	2,583	2,583
Change in warrant valuation	284	9	(373)
Change in contingent consideration valuation	8,499	12,839	9,728
Total operating expenses	131,390	112,145	95,110
Operating loss	(54,043)	(40,311)	(25,773)
Other income (expense):			
Interest income	512	385	49
Interest expense	(8,756)	(12,034)	(5,588)
Net loss before income taxes	(62,287)	(51,960)	(31,312)
Income tax benefit (expense)	(17,436)	1,880	1,107
Net loss	$(79,723)	$(50,080)	$(30,205)
Per share information:			
Net loss per share of common stock, basic and diluted	$(3.90)	$(2.63)	$(2.82)
Weighted average common shares outstanding, basic and diluted	20,465,106	19,070,983	10,721,928
Net loss	$(79,723)	$(50,080)	$(30,205)
Other comprehensive loss:			
Unrealized gain (loss) on available-for-sale securities	1	(1)	—
Comprehensive loss	$(79,722)	$(50,081)	$(30,205)

See accompanying notes to consolidated financial statements.

RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Shareholders' Equity

For the Years Ended December 31, 2018, 2017 and 2016

(amounts in thousands, except share data)	Common Stock Shares	Amount	Additional paid-in capital	Accumulated Deficit	Accumulated other comprehensive loss	Total
Balance, December 31, 2015	9,224,315	$ 92	$ 71,321	$ (31,063)	$ —	$ 40,350
Sale of common stock under Aspire equity facility, net of transaction costs	1,143,940	11	7,364	—	—	7,375
Sales of common stock in public offerings, net of offering costs	8,656,666	87	50,168	—	—	50,255
Issuance of restricted stock units, net of shares withheld for income taxes	18,295	—	(51)	—	—	(51)
Stock-based compensation expense	—	—	3,889	—	—	3,889
Net loss	—	—	—	(30,205)	—	(30,205)
Balance, December 31, 2016	19,043,216	190	132,691	(61,268)	—	71,613
Stock-based compensation expense	—	—	5,546	—	—	5,546
Stock option exercise	7,756	—	53	—	—	53
Issuance of restricted stock units, net of shares withheld for income taxes	76,463	1	(250)	—	—	(249)
Warrants issued in financing facility, net of related tax effect	—	—	1,966	—	—	1,966
Other comprehensive loss	—	—	—	—	(1)	(1)
Net loss	—	—		(50,080)	—	(50,080)
Balance, December 31, 2017	19,127,435	191	140,006	(111,348)	(1)	28,848
Stock-based compensation expense	—	—	7,129	—	—	7,129
Stock option exercise	352,025	4	1,811	—	—	1,815
Issuance of restricted stock units, net of shares withheld for income taxes	122,746	1	(92)	—	—	(91)
Sale of common stock under equity facility, net of transaction costs	1,983,040	20	17,005	—	—	17,025
Cashless exercise of warrants	214,715	2	2,587	—	—	2,589
Revaluation of equity classified	—	—	89	—	—	89

warrants						
Change in other comprehensive loss	—	—	—	—	1	1
Net loss	—	—	—	(79,723)	—	(79,723)
Cumulative effect of adoption of new accounting standards, net of tax	—	—	—	2,818	—	2,818
Balance, December 31, 2018	21,799,961	$ 218	$ 168,535	$ (188,253)	$ —	$ (19,500)

See accompanying notes to consolidated financial statements.

RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

(amounts in thousands)	For the Year ended December 31, 2018	2017	2016
Cash flows from operating activities:			
Net loss	$(79,723)	$(50,080)	$(30,205)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	7,129	5,546	3,889
Non-cash interest expense	1,287	912	1,071
Depreciation expense	5,267	4,864	4,993
Loss on early extinguishment of debt	—	6,772	—
Amortization	2,583	2,583	2,583
Acquired in-process research and development charges	—	766	—
Change in warrant valuation	284	9	(373)
Change in contingent consideration valuation	8,499	12,839	9,728
Deferred income taxes	17,637	(1,690)	(1,423)
Changes in operating assets and liabilities, net of effect of acquisition:			
Inventory	(860)	(1,093)	237
Contract asset	(1,446)	—	—
Prepaid expenses and other current assets	(527)	(2,158)	(325)
Accounts receivable	(3,180)	725	(1,831)
Accounts payable, accrued expenses and other liabilities	(65)	2,963	8,454
Net cash used in operating activities	(43,115)	(17,042)	(3,202)
Cash flows from investing activities:			
Purchase of property and equipment	(10,526)	(6,172)	(3,770)
Purchase of short-term investments	(6,225)	(57,124)	—
Proceeds from maturity of investments	9,750	53,500	—
Acquisition of license agreement	(82)	(519)	—
Net cash used in investing activities	(7,083)	(10,315)	(3,770)
Cash flows from financing activities:			
Proceeds from issuance of long-term debt	10,000	60,000	—
Payments on long-term debt	—	(27,347)	(6,324)
Fees related to early extinguishment of debt	—	(4,420)	—
Payment of deferred financing costs	(961)	(4,178)	—
Proceeds from sale of common stock, net of transaction costs	16,965	—	58,051
Payments of withholdings on shares withheld for income taxes	(91)	(250)	(51)
Proceeds from option exercise	1,815	53	—
Net cash provided by financing activities	27,728	23,858	51,676
Net (decrease) increase in cash and cash equivalents	(22,470)	(3,499)	44,704
Cash and cash equivalents, beginning of year	60,984	64,483	19,779
Cash and cash equivalents, end of year	$38,514	$60,984	$64,483
Supplemental disclosure of cash flow information:			
Cash paid for interest	$8,134	$5,341	$4,517
Cash paid for taxes	$—	$467	$—

Purchase of property, plant and equipment included in accrued expenses and accounts payable	$2,581	$1,274	$808
Common stock issued in connection with equity facility	$357	$—	$—
Amortization of deferred equity costs	$332	$—	$421
Fair value recognized for warrants	$89	$2,143	$—
Withholdings on shares withheld for income taxes included in accrued expenses	$—	$233	$—
Retirement of fully depreciated property, plant and equipment	$88	$161	$—

See accompanying notes to consolidated financial statements.

RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

(amounts in thousands, except share and per share data)

(1) Background

Recro Pharma, Inc., or the Company, was incorporated in Pennsylvania on November 15, 2007. The Company is a specialty pharmaceutical company that operates through two business segments: an Acute Care segment and a revenue-generating contract development and manufacturing, or CDMO segment. Each of these segments are deemed to be reportable segments (see Note 3(m) and Note 17). The Acute Care segment is primarily focused on developing innovative products for hospital and other acute care settings, and the CDMO segment leverages the Company's formulation expertise to develop and manufacture pharmaceutical products using the Company's proprietary delivery technologies for commercial partners who commercialize or plan to commercialize these products. On April 10, 2015, the Company acquired from Alkermes plc, or Alkermes, worldwide rights to intravenous and intramuscular, or injectable, meloxicam, a proprietary long-acting preferential COX-2 inhibitor being developed for the management of moderate to severe pain, as well as a contract manufacturing facility, royalty and formulation business in Gainesville, Georgia. The acquisition is referred to herein as the Gainesville Transaction. In July 2017, the Company submitted a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or the FDA, for its lead investigational product candidate intravenous, or IV, meloxicam 30 mg for the management of moderate to severe pain. In May 2018, the Company received a Complete Response Letter, or CRL, from the FDA regarding its NDA for IV meloxicam. In July 2018, the Company participated in a Type A End-of-Review meeting with the FDA to discuss the topics covered in the CRL. Upon receipt and review of the meeting minutes, the Company resubmitted the NDA for IV meloxicam in September 2018. The FDA has set a date for decision on the NDA under the Prescription Drug User Fee Act, or PDUFA, of March 24, 2019.

(2) Development-Stage Risks and Liquidity

The Company has incurred losses from operations since inception and has an accumulated deficit of $188,253 as of December 31, 2018. Though its CDMO segment has been profitable, the Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its products currently in development. Additional financing will be needed by the Company to fund its operations and to commercially develop its product candidates, including the payment of the Gainesville Transaction contingent payments, which may become due upon achievement of certain development and commercialization milestones for meloxicam (see Note 4). Insufficient funds may cause the Company to delay, reduce the scope of or eliminate one or more of its development, commercialization or expansion activities. The Company may raise such funds through debt refinancing, bank or other loans, sale of assets, through strategic research and development, licensing (including out-licensing) and/or marketing arrangements or through public or private sales of equity or debt securities from time to time. Financing may not be available on acceptable terms, or at all, and failure to raise capital when needed could materially adversely impact the Company's growth plans and its financial condition or results of operations. Additional equity financing, if available, may be dilutive to the holders of its common stock and may involve significant cash payment obligations and covenants that restrict the Company's ability to operate its business. The Company's future operations are highly dependent on a combination of factors, including (i) the continued profitability of the CDMO segment; (ii) the timely and successful completion of additional financing and/or alternative sources of capital, debt, partnering or out-licensing transactions; (iii) the success of its research and development, including the results and timing of its clinical trials; (iv) the development of competitive therapies by other biotechnology and pharmaceutical companies; and, ultimately, (v) regulatory approval and market acceptance of the Company's proposed future products, including IV meloxicam. Management believes that it is probable that the Company will be able to meet its obligations as they become due

within one year after the date the financial statements are issued.

(3) Summary of Significant Accounting Principles

(a) Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements of the Company and its subsidiaries have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The Company's consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated.

In the opinion of management, the accompanying consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company's financial position as of December 31, 2018 and 2017 and its results of operations for the twelve months ended December 31, 2018, 2017 and 2016 and cash flows for the twelve months ended December 31, 2018, 2017 and 2016.

RECRO PHARMA, INC. AND SUBSIDIARIES

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(b) Use of Estimates

The preparation of financial statements and the notes to the financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from such estimates.

(c) Cash and Cash Equivalents

Cash and cash equivalents represents cash in banks and highly liquid short-term investments that have maturities of three months or less when acquired to be cash equivalents. These highly liquid short-term investments are both readily convertible to known amounts of cash and so near their maturity that they present insignificant risk of changes in value because of the changes in interest rates.

(d) Property and Equipment

Property and equipment are recorded at cost less accumulated depreciation and amortization. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the assets, which are as follows: three to ten years for furniture and office equipment; six to ten years for manufacturing equipment; two to five years for vehicles; 35 to 40 years for buildings; and the shorter of the lease term or useful life for leasehold improvements. Repairs and maintenance cost are expensed as incurred.

(e) Business Combinations

In accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 805, “Business Combinations,” or ASC 805, the Company allocates the purchase price of acquired companies to the tangible and intangible assets acquired and liabilities assumed based on their estimated fair values. Valuations are performed to assist in determining the fair values of assets acquired and liabilities assumed, which requires management to make significant estimates and assumptions, in particular with respect to intangible assets and contingent consideration. Management makes estimates of fair value based upon assumptions believed to be reasonable. These estimates are based in part on historical experience and information obtained from management of the acquired companies and expectations of future cash flows. Transaction costs and restructuring costs associated with the transaction are expensed as incurred. In-process research and development, or IPR&D, is the value assigned to those projects for which the related products have not received regulatory approval and have no alternative future use. Determining the portion of the purchase price allocated to IPR&D requires the Company to make significant estimates. In a business combination, the Company capitalizes IPR&D as an intangible asset, and for an asset acquisition the Company expenses IPR&D in the Consolidated Statements of Operations and Comprehensive Loss on the acquisition date

(f) Goodwill and Intangible Assets

Goodwill represents the excess of purchase price over the fair value of net assets acquired by the Company. Goodwill is not amortized, but assessed for impairment on an annual basis or more frequently if impairment indicators exist. The impairment model prescribes a one-step method for determining impairment.

The one-step quantitative test calculates the amount of goodwill impairment as the excess of a reporting unit's carrying amount over its fair value, not to exceed the total amount of goodwill allocated to the reporting unit.

Intangible assets include the Company's royalties and contract manufacturing relationships intangible asset as well as an IPR&D asset. The royalties and contract manufacturing relationships intangible asset is considered a definite-lived intangible asset and is amortized on a straight-line basis over a useful life of six years.

Intangible assets related to IPR&D are considered indefinite-lived intangible assets and are assessed for impairment annually or more frequently if impairment indicators exist. If the associated research and development effort is abandoned, the related assets will be written-off, and the Company will record a noncash impairment loss on its Consolidated Statements of Operations and Comprehensive Loss. For those compounds that reach commercialization, the IPR&D assets will be amortized over their estimated useful lives.

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The impairment test for indefinite-lived intangible assets is a one-step test, which compares the fair value of the intangible asset to its carrying value. If the carrying value exceeds its fair value, an impairment loss is recognized in an amount equal to the excess. Based on accounting standards, it is required that these assets be assessed at least annually for impairment unless a triggering event occurs between annual assessments, which would then require an assessment in the period which a triggering event occurred.

The Company performs its annual goodwill and indefinite-lived intangible asset impairment test as of November 30th, or whenever an event or change in circumstances occurs that would require reassessment of the recoverability of those assets. In performing the evaluation the Company assesses qualitative factors such as overall financial performance of its reporting units, anticipated changes in industry and market conditions, including recent tax reform, and competitive environments. Due to the receipt of the CRL in May 2018, an indicator of potential impairment, the Company performed an impairment test as of June 30, 2018, which indicated that there was no impairment to goodwill or indefinite-lived intangible assets. The Company additionally performed impairment tests as of November 30, 2018 and noted there have been no further triggering events or indicators of impairment as of December 31, 2018. As a result of the impairment tests, the Company determined that there was no impairment to goodwill or indefinite-lived intangible assets for the year ended December 31, 2018.

(g) Revenue Recognition

The Company generates revenues from manufacturing, packaging, research and development, and related services for multiple pharmaceutical companies through its CDMO segment. The agreements that the Company has with its commercial partners provide for manufacturing revenues, sales-based royalties and/or profit sharing components. The Company's revenue policies listed below are reflective of Accounting Standards Update, or ASU, No. 2014-09, "Revenue from Contracts with Customers," or ASU 2014-09, which the Company adopted effective January 1, 2018. See Note 18 for additional information regarding the Company's adoption of ASU 2014-09 and its impact on the Company's financial statements.

Manufacturing and other related services revenue is recognized upon transfer of control of a product to a customer, generally upon shipment, based on a transaction price that reflects the consideration the Company expects to be entitled to as specified in the agreement with the commercial partner, which could include pricing and volume-based adjustments.

In addition to manufacturing and packaging revenue, certain customer agreements may have intellectual property sales-based royalties and/or profit sharing consideration, collectively referred to as royalties, computed on the net product sales of the commercial partner. Royalty revenues are generally recognized under the terms of the applicable license, development and/or supply agreement. For arrangements that include sales-based royalties where the license

for intellectual property is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue when the related sales occur by the commercial partner. For arrangements that include sales-based royalties where the license for intellectual property is not deemed to be the predominant item to which the royalties relate, the Company recognizes revenue upon transfer of control of the manufactured product. In these cases, significant judgment is required to calculate this estimated variable consideration using the most-likely amount method based on historical customer pricing and deductions and is partially constrained due to items that are outside of the Company's control including the uncertainty of the timing of future commercial partner sales, mix of volume, customer stocking and ordering patterns, as well as unforeseen price adjustments made by the Company's commercial partners.

Revenues related to research and development for our CDMO segment are generally recognized over-time as the related services or activities are performed using the output method and in accordance with the contract terms. In agreements which specify milestones, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. Milestone payments related to arrangements under which the Company has continuing performance obligations would be deferred and recognized over the period of performance. Milestone payments that are not within the control of the Company, such as submission for approval to regulators by a commercial partner or approvals from regulators, are not considered probable of being achieved until those submissions are submitted by the customer or approvals are received.

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(h) Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash, cash equivalents, short-term investments and accounts receivable. The Company manages its cash, cash equivalents and short-term investments based on established guidelines relative to diversification and maturities to maintain safety and liquidity.

The Company's accounts receivable balances are concentrated amongst approximately five customers and if any of these customers' receivable balances should be deemed uncollectible, it could have a material adverse effect on the Company's results of operations and financial condition.

The Company's CDMO segment is dependent on its relationships with a small number of commercial partners, with its four largest customers having generated 99% of its revenues for the year ending December 31, 2018. A portion of the Company's revenues are dependent on U.S. based customers selling to end-users outside the U.S.

(i) Research and Development

Research and development costs for the Company's proprietary products/product candidates are charged to expense as incurred. Research and development expenses consist primarily of funds paid to third parties for the provision of services for pre-commercialization and manufacturing scale-up activities, drug development, clinical trials, statistical analysis and report writing and regulatory filing fees and compliance costs. At the end of the reporting period, the Company compares payments made to third-party service providers to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that the Company estimates has been made as a result of the service provided, the Company may record net prepaid or accrued expenses relating to these costs.

Upfront and milestone payments made to third parties who perform research and development services on the Company's behalf are expensed as services are rendered. Costs incurred in obtaining product technology licenses are charged to research and development expense as acquired IPR&D if the technology licensed has not reached technological feasibility and has no alternative future use.

(j) Stock-Based Awards

The Company measures employee stock-based awards at grant-date fair value and recognizes employee compensation expense on a straight-line basis over the vesting period of the award.

Determining the appropriate fair value of stock options requires the input of subjective assumptions, including the expected life of the option and expected stock price volatility. The Company uses the Black-Scholes option pricing model to value its stock option awards. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. As a result, if factors change and/or management uses different assumptions, stock-based compensation expense could be materially different for future awards.

The expected life of stock options was estimated using the "simplified method," as the Company has limited historical information to develop reasonable expectations about future exercise patterns and post-vesting employment

termination behavior for its stock options grants. The simplified method is based on the average of the vesting tranches and the contractual life of each grant. For stock price volatility, the Company uses the historical volatility of our publicly traded stock in order to estimate future stock price trends. The risk-free interest rate is based on U.S. Treasury notes with a term approximating the expected life of the option.

During the year ending December 31, 2016, the Company adopted ASU 2016-09, “Compensation—Stock Compensation (Topic 718) Improvements to Employee Share-Based Payment Accounting” and elected to account for forfeitures as they occur.

For non-employee stock-based awards, the Company recognizes compensation expense on a straight-line basis over the vesting period of each separated vesting tranche of the award, which is known as the accelerated attribution method. The estimation of the number of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from the Company’s current estimates, such amounts are recognized as an adjustment in the period in which estimates are revised.

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(k) Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis, operating losses and tax credit carryforwards. 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. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. A valuation allowance is recorded to the extent it is more likely than not that some portion or all of the deferred tax assets will not be realized.

Unrecognized income tax benefits represent income tax positions taken on income tax returns that have not been recognized in the consolidated financial statements. The Company recognizes the benefit of an income tax position only if it is more likely than not (greater than 50%) that the tax position will be sustained upon tax examination, based solely on the technical merits of the tax position. Otherwise, no benefit is recognized. The tax benefits recognized are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. The Company does not anticipate significant changes in the amount of unrecognized income tax benefits over the next year.

(l) Net Loss Per Common Share

Basic net loss per common share is determined by dividing net loss applicable to common shareholders by the weighted average common shares outstanding during the period. For the years ending December 31, 2018, 2017 and 2016, the outstanding common stock options, warrants and unvested restricted stock units have been excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive.

For purposes of calculating diluted loss per common share, the denominator includes both the weighted average common shares outstanding and the number of common stock equivalents if the inclusion of such common stock equivalents would be dilutive.

The following table sets forth the computation of basic and diluted loss per share:

	Year ended December 31,		
	2018	2017	2016
Basic Loss Per Share			
Net loss	$(79,723)	$(50,080)	$(30,205)
Weighted average common shares outstanding, basic and diluted	20,465,106	19,070,983	10,721,928
Net loss per share of common stock, basic and diluted	$(3.90)	$(2.63)	$(2.82)

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as of December 31, 2018, 2017 and 2016 as they would be anti-dilutive:

	December 31,		
	2018	2017	2016
Options and restricted stock units outstanding	4,878,461	3,865,468	2,619,679
Warrants	838,664	1,133,592	784,928

Amounts in the table above reflect the common stock equivalents of the noted instruments.

(m) Segment Information

The Company determined its reportable segments based on its strategic business units, the commonalities among the products and services within each segment and the manner in which the Company reviews and evaluates operating performance. The Company has identified CDMO and Acute Care as reportable segments. Segment disclosures are included in Note 17. Segment operating profit (loss) is defined as segment revenue less segment operating expenses (segment operating expenses consist of general and administrative expenses, research and development expenses, and the change in valuation of contingent consideration and warrants). The following items are excluded from segment operating profit (loss): interest income and expense, and income tax benefit (expense). Segment assets are those assets and liabilities that are recorded and reported by segment operations.

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(n) Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In June 2018, the FASB issued ASU No. 2018-07, “Compensation – Stock Compensation (Topic 718)” or ASU 2018-07. ASU 2018-07 simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The new guidance expands the scope of ASC 718 “Compensation—Stock Compensation” to include share-based payments granted to nonemployees in exchange for goods or services used or consumed in an entity’s own operations and supersedes the guidance in ASC 505-50 “Equity-Based Payments to Non-Employees”. The guidance is effective for public business entities in annual periods beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted, including in an interim period for which financial statements have not been issued, but not before an entity adopts ASU 2014-09 “Revenue from Contracts with Customers (Topic 606)”. The Company adopted this guidance effective June 30, 2018. There was no impact upon adoption.

In May 2017, the FASB issued ASU No. 2017-09, “Stock Compensation – Scope of Modification Accounting” or ASU 2017-09. ASU 2017-09 provides guidance on which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The new standard was effective for fiscal years beginning after December 15, 2017. The Company adopted the guidance effective January 1, 2018. There was no impact upon adoption.

In January 2017, the FASB issued ASU No. 2017-04 “Intangibles – Goodwill and Other (Topic 350): Simplifying the Accounting for Goodwill Impairment,” or ASU 2017-04. ASU 2017-04 allows companies to apply a one-step quantitative test and record the amount of goodwill impairment as the excess of a reporting unit’s carrying amount over its fair value, not to exceed the total amount of goodwill allocated to the reporting unit. The amendments of the ASU are effective for annual or interim goodwill impairment tests in fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company adopted this guidance as of October 1, 2018 and there was no impact on its consolidated financial statements.

In May 2014, the FASB issued ASU 2014-09. ASU 2014-09 represents a comprehensive new revenue recognition model that requires a company to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which a company expects to be entitled to receive in exchange for those goods or services. This ASU sets forth a new five-step revenue recognition model that replaces the prior revenue recognition guidance in its entirety and is intended to eliminate numerous industry-specific pieces of revenue recognition guidance that have historically existed. In January 2018, the Company adopted the standard using the modified retrospective method. See Note 18 for additional information on the impact of the transition on the Company’s financial statements

Accounting Pronouncements Not Yet Adopted

In August 2018, the FASB issued ASU 2018-13, “Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement,” or ASU 2018-13. ASU 2018-13 removes, modifies and adds certain disclosure requirements in Topic 820 “Fair Value Measurement”. ASU 2018-13

eliminates certain disclosures related to transfers and the valuations process, clarifies the measurement uncertainty disclosure, and requires additional disclosures for Level 3 fair value measurements, including the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. ASU 2018-13 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. The Company is currently evaluating the potential impact on its disclosures.

In February 2016, the FASB issued ASU No. 2016-02, “Leases (Topic 842),” or ASU 2016-02. ASU 2016-02 establishes a wholesale change to lease accounting and introduces a lease model that brings most leases on the balance sheet. It also eliminates the required use of bright-line tests in current U.S. GAAP for determining lease classification. In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842), Targeted Improvements, which provides an alternative transition method permitting the recognition of a cumulative-effect adjustment to retained earnings on the date of adoption rather than restating comparative periods in transition as originally prescribed by Topic 842. The new guidance is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted. The Company plans to adopt this ASU in the first quarter of 2019. The Company will elect the optional transition method to account for the impact of the adoption with a cumulative-effect adjustment in the period of adoption and will not restate prior periods. The Company expects to elect certain practical expedients permitted under the transition guidance. The Company currently expects that most of its operating lease commitments will be subject to the update and recognized as operating lease liabilities and right-of-use assets upon adoption. The Company expects total assets and total liabilities will materially

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increase in the period of adoption in the range of $1.5 to $2.5 million. The Company is in the final stages of evaluating the impact the adoption of this accounting standard will have on its results of operations, cash flows and related disclosures. The Company continues to assess any potential impacts on its internal controls, business processes, and accounting policies related to both the implementation and ongoing compliance of the new guidance.

(4) Acquisition of Gainesville Facility and Meloxicam

On April 10, 2015, the Company completed the Gainesville Transaction. The consideration paid in connection with the Gainesville Transaction consisted of $50,000 cash at closing, a $4,000 working capital adjustment and a seven-year warrant to purchase 350,000 shares of the Company's common stock at an exercise price of $19.46 per share, according to the original agreement. In addition, according to the original agreement, the Company may be required to pay up to an additional $125,000 in milestone payments including $45,000 upon regulatory approval, as well as net sales milestones related to injectable meloxicam and a percentage of future product net sales related to injectable meloxicam between 10% and 12% (subject to a 30% reduction when no longer covered by patent). Under the acquisition method of accounting, the consideration paid and the fair value of the contingent consideration and royalties are allocated to the fair value of the assets acquired and liabilities assumed. The contingent consideration obligation is remeasured each reporting date with changes in fair value recognized as a period charge within the statement of operations (see Note 6 for further information regarding fair value).

In December 2018, the Company entered in to an Amendment to the Purchase and Sale Agreement that restructured the $45,000 milestone to $60,000 therefore increasing the amount the Company may be required to pay Alkermes to $140,000, however, the amendment spread the payments of the development milestone over a seven year period. In addition, the Company amended the warrant agreement with Alkermes, which decreased the exercise price of the warrant to $8.26 per share.

Based on the amended terms of the Alkermes agreement, the contingent consideration consists of four separate components. The first component is (i) a $5,000 payment due January 19, 2019 (30 days after signing such amendment) and (ii) a $5,000 payment due by April 23, 2019. The second components will be payable upon certain regulatory approval and include (i) a $5,000 payment due within 180 days following regulatory approval for IV meloxicam and (ii) $45,000 payable in seven equal annual payments of approximately $6,400 beginning on the first anniversary of such approval. The third component consists of three potential payments, based on the achievement of specified annual revenue targets, the last of which represents over 60% of these milestone payments and currently does not have a fair value assigned to its achievement. The fourth component consists of a royalty payment between 10% and 12% (subject to a 30% reduction when no longer covered by patent) for a defined term on future meloxicam net sales.

The fair value of the first and second contingent consideration components is estimated by applying a risk-adjusted discount rate to the probability-adjusted contingent payments and the expected approval dates. The fair value of the third contingent consideration component is estimated using the Monte Carlo simulation method and applying a risk-adjusted discount rate to the potential payments resulting from probability-weighted revenue projections based upon the expected revenue target attainment dates. The fair value of the fourth contingent consideration component is estimated by applying a risk-adjusted discount rate to the potential payments resulting from probability-weighted

revenue projections and the defined royalty percentage.

These fair values are based on significant inputs not observable in the market, which are referred to in the guidance as Level 3 inputs. The contingent consideration components are classified as liabilities and are subject to the recognition of subsequent changes in fair value through the results of operations.

(5) NMBA Related License Agreement

In June 2017, the Company acquired the exclusive global rights to two novel neuromuscular blocking agents, or NMBAs, and a proprietary chemical reversal agent from Cornell University, or Cornell. The NMBAs and reversal agent are referred to herein as the NMBA Related Compounds. The NMBA Related Compounds include one novel intermediate-acting NMBA that has initiated Phase I clinical trials and two other agents, a novel short-acting NMBA, and a rapid-acting reversal agent proprietary to these NMBAs.

The transaction was accounted for as an asset acquisition, with the total cost of the acquisition of $766 allocated to acquired IPR&D. The Company recorded an upfront payment obligation of $350, as well as operational liabilities and acquisition-related costs of $416, primarily consisting of reimbursement to Cornell for specified past patent, legal and pre-clinical costs.

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In addition, the Company is obligated to make: (i) an annual license maintenance fee payment until the first commercial sale of the NMBA Related Compounds; and (ii) milestone payments upon the achievement of certain milestones, up to a maximum, for each NMBA, of $5,000 for U.S. regulatory approval and commercialization milestones and $3,000 for European regulatory approval and commercialization milestones. The Company is also obligated to pay Cornell royalties on net sales of the NMBA Related Compounds at a rate ranging from low to mid-single digits, depending on the applicable NMBA Related Compounds and whether there is a valid patent claim in the applicable country, subject to an annual minimum royalty amount. Further, the Company will reimburse Cornell ongoing patent costs related to prosecution and maintenance of the patents related to the Cornell patents for the NMBA Related Compounds.

The Company accounted for the transaction as an asset acquisition based on an evaluation of the accounting guidance (ASC Topic 805) and considered the early clinical stage of the novel and unproven NMBA Related Compounds. The Company concluded that the acquired IPR&D of Cornell did not constitute a business as defined under ASC 805 due to the incomplete nature of the inputs and the absence of processes from a market participant perspective. Substantial additional research and development will be required to develop any NMBA Related Compounds into a commercially viable drug candidate, including completion of pre-clinical testing and clinical trials, and, if such clinical trials are successful, application for regulatory approvals and manufacturing repeatability and scale-up. There is risk that a marketable compound may not be well tolerated and may never be approved.

Acquired IPR&D in the asset acquisition was accounted for in accordance with FASB ASC Topic 730, “Research and Development.” At the date of acquisition, the Company determined that the development of the projects underway at Cornell had not yet reached technological feasibility and that the research in process had no alternative future uses. Accordingly, the acquired IPR&D was charged to expense in the Consolidated Statements of Operations and Comprehensive Loss on the acquisition date. The acquired IPR&D charge is expected to be deductible over a 15-year period for income tax purposes.

(6) Fair Value of Financial Instruments

The Company follows the provisions of FASB ASC Topic 820, “Fair Value Measurements and Disclosures,” for fair value measurement recognition and disclosure purposes for its financial assets and financial liabilities that are remeasured and reported at fair value each reporting period. The Company measures certain financial assets and liabilities at fair value on a recurring basis, including cash equivalents, short-term investments, warrants and the contingent consideration. The Company’s assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of financial assets and financial liabilities and their placement within the fair value hierarchy. Categorization is based on a three-tier valuation hierarchy, which prioritizes the inputs used in measuring fair value, as follows:

- Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities
- Level 2: Inputs that are other than quoted prices in active markets for identical assets and liabilities, inputs that are quoted prices for identical or similar assets or liabilities in inactive markets, or other inputs that are either directly or indirectly observable; and
- Level 3: Unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

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The Company has classified assets and liabilities measured at fair value on a recurring basis as follows:

	Fair value measurements at reporting date using Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
At December 31, 2017:			
Assets:			
Cash equivalents			
Money market mutual funds (See Note 7)	$38,959	$ —	$ —
Total cash equivalents	$38,959	$ —	$ —
Short-term investments			
U.S. Treasury obligations (See Note 7)	$3,498	$ —	$ —
Total financial assets	$42,457	$ —	$ —
Liabilities:			
Warrants (See Note 14(d))	$—	$ —	$ 3,406
Contingent consideration (See Note 4)	—	—	82,413
	$—	$ —	$ 85,819
At December 31, 2018:			
Assets:			
Cash equivalents			
Money market mutual funds (See Note 7)	$24,720	$ —	$ —
Commercial paper (See Note 7)	—	2,247	—
U.S. Treasury obligations (See Note 7)	2,748	—	—
Total cash equivalents	$27,468	$ 2,247	$ —
Liabilities:			
Warrants (See Note 14(d))	$—	$ —	$ 1,101
Contingent consideration (See Note 4)	—	—	90,912
	$—	$ —	$ 92,013

The Company developed its own assumptions to determine the value of the warrants that do not have observable inputs or available market data to support the fair value. This method of valuation involves using inputs such as the fair value of the Company's common stock, stock price volatility, the contractual term of the warrants, risk free interest rates and dividend yield. Due to the nature of these inputs, the valuation of the warrants is considered a Level 3 measurement.

The reconciliation of the contingent consideration and warrants measured at fair value on a recurring basis using unobservable inputs (Level 3) is as follows:

	Warrants	Contingent Consideration
Balance at December 31, 2016	$ 3,397	$ 69,574
Additions	—	—
Remeasurement	9	12,839
Balance at December 31, 2017	$ 3,406	$ 82,413
Exercise of warrants	(2,589)	—
Remeasurement	284	8,499
Total at December 31, 2018	$ 1,101	$ 90,912
Current portion as of December 31, 2018	—	10,354
Long-term portion as of December 31, 2018	1,101	80,558

RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

(amounts in thousands, except share and per share data)

The current portion of the contingent consideration represents the estimated probability adjusted fair value that is expected to become payable within one year as of December 31, 2018 (see Note 4 for additional information). The Company plans to reevaluate this classification as it progresses discussions with the FDA regarding the September 2018 resubmission of its NDA and approaches the new PDUFA date of March 24, 2019.

The Company follows the disclosure provisions of FASB ASC Topic 825, “Financial Instruments” (ASC 825), for disclosure purposes for financial assets and financial liabilities that are not measured at fair value. As of December 31, 2018, the financial assets and liabilities recorded on the Consolidated Balance Sheets that are not measured at fair value on a recurring basis include accounts receivable, accounts payable and accrued expenses and approximate fair value due to the short-term nature of these instruments. The fair value of long-term debt, where a quoted market price is not available, is evaluated based on, among other factors, interest rates currently available to the Company for debt with similar terms, remaining payments and considerations of the Company’s creditworthiness. The Company determined that the recorded book value of long-term debt approximated fair value at December 31, 2018 due to the comparison of the terms of the debt, including borrowing rates available to the Company through its recently completed debt refinancing process, availability of additional term loan tranches, and maturity.

(7) Cash Equivalents and Short-term Investments

Cash equivalents as of December 31, 2018 consist of government money market funds, commercial paper and U.S. Treasury obligations. In accordance with FASB ASC Topic 320, “Investments – Debt and Equity Securities,” or ASC 320, the Company classified its entire investment portfolio as of December 31, 2017 as available-for-sale securities with secondary or resale markets, and, as such, its portfolio was reported at fair value with unrealized gains and losses included in Comprehensive Loss in stockholders’ equity and realized gains and losses included in other income. The following is a summary of cash equivalents and available-for-sale securities:

	December 31, 2018			
	Amortized	Gross Unrealized		Estimated Fair
Description	Cost	Gain	Loss	Value
Money market mutual funds	$24,720	$ —	$ —	$ 24,720
Commercial paper	2,247	—	—	2,247
U.S. Treasury obligations	2,747	1	—	2,748
Total cash equivalents	$29,714	$ 1	$ —	$ 29,715

	December 31, 2017			
Description	Amortized Cost	Gross Unrealized Gain	Loss	Estimated Fair Value
Money market mutual funds	$38,959	$ —	$ —	$