Recro Pharma, Inc.
Form 10-K
March 09, 2017

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, 2016

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes 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, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer,” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

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

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 $36.1 million.

As of March 8, 2017, there were 19,050,966 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 2017 annual meeting of shareholders to be filed no later than 120 days after the end of the registrant's fiscal year ended December 31, 2016.

TABLE OF CONTENTS

Index

		Page
PART I		4
Item 1.	Business	4
Item 1A.	Risk Factors	28
Item 1B.	Unresolved Staff Comments	56
Item 2.	Properties	56
Item 3.	Legal Proceedings	57
Item 4.	Mine Safety Disclosures	57
PART II		58
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	58
Item 6.	Selected Financial Data	58
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	60
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	69
Item 8.	Financial Statements and Supplementary Data	70
Item 9.	Changes in Disagreements with Accountants on Accounting and Financial Disclosures	70
Item 9A.	Controls and Procedures	70
Item 9B.	Other Information	71
PART III		72
Item 10.	Directors, Executive Officers and Corporate Governance	72
Item 11.	Executive Compensation	72
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	72

Item 13. Certain Relationships and Related Transactions, and Director Independence 72

Item 14. Principal Accounting Fees and Services 73

PART IV 74

Item 15. Exhibits, Financial Statement Schedules 74

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” and similar expressions are intended to identify forward-looking statements, although not all forward- looking statements contain these identifying words.

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;
- the results, timing and outcome of our clinical trials of injectable meloxicam or our other product candidates, and any future clinical and preclinical studies;
- the ability to obtain and maintain regulatory approval of injectable meloxicam and our product candidates, and the labeling under any approval that we may obtain;
- our ability to successfully commercialize injectable meloxicam or our other product candidates, upon regulatory approval;
- 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 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 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 and manufacturers;
- our ability to obtain patent protection and defend our intellectual property rights against third-parties;
- our ability to maintain our relationships and contracts with our key commercial partners;
- our ability to recruit or retain key scientific, technical, commercial, and management personnel or to retain our executive officers; and
- 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.

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.

3

PART I

Item 1. Business

Overview

We are a specialty pharmaceutical company that operates through two business divisions: an Acute Care division and a revenue-generating contract development and manufacturing, or CDMO division, through which we operate a manufacturing facility in Gainesville, Georgia. We believe that we can bring valuable therapeutic options for patients, prescribers and payors, such as our lead product candidate, injectable meloxicam, and other products, to the hospital and related markets. We believe we can create value for our shareholders through the development, approval and commercialization of our pipeline assets as well as through the ongoing contributions of our cash-flow positive CDMO division. In addition to our pipeline, we are always evaluating acquisition and in-licensing opportunities that can contribute additional revenue and cash flow.

Acute Care

Our Acute Care division is primarily focused on developing innovative products for hospital and related settings. Our lead product candidate is a proprietary injectable form of meloxicam, a long-acting preferential COX-2 inhibitor. Intravenous, or IV, meloxicam has successfully completed two pivotal Phase III clinical trials in prescription of post-operative pain, one evaluating pain relief over a 48-hour period in a hard tissue, post-operative pain model (bunionectomy) and the other evaluating pain relief over a 24-hour period in a soft tissue, post-operative pain model (abdominoplasty). 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 and that it has been well tolerated. Overall we expect to enroll a total of approximately 1,100 patients in our Phase III program. To complete this program, we await final visits for more than 700 patients enrolled following a variety of surgical procedures in our additional safety study of IV meloxicam. Assuming we continue to observe a favorable safety profile in the safety study, we anticipate filing a new drug application, or NDA, for IV meloxicam with the U.S. Food and Drug Administration, or FDA, in the summer of 2017. We believe injectable meloxicam, as a non-opioid product, will overcome many of the issues associated with commonly prescribed opioid therapeutics, including respiratory depression and constipation, along with excessive nausea and vomiting, as well having no addiction potential while maintaining analgesic, or pain relieving, effects. We are pursuing a Section 505(b)(2) regulatory strategy for injectable meloxicam.

Our pipeline also includes other early-stage product candidates. Dex-IN, a proprietary intranasal formulation of dexmedetomidine, or Dex, is in a class of drugs called alpha-2 adrenergic agonists. We have studied Dex-IN for the treatment of post-operative pain and, based on clinical trial results and feedback from the FDA, we are exploring Dex-IN for use in treatment of peri-procedural pain. In addition to Dex-IN, we have another selective alpha-2 agonist product candidate in our pipeline, Fadolmidine, or Fado, which we believe also shows promise in neuropathic pain based on preclinical data.

Pipeline

CDMO

Our CDMO division leverages our formulation expertise to develop and manufacture pharmaceutical products using our proprietary delivery technologies for commercial partners who commercialize or plan to commercialize these products. These collaborations result in revenue streams including royalties, profit sharing, research and development and manufacturing, which support continued operations for our CDMO division and have contributed funds to be used in our research and development in our Acute Care division. 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®, generic Verapamil and Zohydro ER®, as well as development stage products.

Our Strategy

We believe that we can bring valuable therapeutic options for patients, prescribers and payors, such as injectable meloxicam and other projects to the hospital and related markets. We believe we can create value for our shareholders through the development, approval and commercialization of our pipeline assets as well as through the ongoing contributions of our cash-flow positive CDMO division. In addition to our pipeline, we are always evaluating acquisition and in-licensing opportunities that can contribute additional revenue and cash flow. Near term goals for our Acute Care division include:

Complete clinical development and regulatory approval of injectable meloxicam for moderate to severe pain. Our key 2017 goal is to file an NDA, and ultimately receive FDA approval of injectable meloxicam for the management of moderate to severe pain. IV meloxicam has recently successfully completed two pivotal Phase III clinical trials in pain management. To complete our Phase III program, we await final visits for more than 700 patients enrolled following a variety of surgical procedures in our additional safety study of IV meloxicam. Assuming we continue to observe a favorable safety profile in the safety study, we anticipate filing the NDA for IV meloxicam with the FDA in the summer of 2017.

Commercialize injectable meloxicam in the United States independently or with third-parties. We believe injectable meloxicam targets a group of specialist prescribers which would allow for successful marketing and commercialization by a company of our size. We are currently preparing for a potential U.S. commercial launch of IV meloxicam, if approved, and we plan to establish sales, marketing and reimbursement functions to commercialize IV meloxicam in the United States.

Enter into strategic partnerships to maximize the potential of our product candidates outside of the United States. We intend to pursue strategic collaborations with other pharmaceutical companies to develop and commercialize our product candidates outside of

the United States. We believe that our management expertise and unique product candidates make us an attractive partner to potential strategic companies.

Leverage our management and development experience to explore other indications for injectable meloxicam and to develop our other pipeline product candidates. If we have sufficient additional resources, we plan to evaluate injectable meloxicam for potential additional indications. In addition, our early-stage product pipeline includes proprietary drug solutions for peri-procedural pain, chronic pain, post-operative pain and peripheral neuropathy, utilizing multiple delivery systems, including intrathecal/epidural, transdermal, intranasal and sublingual platforms. Our goal is to leverage our drug development expertise along with innovative delivery systems to develop these product candidates to improve quality of life for the millions of people suffering from moderate-to-severe pain annually.

Acquire additional products and product candidates. We may identify and license, co-promote or acquire commercial products or product candidates for use in hospital or related settings.

Near term goals for our CDMO division include:

Expand our contract development and manufacturing business. We are focused on the growth of our development, formulation and manufacturing services. We intend to seek additional manufacturing and development partnerships with partners through ongoing business development efforts, as well as possibly through expansion of our proprietary drug delivery technologies, and service offerings.

Acute Care

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

Our Lead Product Candidate – Injectable Meloxicam

Meloxicam is a long-acting, preferential COX-2 inhibitor that possesses analgesic, anti-inflammatory, and antipyretic activities, which are believed to be related to the inhibition of cyclooxygenase, or COX, and subsequent reduction in prostaglandin biosynthesis.

Our proprietary injectable form of the drug, which utilizes NanoCrystal™ technology, 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 statistics 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 should be limited due to the know side effects of constipation, nausea, vomiting, respiratory depression, the development of tolerance and the potential for addiction 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) have 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 reduces the quality of life for individuals and 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 mandated 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. 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 injectable 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 payors, including Medicare and Medicaid, are highly interested in new non-opioid pain therapies that provide effective post-operative pain relief without the adverse issues associated with opioids.

Injectable Meloxicam Advantages

We believe injectable meloxicam has a number of advantages over existing, FDA approved 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 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. 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. Meloxicam has demonstrated through multiple clinical trials and patient use that it does not cause respiratory depression.

Not considered 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.

Onset of pain relief. IV NanoCrystal™ results in a rapid onset of pain relief in approximately 10 minutes (Study-04). IV Ketorolac, for example, can take up to 30 minutes for the onset of pain relief.

Duration of pain relief. IV meloxicam utilizing NanoCrystal™ technology 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 for every 24 hours.

Time to peak analgesic effect. Clinical data has demonstrated that IV meloxicam reaches peak analgesic effect within approximately 40 minutes of administration, reaching its peak faster than competing non-opioid therapeutics. Ketorolac can take between 1 to 2 hours to reach its peak analgesic effect.

Administration. We believe that IV meloxicam has an administration advantage in terms of bolus injection, whereas ibuprofen and acetaminophen can take up to 15 to 30 minutes to infuse. In addition, there is an Intramuscular, or IM, formulation of meloxicam, while neither ibuprofen nor acetaminophen currently have IM formulations.

GI Tolerability. Unlike opioids, the mechanism of action of meloxicam provides analgesic activity with limited adverse activity on gastrointestinal motility thus limiting or avoiding the common unwanted side effects of opioids, referred to as Opioid Induce 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.

Clinical Development

Multiple clinical trials have been conducted to evaluate the safety, pharmacokinetics and analgesic potential of IV meloxicam. Based on the results of these trials, we believe IV meloxicam has the potential to be a potent analgesic in the management of moderate to severe pain. In early 2016, based on feedback from the FDA, we commenced our Phase III clinical trial program for IV meloxicam. The program includes two pivotal Phase III clinical trials, in both hard and soft tissue post-op patients; both of which have been successfully completed. Overall we expect to enroll a total of approximately 1,100 patients in our Phase III program. To complete this program, we await final visits for more than 700 patients enrolled following a variety of surgical procedures in our additional safety study of IV meloxicam. The population selected for inclusion in the safety study is intended to replicate real world use of injectable meloxicam. Assuming we continue to observe a favorable safety profile in the safety study, we anticipate filing an NDA for IV meloxicam with the FDA in the summer of 2017. In addition, we plan to conduct Phase IIIB clinical trials for IV meloxicam.

Additional studies with IV meloxicam evaluated the pharmacokinetics of IV meloxicam in subjects with mild renal impairment as well as IV meloxicam’s potential to impact electrocardiogram, or ECG, parameters. These studies demonstrated that there is not a meaningful clinical difference in meloxicam plasma exposure in subjects older than 65 years with mild renal impairment compared to

a younger, healthy group of subjects and that therapeutic and supratherapeutic doses of IV meloxicam did not affect cardiac repolarization in the form of prolonged QTcF interval, or in other measures including QTcB, HR, PR and QRS. Per the Pediatric Study Plan Agreement with FDA, two clinical trials will be conducted in the pediatric population. These trials will be initiated following an NDA approval of IV meloxicam.

Phase III Clinical Trials

Study REC-15-016

In July 2016, we announced positive results from one pivotal clinical trial, evaluating pain relief over a 48-hour period in a hard tissue, post-operative pain model (bunionectomy). In the trial, 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 three days. Following the beginning of treatment, patients remained under observation for 48 hours at study centers. Patients were followed for seven 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 (over 15-30 seconds).

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 15 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 (Table 1).

Table 1: Summary of Secondary Endpoints

Parameter	p-value
SPID6	0.0153
SPID12	0.0053
SPID24	0.0084
SPID24-48	0.0050
Time to First Rescue Analgesia	0.0076
Number of Subjects Rescued 0-24 Hours	0.0002
Number of Subjects Rescued 24-48 Hours	0.0009
Number of Subjects Rescued 0-48 Hours	0.0002
Number of Times Rescued 0-24 Hours	0.0025
Number of Times Rescued 24-48 Hours	0.0108
Number of Times Rescued 0-48 Hours	0.0014
% Subjects with >30% Improvement – 6 Hours	0.0451
% Subjects with >30% Improvement – 24 Hours	0.0107
% Subjects with >50% Improvement – 24 Hours	0.0430
PGA of Pain Control at 48 hours	0.0046

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 treated patients, were nausea, headache, pruritus, constipation vomiting, dizziness, flushing and somnolence, and were comparable to the placebo group (Table 2). 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, ECGs, or clinical lab assessments.

Table 2: Adverse Events reported by ≥3% of subjects from any treatment group

	n (%) of Subjects	
Preferred Term	IV meloxicam 30 mg (N=100)	Placebo (N=101)
Subjects with ≥1 TEAE	44 (44.0)	54 (53.5)
Nausea	20 (20.0)	26 (25.7)
Headache	8 (8.0)	12 (11.9)
Vomiting	3 (3.0)	9 (8.9)

Pruritus	8 (8.0)3 (3.0)
Decreased appetite	2 (2.0)7 (6.9)
Constipation	4 (4.0)5 (5.0)
Abdominal pain	— 6 (5.9)
Dizziness	3 (3.0)4 (4.0)
Flushing	3 (3.0)1 (1.0)
Somnolence	3 (3.0)2 (2.0)
ALT increased	— 3 (3.0)

**Two (2) subjects experienced Serious Adverse Events during this study. Both subjects were randomized to placebo.
Study REC-15-015

In November 2016, we announced positive results from the second of our two pivotal clinical trials, evaluating pain relief over a 24-hour period in a soft tissue, post-operative pain model (abdominoplasty). In the trial, 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 three days. Following the beginning of treatment, patients remained under observation for48 hours at study centers. Patients were followed for seven 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 (Table 3).

Table 3: Summary of Secondary Endpoints

Parameter	p-value
SPID12	0.0434
SPID48	0.0040
SPID24-48	0.0028
Number of Subjects Rescued 24-48 Hours	0.0014
Number of Times Rescued 0-24 Hours	0.0275
Number of Times Rescued 24-48 Hours	0.0009
Number of Times Rescued 0-48 Hours	0.0027
Time to Perceptible Pain Relief	0.0050
% Subjects with ≥30% Improvement – 24 Hours	0.0178
PGA of Pain Control at 48 hours	0.0027

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 (≥2% in the IV meloxicam group) AEs were nausea, headache, vomiting, and dizziness (Table 4). 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.

Table 4: Adverse Events reported by ≥2% of subjects from any treatment group

	n (%) of Subjects	
	IV meloxicam 30 mg	Placebo
Preferred Term	(N=110)	(N=109)
Subjects with >=1 TEAE	58 (52.7)	80 (73.4)
Nausea	30 (27.3)	41 (37.6)
Headache	13 (11.8)	18 (16.5)
Vomiting	5 (4.5)	10 (9.2)
Dizziness	4 (3.6)	10 (9.2)

** Four (4) subjects experienced Serious Adverse Events during this study. Three subjects were randomized to placebo and one to IV meloxicam.

Phase II Clinical Trials

IV meloxicam has also been studied in several Phase II clinical trials, including Study IV Meloxicam-04, a Phase II, multicenter, randomized, double-blind, placebo-and active-controlled study in 486 female subjects who underwent open abdominal hysterectomy. Following surgery on post-operative day 1, or Post Op Day 1, subjects received a single dose of either IV placebo, morphine or meloxicam 5 mg, 7.5 mg, 15 mg, 30 mg or 60 mg. Starting at the time of study drug administration and continuing for 24 hours thereafter, subjects had access to rescue medication. During the 24-hour double-blind evaluation period, efficacy measurements of pain intensity and pain relief were made using the 100-mm visual analogue scale to assess pain intensity and a 5-point categorical scale (ranging from none to complete) to assess pain relief

Overall, all active treatment doses produced statistically significant reductions in SPID24 (a co-primary endpoint) compared to placebo ($p < 0.001$), utilizing the LOCF analysis method. In addition, all active treatment doses also produced statistically significant improvement in total pain relief from hour 0 to 24 (a co-primary efficacy endpoint) compared to placebo ($p < 0.001$). Statistically significant decreases in pain intensity from baseline were detected as early as 10 minutes post-dose and continued throughout the 24-hour post-dose period. In general, the greatest decreases were seen in the 30 mg and 60 mg dose groups followed by the 15 mg group (Figure 3).

Figure 3: Pain Intensity Differences at Various Time Points

Rescue medication use during the 24-hour double-blind period was reduced by approximately 90% in the meloxicam 30 mg and 60 mg dose groups, and by 86%, 77%, 81%, and 71% in the 15 mg, 7.5 mg, 5 mg, and morphine groups, respectively, compared to placebo. Statistically significant differences were seen between each active group and placebo ($p < 0.001$). The percentage of subjects using rescue medication is presented in Figure 4. The median time to rescue (based on the lower bound of the 95% confidence interval for the 50th percentile) was greatest for meloxicam 30 mg (21.9 hours), followed by 60 mg (20.6 hours), 15 mg (18.3 hours), 5 mg (12.2 hours), 7.5 mg (8.3 hours), morphine (6.6 hours), and placebo (1.1 hours).

Figure 4: Percentage of Subjects Using Rescue Medication

Study medication was well tolerated. A total of five SAEs were reported in the study, and none were assessed as related to treatment. There were no clinically meaningful trends in vital signs, ECGs or laboratory assessments. AE rates were generally low and consistent with this surgical population under study (Table 5).

Table 5: Adverse Events reported by ≥3% of subjects from any treatment group

					IV Meloxicam 5 mg		7.5 mg		15 mg		30 mg		60 mg	
	Placebo		Morphine		N = 60		N = 91		N = 60		N = 60		N = 89	
	N = 64		N = 62											
	n (%)		n (%)		n (%)		n (%)		n (%)		n (%)		n (%)	
Anemia	2	(3.1)	3	(4.8)	2	(3.3)	12	(13.2)	2	(3.3)	1	(1.7)	9	(10.1)
Leukocytosis	0	(0.0)	0	(0.0)	1	(1.7)	0	(0.0)	0	(0.0)	2	(3.3)	0	(0.0)
Sinus tachycardia	0	(0.0)	0	(0.0)	2	(3.3)	0	(0.0)	0	(0.0)	0	(0.0)	1	(1.1)
Abdominal distension	2	(3.1)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)	0	(0.0)
Constipation	0	(0.0)	3	(4.8)	3	(5.0)	1	(1.1)	1	(1.7)	0	(0.0)	0	(0.0)
Flatulence	0	(0.0)	3	(4.8)	1	(1.7)	1	(1.1)	2	(3.3)	0	(0.0)	0	(0.0)
Nausea	2	(3.1)	1	(1.6)	1	(1.7)	1	(1.1)	1	(1.7)	1	(1.7)	2	(2.2)
Pyrexia	1	(1.6)	2	(3.2)	2	(3.3)	2	(2.2)	0	(0.0)	0	(0.0)	0	(0.0)
Anemia post-operative	0	(0.0)	1	(1.6)	0	(0.0)	0	(0.0)	0	(0.0)	2	(3.3)	0	(0.0)
Hypokalemia	0	(0.0)	2	(3.2)	1	(1.7)	1	(1.1)	0	(0.0)	1	(1.7)	0	(0.0)
Insomnia	3	(4.7)	5	(8.1)	6	(10.0)	4	(4.4)	3	(5.0)	3	(5.0)	4	(4.5)
Ketonuria	5	(7.8)	6	(9.7)	4	(6.7)	9	(9.9)	9	(15.0)	6	(10.0)	9	(10.1)

Our Other Pipeline Candidates

Dex

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

We initially studied Dex-IN for the treatment of post-operative pain. Based on clinical trial results and feedback from the FDA, we are exploring Dex-IN in peri-procedural pain. If approved, Dex-IN would also be the first and only approved peri-procedural pain drug in its class of drugs.

Fado

We also have another selective alpha-2 agonist product candidate in our pipeline, Fado. Fado is similar to Dex and different from clonidine in that it is a full agonist of all subtypes of alpha-2 adrenoreceptor. Unlike Dex, Fado does not cross the blood/brain barrier, and this accounts for the targeting of Fado use for either intrathecal administration for pain or anesthesia, or potentially for topical use to treat pain associated with regional nerve pain from underlying nerve damage, also called “neuropathies.” Various preclinical models of pain have been employed and have demonstrated Fado’s potential as an analgesic, including its potential for use in neuropathies and post-operative pain. In Orion sponsored studies, Fado appeared to delay the onset of pain while doses of Fado greater than 120 mcg also appeared to suppress pain. In addition, Fado was well tolerated by subjects.

CDMO Division

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

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

Product	Indication	Technology	Territory	Revenue Source	Commercial Partner
Ritalin LA®	Attention Deficit Hyperactivity Disorder	OCR (SODAS)	Worldwide	Royalty Manufacturing	Novartis Pharma AG
Focalin XR®	Attention Deficit Hyperactivity Disorder	OCR (SODAS)	Worldwide, except Canada	Royalty Manufacturing	Novartis Pharma AG
Verelan PM®	Hypertension	OCR (SODAS)	United States	Royalty Manufacturing	Lannett Company, Inc.
Verapamil (generic)	Hypertension	OCR (SODAS)	United States	Profit Sharing Manufacturing	Teva Pharmaceutical Industries Ltd.
Zohydro ER®	Severe Pain	OCR (SODAS)	United States	Royalty Manufacturing	Pernix Therapeutics, Inc.

Canada	Royalty	Paladin Labs, Inc.
	Manufacturing	

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.

With each product, we either purchase active drug substance from third parties or receive it from our commercial 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.

Permits and Regulatory Approvals

We hold various licenses for our CDMO division 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.

We do not generally act as the product authorization holder for products that have been developed on behalf of a commercial partner. In such cases, our commercial partner typically holds the relevant authorization from the FDA or other national regulator, and we support this authorization by furnishing a letter of reference to the Drug Master File, or the chemistry, and 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 also 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 division and have contributed funds to be used in our research and development and pre-commercialization activities in our Acute Care division. 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. and Lannett Company, Inc.) having generated 97% of our revenues for the twelve months ended December 31, 2016, of which one customer, Novartis Pharma AG, generated 45% of our revenue under two separate customer agreements, and another customer, Teva Pharmaceutical Industries, Inc., generated 36% of our revenue under one customer 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 patent and patent applications (specifically directed to the prevention of flake like substances) which expire in 2030.

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. If the intranasal patent applications are issued as patents, the resulting patent protection will last into 2032, subject to any disclaimers or extensions. For Fado, we have a pro-drug patent that expires in 2025.

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. We will pay milestone payments to Orion of up to €20.5 million ($21.6 million as of December 31, 2016) after regulatory approval of Dex dosage forms and upon achieving certain sales milestones. Through December 31, 2016, no such milestones have been achieved. The initial term of this license is 15 years from the first commercial sale in the Territory, with automatic two year extensions, unless either party provides written notice of termination.

We are also party to an exclusive license agreement with Orion for the development and commercialization of Fado for use as a human therapeutic, in any dosage form in the Territory. We have the right to sublicense the rights under such license at any time. In consideration for this license, we paid Orion an upfront payment and are required to pay certain lump-sum amounts on completion of certain development milestones, as well as on achievement of certain commercial milestones. We will pay milestone payments to Orion of up to €12.2 million ($12.9 million as of December 31, 2016), based on regulatory filings and approval and on

commercialized net sales levels. We will also pay Orion royalty payments on net sales of Fado ranging from 10% to 15%. Through December 31, 2016, no such milestones have been achieved. The initial term of this license is 15 years from the first commercial sale in the Territory, with automatic three year extensions, unless either party provides written notice of termination at least six months prior to expiration or unless otherwise terminated pursuant to the terms of the license agreement.

Our intellectual property rights related to injectable meloxicam and Dex are held by our Irish subsidiary, Recro Ireland Limited.

CDMO Division

We also own various controlled release formulation patents, including patents in the United States, Canada, and Europe, related to our proprietary delivery technologies that we utilize in our drug development, formulation and manufacturing business through our CDMO division. 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 formulating of Zohydro ER®. We license our U.S. patents and patent applications to our commercial partner, Pernix Therapeutics Holdings, Inc., or Pernix, in the United States. We also own Canadian patents and patent applications relating to the same technology, which we license to our commercial partner, Paladin Labs Inc., in Canada. The patent protection for Zohydro ER® provides for protection of Zohydro ER® through 2034, subject to any extensions or disclaimers.

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 method of treatment 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 and Canada while out-licensing development and commercialization rights for other territories outside the United States and Canada 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. As this target audience is smaller than general practitioners, we believe we have the capabilities to build a sales and marketing infrastructure and effectively market our product candidates upon commercial approval. While our stated intention is to develop and commercialize our product candidates, we will evaluate potential strategic collaborations that could accelerate or enhance our development and, upon approval, commercial success of our product candidates.

We are currently preparing for a potential U.S. commercial launch of IV meloxicam, if approved, and we plan to establish sales, marketing and reimbursement functions to commercialize IV meloxicam in the United States.

Manufacturing and Supply of our 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 drug product manufacturers that could satisfy our clinical study 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 injectable meloxicam. Pursuant to a Development, Manufacturing and Supply Agreement, or Supply Agreement, Alkermes (through a subsidiary), will provide (i) clinical and commercial bulk supplies of injectable meloxicam formulation and (ii) development services with respect to the Chemistry, Manufacturing and Controls section of the NDA for injectable meloxicam. Pursuant to the Supply Agreement, Alkermes will supply us with such quantities of bulk injectable meloxicam formulation as shall be reasonably required for the completion of clinical trials of injectable meloxicam, subject to a maximum of eight clinical batches in any twelve-month period, unless otherwise agreed by the parties. During the term of the Supply Agreement, we will purchase our clinical and commercial supplies of bulk injectable meloxicam formulation exclusively from Alkermes. Sterile fill-finish of injectable meloxicam will be completed by a third-party fill-finish facility. 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.

The Supply Agreement may be terminated earlier (i) by us upon 180 days' written notice following the date of first generic entry; (ii) by either party upon twelve months' written notice following the first anniversary of the approval of the NDA for meloxicam; (iii) by either party upon written notice to the other party in the event of uncured material breach of the other party; and (iv) by Alkermes upon written notice in certain events of uncured non-payment.

Dex

We are party to an API supply agreement with Orion, whereby Orion provides us with API for the development and commercialization of our Dex product candidates. 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 initial term of the agreement is the later of 15 years from the first commercial sale and 15 years after the effective date of the agreement, and in each case, will be automatically extended for one or more periods of two years unless terminated. After the initial term, the agreement may be terminated upon six months' notice to the other party.

The single unit dose intranasal sprayer for Dex-IN is manufactured by a supplier of proprietary components and devices, and equipment is leased from the device supplier for filling at a contract manufacturer. It is possible that we will continue with this arrangement through clinical development, evaluate the option of entering a manufacturing agreement with the device originator or evaluate alternative devices prior to commercialization. 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 payors. 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 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 therapeutics in the pain relief area, including Johnson & Johnson, Purdue Pharma, L.P., Mallinckrodt plc, Teva Pharmaceutical Industries, Inc., Depomed, Inc. and Pacira Pharmaceuticals, Inc. Purdue is the primary competitor in the manufacture, marketing and commercialization 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., AcelRx Pharmaceuticals, Inc., Durect Corporation, Heron Therapeutics, Inc., Trevena, Inc. and Cara Therapeutics, Inc. are currently developing post-operative pain therapeutics that could compete with us in the future.

With our CDMO division, we compete with contract pharmaceutical formulation and manufacturing companies such as Catalent, Inc., Patheon Holdings Coôperatief U.A., Adare Pharmaceuticals, Inc., Metrics, Inc., a subsidiary of Mayne Pharma Group Limited, and other formulation, development and manufacture-related service providers.

Research and Development

Research activities represent a significant part of our businesses. In the years ended December 31, 2016 and 2015, respectively, we incurred research and development expenses of $33.3 million and $12.3 million, respectively.

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, Dex and Fado, 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 institutional review board, or 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.

In addition, under the Pediatric Research Equity Act of 2003, or PREA, 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 quantities of our product candidates. Future FDA and state inspections may identify compliance issues at our site 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

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. 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.

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.

There is a risk that DEA regulations may interfere with the manufacture and supply of the drugs sold commercially, and thus with our ability to produce products in the volume needed to meet commercial demand.

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 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.

Third-Party Payor Coverage and Reimbursement

In both the United States and foreign markets, our ability to commercialize our product candidates successfully, and to attract commercialization partners for our product candidates, depends in significant part on the availability of adequate financial coverage and reimbursement from third-party payors, including, in the United States, governmental payors such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. Medicare is a federally funded program managed by the Centers for Medicare and Medicaid Services, or 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 private payor 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. Private payors often rely on the lead of the governmental payors in rendering coverage and reimbursement determinations. Therefore, achieving favorable CMS coverage and reimbursement is usually a significant gating issue for successful introduction of 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. Prices at which we or our customers seek reimbursement for our product candidates can be subject to challenge, reduction or denial by the government and other payors.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government healthcare programs and other third-party payors 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 payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products.

Payors also are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price, or ASP, average manufacturer price, or AMP, and actual 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 payors 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 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.

In addition, 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 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, manufacture, 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 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 payors 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 payors 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 private payors 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 payors 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 payors.

In March 2010, President Obama signed into law the Affordable Care Act. This law 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. Moreover, legislative changes to the Affordable Care Act remain possible and appear likely in the 115th United States Congress and under the Trump Administration, which could include changes that, among other things, decrease the number of individuals with health coverage or allow the federal government to negotiate drug prices directly with pharmaceutical manufacturers. 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 physician sunshine laws and regulations. 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, or OIG, 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 federal healthcare programs Anti-Kickback Statute, or AKS, which prohibits individuals and entities from, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, or recommendation of an item or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value. The government can establish a violation of the AKS without proving that the individual or entity had actual knowledge of the statute or specific intent to violate it;
- the federal civil False Claims Act, which prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, claims for payment of government funds that are false or fraudulent, and making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes civil and criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program and creates federal criminal laws that prohibit 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;

- the federal transparency requirements under the Health Care Reform Law, which require manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value provided to physicians and teaching hospitals and physician ownership and investment interests;
- 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), which, govern the collection, use, disclosure, and protection of health-related and other personal information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to implement compliance programs, comply with the pharmaceutical industry's voluntary

compliance guidelines and the relevant compliance guidance promulgated by the federal government, or to track and report gifts, compensation and other remuneration provided to physicians and other health care providers; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

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.

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). Case T-670/16 is still pending. 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 entered into force on May 24, 2016 and will apply from May 25, 2018. The EU Data Protection Regulation will increase the responsibility and liability in relation to personal data processed in the European Union and will also introduce 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.

Employees

We currently have 195 full-time employees and 1 temporary employee. None of our employees are covered by collective bargaining agreements, and we consider relations with our employees to be good.

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 [1] 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.

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 $31.3 million and $12.5 million for the years ended December 31, 2016 and 2015, respectively. As of December 31, 2016, we had an accumulated deficit of $61.3 million.

We have financed our operations through the sale of debt and equity securities, a $50.0 million credit facility with OrbiMed Royalty Opportunities, II, LP, or OrbiMed, and revenue generated by our CDMO division. We have used revenue generated by our CDMO division primarily to fund operations at our CDMO division, to make payments under our credit facility and to partially fund our research and development and pre-commercialization activities. We believe that our CDMO division 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 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 generate additional revenues from sales of our product candidates. To date, none of our product candidates have been commercialized, and revenues generated by our CDMO division 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:

- completing the clinical development of our product candidates;
- obtaining regulatory approval for our product candidates;
- launching and commercializing our product candidates;
- obtaining and maintaining patent protection for our product candidates; and
- our ability to generate increased revenue from our CDMO division.

We expect to continue to incur substantial and increased expenses as we continue our clinical and pre-commercialization activities for injectable meloxicam, and expand our research and development activities and advance our clinical programs. Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. 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 our 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 to market our product candidates 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.

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.

We have a limited operating history, which may make it difficult to predict our future performance or evaluate our business and prospects.

We were incorporated in 2007. Since inception, 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. In addition, our CDMO division was acquired in April 2015, and our experience operating such business is limited. Consequently, we have a very limited amount of information to use in evaluating the potential future success or viability of our business and any such evaluation of our business and prospects may not be accurate.

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

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We expect our research and development expenses to increase in connection with our ongoing clinical and pre-commercialization activities,

particularly as we advance our clinical programs. In addition, maintaining a cGMP pharmaceutical manufacturing facility is expensive. While our CDMO division generates revenue, that revenue alone is not sufficient to support our product development operations. 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 facility 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 will be sufficient to fund our current operations over the next 12 months. However, changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. For example, our clinical trials may encounter technical, enrollment or other difficulties that could increase our development costs more than we expect. We will need to raise additional funding to make milestone payments due to Alkermes upon submission and/or approval of the NDA for injectable meloxicam, to commercialize injectable meloxicam, if approved by the FDA, and 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:

- curtail the development programs for our product candidates or significantly delay, scale back or discontinue the development or commercialization of our product candidates;
- seek collaboration partners for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;
- 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 or discontinue our CDMO division.

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 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. To the extent that we raise additional capital through the sale of equity or convertible debt securities, 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, which could also result in dilution of our existing shareholders' ownership. 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 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 division;
- variations in the level of expenses related to our development programs;

- the success of our clinical trials through all phases of clinical development;
- any delays in regulatory review and approval of product candidates in clinical development;
- potential side effects of our future products 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 pre-commercialization activities;
- our ability to establish an effective sales and marketing infrastructure;
- our dependency on third parties to supply and manufacture our product candidates and delivery devices;
- 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 or in-licensing of new products or product candidates; and
- the level of market acceptance for any approved product candidates and underlying demand for that product and wholesalers' buying patterns.

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.

In connection with the Gainesville Transaction, we incurred significant indebtedness, which could adversely affect our business.

Prior to our acquisition from Alkermes of certain assets, including the worldwide rights to injectable meloxicam and the development, formulation and manufacturing business that comprised our CDMO division, which we refer to herein as the Gainesville Transaction in April 2015, we had no outstanding indebtedness. Contemporaneously with the closing of the Gainesville Transaction, we entered into a $50.0 million credit agreement with OrbiMed. As of December 31, 2016, we had an outstanding balance under the credit agreement of $27.3 million. The credit agreement provides for certain mandatory prepayment events, including a quarterly excess cash flow prepayment requirement at OrbiMed's request, based on the terms of the credit facility. As of December 31, 2016, we have paid $22.7 million of the outstanding principal on our senior secured term loan from free cash flow generated by our CDMO division.

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

- requires us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, reducing the availability of our cash flow to fund working capital, capital expenditures, development activity, acquisitions and other general corporate purposes;
- 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;
- makes us more vulnerable to increases in interest rates, as borrowings under our senior secured credit facility are at variable rates;
- limits our ability to obtain additional financing in the future for working capital or other purposes;
- places us at a competitive disadvantage compared to our competitors that have less indebtedness; and
- prohibits us from making intercompany cash transfers without the consent of OrbiMed.

Any of the above listed factors could materially adversely affect our business, financial condition, results of operations and cash flows. Our credit agreement with OrbiMed also contains certain financial and other covenants, including a minimum liquidity requirement and minimum revenue targets, maximum leverage ratios and includes limitations on, among other things, additional indebtedness, paying dividends in certain circumstances, acquisitions and certain investments. Any failure to comply with the terms, covenants and conditions of the term loan may result in an event of default under such agreement, and could have a material adverse effect on our business, financial

condition and results of operation.

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 certain foreign jurisdictions. 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 and changes in tax laws. We regularly assess all of 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 us or to our subsidiaries will not be changed in a manner which adversely affects our shareholders.

Risks Related to Clinical Development and Regulatory Approval

We are substantially dependent on the success of our lead product candidate injectable meloxicam, which is in a later stage of development than our other product candidates. To the extent regulatory approval of injectable 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, injectable 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 develop, obtain regulatory approval for, and successfully commercialize injectable meloxicam. The regulatory approval of injectable meloxicam is subject to many risks, including the risks discussed in other risk factors, and injectable 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 injectable meloxicam do not meet our or others' expectations, the market price of our common stock could decline significantly.

We have recently completed two Phase III clinical trials for IV meloxicam. Overall we expect to enroll a total of approximately 1,100 patients in our Phase III program. To complete this program, we await final visits for more than 700 patients enrolled following a variety of surgical procedures in our additional safety study of IV meloxicam. Assuming we continue to observe a favorable safety profile in the safety study, we anticipate filing a new drug application, or NDA, for IV meloxicam with the U.S. Food and Drug Administration, or FDA, in the summer of 2017. We cannot be certain that the NDA will be accepted for filing and review by the FDA, or ultimately be approved. Although we have discussed our clinical development plans with the FDA, the agency may ultimately determine that our Phase III clinical trials are not sufficient for regulatory approval or that our NDA is not otherwise complete. The FDA may also audit one or more of our manufacturing facilities or clinical trial sites, and if any site reveals anomalies or does not otherwise pass inspection, the FDA could delay or reject our NDA. In either case, our development of IV meloxicam may be delayed and we may incur additional costs and be required to devote additional resources to address the FDA's concerns. If the FDA requires us to conduct additional clinical trials or studies or requires our manufacturer to improve or change its practices, our timeline for commercialization of IV meloxicam will be delayed and we will incur additional costs. Further, there can be no assurance that we will complete the other clinical and non-clinical studies or address manufacturing issues in a manner that is acceptable to the FDA. In addition, we plan to conduct Phase IIIB clinical trials for IV meloxicam, and those trials could fail or produce results that are adverse or inconclusive.

Any delay or setback in the development or regulatory approval of injectable meloxicam could adversely affect our business and cause our stock price to decline. Should our on-going injectable meloxicam clinical development fail to be completed in a timely manner or at all, or be sufficient to support regulatory approval, we may be forced to rely on

our other product candidates, which are at an earlier development stage and will require additional time and resources to obtain regulatory approval and proceed with commercialization. We cannot assure you that our on-going clinical development for injectable meloxicam will be completed in a timely manner, or at all, or that we will be able to obtain approval for injectable meloxicam from the FDA.

Even if the FDA grants approval of injectable meloxicam, the terms of the approval may limit its commercial potential.

Even if injectable meloxicam were to successfully obtain approval from the FDA, any such approval might significantly limit the approved indications for use, including more limited patient populations, require that precautions, contraindications or warnings be included on the product labeling, including black box warnings, require expensive and time-consuming post-approval clinical studies, REMS, or surveillance as conditions of approval, or, through the product label, the approval may limit the claims that we may make, which may impede the successful commercialization of our product candidates. If the approval of injectable meloxicam contains significant limitations, our ability to market to our full target market will be reduced and our ability to realize the full market potential of injectable meloxicam will be harmed and we may have to discontinue the commercialization of injectable meloxicam or limit our sales and marketing efforts, which in turn could limit our ability to achieve profitability.

Our development and commercialization strategy for injectable 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 approved product. The FDA may also require companies to perform additional clinical trials or measurements to support any deviation from the previously approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant. 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. We plan to submit an NDA for injectable meloxicam under Section 505(b)(2) and as such the NDA will rely, 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 injectable 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), over the last few years some pharmaceutical companies and others 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) 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 our product candidates, including injectable meloxicam.

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 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. 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 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 patients 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.

If clinical trials for our 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.

Our 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 our 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 the course of our on-going safety study and planned Phase IIIB clinical trials. Our ability to obtain regulatory approval for our 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.

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 the course of 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.

We have not previously submitted an NDA or any similar drug approval filing to the FDA or any comparable foreign authority for any product candidate, and we cannot be certain that any of our product candidates will receive regulatory approval. If we do not receive regulatory approval for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market one or more 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.

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 in 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. Our product candidates 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 a pending application for marketing authorization or supplements to an NDA or to an application for marketing authorization submitted by us;
- seize our product candidate; and/or
- refuse to allow us to enter into supply contracts, including government contracts.

In addition, if we commercialize our product candidates, we will be subject to a variety of additional regulatory risks. In particular, upon commercialization of our product candidates, our relationships with health care providers and third-party payors in the United States and elsewhere will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to significant civil, criminal and administrative sanctions including penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm and diminished profits and future earnings.

These laws and regulations related to our commercialization efforts are described in greater detail in the section above under “Government Regulation” entitled “Other Healthcare Laws and Compliance Requirements.” Many of these laws are vigorously

enforced both through government investigations and enforcement actions and, in the case of the federal civil False Claims Act, through lawsuits brought by private whistleblowers. In recent years, pharmaceutical and other healthcare companies have been investigated or prosecuted under these laws for a wide range of alleged improper promotional and marketing activities, such as: allegedly providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicaid for non-covered, off-label uses; providing inappropriate patient and product support services, and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. We will make every effort to structure our relationships and business operations to comply with all applicable laws, including structuring our activities to comply with any available statutory exceptions or regulatory safe harbors. However, because of the breadth of these laws and the narrowness of the exceptions and safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws. Even if we are not found to have violated the law, responding to whistleblower lawsuits, government investigations or enforcement actions, defending any claims raised, and entering into settlement agreements would be expensive and time-consuming, and could have a material adverse effect on our reputation, financial condition, and business operations.

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 our products and generate revenues which would have a material adverse effect on our business, financial condition and results of operations.

Injectable meloxicam and our other product candidates, if approved, may require REMS, which may significantly increase our costs.

Our 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 to be required as part of the FDA’s approval of injectable meloxicam or our other product candidates. Depending on the extent of the REMS requirements, our costs to commercialize injectable meloxicam or our other product candidates may increase significantly and distribution restrictions could limit sales. Similar obstacles may arise in countries outside of the United States.

Even if we obtain FDA approval for injectable 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, similarly to the U.S., 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.

Risks Related to Our Reliance on Third Parties

We rely on limited sources of supply for our product candidates, and any disruption in the chain of supply may cause delay in developing and commercializing our product candidates.

Alkermes is currently our sole supplier of bulk injectable meloxicam formulation, and we intend to enter into an agreement with a contract manufacturer for the provision of sterile fill and finish services. Currently, Alkermes is the only established supplier of bulk injectable meloxicam formulation. Although the supply agreement that we have with Alkermes allow us to qualify and purchase from an alternative supplier 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.

Our reliance on a limited number of vendors and, in particular, Alkermes, as our single manufacturer of injectable meloxicam, exposes us to risks which could delay FDA approval of our product candidates and commercialization of our products, result in higher costs, or deprive us of potential product revenues. These contract manufacturers may encounter difficulties in achieving the volume of production needed to satisfy clinical or commercial demand, may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, may experience shortages of qualified personnel to adequately staff production operations or may increase prices for our product candidates which could impact our ability to effectively compete on price terms. Our contract manufacturers could also default on their agreements with us to meet our requirements for commercialization of injectable meloxicam or our other product candidates.

Our reliance on third parties reduces our control over our product candidate development and commercialization activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards. The FDA and other equivalent regulatory authorities in other countries require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP and similar foreign standards. Any failure by our third party manufacturer to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, such failure could be the basis for the FDA or equivalent regulatory authorities in other countries to issue a warning or untitled letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction, imposing civil penalties or pursuing criminal prosecution.

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

As we scale up manufacturing of injectable meloxicam and our other product candidates and conduct required stability testing, product-packaging, equipment and process-related issues may require refinement or resolution in order to proceed with our planned clinical trials and to obtain regulatory approval for commercial marketing. We may identify issues in our product or delivery devices, which could result in increased scrutiny by regulatory authorities, delays in our clinical program and regulatory approvals, increases in our operating expenses, or failure to obtain or maintain approval for our products.

We use third parties to assist with conducting, supervising and monitoring portions of our 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 injectable meloxicam and our other product candidates, as well as the execution of nonclinical studies. We control only certain aspects of our third parties' activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, and legal, regulatory and scientific standards, and our use of third parties does not relieve us of our regulatory responsibilities.

We and our contractors are required to comply with cGCPs, which are regulations and guidelines enforced by the FDA and equivalent regulatory authorities in other countries for all of our product candidates in clinical development. The FDA and the equivalent regulatory authorities in other countries enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our contractors fail to comply with applicable cGCPs, the clinical data generated in our

clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials for injectable meloxicam and our other 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. 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 injectable meloxicam or our other product candidates. As a result, our financial results and the commercial prospects for injectable 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 Commercialization of Our Product Candidates

If we are unable to successfully commercialize injectable 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 injectable meloxicam will depend on many factors, including but not limited to:

- the results of our proposed Phase IIIB clinical trials;
- our ability to manufacture commercial quantities of injectable meloxicam at reasonable cost and with sufficient speed to meet commercial demand;
- our ability to build a sales and marketing organization to market injectable meloxicam;
- our success in educating physicians, patients and caregivers about the benefits, administration and use of injectable meloxicam;
- 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 injectable meloxicam;
- the availability of coverage and adequate reimbursement for injectable meloxicam;
- our ability to contract with specialty pharmaceutical distributors on acceptable terms;
- the effectiveness of our marketing campaigns;
- our effective use of promotional resources;
- our success in obtaining formulary approvals; and
- a continued acceptable profile for injectable 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 injectable meloxicam, even if we receive regulatory approval. 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.

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

Physicians may not prescribe any of our 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 clinical indications for which each of our product candidates are approved, including any 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 proposed Phase IIIB clinical trials;
- 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;
- pricing and cost-effectiveness;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- our ability to convince hospitals to include injectable 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.

If injectable meloxicam or any of our other product candidates are approved, but does not achieve an adequate level of acceptance by physicians, patients and health care payors, we may not generate sufficient revenue and we may not become or remain profitable. Similar obstacles may arise in other countries.

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

We currently have a limited organization for the sales, marketing and distribution of injectable meloxicam or our other product candidates, and the cost of continuing to establish, expand and maintain such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved, we must 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 injectable meloxicam is to develop a specialty sales force and/or collaborate with third parties to promote the product to healthcare professionals and third-party payors 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.

We are subject to intense competition and, if we are unable to compete effectively, our 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 injectable 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 therapeutics in the pain relief area, including Johnson & Johnson, Purdue Pharma, L.P., Mallinckrodt plc, Teva Pharmaceutical Industries, Inc., Depomed, Inc. and Pacira Pharmaceuticals, Inc. Purdue is the primary competitor in the manufacture, marketing and commercialization 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., AcelRx Pharmaceuticals, Inc., Durect Corporation, Heron Therapeutics, Inc., 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, 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 may also be more successful than us in manufacturing and marketing their products. These advantages could materially impact our ability to develop and commercialize injectable 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.

Hospital formulary approval and reimbursement may not be available for injectable meloxicam and our other product candidates, which could make it difficult for us to sell our products profitably.

Failure to obtain timely hospital formulary approval will limit our commercial success. Obtaining hospital formulary approval can be an expensive and time consuming process. We cannot be certain if and when we will obtain the formulary approval to allow us to sell our products into our target markets.

Furthermore, market acceptance and sales of injectable meloxicam or any future product candidates that we develop, will depend on reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third-party payors, such as private health insurers, hospitals and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. We cannot be sure that reimbursement will be available for injectable meloxicam or any future

product candidates. Also, reimbursement amounts may reduce the demand for, or the price of, our products. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize injectable meloxicam or any future product candidates that we develop.

The availability of numerous generic pain medications may impact the reimbursement available for meloxicam from some third-party payors. We expect to experience pricing pressures in connection with the sale of injectable meloxicam and any other product candidates that we develop, due to the trend toward managed healthcare and the increasing influence of health maintenance organizations. If we fail to successfully secure and maintain reimbursement coverage for our products, or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed.

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 intend to enter into agreements with third parties to market injectable meloxicam or other product candidates outside the United States and Canada. 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; 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.

Even if we are able to commercialize any of our product candidates, these products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates even if our product candidates obtain marketing approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available in a timely manner from government third-party payors, including governmental healthcare programs such as Medicare and Medicaid, commercial health insurers and managed care organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. Third-party payors may 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. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government healthcare programs and other third-party payors 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 payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, if our proposed Phase IIIB clinical trials for IV meloxicam do not show improved outcomes relative to the current standard of care, obtaining payor coverage for IV meloxicam, once approved, could become more difficult in the future. We cannot be sure that coverage and reimbursement will be available promptly or at all for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases. Limited coverage may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

Payors also are increasingly considering new metrics as the basis for reimbursement rates, such as ASP, AMP and actual 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 NADAC 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 payors to cover our products for which we receive regulatory approval.

If we successfully commercialize any of our products, we may participate in the Medicaid Drug Rebate program, the Public Health Service's 340B drug pricing program, the FSS pricing program established by Section 603 of the VHCA, and the TRICARE program. These programs are described in greater detail in the section above under "Government Regulation" entitled "Third Party Payor Coverage and Reimbursement." 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 and could adversely affect our business and operating results.

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 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 payors 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 we obtain marketing approval. Third-party payors 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 private payors 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.

Changes in healthcare law and implementing regulations, including those based on recently enacted and future legislation, as well as changes in healthcare policy, may increase the difficulty and cost for us to commercialize our 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 our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidate 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.

In recent years, Congress has considered reductions in Medicare reimbursement levels for drugs administered by physicians. CMS 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, which in turn would affect the price we can receive for those products. While Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payors 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 payors.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the Affordable Care Act). This law 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. 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. Moreover, legislative changes to the Affordable Care Act remain possible and appear likely in the 115th United States Congress and under the Trump Administration, which could include changes that, among other things, decrease the number of individuals with health coverage or allow the federal government to negotiate drug prices directly with pharmaceutical manufacturers. 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 our industry generally and on our ability to successfully commercialize our product candidates, if approved.

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.

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 product 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 payors. 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.

If we are able to successfully commercialize any of our product candidates and if we participate in the Medicaid drug rebate program or other governmental pricing programs, failure to comply with reporting and payment obligations under these programs could result in additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The Medicaid Drug Rebate Program and other governmental pricing programs require participating manufacturers to report pricing data to the government. Pricing calculations vary among products and programs and include average manufacturer price and best price for the Medicaid Drug Rebate Program, average sales price for certain categories of drugs that are paid under Part B of the Medicare program, and non-federal average manufacturer price for the FSS

pricing program. If we successfully commercialize any of our product candidates and participate in such governmental pricing programs, we will be liable for errors associated with our submission of pricing data. That liability could be significant. For example, if we are found to have knowingly submitted false average manufacturer price, average sales price, best price, or non-federal average manufacturer price information to the government, we may be liable for civil monetary penalties in the amount of $178,156 per item of false information. If we are found to have made a misrepresentation in the reporting of average sales price, the statute provides for civil monetary penalties of up to $12,856 for each misrepresentation for each day in which the misrepresentation was applied. Our failure to submit monthly/quarterly average manufacturer price, average sales price, and best price, and quarterly/annual non-federal average manufacturer price data on a timely basis could result in a civil monetary penalty of $17,816 per day for each day the information is late beyond the due date. Such failure also could be grounds for other sanctions, such as termination from the Medicaid Drug Rebate Program.

Risks Related to Our CDMO Division

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

Our CDMO division is dependent on our relationships with a small number of commercial partners, with our four largest customers (Novartis AG, Teva Pharmaceutical Industries, Inc., Pernix Therapeutics, Inc. and Lannett Company, Inc.) having generated 97% of our revenues for the year ended December 31, 2016, of which one customer generated 45% of our revenue under two separate customer agreements, and another customer generated 36% of our revenue under one customer agreement. Our contracts with our commercial partners are for a short term, generally one year. If any one or more of these commercial partners fails to renew their contract, 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 of 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 OrbiMed include minimum revenue targets for our CDMO division, 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 OrbiMed 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, we rely on a limited number of suppliers to provide the raw materials needed for the manufacture of these products. We may 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 facility also requires specialized personnel and is expensive to operate and maintain. Any suspension of the sale of products of our commercial partners to be manufactured in our facility may cause operating losses as we continue to operate the facility 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.

Our development and formulation services projects are typically for a shorter term than our manufacturing projects, and any failure by us to maintain a high 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 acts 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 negatively affect 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 facility is 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 facility, there are increased risks associated with cGMP compliance. Our inability to demonstrate ongoing cGMP compliance could require us to engage in 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 facility 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 finding 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 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 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 offerings 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.

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 facility is located in Gainesville, Georgia, where natural disasters or similar events, like blizzards, tornadoes, fires, floods 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 facility, damaged critical infrastructure, 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.

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.

Risks Related to Our Business Operations and Industry

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 grow the size of our organization, and we may experience difficulties in managing this growth.

As our development and commercialization strategies develop, we will need additional managerial, operational, sales, marketing, financial and other resources. Our management, personnel and systems currently in place may not be adequate to support this future growth. 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. 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 sales and marketing personnel engaged in connection with the commercialization of any approved product;

- 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.

As our operations expand, we will need to manage additional relationships with various strategic collaborators, 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. 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 alliance 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 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 division, 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.

In addition, our business conducted by our CDMO division 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.

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.

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 division 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 of $15.0 million 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 Securities and Exchange Commission, or 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.

The security of our information technology systems may be compromised, and confidential information, including non-public personal information that we maintain, could be improperly disclosed.

Our information technology systems may be vulnerable to physical or electronic intrusions, computer viruses or other attacks. As part of our business, we maintain large amounts of confidential information, including non-public personal information on patients and our employees. Breaches in security 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.

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 data protection laws and regulations (i.e., laws and regulations that address privacy and data security). 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 FTC Act and HIPAA), govern the collection, use, disclosure, and protection of health-related and other personal information. Failure to comply with data protection laws and regulations could result in government enforcement actions and create liability for us (which could include civil and/or criminal penalties), private litigation and/or adverse publicity that could negatively affect our operating results and business.

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

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such an event could cause interruption of our 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 the extent that any disruption or security breach were to result in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the development of our product candidates could be delayed.

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, 2016, 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 patent and patent applications (specifically directed to the prevention of flake like substances) which expire in 2030. As of December 31, 2016, we own five patents relating to Zohydro-ER®, which have expiration dates of November 1, 2019, November 1, 2019, September 12, 2034, September 12, 2034 and September 12, 2034. We also own Canadian patent applications that are still pending relating to the same technology, which we license to our commercial partner, Paladin Labs Inc., in Canada. As of December 31, 2016, we are the owner of record of four issued U.S. patents related to Fado and eight issued foreign patents to Dex. As of December 31, 2016, we are also the owner of record and are prosecuting three U.S. non-provisional patent applications and 39 foreign national patent applications related to either Dex or Fado. In addition, we have recently received ownership from Orion of one issued U.S. patent and 49 granted foreign patents (including numerous European Patent Office member and extension states as well as Eurasian members) related to a pro-drug of Fado. 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 in 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 composition of matter patents for Dex and Fado are licensed from Orion. The composition of matter patent for Dex expired in January 2014, and the composition of matter patent for Fado expired in October 2016. The composition of matter patent for a single pro-drug of Fado will expire in April 2025. If no additional patent protection is obtained, these patent expirations will impact our ability to prevent third parties from marketing generic equivalents.

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 were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we 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. 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. 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. On September 16, 2011, the Leahy Smith America Invents Act, or the Leahy Smith Act, was signed into law. The Leahy Smith Act includes a number of significant changes to United States patent law. 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, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy Smith Act will have on the operation of our

business. However, 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.

We do not own worldwide rights to all of our product candidates or the exclusive rights to all formulations.

We own worldwide rights to injectable meloxicam. We have an exclusive license from Orion for the development and, subsequent to approval, the commercialization of Dex-IN for use in the treatment of pain in humans the licensed dosage forms, but specifically excluding delivery vehicles for administration by injection or infusion, in the Territory. Orion retains the rights to develop and commercialize Dex for all uses and indications other than pain in humans and for use in combination products in that field, and we have granted Orion a license to use our clinical trial data, patents and know-how for such purpose; provided, however that Orion cannot undertake development activities in the United States, Australia or South Africa with respect to treatment of pain in humans in any licensed dosage form until four years after our first product is granted regulatory approval in the United States. It is possible, therefore, that Orion may develop and commercialize competing products in the territories retained by it and/or combination products for Dex in the Territory. We are unaware of any such programs at Orion at this time. We have a right of first refusal to commercialize any such product developed by Orion in the Territory. However, there is no guarantee that we would have the resources to exercise this right or, if we did, that we would be able to reach mutually agreeable terms with Orion.

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 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. We and our commercial partners have been successful or have settled our Paragraph IV litigation to date, but 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 product revenue for our manufacturing business, which could have a material adverse effect on our business, results of operations, financial condition and prospects. In addition, we are currently involved in an interference in front of the United States Patent and Trademark Office with another party, which involves a patent application relating to Zohydro ER®, for which we and the other party each received an adverse decision with regard to the interference claims. The other party has appealed their interference claims to the Court of Appeals for the Federal Circuit, and we intend to vigorously defend the prior decision of the United States Patent and Trademark Office. The interference could 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 product revenue for our manufacturing business 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 upon 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 USPTO 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.

We have not yet registered our trademarks, and failure to secure those registrations could adversely affect our business.

We have not registered our Recro trademark in the United States or the other potential markets for our products. It is possible that when we do file for such registrations one or more of the applications could be subject to opposition or cancellation after the marks are registered. The registrations, if they become effective, will be subject to use and maintenance requirements. It is also possible that there are names or symbols other than “Recro Pharma” and “Recro Gainesville” that may be protectable marks for which we have not sought registration, and failure to secure those registrations could adversely affect our business. Opposition or cancellation proceedings may be filed against our future trademark registrations and the trademarks may not survive such proceedings.

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®, generic Verapamil 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

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 17.3% of our outstanding common stock as of December 31, 2016. 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.

The market price and trading volume of our common stock has 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:

- 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; and
- actions by institutional shareholders.

These broad market and industry factors may decrease the market price of our common stock, regardless of our actual operating performance. The stock market in general has from time to time experienced extreme price and volume fluctuations, including recently. 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. This litigation, if instituted 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 to 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) the beginning of the first fiscal year following the fifth anniversary of our initial public offering, or January 1, 2020, (2) the beginning of the first fiscal year after our annual gross revenue is $1.0 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. We have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the JOBS Act. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

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.

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.

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 are located at 490 Lapp Road, Malvern, PA 19355, where we occupy approximately 17,517 square feet of leased laboratory and office space pursuant to a six-year lease, which expires on December 31, 2022. We currently own and operate a 97,000 square foot, DEA-licensed facility in Gainesville, Georgia.

Item 3. Legal Proceedings

As part of the Gainesville Transaction, we acquired the rights to Zohydro ER®, which we license to our commercial partner, Pernix Therapeutics Holdings, Inc., or Pernix, in the United States, and which is subject to ongoing intellectual property litigation and proceedings.

Zohydro ER® has been subject to six paragraph IV certifications, two of which were filed in 2014 by Actavis plc, or Actavis, and Alvogen Pine Brook, Inc., or Alvogen, regarding the filing of Abbreviated NDAs, or ANDAs, with the FDA for a generic version of Zohydro ER®, one of which was filed in April 2015, by Actavis regarding the filing of a supplemental ANDA, or sANDA, and another three of which were filed in November 2015 and October 2016, by Actavis, and in December 2015, by Alvogen regarding one of our recently issued patents relating to a formulation of Zohydro ER®. These certification notices allege that the three U.S. patents listed in the FDA's Orange Book for Zohydro ER®, with an expiration date in November 2019 or September 2034, will not be infringed by Actavis' or Alvogen's proposed products, are invalid and/or are unenforceable. In 2014, Daravita Limited (a subsidiary of Alkermes and our predecessor in interest) filed suit against each of Actavis and Alvogen in the U.S. District Court for the District of Delaware based on the ANDAs, and in 2015, we filed suit against Actavis in the U.S. District Court for the District of Delaware based on the sANDA. In addition, in April 2015, the U.S. Patent and Trademark Office declared an interference between one of our patent applications relating to a dosage form of Zohydro ER® and two Purdue Pharma, LP, or Purdue, applications. On April 29, 2016, the USPTO found our claims and the Purdue claims involved in the interference to be invalid. Purdue appealed this decision to the U.S. Court of Appeals for the Federal Circuit on June 28, 2016.

Under our license agreement with Pernix, we have the right to control the enforcement of our patents and related proceedings involving Zohydro ER® and any prospective generic entrant, and Pernix has the obligation to reimburse us for all reasonable costs of such actions. On September 29, 2016, we entered into a settlement agreement with Alvogen pursuant to which the case against Alvogen was dismissed. In February 2017, the Court in the Actavis case ruled in our favor and enjoined Actavis from selling the proposed generic version of Zohydro ER®.

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." The following table sets forth the high and low sales price of our common stock, as reported by the NASDAQ Capital Market for the periods indicated:

	High	Low
Year Ended December 31, 2016		
Fourth Quarter	$10.17	$5.89
Third Quarter	$12.50	$7.51
Second Quarter	$8.78	$5.95
First Quarter	$9.20	$5.59
Year Ended December 31, 2015		
Fourth Quarter	$12.86	$7.58
Third Quarter	$18.30	$11.06
Second Quarter	$15.40	$6.56
First Quarter	$9.93	$2.80

Holders of Common Stock

As of March 6, 2017, there were 9 holders of record of our common stock.

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 OrbiMed. 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.

Use of Proceeds

None.

Item 6. Selected Financial Data

The following tables present our selected financial data for the periods indicated. The selected financial data as of and for the years ended December 31, 2016 and 2015 have been derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K. The selected financial data as of and for the years ended December 31, 2014, 2013 and 2012 is 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,				
	2016	2015	2014	2013	2012
	(in thousands, except share and per share data)				
Consolidated Statements of Operations Data:					
Revenue:					
Manufacturing, royalty and profit sharing revenue	$67,594	$49,284	$—	$—	$—
Research and development revenue	1,743	2,668	—	—	—
Total revenue	69,337	51,952	—	—	—
Operating expenses:					
Cost of sales (excluding amortization of intangible assets)	37,152	28,054	—	—	—
Research and development	33,278	12,281	7,874	544	542
General and administrative	12,742	13,017	3,998	546	339
Amortization of intangible assets	2,583	1,884	—	—	—
Change in warrant valuation	(373)	(1,560)	—	—	—
Change in contingent consideration valuation	9,728	5,246	—	—	—
Total operating expenses	95,110	58,922	11,872	1,090	881
Operating loss	(25,773)	(6,970)	(11,872)	(1,090)	(881)
Other income (expense):					
Interest income	49	12	11	—	—
Grant income		—	—	—	85
Interest expense	(5,588)	(5,560)	(4,273)	(868)	(740)
Loss before income taxes	(31,312)	(12,518)	(16,134)	(1,958)	(1,536)
Income tax benefit	1,107	15,551	—	—	—
Net income (loss)	(30,205)	3,033	(16,134)	(1,958)	(1,536)
Accretion of redeemable convertible preferred stock and deemed dividend	—	—	(1,270)	(440)	(413)
Net income (loss) applicable to common shareholders	$(30,205)	$3,033	$(17,404)	$(2,398)	$(1,949)
Basic net income (loss) per common share	$(2.82)	$0.36	$(2.79)	$(15.41)	$(12.53)
Diluted net income (loss) per common share	$(2.82)	$0.21	$(2.79)	$(15.41)	$(12.53)
Weighted average basic common shares outstanding	10,721,928	8,491,025	6,238,581	155,600	155,600
Weighted average diluted common shares outstanding	10,721,928	8,749,234	6,238,581	155,600	155,600

	As of December 31,				
	2016	2015	2014	2013	2012
	(in thousands)				
Consolidated Balance Sheet Data:					

Cash and cash equivalents	$64,483	$19,779	$19,682	$13	$53
Working capital	68,497	29,189	18,928	(12,080)	(10,123)
Total assets	182,997	138,697	20,374	851	154
Debt, net	24,388	29,760	—	—	—
Convertible notes payable	—	—	—	11,907	10,159
Series A redeemable convertible preferred stock	—	—	—	5,880	5,440
Total shareholders' equity (deficit)	71,613	40,350	18,928	(17,960)	(15,562)

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 divisions: an Acute Care division and a revenue-generating CDMO division. Each of these divisions are deemed to be reportable segments for financial reporting purposes.

Our Acute Care segment is primarily focused on developing innovative products for hospital and related settings. Our lead product candidate, IV meloxicam, has successfully completed two pivotal Phase III clinical trials in prescription of post-operative pain. Overall we expect to enroll a total of approximately 1,100 patients in our Phase III program. To complete this program, we await final visits for more than 700 patients enrolled following a variety of surgical procedures in our additional safety study of IV meloxicam. Assuming we continue to observe a favorable safety profile in the safety study, we anticipate filing an NDA, for injectable meloxicam with the FDA, in the summer of 2017. Our Acute Care segment has no revenue and our costs consist primarily of expenses incurred in conducting our clinical trials and preclinical studies, acquiring clinical trial materials, regulatory activities and personnel costs.

Our CDMO segment leverages our formulation expertise to develop and manufacture pharmaceutical products using our proprietary delivery technologies for commercial partners who commercialize or plan to commercialize these products. These collaborations result in revenue streams including royalties, profit sharing, research and development and manufacturing, 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 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®, generic Verapamil and Zohydro ER®, as well as development stage products. Our CDMO segment's revenue streams are derived from manufacturing, royalty and profit sharing revenues as well as our research and development of services performed for commercial partners.

We have a limited operating history. In addition to revenue generated from our CDMO segment, we have funded our operations to date primarily from proceeds received from public offerings and private placements of convertible preferred stock, convertible notes and common stock. On March 12, 2014, we closed our initial public offering, or IPO, in which we sold 4,312,500 shares of common stock for net proceeds of approximately $30.3 million. On July 7, 2015, we closed a Private Placement with certain accredited investors in which we sold 1,379,311 shares of common stock at a price per share of $11.60, for net proceeds of approximately $14.8 million. On August 19, 2016, we closed an underwritten public offering in which we sold 1,986,666 shares of common stock at a price per share of $7.50 for net proceeds of approximately $13.4 million. On December 16, 2016, we closed an underwritten public offering in which we sold 6,670,000 shares of common stock at a price per share of $6.00 for net proceeds of approximately $36.9 million. As of December 31, 2016, we have also sold 1,143,940 shares of common stock under a common stock purchase agreement with Aspire Capital, LLC, or the Aspire Agreement, for proceeds of approximately $7.8 million. The Aspire Agreement expired in February 2017.

We have incurred losses and generated negative cash flows from operations since inception. As of December 31, 2016, we had an accumulated deficit of $61.3 million. 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 and clinical trials. We have used revenue generated by our CDMO segment primarily to fund operations at our Gainesville, Georgia manufacturing facility, 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's 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 operations. We expect to incur increasing expenses over the next several years to develop both injectable meloxicam. For IV meloxicam, we plan to complete our Phase III safety trial and prepare for NDA submission, as well as continue pre-commercial activities. Based upon the availability of additional financial resources, we may also develop and commercialize our other product candidates in our pipeline, including additional proprietary formulations of injectable meloxicam, Dex and Fado.

We expect that annual operating results of operations will fluctuate for the foreseeable future due to several factors. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future.

On April 10, 2015, we completed the Gainesville Transaction. The Gainesville Transaction transformed our business through the addition of a revenue-generating business and the increase in our workforce as a result of the addition of the employees at our Gainesville, Georgia manufacturing facility. 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, we may be required to pay up to an additional $125.0 million in milestone payments (including, at our election, either (i) $10 million upon NDA filing and $30 million upon regulatory approval or (ii) an aggregate of $45 million upon regulatory approval, as well as net sales milestones) and a percentage of future product net sales related to injectable meloxicam.

The up-front payment was funded with $50.0 million in borrowings under a credit agreement that we entered into with OrbiMed and cash on hand. The interest rate under the credit agreement is equal to LIBOR plus 14.0%, with a 1.0% LIBOR floor. Pursuant to the credit agreement, we issued OrbiMed a warrant to purchase an aggregate of 294,928 shares of our common stock at an exercise price of $3.28 per share, subject to certain adjustments.

Financial Overview

Revenues

During the years ended December 31, 2016 and 2015, we recognized revenues in four categories: manufacturing revenue, royalty, profit sharing and research and development revenue. All revenue is generated from our CDMO segment.

Manufacturing revenues— We recognize manufacturing revenues from the sale of products we manufacture for our commercial partners. Manufacturing revenues are recognized when persuasive evidence of an arrangement exists, shipment has occurred and title to the product and associated risk of loss has passed to the customer, the sales price is fixed or determinable and collectability is reasonably assured.

Royalty revenues— We recognize royalty revenues related to the sale of products by our commercial partners that incorporate our technologies. Royalties are earned under the terms of a license and supply agreement in the period the products are sold by a commercial partner and collectability is reasonably assured.

Profit sharing revenue—We recognize revenue from profit sharing related to the sale of certain of our manufactured products by our commercial partners. Profit sharing revenue is earned under the terms of a license and supply agreement in the period the products are sold and expenses are incurred by our commercial partner and collectability is reasonably assured.

Research and development revenue—Research and development revenue consists of funding that compensates us for formulation, pre-clinical and clinical testing performed by our CDMO segment under research and development arrangements with commercial partners. We generally bill our commercial partners under research and development arrangements using a full-time equivalent or hourly rate, plus direct external costs, if any.

Research and Development Expenses

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

- expenses incurred under agreements with contract research 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 materials and manufacturing services;

- costs related to facilities, depreciation and other allocated expenses;
- costs associated with non-clinical and regulatory activities;
- salaries and related costs for personnel in research and development and regulatory functions.
- costs associated with pre-commercialization activities; and
- costs related to scale up and validation for injectable meloxicam.

In addition, research and development expenses consist of costs incurred our CDMO segment in connection with research and development services performed for our partners, as well as other product development activities. We expense research and development costs as incurred. Advanced payments for goods and services that will be used in future research and development activities are initially recorded as prepaid expenses and expensed as the activity is performed or when the goods have been received.

The majority of our external research and development costs relate to clinical trials, analysis and testing of the product and patent costs. We currently use third parties for a portion of our administration, manufacturing and regulatory affairs. Costs related to facilities, depreciation, and support are not charged to specific programs.

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

- the duration of clinical trials, which varies substantially according to the type, complexity and novelty of the product candidate;
- the imposition by the FDA and comparable agencies in foreign countries of substantial requirements on the introduction of therapeutic pharmaceutical products, which may require lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures;
- the possibility that data obtained from nonclinical 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;
- the costs, timing and outcome of regulatory review of a product candidate;
- 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, 2016.

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, as well as ongoing assessments of such product candidate’s commercial potential. 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 other product candidates will generate revenues and cash flows.

We expect our research and development costs to primarily relate to injectable meloxicam for the foreseeable future as we advance this product candidate through the remaining clinical trials in our Phase III program, manufacturing scale-up and other pre-approval 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 out 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.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, marketing and finance functions. General and administrative expenses also include professional fees for legal, including patent related expenses, consulting, auditing and tax services, and stock compensation expense.

We expect to continue to have greater expenses relating to our operations as a public company, injectable meloxicam pre-commercialization costs, including increased headcount and increased salary, consulting, legal and compliance, accounting, insurance and investor relations costs. We also expect that our patent costs will continue to increase due to the new patents acquired through the Gainesville Transaction and, in addition, due to the higher annuity fees that will be due on patents that are issued. In addition, if additional formulation technology is developed for our product candidates, patent expenses could increase further.

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, which is considered an indefinite-lived intangible asset that is assessed for impairment annually or more frequently if impairment indicators exist.

Change in Fair Value of Contingent Consideration

In connection with the acquisition of injectable meloxicam in the Gainesville Transaction, we are required to pay up to an additional $125.0 million in milestone payments (including, at our election, either (i) $10 million upon NDA filing and $30 million upon regulatory approval or (ii) an aggregate of $45 million upon regulatory approval, as well as net sales milestones) and royalties on future net product sales of 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. Each reporting period, we revalue this estimated obligation with changes in fair value recognized as a non-cash operating expense or income.

Change in Fair Value of Warrants

We have classified as liabilities certain warrants outstanding which contain a contingent net cash settlement feature, or an anti-dilution provision. The fair value of these warrants are remeasured through settlement or expiration with changes in fair value recognized as a period charge within the statement of operations.

Interest Expense

Interest expense for the years ended December 31, 2016 and 2015 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, 2016, we had approximately $4.2 million of federal net operating loss carryforwards. We also had federal and state research and development tax credit carryforwards of $2.8 million available to offset future taxable income. U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. 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. As a result, we may not be able to take full advantage of these carryforwards for federal and state tax purposes.

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 are currently undergoing an analysis to determine whether or not ownership changes, as defined by the Act, have occurred since inception. We preliminarily 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. Although the carryforwards will be limited, we have determined that none of the net operating losses will expire prior to being utilized as a result of the changes. In addition, state net operating loss carryforwards may be further limited, including Pennsylvania, which has a limitation equal to the greater of 30.0% of taxable income after modifications and apportionment or $5,000,000 on state net operating losses utilized in any one year. In addition, since we will need to raise substantial additional funding to finance our operations, we may undergo further ownership changes in the future, 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 taxable income may be subject to limitations, which could result in increased future tax liabilities to us.

Results of Operations

Comparison of the Years Ended December 31, 2016 and 2015

	Year ended December 31,	
	2016	2015
	(amounts in thousands)	
Revenue:		
Manufacturing, royalty and profit sharing revenue	$67,594	$49,284
Research and development revenue	1,743	2,668
Total revenues	69,337	51,952
Operating expenses:		
Cost of sales (excluding amortization of intangible assets)	37,152	28,054
Research and development	33,278	12,281
General and administrative	12,742	13,017
Amortization of intangible assets	2,583	1,884
Change in warrant valuation	(373)	(1,560)
Change in contingent consideration valuation	9,728	5,246
Total operating expenses	95,110	58,922
Operating loss	(25,773)	(6,970)
Other income (expense):		
Interest income (expense)	(5,539)	(5,548)
Loss before income taxes	(31,312)	(12,518)
Income tax benefit	1,107	15,551
Net income (loss)	$(30,205)	$3,033

Revenue and costs of sales. Our revenues were $69.3 million and $52.0 million and cost of sales were $37.2 million and $28.1 million for the years ended December 31, 2016 and 2015, respectively. The increase of $17.3 million in revenue and $9.1 million in cost of sales was primarily the result 2016 representing a full year of operation of our CDMO segment, which was only included in approximately nine months of 2015 (following the closing of the Gainesville Transaction early in the second quarter of 2015). In 2016 revenues also included $2.3 million related to a one-time contractually based manufacturing revenue payment from one of our commercial partners and approximately $1.1 million in higher profit-share revenue from another commercial partner’s new customer base.

Research and Development. Our research and development expenses were $33.3 million and $12.3 million for the years ended December 31, 2016 and 2015, respectively, an increase of $21.0 million and 171% from December 31, 2015, primarily due to an increase of $19.5 million in our IV meloxicam clinical expenses and $2.5 million in increased salaries and benefits expense due to increased headcount partially offset by a decrease in pre-commercial manufacturing costs and other pipeline clinical expenses.

General and Administrative. Our general and administrative expenses were $12.7 million and $13.0 million for the years ended December 31, 2016 and 2015, respectively, a decrease of $0.3 million and 2.3% from December 31, 2015 primarily due to lower professional fees (due to expenses incurred in the 2015 Gainesville Transaction), partially offset by higher headcount and pre-commercialization expenses in 2016.

Amortization of Intangible Assets. Amortization expense was $2.6 million and $1.9 million for the years ended December 31, 2016 and 2015, respectively, which was exclusively related to the amortization of our royalties and contract manufacturing relationships intangible asset over its six year estimated useful life. The amortization recorded during the year December 31,2015 represents a partial year.

Interest Expense, net. Interest expense, net was $5.5 million during the years ended December 31, 2016 and 2015, as a result of interest expense incurred on our OrbiMed senior secured term loan and amortization of the related financing costs. Though the debt has been paid down by $22.7 million, interest expense in 2016 equaled 2015 as the interest for 2015 was over a nine month period as compared to a full year in 2016. The interest rate under the credit agreement with OrbiMed is equal to LIBOR plus 14.0%, with a 1.0% LIBOR floor.

Income Tax Expense. Income tax benefit was $1.1 million for the year ended December 31, 2016 due to income tax related to our US operations offset by our federal research and development credits. 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. As there was a full valuation allowance against our net deferred tax assets as of December 31, 2015, there was no income tax expense recorded for the year ended December 31, 2015.

Operating Income (Loss) per Segment.

CDMO Segment-

Our CDMO's gross margin percentage was 46% in 2016 and 2015. CDMO revenues for the year ended December 31, 2016 included $2.3 million related to a one-time contractually based manufacturing revenue payment from one of our commercial partners and an approximately $1.1 million higher profit-share revenue from another commercial partner's new customer base, which increased the gross margin by 4.9% in 2016.

CDMO's operating expenses (excluding cost of sales) increased by $1.6 million, from $6.3 million in 2015 to $7.9 million in 2016. Research and development expenses increased by $1.9 million or 68% due to 2016 representing a full year of operation of our CDMO segment, which was only included for approximately nine months of 2015 due to the closing of the Gainesville Transaction early in the second quarter of 2015 and due to increases in formulation expenses and rent allocation expenses in 2016. General and administration expenses decreased by $1.0 million or, 61%, due to a decrease in patent costs, and partially offset by an increase in stock-based compensation and business development expenses. Amortization of intangibles increased by $0.7 million.

All of the above contributed to CDMO's operating income of $24.2 million for 2016, which included non-cash charges of $5.0 million for depreciation and amortization and $ 0.8 million for stock-based compensation.

Acute Care Segment-

Acute Care's operating expenses increased $25.5 million from $24.5 million in 2015 to $50.0 million in 2016. Research and development expenses increased $19.1 million or 202% as a result of the costs of two Phase III clinical studies and a safety study being conducted in 2016 and increased salaries and benefits due to additional headcount. General and administrative costs increased by $0.7 million, or 6%, as a result of increased salaries and benefits due to headcount, and increased pre-commercialization expenses. The warrant valuation decreased $0.4 million and contingent consideration increased by $9.7 million.

All of the above contributed to Acute Care's operating loss of $50.0 million for 2016 which included non-cash charges of $0.04 million for depreciation and amortization and $3.1 million for stock-based compensation.

Liquidity and Capital Resources

As of December 31, 2016, we had $64.5 million in cash and net cash equivalents.

Since inception through December 31, 2016, we have financed our product development, operations and capital expenditures primarily from private sales of $13.6 million of our Series A Stock and Bridge Notes, $30.3 million from our IPO, and $72.4 million in sales of common stock, including $57.6 million raised in 2016. Revenues from our CDMO segment are used primarily to fund operations at our Gainesville, Georgia manufacturing facility, to make payments under our credit facility and to partially fund the development and pre-commercialization activities of our Acute Care segment. During the year ended December 31, 2016, our capital expenditures were $3.8 million.

We will need to raise substantial additional funds in order to fund the payments which may become due, including milestone payments owed to Alkermes plc or other licensing partners, to continue our clinical trials of our product candidates, to commercialize any product candidates or technologies 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 the cost of clinical studies and other actions needed to obtain regulatory approval of our products in development, and the costs of commercialization activities, as well as the continued profitability of our CDMO segment. If additional funds are required, we may raise such funds through debt refinancing, bank or other loans, through strategic research and development, 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 our failure to raise capital when needed could materially adversely impact our growth plans and our financial condition or results of operations. Additional 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.

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. The unpaid principal amount under the credit agreement is due and payable on the five year anniversary of the loan provided thereunder by OrbiMed. The credit agreement also provides for certain mandatory prepayment events, including a quarterly excess cash flow prepayment requirement at OrbiMed's request. We may make voluntary prepayments in whole or in part, subject to: (i) on or prior to the 36 month anniversary of the closing of the credit agreement, payment of a buy-out premium amount equal to (A) for full prepayments, $75 million less all previously prepaid principal amount and all previously paid interest or (B) for partial prepayments of the unpaid principal amount, 0.5 times the partial prepayment amount less interest payments previously paid in respect to the partial prepayment amount and; and (ii) after the 36 month anniversary of the closing of the credit agreement, payment of an exit fee amount equal to 10% of the amount of any prepayments. As defined by the agreement, based upon our CDMO segment financial results, OrbiMed has the option to require us to prepay a portion of the Loan balance based upon an Excess Cash Flow calculation. No payments under this option shall be subject to the buy-out premium. The credit agreement carries interest at three-month LIBOR plus 14.0% with 1.0% floor. This obligation is secured by substantially all of our assets. As of December 31, 2016, we have paid $22.7 million of the outstanding principal on our senior secured term loan from free cash flow.

Sources and Uses of Cash

Cash used in operations was $3.2 million for the year ended December 31, 2016, compared to cash provided from operations of $8.5 million for the year ended December 31, 2015, which represents our operating losses less our stock-based compensation, depreciation, non-cash interest expense, 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 $3.8 million and $55.1 million for the years ended December 31, 2016 and 2015, respectively. Capital expenditures were $3.8 million and $2.4 million for the years ended December 31, 2016 and 2015, respectively. Cash used in investing activities for 2015 includes the Gainesville Transaction investment of $52.7 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 $50.3 million, $7.8 million in proceeds from the sale of shares of common stock through our common stock purchase agreement with Aspire Capital, offset by the excess cash flow payments of $6.3 million made related to the OrbiMed credit agreement. Cash provided by financing activities was $46.7 million for the year ended December 31, 2015, primarily as a result of the credit agreement with OrbiMed for $50.0 million, net of the payment of $1.7 million of issuance costs incurred in conjunction with the agreement, closing on $14.8 million of net proceeds from a private placement of our common stock and a principal payment of $16.3 million made on the OrbiMed credit agreement.

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

- the timing and expenses of trials prior to an NDA for injectable meloxicam;
- the timing and outcome of the FDA's review of an NDA for injectable meloxicam if our trials are successful;
- the timing and outcome of our Phase IIIB clinical studies for injectable meloxicam;
- the extent to which the FDA may require us to perform additional preclinical studies, clinical trials or pre-commercial manufacturing of injectable meloxicam;
- the timing to fund the Gainesville Transaction regulatory milestone payments and other contingent consideration;
- the costs of our commercialization activities if approved by the FDA;
- the cost of purchasing manufacturing and other capital equipment for our potential products;
- 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 extent to which we acquire or invest in products, businesses and technologies;
- the timing and extent of our manufacturing and capital expenditures related to our CDMO division;
- our ability to maintain our relationships and contracts with our commercial partners;
- 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; and
- the costs of preparing, submitting and prosecuting patent applications and maintaining, enforcing and defending intellectual property claims.

We might use existing cash and cash equivalents on hand, additional debt or equity financing or a combination of the three 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 securities. This dilution may be significant depending upon the amount of equity securities that we issue and the prices at which we issue any securities.

Contractual Commitments

The following is a discussion of our contractual commitments as of December 31, 2016.

Licenses

We are involved with in-licensing of product candidates that are generally associated with payments to the partner from whom we have licensed the product. Such payments frequently take the form of:

- an up-front payment, the size of which varies depending on the phase of the product candidate and how many other companies would like to obtain the product, which is paid very soon after signing a license agreement;
- royalties as a percentage of net sales of the product; and
- milestone payments which are paid when certain parts of the overall development program and regulatory milestones (such as filing an IND or an NDA) are successfully accomplished, as well meeting certain sales thresholds.

For example, 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 certain dosage forms in the Territory. 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. We will pay milestone payments to Orion of up to €20.5 million ($21.6 million as of December 31, 2016) after regulatory approval of Dex dosage forms and upon achieving certain sales milestones. Through December 31, 2016, no such milestones have been achieved. We are also party to an exclusive license agreement with Orion for the development and commercialization of Fado for use as a human therapeutic, in any dosage form in the Territory. We are required to pay Orion lump-sum amounts on completion of certain development milestones and on achievement of certain commercial milestone, as well as a royalty on net sales during the term, which varies from 10% or 15%. We will pay milestone payments to Orion of up to €12.2 million ($12.9 million as of December 31, 2016), after regulatory filing and approval and upon achieving certain sales milestones. Through December 31, 2016, no such milestones have been achieved.

We may also out-license products, for which we hold the rights, to other companies for commercialization in other territories, or at times, for other uses and would seek appropriate compensation.

Contingent Consideration

Pursuant to the purchase and sale agreement governing the Gainesville Transaction, we agreed to pay to Alkermes up to an additional $125.0 million in milestone payments (including, at our election, either (i) $10 million upon NDA filing and $30 million upon regulatory approval or (ii) an aggregate of $45 million upon regulatory approval, as well as net sales milestones) and royalties on future product sales of injectable meloxicam between 10% and 12% (subject to a 30% reduction when no longer covered by patent). Through December 31, 2016, no milestones have been achieved.

Product Manufacturing

We are party to a supply agreement with Alkermes for the clinical and, if approved by the FDA, commercial supply of injectable meloxicam. Pursuant to our agreement with Alkermes, we will purchase our clinical and commercial supplies of bulk injectable meloxicam formulation exclusively from Alkermes, subject to certain exceptions, for a period of time. We are also party to an API supply agreement with Orion, whereby Orion provides us with API for the development and commercialization of our Dex product candidates. 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.

Leases

In August 2016, we entered into a six-year lease commencing on January 1, 2017 of our Malvern facility that expires on December 31, 2022. Our CMDO facility leases local space for additional equipment and documentation storage on a month to month basis.

Debt

Pursuant to our credit agreement with OrbiMed, OrbiMed provided us with a term loan in the original principal amount of $50.0 million on April 10, 2015. The unpaid principal amount under the credit agreement is due and payable in April 2020. The credit agreement also provides for certain mandatory prepayment events, including a quarterly excess cash flow prepayment requirement at OrbiMed's request. As defined by the agreement, based upon our CDMO segment financial results, OrbiMed has the option to require the Company to prepay a portion of the loan balance based upon an Excess Cash Flow calculation. As of December 31, 2016, we have paid $22.7 million of the outstanding principal on our senior secured term loan from free cash flow.

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. generally accepted accounting principles. 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 two-step goodwill impairment test consists of the following steps. The first step compares a reporting unit's fair value to its carrying amount to identify potential goodwill impairment. If the carrying amount of a reporting unit exceeds the reporting unit's fair value, the second step of the impairment test must be completed to measure the amount of the reporting unit's goodwill impairment loss, if any. Step two requires an assignment of the reporting unit's fair value to the reporting unit's assets and liabilities to determine the implied fair value of the reporting unit's goodwill. The implied fair value of the reporting unit's goodwill is then compared with the carrying amount of the reporting unit's goodwill to determine the goodwill impairment loss to be recognized, if any. 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 even has modified their estimated useful lives.

Classification of debt—Under our credit agreement with OrbiMed, OrbiMed, at its option, has the right to require us to prepay the principal balance outstanding under the loan based on quarterly Excess Cash Flows of our CDMO segment, as defined in the credit

agreement. Accounting policies require that we estimate the amount of the Excess Cash Flow payments that could be payable within one year of December 31, 2016 upon request of OrbiMed and classify this amount as current debt in the consolidated balance sheet. Changes in estimates of future cash flows caused by items such as customer and product demand, changing operating cost structure or other unforeseen events or changes in market conditions, could cause actual future cash flows to vary from our estimates.

Revenue Recognition—We generate revenues from development, formulation, manufacturing, and related services for multiple pharmaceutical companies. The agreements we have with our commercial partners provide for manufacturing revenues, royalties and/or profit sharing components, and research and development revenue.

Manufacturing revenues are recognized when persuasive evidence of an arrangement exists, shipment has occurred and title to the product and associated risk of loss has passed to the customer, the sales price is fixed or determinable and collectability is reasonably assured

In addition to manufacturing revenue, our customer agreements have royalties and/or profit sharing payments, computed on the net product sales of our partner. Royalties are earned under the terms of a license and supply agreement in the period the products are sold by a commercial partner and collectability is reasonably assured. Profit sharing revenue is earned under the terms of a license and supply agreement in the period the products are sold and expenses are incurred by our commercial partner and collectability is reasonably assured.

Research and development revenue consists of funding that compensates us for formulation, pre-clinical and clinical testing performed by our CDMO segment under research and development arrangements with commercial partners. We generally bill our commercial partners under research and development arrangements using a full-time equivalent, or FTE, or hourly rate, plus direct external costs, if any.

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 NOL and credit carryforwards can be utilized.

We continue to maintain a valuation allowance against certain other deferred tax assets where realizability is not certain. We periodically evaluate the likelihood of the realization of deferred tax assets and reduce the carrying amount of these deferred tax assets by a valuation allowances to the extent we believe a portion will not be realized. 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, 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 are not realizable in a future period, 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, 2016, we had approximately $57.6 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, 2016, all less than 90 days, 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 OrbiMed senior secured term loan interest expense is based on the current committed rate of LIBOR plus 14% with a 1.0% LIBOR floor. A fluctuation in LIBOR of 0.25% would result in a charge of $0.1 million of interest expense.

We have license agreements with Orion for Dex and Fado 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, 2016, 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 Dex or Fado. 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 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, 2016. 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, 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, 2016, 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, 2016. 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, 2016, 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
None.

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 2017 Annual Meeting of Shareholders (the "Proxy Statement") under the headings Board 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.

Item 11. Executive Compensation

Information with respect to this item will be set forth in the Proxy Statement under the headings "Director Compensation," and "Executive Compensation" 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		Weighted-average exercise price of outstanding options(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	2,255,679	(2)	$ 6.75	1,212,422	
Equity compensation plans not approved by security holders	364,000	(3)	$ 8.64	—	(4)
Total	2,619,679		$ 7.01	1,212,422	

(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 2,247,929 shares of common stock and (ii) restricted stock units covering an aggregate of 7,750 shares of common stock. Shares in settlement of vested restricted stock units are deliverable within 30 days of the vesting date.

(3)

Reflects option grants 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 filed in the Company’s registration statement on Form S-8 with the Securities and Exchange Commission on December 23, 2015.

(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, 2016 and 2015

Consolidated Statements of Operations for the years ended December 31, 2016 and 2015

Consolidated Statements of Shareholders' Equity for the years ended December 31, 2016 and 2015

Consolidated Statements of Cash Flows for the years ended December 31, 2016 and 2015

(a)(2) Consolidated Financial Statement Schedules.

Not applicable.

(a)(3) Exhibits:

A list of exhibits to this Annual Report on Form 10-K is set forth on the Exhibit Index immediately preceding such exhibits and is incorporated herein by reference.

(b) Exhibits

See Exhibit Index.

(c) Not applicable

RECRO PHARMA, INC. AND SUBSIDIARIES

Index to Consolidated Financial Statements

	Page
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets	F-3
Consolidated Statements of Operations	F-4
Consolidated Statements of Shareholders' Equity	F-5
Consolidated Statements of Cash Flows	F-6
Notes to Consolidated Financial Statements	F-7

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders

Recro Pharma, Inc.:

We have audited the accompanying consolidated balance sheets of Recro Pharma, Inc. and subsidiaries (the Company) as of December 31, 2016 and 2015, and the related consolidated statements of operations, shareholders' equity, and cash flows for the years then ended. 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 conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Recro Pharma, Inc. and subsidiaries as of December 31, 2016 and 2015, and the results of their operations and their cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

/s/ KPMG LLP

Philadelphia, Pennsylvania

March 9, 2017

RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

(amounts in thousands, except share and per share data)	December 31, 2016	2015
Assets		
Current assets:		
Cash and cash equivalents	$64,483	$19,779
Accounts receivable	10,411	8,580
Inventory	8,746	8,982
Prepaid expenses and other current assets	1,118	793
Deferred equity costs	—	542
Total current assets	84,758	38,676
Property, plant and equipment, net	37,300	37,922
Deferred income taxes	17,060	15,637
Intangible assets, net	37,433	40,016
Goodwill	6,446	6,446
Total assets	$182,997	$138,697
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$4,132	$1,553
Accrued expenses	9,893	3,418
Current portion of long-term debt, net	2,236	4,516
Total current liabilities	16,261	9,487
Long-term debt, net	22,152	25,244
Warrants	3,397	3,770
Contingent consideration	69,574	59,846
Total liabilities	111,384	98,347
Commitments and contingencies (Note 11)		
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, 19,043,216 shares at December 31, 2016 and 9,224,315 shares at December 31, 2015	190	92
Additional paid-in capital	132,691	71,321
Accumulated deficit	(61,268)	(31,063)
Total shareholders' equity	71,613	40,350
Total liabilities and shareholders' equity	$182,997	$138,697

See accompanying notes to consolidated financial statements.

F-3

RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Operations

(amounts in thousands, except share and per share data)	Year ended December 31, 2016	2015
Revenue:		
Manufacturing, royalty and profit sharing revenue	$67,594	$49,284
Research and development revenue	1,743	2,668
Total revenues	69,337	51,952
Operating expenses:		
Cost of sales (excluding amortization of intangible assets)	37,152	28,054
Research and development	33,278	12,281
General and administrative	12,742	13,017
Amortization of intangible assets	2,583	1,884
Change in warrant valuation	(373)	(1,560)
Change in contingent consideration valuation	9,728	5,246
Total operating expenses	95,110	58,922
Operating loss	(25,773)	(6,970)
Other income (expense):		
Interest income	49	12
Interest expense	(5,588)	(5,560)
Net loss before income taxes	(31,312)	(12,518)
Income tax benefit	1,107	15,551
Net income (loss)	$(30,205)	$3,033
Basic net income (loss) per common share	$(2.82)	$0.36
Diluted net income (loss) per common share	$(2.82)	$0.21
Weighted average basic common shares outstanding	10,721,928	8,491,025
Weighted average diluted common shares outstanding	10,721,928	8,749,234

See accompanying notes to consolidated financial statements.

RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Shareholders' Equity

For the Years Ended December 31, 2016 and 2015

	Shareholders' Equity (Deficit)				
	Common Stock		Additional paid	Accumulated	
(amounts in thousands, except share data)	Shares	Amount	in capital	Deficit	Total
Balance, December 31, 2014	7,707,600	$ 77	$ 52,947	$ (34,096)	$ 18,928
Shares issued in equity financing facility	96,463	1	284	—	285
Stock option exercise	38,000	—	228	—	228
Stock-based compensation expense	—	—	3,064	—	3,064
Sale of common stock, net of offering costs	1,379,311	14	14,798	—	14,812
Cashless warrant exercises	2,941	—	—	—	—
Net income	—	—	—	3,033	3,033
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

See accompanying notes to consolidated financial statements.

RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

(amounts in thousands)	Year ended December 31, 2016	2015
Cash flows from operating activities:		
Net income (loss)	$(30,205)	$3,033
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Stock-based compensation	3,889	3,064
Non-cash interest expense	1,071	668
Depreciation expense	4,993	4,120
Amortization	2,583	1,884
Change in warrant valuation	(373)	(1,560)
Change in contingent consideration valuation	9,728	5,246
Deferred income taxes	(1,423)	(15,637)
Changes in operating assets and liabilities, net of effect of acquisition:		
Inventory	237	1,271
Prepaid expenses and other current assets	(325)	225
Accounts receivable	(1,831)	3,992
Accounts payable and accrued expenses	8,454	2,152
Net cash provided by (used in) operating activities	(3,202)	8,458
Cash flows from investing activities:		
Acquisition of Gainesville, net of cash acquired	—	(52,690)
Purchase of property and equipment	(3,770)	(2,411)
Net cash used in investing activities	(3,770)	(55,101)
Cash flows from financing activities:		
Proceeds from sales of common stock, net of offering costs	50,255	14,812
Proceeds from Aspire facility	7,796	—
Proceeds from long-term debt	—	50,000
Payments on long-term debt	(6,324)	(16,329)
Payment of debt issuance costs	—	(1,718)
Payment of deferred equity costs	—	(253)
Payments of withholdings on shares withheld for income taxes	(51)	—
Proceeds from option exercise	—	228
Net cash provided by financing activities	51,676	46,740
Net increase in cash and cash equivalents	44,704	97
Cash and cash equivalents, beginning of year	19,779	19,682
Cash and cash equivalents, end of year	$64,483	$19,779
Supplemental disclosure of cash flow information:		
Common stock issued in connection with equity facility	$—	$285
Cash paid for interest	$4,517	$4,892
Amortization of deferred equity costs	$421	$—
Purchase of property, plant and equipment included in accrued expenses and accounts	$808	$208

payable

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 divisions: an Acute Care division and a revenue-generating contract development and manufacturing, or CDMO, division. Each of these divisions are deemed to be reportable segments (see Note 3(n) and Note 14). The Acute Care division is primarily focused on developing innovative products for hospital and related settings, and the CDMO division 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, Phase III-ready, long-acting preferential COX-2 inhibitor for the treatment of moderate to severe acute 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.

(2) Development-Stage Risks and Liquidity

The Company has incurred losses from operations since inception and has an accumulated deficit of $61,268 as of December 31, 2016. 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. Substantial additional financing will be needed by the Company to fund its operations and to commercially develop its product candidates including Gainesville Transaction contingent payments which may become due. 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 and partnering 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. However, management believes that the Company's existing cash as of December 31, 2016 will be sufficient to fund its operations through March 2018.

(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, 2016 and its results of operations for the twelve months ended December 31, 2016 and 2015 and cash flows for the twelve months ended December 31, 2016 and 2015.

(b) Use of Estimates

The preparation of 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

The Company considers all highly liquid investments that have maturities of three months or less when acquired to be cash equivalents. Cash equivalents as of December 31, 2016 and 2015 consisted of money market mutual funds and government and agency bonds.

RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

(d) Fair Value of Financial Instruments

Management believes that the carrying amounts of the Company's financial instruments, including cash equivalents, accounts receivable, accounts payable, and accrued expenses, approximate fair value due to the short-term nature of those instruments. Management believes the carrying value of debt approximates fair value as the interest rates are reflective of the rate the Company could obtain on debt with similar terms and conditions.

(e) Inventory

Inventory is stated at the lower of cost or market value. Cost is determined using the first-in, first-out method. Included in inventory are raw materials used in production of commercial products.

(f) 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, office and computer 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.

(g) 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 two-step method for determining impairment.

The first step compares a reporting unit's fair value to its carrying amount to identify potential goodwill impairment. If the carrying amount of a reporting unit exceeds the reporting unit's fair value, the second step of the impairment test must be completed to measure the amount of the reporting unit's goodwill impairment loss, if any. Step two requires an assignment of the reporting unit's fair value to the reporting unit's assets and liabilities to determine the implied fair value of the reporting unit's goodwill. The implied fair value of the reporting unit's goodwill is then compared with the carrying amount of the reporting unit's goodwill to determine the goodwill impairment loss to be recognized, if any.

Intangible assets include the Company's royalties and contract manufacturing relationships intangible asset as well as an in-process research and development, or 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 lives 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. For those compounds that reach commercialization, the IPR&D assets will be amortized over their estimated useful lives.

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. 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, 2016.

(h) Revenue Recognition

The Company generates revenues from manufacturing, packaging and related services for multiple pharmaceutical companies. The agreements that the Company has with its commercial partners provide for manufacturing revenues, royalties and/or profit sharing components.

RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

Manufacturing and other related services revenue is recognized when persuasive evidence of an arrangement exists, shipment has occurred and the title to the product and associated risk of loss has passed to the customer, the sales price is fixed or determinable and collectability is reasonably assured.

In addition to manufacturing and packaging revenue, the customer agreements have royalties and/or profit sharing payments, computed on the net product sales of the partner. Royalty and profit sharing revenues are generally recognized under the terms of the license and supply agreement in the period the products are sold and expenses are incurred by our commercial partner and collectability is reasonably assured.

Revenues related to research and development are generally recognized as the related services or activities are performed, 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.

(i) Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash, cash equivalents and accounts receivable. The Company's policy is to limit the amount of credit exposure to any one financial institution and place its cash and cash equivalents with financial institutions evaluated as being creditworthy. To date, the Company has not experienced any losses on its cash equivalents.

Five customers represent 100% of the Company's trade accounts receivable at December 31, 2016 and four customers represent approximately 96.8% of the Company's 2016 revenues.

(j) 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 manufacturing of clinical supplies, drug development, clinical trials, statistical analysis and report writing, and regulatory 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 expense 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 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.

(k) 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 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 comparable public companies as a basis for its expected volatility to calculate the fair value of options grants. The risk-free interest rate is based on U.S. Treasury notes with a term approximating the expected life of the option.

RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

Nonemployee stock-based awards are revalued until an award vests and recognizes compensation expense on a straight-line basis over the vesting period of each separated vesting tranche of the award, or 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.

(l) 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 bases and operating loss 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 accrues interest and related penalties are classified as income tax expense in the Consolidated Statements of Operations. The Company does not anticipate significant changes in the amount of unrecognized income tax benefits over the next year.

(m) Net Income (Loss) Per Common Share

Basic net income (loss) per common share is determined by dividing net income (loss) applicable to common shareholders by the weighted average common shares outstanding during the period. For all periods presented, the outstanding common stock options, unvested restricted stock units and warrants have been excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive. Therefore, the weighted average shares used to calculate both basic and diluted net loss per share are the same.

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as of December 31, 2016 and 2015, as they would be anti-dilutive:

	December 31,	
	2016	2015
Options and restricted stock units outstanding	2,619,679	1,153,950
Warrants	784,928	490,000

F-10

RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

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

	December 31, 2016	2015
Basic Earnings Per Share		
Net income (loss)	$(30,205)	$3,033
Common stock outstanding (weighted average)	10,721,928	8,491,025
Basic net income (loss) per share	$(2.82)	$0.36
Diluted Earnings Per Share		
Net income (loss)	$(30,205)	$3,033
Add change in warrant valuation	—	(1,174)
Diluted net income (loss)	$(30,205)	$1,859
Common stock outstanding (weighted average)	10,721,928	8,491,025
Add shares from outstanding warrants and stock options	—	258,209
Common stock equivalents	10,721,928	8,749,234
Diluted net income (loss) per share	$(2.82)	$0.21

(n) 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 14. 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. Segment operating capital employed represents segment assets less segment liabilities.

(o) Recent Accounting Pronouncements

In January 2017, the Financial Accounting Standards Board or, FASB, issued updated guidance on the annual goodwill impairment test. The amended guidance 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 Accounting Standards Update (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 is currently evaluating the effect that this guidance may have on its consolidated financial statements.

In August 2016, the FASB issued updated guidance in the classification of certain cash receipts and payments in the statement of cash flows where diversity in practice exists. This new guidance is effective for annual periods beginning

after December 15, 2017, with early adoption permitted. The Company is currently evaluating the effect that the updated standard will have on its consolidated financial statements and related disclosures.

In March 2016, the FASB issued updated guidance on the accounting for share-based payment transactions including the income tax consequences, classification of awards as either equity or liabilities, employee tax withholding, calculation of shares for use in diluted earnings per share and the classification on the statement of cash flows. The new guidance is effective for annual periods beginning after December 15, 2016, with early adoption permitted. The Company early adopted the guidance effective July 1, 2016. The guidance did not have a material impact to the consolidated financial statements upon adoption.

In February 2016, the FASB issued updated guidance regarding the accounting for and disclosures of leases. This new ASU represents 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. The effective for annual and interim periods begins after December 15, 2018, with early adoption permitted. The Company is currently evaluating the effect that this guidance may have on its consolidated financial statements.

RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

In November 2015, the FASB issued updated guidance on the presentation requirements for deferred income tax liabilities and assets to be classified as noncurrent in a classified statement of financial position. The update is effective for financial statements issued for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years, and early adoption is permitted for all entities as of the beginning of an interim or annual reporting period. The Company adopted this guidance during the year ended December 31, 2015.

In September 2015, the FASB issued updated guidance regarding the accounting for and disclosure of measurement-period adjustments that occur in periods after a business combination is consummated. This update requires that the acquirer recognize measurement-period adjustments in the reporting period in which they are determined. Prior period information should not be revised. This update also requires an entity to present separately on the face of the income statement or disclose in the notes the amount recorded in the current-period income statement that would have been recorded in previous reporting periods if the adjustments had been recognized as of the acquisition date. The effective date for annual and interim periods begins after December 15, 2016. The Company is currently evaluating the effect that this guidance may have on its consolidated financial statements.

In August 2014, the FASB issued updated guidance regarding the going concern assumption. The amendments in this update will explicitly require a company’s management to assess an entity’s ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. This new guidance is effective for annual periods beginning after December 15, 2016, with early adoption permitted. The Company adopted this new standard effective for the year ended December 31, 2016.

In July 2015, the FASB issued updated guidance which changes the measurement principle for inventory from the lower of cost or market to the lower of cost and net realizable value. The amendments in this guidance do not apply to inventory that is measured using last-in, first-out or, LIFO, or the retail inventory method. The amendments apply to all other inventory, which includes inventory that is measured using first-in, first-out or average cost. Within the scope of this new guidance, an entity should measure inventory at the lower of cost and net realizable value; where, net realizable value is defined as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The new guidance is effective for annual periods beginning after December 15, 2016, with early adoption permitted. The new guidance must be applied on a prospective basis. The Company is evaluating the effect that the new guidance will have on its consolidated financial statements and related disclosures.

In May 2014, the FASB issued updated guidance regarding the accounting for and disclosures of revenue recognition, with an effective date for annual and interim periods beginning after December 15, 2016. The update provides a single comprehensive model for accounting for revenue from contracts with customers. The model requires that revenue recognized reflect the actual consideration to which the entity expects to be entitled in exchange for the goods or services defined in the contract, including in situations with multiple performance obligations. In July 2015, the FASB deferred the effective date by one year. The guidance will be effective for annual and interim periods beginning after December 15, 2017. The new standard permits two methods of adoption: the full retrospective method, which requires the standard to be applied to each prior period presented, or the modified retrospective method, which requires the cumulative effect of adoption to be recognized as an adjustment to opening retained earnings in the period of adoption. The Company currently anticipates adopting the standard using the modified retrospective method. The Company plans to complete an analysis of existing contracts with its customers and assessed the differences in

accounting for such contracts under ASU 2014-09 compared with current revenue accounting standards by the end of the second quarter. The new standard will result in additional revenue-related disclosures in the footnotes to the consolidated financial statements. The Company will continue to assess new customer contracts during 2017. Adoption of this standard will require changes to business processes, systems and controls to support the additional required disclosures. The Company is in the process of identifying such changes.

(4) Acquisition of Gainesville Facility and Meloxicam

On April 10, 2015, the Company completed the Gainesville Transaction. The consideration paid in connection with the Acquisition consisted of $50.0 million cash at closing, a $4.0 million 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. In addition, the Company may be required to pay up to an additional $125.0 million in milestone payments (including, the Company's election, either (i) $10 million upon a new drug application or, NDA, filing and $30 million upon regulatory approval or (ii) an aggregate of $45 million upon regulatory approval, as well as net sales milestones) and a percentage of future product net sales related to injectable meloxicam. 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

RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

consideration obligation is remeasured each reporting date with changes in fair value recognized as a period charge within the statement of operations (see note 5 for further information regarding fair value).

The following was the purchase price allocation for the Gainesville Transaction:

Purchase price agreement	$50,000
Fair value of warrants	2,470
Fair value of contingent consideration	54,600
Working capital adjustment	4,010
	$111,080

The contingent consideration consists of three separate components. The first component consists of two potential payments, which will be payable upon the submission of the NDA for meloxicam, and the related regulatory approval, respectively. The second component consists of three potential payments, based on the achievement of specified annual revenue targets. The third component consists of a royalty payment for a defined term on future meloxicam net sales.

The fair value of the first contingent consideration component recognized on the acquisition date was estimated by applying a risk adjusted discount rate to the probability adjusted contingent payments and the expected approval dates. The fair value of the second contingent consideration component recognized on the acquisition date was estimated by applying a risk adjusted discount rate to the potential payments resulting from probability weighted revenue projections and expected revenue target attainment dates. The fair value of the third contingent consideration component recognized on the acquisition date was 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.

The results of operations of the acquired business, which has become the CDMO division, have been included in the consolidated statement of operations beginning April 10, 2015.

The following represents the assets acquired and the liabilities assumed in connection with the Gainesville Transaction, reconciled to the purchase price:

	Amount
Accounts receivable	$12,519
Inventory	10,253

Prepaid expenses	380
Property, plant and equipment	39,424
Intangible assets	41,900
Goodwill	6,446
Total assets acquired	110,922
Accounts payable and accrued expenses	1,162
Warrants	2,470
Contingent consideration	54,600
Total liabilities assumed	58,232
Cash paid, net of $1,320 of cash acquired	$52,690

RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

The fair value of the property, plant and equipment and their weighted-average useful lives are as follows:

	Estimated Fair Value	Estimated Useful Life
Buildings and improvements	$ 16,371	35 years
Land	3,263	N/A
Furniture, office & computer equipment	2,510	4-5 years
Vehicles	30	2 years
Manufacturing equipment	17,250	6-7 years
	$ 39,424	

The estimated fair value of property, plant and equipment was determined using the cost and sales approaches.

The fair value of the identifiable intangible assets and their weighted-average useful lives are as follows:

	Estimated Fair Value	Weighted Average Estimated Useful Life
Royalties and contract manufacturing relationships	15,500	6
In-process research and development	26,400	N/A
Total intangible assets	41,900	

The IPR&D asset and customer relationships were valued using the multi-period excess earnings method, which is an income approach in which excess earnings are the earnings remaining after deducting the market rates of return on the estimated values of contributory assets, including debt-free net working capital, tangible and intangible assets. The excess earnings are thereby calculated for each quarter of a multi-quarter projection period discounted to a present value utilizing an appropriate discount rate for the subject asset.

The unaudited pro forma combined results of operations for the year ended December 31, 2015 (assuming the closing of the Gainesville Transaction had occurred on January 1, 2015) are as follows:

	For the year ended December 31, 2015
Revenue	$ 71,684
Net income	6,016

(5) Fair Value of Financial Instruments

The Company follows FASB accounting guidance on fair value measurements for financial assets and liabilities measured on a recurring basis. The guidance requires fair value measurements to maximize the use of "observable inputs." The three-level hierarchy of inputs to measure fair value are as follows:

- Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities
- Level 2: Significant other observable inputs other than Level 1 prices such as quoted prices in markets that are not active, or inputs that are observable, either directly or indirectly, for substantially the full term of the asset or liability
- Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity)

RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

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, 2015:			
Assets:			
Money market mutual funds	$5,081	$ —	$ —
Government and agency bonds	10,250	—	—
Cash equivalents	$15,331	$ —	$ —
Liabilities:			
Warrants	—	—	$ 3,770
Contingent consideration	—	—	59,846
	$—	$ —	$ 63,616
At December 31, 2016:			
Assets:			
Money market mutual funds	$37,079	$ —	$ —
Government and agency bonds	20,517	—	—
Cash equivalents	$57,596	$ —	$ —
Liabilities:			
Warrants	—	—	$ 3,397
Contingent consideration	—	—	69,574
	$—	$ —	$ 72,971

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, 2015	$ 3,770	$ 59,846
Additions	—	—
Remeasurement	(373)	9,728
Balance at December 31, 2016	$ 3,397	$ 69,574

(6) Inventory

Inventory consists of the following:

	December 31, 2016	December 31, 2015
Raw materials	$ 2,557	$ 2,933
Work in process	4,396	4,340
Finished goods	1,793	1,709
	$ 8,746	$ 8,982

RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

(7) Property, Plant and Equipment
Property, plant and equipment consists of the following:

	December 31, 2016	December 31, 2015
Land	$ 3,263	$ 3,263
Building and improvements	15,613	15,412
Furniture, office and computer equipment	3,811	2,888
Vehicles	30	30
Manufacturing equipment	21,508	19,504
Construction in Progress	2,198	955
	46,423	42,052
Less: accumulated depreciation and amortization	9,123	4,130
Property, plant and equipment, net	$ 37,300	$ 37,922

Depreciation expense for the years ended December 31, 2016 and 2015 was $4,993 and $4,120.

(8) Intangible Assets
The following represents the balance of the intangible assets at December 31, 2016:

	Cost	Accumulated Amortization	Net Intangible Assets
Royalties and contract manufacturing relationships:	$15,500	$ 4,467	$ 11,033
In-process research and development	26,400	—	26,400
Total	$41,900	$ 4,467	$ 37,433

Amortization expense for the years ended December 31, 2016 and 2015 was $2,583 and $1,884, respectively. The amortization expense for the next four years will be $2,583 per year and $701 in the final year.

(9) Accrued Expenses
Accrued expenses consist of the following:

	December 31, 2016	2015
Clinical trial and related costs	$2,564	$1,364

Professional and consulting fees	360	863
Payroll and related costs	4,547	697
Property plant and equipment	720	—
Deferred revenue	418	—
Income tax payable	311	86
Other	973	408
	$9,893	$3,418

(10) Long-Term Debt

The Company financed the Gainesville Transaction with cash on hand and a $50,000 five-year senior secured term loan, pursuant to a credit agreement, entered into on April 10, 2015, with OrbiMed Royalty Opportunities II, LP, or OrbiMed. The unpaid principal amount under the credit agreement is due and payable on the five year anniversary of the loan provided thereunder by OrbiMed. The credit agreement also provides for certain mandatory prepayment events, including a quarterly excess cash flow prepayment requirement at OrbiMed's request. The Company may make voluntary prepayments in whole or in part, subject to: (i) on or prior to the 36 month anniversary of the closing of the credit agreement, payment of a buy-out premium amount equal to (A) for full prepayments of the unpaid principal amount, $75,000 less all previously prepaid principal amounts

RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

and all previously paid interest or (B) for partial prepayments of the unpaid principal amount, 0.5 times the partial prepayment amount less interest payments previously paid in respect to the partial prepayment amount and (ii) after the 36 month anniversary of the closing of the credit agreement, payment of an exit fee amount equal to 10% of the amount of any prepayments. As defined by the agreement, based upon the CDMO segment financial results, OrbiMed has the option to require the Company to prepay a portion of the loan balance based upon an Excess Cash Flow. No payments under this option shall be subject to the buy-out premium As of December 31, 2016, the Company has paid $22,653 of principal payments on the senior secured loan from the Excess Cash Flow calculation. The credit agreement carries interest at three month LIBOR plus 14.0% with a 1.0% floor. The Company's obligations under the senior term loan are secured by substantially all of the Company's assets.

The credit agreement contains certain usual and customary affirmative and negative covenants, as well as financial covenants that the Company will need to satisfy on a monthly and quarterly basis. As of December 31, 2016, the Company was in compliance with the covenants.

The Company issued to OrbiMed a warrant to purchase 294,928 shares of common stock, with an exercise price of $3.28 per share. The warrant is exercisable through April 10, 2022. The initial fair value of the warrant of $2,861 was recorded as debt issuance costs.

Debt issuance costs related to the term loan of $4,579, including the initial warrant fair value of $2,861, are being amortized to interest expense over the five year term of the loan and netted with the loan principal amount. The unamortized balance of debt issuance costs is $2,959 as of December 31, 2016. As of December 31, 2016, the long-term debt balance is comprised of the following:

Principal balance outstanding	$27,347
Unamortized deferred issuance costs	(2,959)
	$24,388
Current portion	(2,236)
	$22,152

The Company has estimated the amount of the Excess Cash Flow payments that could be payable within one year of December 31, 2016 upon request of OrbiMed and has classified that amount as a current debt in the accompanying consolidated balance sheet.

(11) Commitments and Contingencies

(a) License and Supply Agreements

In August 2008, the Company entered into a License Agreement with Orion Corporation (Orion) for Non-Injectable Dexmedetomidine. Under the Dexmedetomidine License Agreement, the Company was granted an exclusive license under the Orion Know-How and Cygnus/Farmos Patent to commercialize products in the territory, as defined in such agreement, and to use, research, develop, and manufacture products 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, and to use, research, develop, and manufacture products worldwide solely for purposes of commercialization. The Company also entered into a supply agreement with Orion in which Orion will supply the Company with Dexmedetomidine at no cost during the product development period and upon FDA approval, Orion will supply commercial quantities of bulk active pharmaceutical ingredient Dexmedetomidine, for commercialization.

The Company will pay up to €20,500 ($21.6 million as of December 31, 2016) in contingent milestones upon the achievement of certain regulatory and commercialization events. There are also royalty payments to be paid at varying percentages of net sales, which generally range from 10% to 20% depending on annual sales levels. No amounts were due or payable during 2016 or 2015.

In July 2010, the Company entered into a License Agreement with Orion for Fadolmidine. Under the Fadolmidine License Agreement, the Company was granted an exclusive license under the Orion Know-How and Orion Patent Rights (each as defined in the License Agreement) to commercialize products in the territory, as defined in such agreement, and to use, research, develop, and manufacture products worldwide solely for purposes of commercialization.

RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

The Company will pay up to an additional €12,200 ($12.9 million as of December 31, 2016) in contingent milestones upon the achievement of certain regulatory and commercialization events. There are also royalty payments to be paid at varying percentages, which range from 10% to 15% of net sales. No amounts were due or payable during 2016 or 2015.

As of December 31, 2016, the Company had $3,329 of non-cancellable commitments at our CDMO segment facility for capital expenditures and material and services.

(b) Agreements with Alkermes

Pursuant to the purchase and sale agreement governing the Gainesville Transaction, the Company agreed to pay to Alkermes up to an additional $125.0 million in milestone payments (including, at the Company's election, either (i) $10 million upon NDA filing and $30 million upon regulatory approval or (ii) an aggregate of $45 million upon regulatory approval, as well as net sales milestones related to injectable meloxicam and royalties on future product sales of injectable meloxicam between 10% and 12% (subject to a 30% reduction when no longer covered by patent).

In July 2015, the Company also entered into a Development, Manufacturing and Supply Agreement, or Supply Agreement, with Alkermes (through a subsidiary of Alkermes), pursuant to which Alkermes will (i) provide clinical and, if elected by the Company, commercial bulk supplies of injectable meloxicam formulation and (ii) provide development services with respect to the Chemistry, Manufacturing and Controls section of a NDA for injectable meloxicam. Pursuant to the Supply Agreement, Alkermes will supply the Company with such quantities of bulk injectable meloxicam formulation as shall be reasonably required for the completion of clinical trials of injectable meloxicam, subject to a maximum of eight clinical batches in any twelve-month period unless otherwise agreed by the parties. The Company has elected to have Alkermes supply its initial commercial requirements of bulk injectable meloxicam formulation. During the term of the Supply Agreement, the Company will purchase its clinical and commercial supplies of bulk injectable meloxicam formulation exclusively from Alkermes, subject to certain exceptions, for a period of time.

(c) Litigation

The Company is involved, from time to time, in various claims and legal proceedings arising in the ordinary course of its business. Except as disclosed below, the Company is not currently a party to any such claims or proceedings that, if decided adversely to it, would either individually or in the aggregate have a material adverse effect on its business, financial condition or results of operations.

As part of the Gainesville Transaction, the Company acquired the rights to Zohydro ER®, which the Company licenses to its commercial partner, Pernix Therapeutics Holdings, Inc., or Pernix, in the United States, and which is subject to ongoing intellectual property litigation and proceedings.

Zohydro ER® is subject to six paragraph IV certifications, two of which were filed in 2014 by Actavis plc, or Actavis, and Alvogen Pine Brook, Inc., or Alvogen, regarding the filing of Abbreviated NDAs, or ANDAs, with the FDA for a generic version of Zohydro ER®, one of which was filed in April 2015, by Actavis regarding the filing of a supplemental ANDA, or sANDA, and another three of which were filed in November 2015 and October 2016, by Actavis, and in December 2015, by Alvogen regarding one of our recently issued patents relating to a formulation of Zohydro ER®. These certification notices allege that three U.S. patents listed in the FDA's Orange Book for Zohydro

ER®, with an expiration date of November 2019 and September 2034, will not be infringed by Actavis' or Alvogen's proposed products, are invalid and/or are unenforceable. In 2014, Davrata Limited (a subsidiary of Alkermes and the Company's predecessor in interest) filed suit against each of Actavis and Alvogen in the U.S. District Court for the District of Delaware based on the ANDAs, and in 2015, the Company filed suit against Actavis in the U.S. District Court of the District of Delaware based on the sANDA.

Under the Company's license agreement with Pernix, the Company has the right to control the enforcement of the Company's patents and related proceedings involving Zohydro ER® and any prospective generic entrant, and Pernix has the obligation to reimburse the Company for all reasonable costs of paragraph IV certification actions. On September 29, 2016, the Company entered into a settlement agreement with Alvogen pursuant to which the case against Alvogen was dismissed. In February 2017, the Court in the Actavis case ruled in the Company's favor and enjoined Actavis from selling the proposed generic version of Zohydro ER ®.

RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

(d) Leases

In August 2016, the Company entered into a six-year lease commencing on January 1, 2017 for the Malvern facility that expires on December 31, 2022. In the life of the lease term, the Company may be liable for up to $1,999 of rent expense as well as additional operating and tenant improvement expenses.

Future minimum lease payments, excluding operating expenses and tenant improvements for the lease are as follows:

	Lease payments
2017	$ 244
2018	329
2019	340
2020	351
2021	362
2022	373
Total	$ 1,999

(12) Capital Structure

(a) Common Stock

The Company is authorized to issue 50,000,000 shares of common stock, with a par value of $0.01 per share.

On March 12, 2014, the Company completed an IPO in which the Company sold 4,312,500 shares of common stock at $8.00 per share resulting in gross proceeds of $34,500. In connection with the IPO, the Company paid $4,244 in underwriting discounts, commissions and offering costs resulting in net proceeds of $30,256. Also in connection with the IPO, all of the outstanding shares of the Company’s Series A Redeemable Convertible Preferred Stock, or Series A Stock, including accreted dividends, and Bridge Notes, including accrued interest, were converted into common stock.

On July 7, 2015, the Company closed a private placement with certain accredited investors in which the Company sold 1,379,311 shares of common stock at a price of $11.60 per share, for net proceeds of $14,812. The Company paid the placement agents a fee equal to 6.0% of the aggregate gross proceeds from the private placement, plus reimbursement of certain expenses.

On August 19, 2016, the Company closed an underwritten public offering in which the company sold 1,986,666 shares of common stock at a price per share of $7.50 for net proceeds of $13,367 after deducting underwriting commissions and offering expenses.

On December 16, 2016, the Company closed an underwritten public offering in which the company sold 6,670,000 shares of common stock at a price per share of $6.00 for net proceeds of $36,888 after deduction underwriting

commissions and offering expenses.

(b) Common Stock Purchase Agreement

On February 2, 2015, the Company entered into a Common Stock Purchase Agreement, or the Purchase Agreement, with Aspire Capital Fund, LLC, or Aspire Capital, pursuant to which Aspire Capital is committed to purchase, at the Company's election, up to an aggregate of $10,000 of shares of the Company's common stock over the 24-month term of the Purchase Agreement. On the execution of the Purchase Agreement, the Company issued 96,463 shares of common stock to Aspire Capital with a fair value of $285, as consideration for entering in the Purchase Agreement. In addition, the Company incurred $253 of costs in connection with the Aspire Capital facility, which, along with the fair value of the common stock has been recorded as deferred equity costs. During 2016, the Company sold 1,143,940 shares of common stock under the Purchase Agreement for $7,796.

(c) Preferred Stock

The Company is authorized to issue 10,000,000 shares of preferred stock, with a par value of $0.01 per share. As of December 31, 2016, no preferred stock was issued or outstanding.

RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

(d) Warrants

As of December 31, 2016, the Company had the following warrants outstanding to purchase shares of the Company's common stock:

Number of Shares	Exercise Price per Share	Expiration Date
140,000	$ 12.00	March 2018
350,000	$ 19.46	April 2022
294,928	$ 3.28	April 2022

The warrant to purchase 350,000 shares is liability classified since it contains a contingent net cash settlement feature. The warrant to purchase 294,928 shares is liability classified since it contains an anti-dilution provision. The fair value of both warrants will be remeasured through settlement or expiration with changes in fair value recognized as a period charge within the statement of operations.

(13) Stock-Based Compensation

The Company established the 2008 Stock Option Plan, or the 2008 Plan, which allows for the granting of common stock awards, stock appreciation rights, and incentive and nonqualified stock options to purchase shares of the Company's common stock to designated employees, nonemployee directors, and consultants and advisors. As of December 31, 2016, no stock appreciation rights have been issued. Subsequent to adoption, the 2008 Plan was amended to increase the authorized number of shares available for grant to 444,000 shares of common stock. In October 2013, the Company established the 2013 Equity Incentive Plan, or the 2013 Plan, which allows for the grant of stock options, stock appreciation rights and stock awards for a total of 600,000 shares of common stock. In June 2015, the Company's shareholders approved the Amended and Restated Equity Incentive Plan, or the A&R Plan, which amended and restated the 2013 Plan and increased the aggregate amount of shares available for issuance to 2,000,000. In December 2016 and 2015, per the "Evergreen" provision of the plan, shares were increased by 619,181 and 461,215, respectively, which represents 5% of outstanding common stock at the time of increase. The total number of options in the 2013 plan as of December 31, 2016 is 3,080,396.

Stock options are exercisable generally for a period of 10 years from the date of grant and generally vest over four years. As of December 31, 2016, 1,212,248 shares and 174 shares are available for future grants under the 2013 Plan and 2008 Plan, respectively.

The weighted average grant-date fair value of the options awarded to employees during the years ended December 31, 2016 and 2015 was $5.08 and $8.10, respectively. The fair value of the options was estimated on the date of grant using a Black-Scholes option pricing model with the following assumptions:

	2016	2015
Range of expected option life	6 years	6-7 years
Expected volatility	82.47%	77.39%
Risk-free interest rate	1.07-2.09%	2.06-2.51%
Expected dividend yield	—	—

RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

The following table summarizes stock option activity during the year ended December 31, 2016:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life
Balance, December 31, 2014	1,033,300	$ 5.77	
Granted	1,079,550	8.26	
Exercised	(38,000)	6.00	
Expired/forfeited/cancelled	(32,656)	11.20	
Balance, December 31, 2015	2,042,194	7.00	
Granted	596,106	7.21	
Exercised	—	—	
Expired/forfeited/cancelled	(26,371)	10.86	
Balance, December 31, 2016	2,611,929	$ 7.01	7.4 years
Vested	1,410,596	$ 6.41	6.2 years
Vested and expected to vest	2,530,261	$ 6.67	7.4 years

Included in the table above are 364,000 of options granted outside the plan. The grants were made pursuant to the NASDAQ inducement grant exception in accordance with NASDAQ Listing Rule 5635(c)(4). Also included in the table above are 105,300 performance based options granted to the Chief Executive Officer in December 2015. As of December 31, 2016, all 105,300 of these options vested upon meeting the performance targets, resulting in compensation expense of $551.

The following table summarizes restricted stock units activity during the year ended December 31, 2016.

	Number of shares
Balance, December 31, 2015	32,200
Granted	—
Vested	(24,450)
Balance, December 31, 2016	7,750
Expected to vest	7,750

In December 2015, the Company granted 32,200 performance-based restricted stock units, or RSUs, which vest based on attaining clinical and operational goals during 2016. Included in the 24,450 units of restricted stock vested during the year ended December 31, 2016 are 6,155 shares with a weighted average fair value of $8.30 per share that were withheld for withholding tax purposes upon vesting of such awards from stockholders who elected to net share settle such tax withholding obligation. The remaining 7,750 restricted stock units outstanding as of December 31, 2016 vested upon the achievement of the 2016 performance goals as determined by the Board of Directors in January 2017.

Stock-based compensation expense for the years ended December 31, 2016 and 2015 was $3,889 and $3,064, respectively.

As of December 31, 2016, there was $7,198 of unrecognized compensation expense related to unvested options and RSUs that are expected to vest and will be expensed over a weighted average period of 2.8 years.

The aggregate intrinsic value represents the total amount by which the fair value of the common stock subject to options exceeds the exercise price of the related options. As of December 31, 2016, the aggregate intrinsic value of the vested and unvested options was $2,881 and $1,382, respectively.

In January 2017, the Company granted 465,250 options, as well as 91,150 performance-based restricted stock units, and 147,400 time-based restricted stock units which are not included in the above table.

(14) Segment Reporting

The Company operates through two business segments: an Acute Care segment and a revenue-generating CDMO segment. The Acute Care segment is primarily focused on developing innovative products for hospital and related 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

RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

products. Acute Care has no revenue and its costs consist primarily of expenses incurred in conducting the Company's clinical and preclinical studies, acquiring clinical trial materials, regulatory activities and personnel costs. CDMO revenue streams are derived from manufacturing, royalty and profit sharing revenues as well as our CDMO's research and development of services performed for commercial partners.

The accounting policies of the segments are the same as those described in the summary of significant account policies (see Note 3). The Company evaluates performance of its reportable segments based on revenue and operating income (loss). The Company does not allocate interest income, interest expense or income taxes to its operating segments.

The following table summarizes segment information as of and for the years ended December 31, 2016 and 2015:

	Years Ended December 31,	
	2016	2015
Revenues:		
CDMO	$69,337	$51,952
Acute Care	—	—
Total	$69,337	$51,952
Operating income (loss):		
CDMO	$24,232	$17,558
Acute Care	(50,005)	(24,528)
Total	$(25,773)	$(6,970)
Depreciation and amortization:		
CDMO	$7,572	$6,004
Acute Care	4	—
Total	$7,576	$6,004
Capital expenditures:		
CDMO	$3,735	$2,411
Acute Care	35	—
Total	$3,770	$2,411

	December 31,	
	2016	2015
Total assets:		
CDMO	$77,828	$81,430
Acute Care	105,169	57,267

Total	$182,997	$138,697

(15) Income Taxes

The components of loss before income tax are as follows:

	December 31,	
	2016	2015
Domestic	$1,207	$(10,002)
Foreign	(32,519)	(2,516)
Loss before income taxes	$(31,312)	$(12,518)

RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

The components of income tax provision (benefit) are as follows:

	December 31,	
	2016	2015
Current:		
Federal	$298	$83
State and local	18	3
Foreign	—	—
	316	86
Deferred:		
Federal	$(1,607)	$(13,418)
State and local	184	(2,219)
Foreign	—	—
	(1,423)	(15,637)
	$(1,107)	$(15,551)

A reconciliation of the statutory U.S. federal income tax rate to the Company's effective tax rate is as follows:

	Year ended December 31,	
	2016	2015
U.S. federal statutory income tax rate	34.0 %	34.0 %
Foreign tax rate differential	(22.3)%	(4.3)%
State taxes, net of federal benefit	(0.1)%	2.6 %
Nondeductible expenses	0.5 %	4.2 %
Research and development credits	4.5 %	1.7 %
Change in valuation allowance	(13.1)%	86.1 %
Effective income tax rate	3.5 %	124.3%

The tax effects of temporary differences that gave rise to significant portions of the deferred tax assets were as follows:

	December 31,	
	2016	2015
Net operating loss carryforwards	$6,742	$5,754

Research and development credits	3,108	1,343
Capitalized start-up costs	2,343	2,590
Intangibles	2,181	597
Contingent consideration	5,364	1,932
Stock-based compensation	2,718	1,256
Other temporary differences	517	2,480
Gross deferred tax asset	22,973	15,952
Valuation allowance	(4,379)	(315)
Net deferred tax asset	18,594	15,637
Deferred tax liability	(1,534)	—
Net deferred taxes	$17,060	$15,637

In assessing the realizability of the net deferred tax asset, the Company considers all relevant positive and negative evidence in determining whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The realization of the gross deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of the net operating loss carryforwards. During 2015, in connection with an international corporate restructuring, it was determined that the Company would more likely than not realize its deferred tax assets associated with its US operations. Accordingly, the Company recorded a benefit associated with the release of its prior year valuation allowance in the amount of $11,087. The Company believes that it is more likely than not that the Company’s deferred income tax asset associated with its foreign net operating losses will not be realized in the immediate future. As such, there is a full valuation allowance against the net deferred tax assets associated with foreign operations as of December 31, 2016 and 2015.

RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

The following table summarizes carryforwards of Federal net operating losses and tax credits as of December 31, 2016:

	Amount	Expiration
Federal net operating losses	$4,206	2030 – 2035
State net operating losses	$14,149	2030 – 2035
Foreign net operating losses	$35,035	No expiration
Research and development credits	$2,817	2028 – 2034

Under the Tax Reform Act of 1986 (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. The Company has done an analysis to determine whether or not ownership changes, as defined by the Act, have occurred since inception. The Company determined that it experienced ownership changes, as defined by the Act, during the 2008, 2014 and 2016 tax years as a result of past financings; accordingly, the Company's ability to utilize the aforementioned carryforwards will be limited. Although the carryforwards will be limited, the Company has determined that none of the net operating losses will expire prior to being utilized as a result of the changes. In addition, state net operating loss carryforwards may be further limited, including Pennsylvania, which has a limitation equal to the greater of 30.0% of taxable income after modifications and apportionment or $5,000,000 on state net operating losses utilized in any one year.

The Company will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2016, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's statements of operations. Due to net operating loss and tax credit carry forwards that remain unutilized, income tax returns for tax years from inception through 2015 remain subject to examination by the taxing jurisdictions.

(16) Related Party Transactions

The Company's President and Chief Executive Officer, or CEO, owns a majority of the stock of Malvern Consulting Group, or MCG, a pharmaceutical incubator and consulting firm. The CEO's husband, who is also a shareholder of the Company, is a consultant and a shareholder of MCG. In addition, the CEO's son is the President and a shareholder of MCG. During 2015 and 2016, certain immediate family members of the CEO were employees of MCG, including the CEO's brother and sister-in-law. Since formation, the Company entered into various transactions with MCG, as detailed below. However, since becoming a public company, the Company sought to decrease its involvement with MCG and as of December 31, 2016, the Company no longer has any involvement or transactions with MCG.

During 2016 and 2015, certain of the Company's executive officers, our CEO, our Senior Vice President, Development and our Senior Vice President, Regulatory Affairs and Quality Assurance, who is also the CEO's sister, provided minimal consulting services from time to time to MCG. Until December 31, 2016, the Company was a party to a Master Consulting Services Agreement with MCG. Pursuant to the agreement, MCG provided the Company with

certain consulting services for a fee based upon hourly rates previously approved by our Board of Directors. In consideration for such services, the Company recorded $363 and $465 in 2016 and 2015, respectively. A portion of these amounts were used during 2016 and 2015 to pay a portion of the respective salaries of MCG employees that, as described above, included immediate family members of the Company's CEO.

Until December 31, 2016, the Company was party to an Office Services Agreement with MCG for the lease of an aggregate of 8,458 square feet of office and lab space located at our Malvern, facility and the provision of IT services and general office support. Pursuant to the Office Services Agreement, the Company paid MCG $206 and $114 in 2016 and 2015, respectively. The Company terminated this agreement on December 31, 2016 and are now party to a six-year lease directly with the landlord of the Company's Malvern facility (see Note 11).

As of December 31, 2016, the Company has terminated the Master Consulting Agreement, the Office Services Agreement and MCG no longer provides any services or has any contracts with the Company.

The Company's Senior Vice President, Regulatory and Quality, who is the CEO's sister, has held that position since 2014. Effective January 1, 2017, the CEO's sister-in-law and brother, respectively, terminated their employment with MCG and were hired as the Company's Director of Human Resources and our Vice President, Manufacturing. The Board approved these hires consistent with the Company's related person transaction policy.

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: March 9, 2017

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	March 9, 2017
Gerri A. Henwood	(Principal Executive Officer)	
/s/ Michael Celano	Chief Financial Officer	March 9, 2017
Michael Celano	(Principal Financial Officer)	
/s/ Donna Nichols	Chief Accounting Officer	March 9, 2017
Donna Nichols		
/s/ Alfred Altomari	Director	March 9, 2017
Alfred Altomari		
/s/ William L. Ashton	Director	March 9, 2017

William L. Ashton		
/s/ Michael Berelowitz	Director	March 9, 2017
Michael Berelowitz		
/s/ Winston J. Churchill	Director	March 9, 2017
Winston J. Churchill		
/s/ Karen Flynn	Director	March 9, 2017
Karen Flynn		
/s/ Bryan M. Reasons	Director	March 9, 2017
Bryan M. Reasons		
/s/ Wayne B. Weisman	Director	March 9, 2017
Wayne B. Weisman		

EXHIBIT INDEX

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).
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	Investor Rights Agreement, dated September 4, 2008, by and among Recro Pharma, Inc., and the investors party thereto.	Incorporated herein by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1/A filed on November 29, 2013 (File No. 333-191879).
4.3	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).
4.4	Form of OrbiMed Warrant.	Incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on March 11, 2015 (File No. 001-36329).
4.5	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).
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†	Fadolmidine License Agreement, dated July 21, 2010, by and among Recro Pharma, Inc. and Orion Corporation.	Incorporated herein by reference to Exhibit 10.4 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 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).

Exhibit No.	Description	Method of Filing
10.6•	Separation and Mutual Release Agreement, dated December 8, 2015, between Recro Pharma, Inc. and Charles Garner.	Incorporated herein by reference to Exhibit 10.6 to the Company's Post-Effective Amendment on Form S-1 filed on December 23, 2015 (File No. 333-201841).
10.7•	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).
10.8•	Employment Agreement, dated October 9, 2013, between Recro Pharma, Inc. and Randall Mack.	Incorporated herein by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1/A filed on November 29, 2013 (File No. 333-191879).
10.9•	Employment Agreement, dated October 9, 2013, between Recro Pharma, Inc. and Diane Myers.	Incorporated herein by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1/A filed on November 29, 2013 (File No. 333-191879).
10.10•	Employment Agreement, dated October 9, 2013, between Recro Pharma, Inc. and Donna Nichols.	Incorporated herein by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1/A filed on November 29, 2013 (File No. 333-191879).
10.11•	Employment Agreement, dated December 1, 2015, between Recro Pharma, Inc. and Stewart McCallum, M.D.	Incorporated herein by reference to Exhibit 10.33 to the Company's Post-Effective Amendment on Form S-1 filed on December 23, 2015 (File No. 333-201841).
10.12•	Employment Agreement, dated February 16, 2016, between Recro Pharma, Inc. and Fred Graff.	Incorporated herein by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K filed on March 24, 2016 (File No. 001-36329).
10.13•	Form of Amendment to the Employment Agreement of each of Gerri Henwood, Randall Mack, Diane Myers and Donna Nichols.	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).
10.14•	2013 Equity Incentive Plan.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 13, 2014 (File No. 001-36329).
10.15•	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).
10.16•	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).
10.17•		

	Form of 2013 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).
10.18•	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).
10.19•	Recro Pharma, Inc. Amended and Restated Equity Incentive Plan.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 26, 2015 (File No. 001-36329).
10.20•	Form of Award Agreement for 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).
10.21	Master Consulting Services Agreement, dated October 10, 2013, by and between Recro Pharma, Inc. and Malvern Consulting Group, Inc.	Incorporated herein by reference to Exhibit 10.14 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
10.22†	Credit Agreement, dated as of March 7, 2015, by and between Recro Pharma LLC and OrbiMed Royalty Opportunities II, LP.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 11, 2015 (File No. 001-36329).
10.23	First Amendment to Credit Agreement, dated April 10, 2015, by and among Recro Pharma LLC and OrbiMed Royalty Opportunities II, LP	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 16, 2015 (File No. 001-36329).
10.24	Second Amendment to Credit Agreement, dated April 27, 2015, by and among Recro Pharma LLC and OrbiMed Royalty Opportunities II, LP	Filed herewith.
10.25	Third Amendment to Credit Agreement, dated July 9, 2015, by and among Recro Pharma LLC and OrbiMed Royalty Opportunities II, LP	Filed herewith.
10.26	Fourth Amendment to Credit Agreement, dated August 31, 2015, by and among Recro Pharma LLC and OrbiMed Royalty Opportunities II, LP	Filed herewith.
10.27	Fifth Amendment to Credit Agreement, dated November 12, 2015, by and between Recro Gainesville LLC and OrbiMed Royalty Opportunities, LP	Incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on November 13, 2015 (File No. 001-36329).
10.28	Sixth Amendment to Credit Agreement, dated July 29, 2016, by and among Recro Pharma LLC and OrbiMed Royalty Opportunities II, LP	Filed herewith.
10.29	Seventh Amendment to Credit Agreement, dated December 12, 2016, by and among Recro Pharma LLC and OrbiMed Royalty Opportunities II, LP	Filed herewith.
10.30	Guarantee, dated as of March 7, 2015, by Recro Pharma, Inc. in favor of OrbiMed Royalty Opportunities II, LP.	Incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on March 11, 2015 (File No. 001-36329).
10.31†	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).

10.32	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).
10.33†	Transition Services Agreement, dated as of April 10, 2015, by and among Alkermes Pharma Ireland Limited, Recro Pharma, Inc., DV Technology LLC, and Alkermes Gainesville LLC.	Incorporated herein by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed on May 12, 2015 (File No. 001-36329).
10.34†	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).
10.35†	First Amendment to the Development, Manufacturing and Supply Agreement, dated October 19, 2016, by and between Alkermes Pharma Ireland Limited and Recro Pharma, Inc.	Filed herewith.
10.36†	Second Amendment to the Development, Manufacturing and Supply Agreement, dated February 1, 2017, by and between Alkermes Pharma Ireland Limited and Recro Pharma, Inc.	Filed herewith.
10.37†	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).

Exhibit No.	Description	Method of Filing
10.38	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).
10.39	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).
10.40	Form of Securities Purchase Agreement, dated July 1,2015, by and among Recro Pharma, Inc. and the purchasers party thereto.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 8, 2015 (File No. 001-36329).
21.1	Subsidiaries of Recro Pharma, Inc.	Filed herewith.
23.1	Consent of KPMG LLP, Independent Registered Public Accounting Firm.	Filed herewith.
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.