Recro Pharma, Inc.
Form 10-K
March 24, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2015

¨ **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 x

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 x

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

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 x 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. x

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 x

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

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 $31.7 million.

As of March 21, 2016, there were 9,318,255 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 2016 annual meeting of shareholders to be filed no later than 120 days after the end of the registrant s fiscal year ended December 31, 2015.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K and the documents incorporated by reference herein contain forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this Annual Report on Form 10-K or the documents incorporated by reference herein regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words anticipate, believe, estimate, expect, intend, may, predict, project, will, would and similar expressions are intended to identify forward-looking statements, although n 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:

- the results and timing of our clinical trials of injectable meloxicam, Dex or our other product candidates, and any future clinical and preclinical studies;
- the ability to obtain and maintain regulatory approval of our product candidates, and the labeling under any approval that we may obtain;
- regulatory developments in the United States and foreign countries;
- our plans to develop and commercialize our product candidates;
- our ability to raise future financing for continued development;
- the performance of our third-party suppliers and manufacturers;
- our ability to obtain patent protection and defend our intellectual property rights;
- our ability to successfully implement our strategy;
- our ability to maintain our relationships and contracts with our commercial partners;
- 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;

our ability to successfully integrate our acquisition of certain assets acquired in the Gainesville Transaction (as defined herein); and

our ability to meet required debt payments and operate under increased leverage and associated lending covenants.

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.

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PART I

Item 1. Business

Overview

We are a revenue-generating, specialty pharmaceutical company focused on products for hospitals and ambulatory care settings, that is currently developing non-opioid products for treatment of serious acute pain. Our lead product candidate is a proprietary injectable form of meloxicam. Meloxicam is a long-acting preferential COX-2 inhibitor, and the oral form of meloxicam has been marketed by Boehringer Ingelheim Pharmaceuticals, Inc. since the 1990s as Mobic®. Intravenous, or IV, meloxicam has successfully completed multiple Phase II clinical trials for the treatment of moderate to severe pain. We believe injectable 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. Based on feedback from the U.S. Food and Drug Administration, or FDA, we have initiated a Phase III program that includes two pivotal clinical trials, as well as other trials. We expect to enroll a total of approximately 1,100 patients in these trials. One pivotal clinical trial, which began dosing in January 2016, is designed to demonstrate pain relief over a 24-hour period in a soft tissue, post-operative pain model (abdominoplasty) and the other pivotal clinical trial, for which we announced first patient dosing in February 2016, is designed to demonstrate pain relief over a 48-hour period in a hard tissue, post-operative pain model (bunionectomy).

Our pipeline also includes Dex-IN, a proprietary intranasal formulation of dexmedetomidine, or Dex, which successfully completed a Phase II clinical trial in post-operative pain. Dex, which is in a class of drugs called alpha-2 adrenergic agonists, is an FDA approved and commercial injectable drug, sold by Hospira, Inc. in the United States under the brand name Precedex® and by Orion Corporation, or Orion, in Europe under the brand name Dexdor®. In October 2015, we met with the FDA to obtain feedback on the Phase II efficacy and safety data and our proposed Dex-IN clinical development program. Based on feedback from the FDA regarding Dex-IN s benefit-risk profile, specifically its efficacy and blood pressure effects, which was demonstrated in post-operative pain, and the subsequent requirements for a post-operative pain clinical program, we have determined not to pursue Dex-IN in post-operative pain due to time, cost and associated risk. We plan to pursue Dex-IN, as discussed with the FDA, 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.

As our product candidates are not in the opioid class of drugs, we believe they will overcome many of the issues associated with commonly prescribed opioid therapeutics, including addiction, misuse/diversion, respiratory depression and constipation while maintaining analgesic, or pain relieving, effects. We are pursuing a Section 505(b)(2) regulatory strategy for injectable meloxicam and Dex-IN.

We also have a sublingual formulation of Dex, Dex-SL, which may be appropriate for use in treating chronic pain. In addition to Dex, we have a second selective alpha-2 agonist product candidate in development, Fadolmidine, or Fado, which has been shown to be effective in a post-bunionectomy Phase II pain study conducted by Orion. Based on preclinical data, we believe Fado also shows promise in neuropathic pain.

We own the worldwide rights to injectable meloxicam, which we acquired from Alkermes plc, or Alkermes, in April 2015. Under our license with Orion, upon regulatory approval, we will have commercial rights for Dex-IN and Dex-SL 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, 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. Similarly, under our license agreement with Orion, upon regulatory approval, we will have commercial rights related to Fado in the Territory for all indications in humans.

In summary, our product candidates for pain indications include:

- injectable meloxicam, a product candidate in development for the treatment of acute post-operative pain;
- Dex-IN, a product candidate in development for the treatment of acute peri-procedural pain;
- Dex-SL, a product candidate for the treatment of chronic pain; and
- Fado, a product candidate administered by injection into the intrathecal space for pain associated with surgery or certain types of chronic pain associated with nerve damage to local tissues (neuropathies), especially of the lower extremities, which can occur in diabetic patients.

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Pipeline

We currently own and operate an 87,000 square foot, DEA-licensed manufacturing facility that makes five commercial products and receives royalties associated with the sales of these products. We manufacture the following products for our commercial partners: Ritalin LA®, Focalin XR®, Verelan PM®, generic Verapamil and Zohydro ER®, as well as development stage products. The campus includes an additional 10,000 square feet, which is comprised of administrative space and certain utilities areas.

Background

We have a limited operating history. We were incorporated in 2007, and began operating in 2008. We are currently developing non-opioid products for the treatment of acute pain. Our focus is on the development and commercialization of these products and other potential products that may be useful in hospitals or ambulatory care settings.

We have funded our operations to date primarily from proceeds received from private placements of convertible preferred stock, convertible notes and common stock and our initial public offering of common stock, or IPO. On March 12, 2014, we announced the closing of the IPO of 4,312,500 shares of common stock, including the full exercise of the underwriters over-allotment, at a public offering price of $8.00 per share. Total gross proceeds from the IPO were $34.5 million before deducting underwriting discounts and commissions and other offering expenses payable by us, resulting in net proceeds of $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 of $11.60 per share, for net proceeds of approximately $14.8 million.

We have incurred losses from operations since inception. As of December 31, 2015, we had an accumulated deficit of $31.1 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 expect to incur increasing expenses over the next several years to develop injectable meloxicam, including two pivotal Phase III clinical trials for the management of acute post-operative pain. We also expect to incur additional expenses with regard to Dex, including a Phase II program in peri-procedural pain, and our other product candidates. Based upon additional financial resources, we may develop and commercialize our proprietary formulations of injectable meloxicam and Dex.

We expect that annual 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 our acquisition from Alkermes of certain assets, including the worldwide rights to injectable meloxicam and the contract manufacturing facility, royalty and formulation business in Gainesville, Georgia, now operating through our subsidiary, Recro Gainesville LLC, or Gainesville. We refer to the acquisition herein as the Gainesville Transaction. The Gainesville Transaction transformed our business through the addition of a revenue-generating manufacturing business and increase in our workforce as a result of the addition of the Gainesville employees.

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The consideration paid in connection with the Gainesville Transaction consisted of $50.0 million, 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 $120.0 million in milestone payments upon the achievement of certain regulatory and net sales milestones and royalties on 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 Royalty Opportunities II, LP, or 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.

Post-Operative Pain Market Overview

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. While opioids are generally considered the most effective treatment for post-operative pain, they raise serious concerns due to addiction, illicit use, respiratory depression and other side effects, including constipation, nausea, vomiting and intolerance. Due to their addictive potential, opioids are regulated as controlled substances and are listed on Schedule II and III by the DEA. As a result of these 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. 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) has increased significantly over the past 14 years. It notes the following trends:

- Prescription painkiller overdoses killed 18,893 people in the United States in 2014;
- In 2014, about 10.3 million Americans (age 12 or older) reported nonmedical use of prescription painkillers in the past year; and
- Emergency department visits involved with misusing or abusing prescription opioid painkillers increased 153% between 2004 and 2011.

We believe that injectable meloxicam offers an attractive alternative for pain relief without the risks associated with opioids. Accordingly, we believe that physicians and third-party payors, including Medicare and Medicaid, are highly interested in new non-opioid pain therapies that provide effective pain relief without the adverse issues associated with opioids.

Cancer Breakthrough Pain Market Overview

In addition to peri-procedural pain relief, we believe Dex-IN may provide a good alternative therapeutic for cancer breakthrough pain relief. It is estimated that 80% of patients taking long-acting medication for chronic pain experience breakthrough pain. Breakthrough pain comes on very rapidly and can last from three to 30 minutes. Currently, cancer breakthrough pain is primarily treated with fast acting opioids mainly fentanyl, such as Fentora® and Actiq® (marketed by Teva Pharmaceutical Industries Ltd.). However, because these therapeutics are opioids, they raise the same concerns discussed above.

Our Strategy

We intend to maximize the value of our development candidates. This strategy could include developing our candidates through approval and ultimately self-commercialization, out-licensing, partnering on certain assets, or selling the Company or the assets. We believe our product candidates and their proposed indications target a narrow group of specialist prescribers which would allow for the successful marketing and commercialization of the product candidates by a company of our size. However, Dex-SL may target a broader group of prescribers and, if so, will likely require a partner. Our broader corporate strategy includes the following:

Focus on developing IV meloxicam for acute post-operative pain. Our key goal is to file a new drug application, or NDA, and receive FDA approval of IV meloxicam for the management of moderate to severe pain. Based on feedback from the FDA, we initiated a Phase III program in 2016 that includes two pivotal clinical trials, as well as other trials. We expect to enroll a total of approximately 1,100 patients in these trials. One pivotal clinical trial, which began dosing in January 2016, is designed to demonstrate pain relief over a 24-hour period in a soft tissue, post-operative pain model and the other pivotal clinical trial, for which we announced first patient dosing in February 2016, is designed to demonstrate pain relief over a 48-hour period in a hard tissue, post-operative pain model. We believe developing IV meloxicam for the management of moderate to severe pain indication provides us the fastest and best path to building a specialty pharmaceutical company focused on options for pain management. Therefore, we are initially concentrating our management focus and resources on attaining this goal.

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Evaluate Dex-IN for use in short clinical procedures associated with pain and discomfort that are performed in settings where IV access is not typically available. As discussed with the FDA, we plan to pursue Dex-IN in peri-procedural pain.

Develop our manufacturing business. Our DEA-licensed facility currently manufactures five commercial products for pharmaceutical partners. We intend to seek additional manufacturing and related programs for commercial products through business development efforts, as well as through expanding development of our proprietary drug formulations.

Leverage our management and development experience for other indications and product candidates. If we have sufficient additional resources, we plan to develop our existing drug candidates, as well as those we may identify in the future, for potential additional indications. While our current focus is on seeking FDA approval for IV meloxicam for the treatment of moderate to severe pain, we also have in development proprietary drug solutions for peri-procedural pain and pain resulting from cancer, musculoskeletal disorders and peripheral neuropathy. One goal is to leverage our drug development expertise along with innovative delivery systems to optimize absorption, improve effectiveness and reduce side effects to optimize pain relief and improve quality of life for the millions of people suffering from moderate-to-severe pain annually. We have multiple delivery systems in development, including intrathecal/epidural, transdermal, intranasal and sublingual platforms.

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.

Meloxicam Overview

Meloxicam is a long-acting, preferential COX-2 inhibitor that possesses anti-inflammatory, analgesic, and antipyretic activities, which are believed to be related to the inhibition of cyclooxygenase, or COX, and subsequent reduction in prostaglandin biosynthesis. Meloxicam has been marketed by Boehringer Ingelheim Pharmaceuticals, Inc. since the 1990s as an oral agent, Mobic®. Mobic tablets and suspension are indicated for the relief of the signs and symptoms of osteoarthritis and rheumatoid arthritis and the relief of the signs and symptoms of pauciarticular or polyarticular juvenile rheumatoid arthritis in patients 2 years or older.

Meloxicam has a slow onset of action orally, and is not currently approved for the treatment of acute pain. The oral form has a prolonged absorption time, with the time of maximum observed plasma concentration, or tmax, being approximately 5-6 hours following oral administration, which is consistent with its poor aqueous solubility. Our proprietary injectable form of the drug, which utilizes NanoCrystal technology, provides a faster onset of action of meloxicam, thus providing a rapid and sustained treatment of acute pain via the IV or intramuscular, or IM, administration routes.

Injectable Meloxicam Advantages

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

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 codeine, fentanyl, sufentanil, hydrocodone and oxycodone.

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.

Onset of pain relief. While the oral form of meloxicam can take 60 minutes or more for pain relief, the utilization of NanoCrystal™ technology in the IV formulation results in a more rapid onset of pain relief of less than 10 minutes. Ketorolac, for example, can take up to 40 minutes for the onset of pain relief.

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Duration of pain relief. IV meloxicam utilizing NanoCrystal™ technology has demonstrated the potential to be an effective analgesic for up to 18 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.

Additionally, 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 IM formulation of meloxicam, while neither ibuprofen nor acetaminophen currently have IM formulations.

Clinical Trial Overview

In January 2016, we began a pivotal Phase III clinical trial evaluating IV meloxicam for acute post-operative pain in patients following mini abdominoplasty surgery. In this multicenter, randomized, double-blind, placebo-controlled clinical trial, IV meloxicam s efficacy and safety will be evaluated in the management of post-operative pain following abdominoplasty surgery, a representative soft tissue surgery. Approximately 200 patients will be assigned randomly to a post-operative regimen of IV meloxicam (30 mg) or placebo in a 1:1 ratio, once every 24 hours, for up to 3 doses following surgery. The primary efficacy endpoint of this Phase III study is the summed pain intensity difference over the first 24 hours, or SPID24, compared to placebo. In February 2016, we announced that first patient dosing in a pivotal Phase III clinical trial evaluating IV meloxicam for acute post-operative pain in patients following bunionectomy surgery had begun. In this multicenter, randomized, double-blind, placebo-controlled clinical trial, IV meloxicam s efficacy and safety will be evaluated in the management of post-operative pain following bunionectomy surgery, a representative hard tissue surgery. Approximately 200 patients will be assigned randomly to a post-operative regimen of IV meloxicam (30 mg) or placebo in a 1:1 ratio, once every 24 hours, for up to 3 doses following surgery. The primary efficacy endpoint of this Phase III study is the summed pain intensity difference over the first 48 hours, or SPID48, compared to placebo. We expect to report top-line results from each of these Phase III studies by year end 2016.

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.

Pharmacokinetic Studies

Pharmacokinetic studies have examined single and multiple doses of IV meloxicam. In general terms, IV administration resulted in peak plasma concentrations immediately follow dosing. When compared to oral Mobic, IV meloxicam had similar areas under the plasma drug concentration-time curve and half-lives for doses of 15 mg, 30 mg and 60 mg.

Study REC-15-014

This was a Phase II, randomized, single-center, double-blind, placebo-controlled study evaluating IV meloxicam in the management of post-operative pain following bunionectomy surgery. Fifty-nine patients who met the eligibility criteria were randomized to receive either IV meloxicam (30 mg or 60 mg dosage groups) or placebo once daily for two days. Following the beginning of treatment, patients remained under observation for 48 hours at study centers.

Patients were followed for 7 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 the safety of IV meloxicam when administered as a bolus injection (over 15-30 seconds).

The safety results demonstrated that IV meloxicam was well tolerated with no serious adverse events, bleeding events or injection site reactions. The most common adverse events, or AEs, were nausea, headache, dizziness, pruritus and vomiting and were comparable to the placebo group. There were no discontinuations due to AEs. The majority of treatment emergent AEs, or TEAEs, were mild in nature and determined by investigators to be not related or possibly related to study drug. There were no vital signs changes that necessitated treatment. There were no observed changes in the evaluation of ECGs. No clinically meaningful lab changes were observed in the meloxicam treatment groups (Table 1).

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Table 1: Adverse Events reported by ≥2% of subjects from any treatment group

	Placebo N = 19 n (%)	IV Meloxicam 30 mg N = 20 n (%)	IV Meloxicam 60 mg N = 20 n (%)
Nausea	4(21.1)	6(30.0)	4(20.0)
Headache	4(21.1)	2(10.0)	3(15.0)
Dizziness	1(5.3)	3(15.0)	2(10.0)
Pruritus	0(0.0)	1(5.0)	2(10.0)
Vomiting	1(5.3)	3(15.0)	0(0.0)
Decreased appetite	2(10.5)	0(0.0)	1(5.0)
Erythema	1(5.3)	2(10.0)	0(0.0)
Constipation	0(0.0)	1(5.0)	1(5.0)
GGT increased	2(10.5)	0(0.0)	0(0.0)
Muscle spasms	0(0.0)	2(10.0)	0(0.0)
Somnolence	0(0.0)	1(5.0)	1(5.0)

The primary efficacy endpoint of the trial was SPID48 (0-48). Secondary efficacy endpoints included use of opioid rescue medication, SPIDs over various time intervals, and patient global assessment, or PGA, of pain control. Both the 30 mg and 60 mg IV meloxicam treatment arms demonstrated statistically significant reductions in pain intensity, as measured by SPID48 (p=0.0007 and p=0.0027, respectively) compared to placebo (Figure 1). Although there were observed differences in opioid consumption among the meloxicam dose groups and the placebo group, in general these differences did not meet statistical significance.

Figure 1: SPID48

Pain intensity was measured at various time points throughout the study. Differences in pain intensity were observed as early as 10 minutes and continued throughout the 48 hour observation period. Overall the 30 mg and 60 mg dose groups performed in a very comparable fashion (Figure 2).

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Figure 2: Pain Intensity Differences for Each Time Point

Study N1539-04

This was 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 VAS 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 TOTPAR24 (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 postdose 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).

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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).

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Figure 4: Percentage of Subjects Using Rescue Medication

Study medication was well tolerated. A total of five serious adverse events, or SAEs, were reported in the study, and none were assessed as related to treatment. There were no clinically meaningful trends in vital signs, electrocardiograms or laboratory assessments. Adverse event rates were generally low and consistent with this surgical population under study (Table 2).

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

	Placebo N = 64 n (%)	Morphine N = 62 n (%)	IV Meloxicam 5 mg N = 60 n (%)	IV Meloxicam 7.5 mg N = 91 n (%)	IV Meloxicam 15 mg N = 60 n (%)	IV Meloxicam 30 mg N = 60 n (%)	IV Meloxicam 60 mg N = 89 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)

Study N1539-02

This Phase II study was a randomized, double-blind, double-dummy, placebo-controlled, active-controlled, single center study in 230 subjects who underwent third molar extraction surgery. Subjects received a single dose of either IV placebo, oral ibuprofen 400 mg, or IV meloxicam 15 mg, 30 mg or 60 mg. Starting at the time of study drug administration and continuing for 24 hours thereafter, subjects were given access to rescue medication for pain not relieved by the study drug. SPID24 was the primary endpoint utilizing the LOCF analysis method for this study.

Overall, the results of this study consistently demonstrated that IV meloxicam produced the greatest reduction in pain, followed by the 30 mg and 15 mg doses, as well as ibuprofen 400 mg. Highly statistically significant differences were seen among the treatments for the primary endpoint, SPID24, as well as in every efficacy analysis.

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The onset of action was rapid for the IV meloxicam doses, with statistically significant differences in pain intensity and pain reduction detected among the treatments as early as 10 minutes. For the IV meloxicam doses, analgesia was sustained, with statistically significant differences in pain intensity and pain relief evident through 24 hours postdose.

The use of rescue medication was reduced by 93%, 86%, and 87% by the IV meloxicam 60 mg, 30 mg, and 15 mg doses, respectively, compared to placebo.

Overall, treatment with IV meloxicam was well-tolerated after a single-dose up to 60 mg. There were no SAEs or discontinuations due to an adverse event, reported in this study. There were no clinically meaningful trends in vital signs or laboratory assessments. Adverse event rates were generally low and consistent with this surgical population.

Study N1539-05

This study was a Phase II, single-center, randomized, double-blind, placebo- and active-controlled, study conducted in subjects undergoing abdominal laparoscopic surgery. Allowed procedures included biliary tree surgery, common bile duct exploration/surgery, cholecystectomy and inguinal hernia surgery. Subjects received either IV placebo; IV ketorolac every 6 hours; or IV meloxicam 7.5 mg every 12 hours, 15 mg every 12 hours, or 30 mg once daily, for up to 48 hours. Rescue medication was available any time after the initial dose of study drug. The study was expected to enroll 250 subjects. However, the prior sponsor decided to terminate this study for business reasons. A total of 50 subjects had been enrolled prior to the study s discontinuation. Although a full efficacy analysis was not completed due to the early termination, analysis of the data from the enrolled subjects demonstrated that IV meloxicam 30 mg once daily produced a statistically significant difference compared to placebo for the SPID48.

Overall, study medication was well tolerated. The most frequently reported AEs for all subjects were headache, dry mouth, dysuria, nausea, fatigue and dizziness. There was no apparent trend in occurrence of AEs and treatment group. One SAE was reported by a subject in the ketorolac group. One subject in the IV meloxicam 7.5 mg every 12 hours group discontinued due to maculopapular rash.

Dexmedetomidine Overview

Dex is a selective alpha-2 adrenergic agonist that has demonstrated sedative, analgesic and anxiolytic properties. Dex was developed in the 1990s by Abbott, initially for an indication as a short term sedative in the intensive care setting; however, a subsequent indication included use as a procedural sedative. Hospira currently markets IV Dex trademarked Precedex® in the United States. Orion received European approval to market IV Dex as an ICU sedative in the European Union, trademarked as Dexdor®. Dex has an extensive history of safe intravenous use, utilizing its sedative properties. We have formulated Dex at a significantly lower dose (perhaps as low as 1/10th for our intranasal product) 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. Because we are pursuing a 505(b)(2) regulatory strategy, we have the ability to reference and access the patient data from the IV registration studies in 4,765 Dex-treated patients conducted in connection with these approvals in support of our filings.

We initially studied Dex-IN for the treatment of post-operative pain. In our completed Phase II trial, REC-14-013, Dex-IN met the primary endpoint of the clinical trial in demonstrating significant improvement for SPID48 compared with placebo (p£0.025). In October 2015, we met with the FDA to obtain feedback on the Phase II efficacy and safety data and for our proposed Dex-IN clinical development program. Based on feedback from the FDA regarding Dex-IN s benefit-risk profile, specifically its efficacy and blood pressure effects, which was demonstrated in post-operative pain, and the subsequent requirements for a post-operative pain clinical program, we have determined not to pursue Dex-IN in post-operative pain due to time, cost and associated risk. We plan to pursue Dex-IN, as

discussed with the FDA, 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.

Dex-IN Advantages

We believe there is a clear unmet need for effective, well tolerated, non-opioid analgesics that can be used as a component of an effective peri-procedural pain management program. Based on the positive analgesic results observed in the Dex-IN Phase II post-operative pain study, and the safety profile and labeling for the marketed Dex product, we believe Dex has the potential to offer the following advantages:

Dex has demonstrated anxiolytic, or anxiety-reducing, properties. In the NDA studies for Dex it was demonstrated that Dex is a drug that also has anxiolytic properties. Patients experiencing pain typically see an increase in anxiety. We believe Dex s ability to help lessen anxiety will be beneficial in the peri-procedural setting.

Dex is not associated with constipation, nausea or vomiting. Dex s mechanism of action provides analgesic activity with very limited activity on the gastrointestinal tract, thus limiting the unwanted side effects of constipation, nausea and vomiting.

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Dex does not cause respiratory depression. 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 is defined by decreased lung ventilation leading to increased carbon dioxide levels and can be life threatening. Dex has demonstrated through multiple clinical trials and patient use that it does not cause respiratory depression.

Dex is 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 codeine, fentanyl, sufentanil, hydrocodone and oxycodone.

Dex has not demonstrated habituative effects. Preclinical studies in monkeys and rats have showed that Dex has a weak potential for drug addiction and dependence.

Patients utilizing Dex have been observed to be cognitively intact. We believe that patients utilizing opioid analgesics become cognitively impaired, impacting the patient s ability to perform routine mental and physical tasks. Based upon published studies, patients utilizing Dex do not appear to experience cognitive impairment.

Clinical Trial Overview

Under our investigational new drug applications, or INDs, we have studied various dosage forms of Dex in nine completed studies, including two Phase Ib and two Phase II placebo controlled studies, in over 300 subjects, to evaluate the analgesic efficacy, safety and pharmacokinetics of Dex. After an interim analysis in September 2014, we closed our Post Op Day 0 Phase II clinical trial of Dex-IN in the treatment of acute post-operative pain following bunionectomy surgery. While the trial was not expected to reach statistical significance, a trend toward analgesia was observed in a subset of patients. In our completed second Phase II trial, REC-14-013, Dex-IN met the primary endpoint of the clinical trial in demonstrating significant improvement in SPID48 compared with placebo (p£0.025). Based upon the results of these trials, we believe that our formulations of Dex have demonstrated analgesic potential for post-operative pain. In October 2015, we met with the FDA to obtain feedback on the Phase II efficacy and safety data, and for our proposed Dex-IN clinical development program. Based on feedback from the FDA regarding Dex-IN s benefit-risk profile, specifically its efficacy and blood pressure effects, which was demonstrated in post-operative pain, and the subsequent requirements for a post-operative pain clinical program, we have determined not to pursue Dex-IN in post-operative pain due to time, cost and associated risk. We plan to pursue Dex-IN, as discussed with the FDA, in peri-procedural pain.

REC-14-013

Our most recent completed Phase II study utilized Dex-IN initiating dosing of study medication on Post Op Day 1 following bunionectomy surgery. The Phase II trial was a randomized, multicenter, double-blind, placebo-controlled study to evaluate the efficacy and safety of Dex-IN in adult subjects undergoing bunionectomy surgery. Subjects were randomized to either a 50 mg dose of Dex-IN or a placebo intranasal dose given every six hours. Following the beginning of treatment, subjects remained under observation for 48 hours at study centers. Subjects were followed for seven days after the initial dose of study medication. There was an oral opioid rescue treatment available to patients in either treatment group. A total of 168 subjects were enrolled in the study. The key subject characteristics are listed in Table 3 below. One subject discontinued as a result of a serious adverse event of hypotension.

Table 3: Summary of Key Subject Characteristics REC-14-013

Characteristic	Placebo (N = 84)	DEX-IN 50 µg (N =84)
Female, n (%)	75 (89.3)	79 (94.0)
Age, Mean	44	43.9
(range)	(46 - 70)	(46 - 69)
Discontinued Subjects, n (%)	3 (3.6)	4 (4.8)
Lack of Efficacy	3 (3.6)	3 (3.6)
Adverse Event	0	1 (1.2)
Race, n (%)		
White	56 (66.7)	59 (70.2)
Black/African American	21 (25.0)	20 (23.8)
Other	7 (8.4)	5 (6.0)
Baseline PI Score, Mean	6.7	6.4
(range)	(4 - 10)	(4 - 10)

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The primary efficacy endpoint of the trial was SPID48, starting treatment on Post Op Day 1, utilizing the LOCF analysis method. Dex-IN met the primary endpoint of the clinical trial (p£0.025).

In general, DEX-IN was well tolerated. The most frequently reported adverse events reported in the Dex-IN group from the REC-14-013 trial are summarized in Table 4 below.

Table 4: Summary of Key Safety Data of Interest REC-14-013

	n (%) of Subjects	
Adverse Event	**Placebo (N = 84)**	**DEX-IN 50 µg (N =84)**
BP Decreased	3 (3.6)	22 (26.2)
Nausea	14 (16.7)	13 (15.5)
Nasal Discomfort	2 (2.4)	7 (8.3)
Headache	4 (4.8)	6 (7.1)
Vomiting	6 (7.1)	4 (4.8)
Nasal Dryness	3 (3.6)	4 (4.8)
Nasal Congestion	1 (1.2)	4 (4.8)
Nasal Obstruction	2 (2.4)	3 (3.6)
Bradycardia	0	3 (3.6)
Dizziness	1 (1.2)	3 (3.6)
Hypotension	0	3 (3.6)

No patients with blood pressure decrease, hypotension nor with bradycardia required medication to treat these events. All nasal related adverse events were rated as mild, except one case of nasal congestion rated as moderate.

REC-13-012

This Phase II trial was a randomized, multicenter double-blind, placebo-controlled study to evaluate the efficacy and safety of Dex-IN, in 95 adult subjects undergoing bunionectomy surgery with treatment beginning on Post Op Day 0. While analgesia and a reduction in opioid use were observed in a subset of patients at the planned interim analysis, we elected to discontinue the study as it was not expected to reach statistical significance. In this study, Dex-IN was well tolerated with no serious adverse events reported. Four subjects discontinued due to symptomatic hypotension and one subject discontinued due to fever. Additionally, one subject discontinued placebo due to nausea and vomiting.

No other adverse events of symptomatic hypotension were seen in the 95 patients treated. Asymptomatic decreases in blood pressure were seen throughout the study, including 10 Dex-IN patients that had an adverse event of BP decreased. In addition, one patient in the Dex-IN 50 mcg treatment group and two patients in the placebo treatment group had a heart rate of 50 bpm or below, along with a notable change from baseline heart rate. Lastly, no clinically significant changes were seen in electrocardiograms in any treatment group, and there were no clinically significant changes in clinical laboratory studies.

Fadolmidine Overview

Our third product candidate under development, Fado, also belongs to the alpha-2 adrenergic agonist receptor class. 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.

Fadolmidine Clinical Trials

In Orion sponsored studies, the safety and efficacy of Fado had been assessed in one Phase I study and in one Phase II study. In these studies, a total of 130 subjects received Fado. The Phase II study was a randomized, single blind, controlled dose-escalation study. The aim of the study was to assess the safety, tolerability and efficacy of Fado when administered intrathecally with bupivacaine to induce spinal anesthesia in subjects undergoing bunionectomy surgery. Fado doses of 40, 60, 80, 100, 120, 140, 160, 180, 200, 220 and 240 mcg were administered with 5 mg of bupivacaine. At each dose level, six subjects were randomized to receive combination treatment, and one subject to receive only isobaric bupivacaine 10 mg. In this study, Fado was shown to have beneficial effects. The time to first post-operative dose of rescue drug (patient controlled mini doses of morphine, called PCA) was longer with increasing Fado dose, while total morphine use in the first ten hours was reduced. The subjects not only used less morphine, but also reported less pain. All doses of Fado appeared to delay the onset of pain while doses of Fado greater than 120 mcg also appeared to suppress pain.

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Fado was well tolerated by subjects. Incontinence and bradycardia were observed only at the highest dose studied. The incidence of nausea and vomiting was higher on Fado compared to bupivacaine 10 mg alone, despite the reduction in intravenous morphine administered. Sedation did not appear to be increased on Fado. There were significant reductions in blood pressure after intrathecal Fado was added to bupivacaine. These reductions were dose-dependent.

Contract Manufacturing Overview

We currently own and operate an 87,000 square foot, DEA-licensed manufacturing facility that makes five commercial products, and we receive royalties associated with the sales of these products. This facility has been inspected by U.S., EU, Turkish and Brazilian regulatory authorities for compliance with required cGMP standards for continued commercial manufacturing. We manufacture the following products for our commercial partners: Ritalin LA® (Novartis Pharma AG), Focalin XR® (Novartis Pharma AG), Verelan PM® (Kremers Urban Pharmaceuticals, Inc.), generic Verapamil (Actavis plc) and Zohydro ER® (Pernix Therapeutics Holdings, Inc. and Paladin Labs Inc.). In each case, we either purchase active drug product from third parties or receive it from our commercial partners to formulate product using our technologies. The manufacture of these products for clinical trials and commercial use is subject to cGMPs and other regulatory agency regulations. Our manufacturing and development capabilities include formulation through process development, scale-up and full-scale commercial manufacturing and specialized capabilities for the development and manufacturing of controlled substances.

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 Gainesville 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 Gainvesville 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 copy of 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.

Material Customer Agreements

We have entered into commercial supply agreements with each commercial partner of our contract manufacturing business. Under each of these commercial supply agreements, we generally license certain intellectual property to our commercial partners and manufacture and supply the respective products for each of our commercial partners. Each commercial partner generally remains responsible for distributing, marketing and promoting their respective products.

Actavis

Pursuant to an amended and restated license and supply agreement, or the License and Supply Agreement, between us and Watson Laboratories, Inc., a subsidiary of Actavis plc, or Actavis, we exclusively manufacture generic Verapamil

for Actavis. We receive a percentage profit share from Actavis on all U.S. sales of Verapamil and are compensated for manufacturing the product at cost (or, where product is supplied in finished form, at manufacturing cost plus a mark-up). Actavis represented 33.0% of our revenues for the year ended December 31, 2015.

Under the License and Supply Agreement, we also license certain intellectual property to Actavis and maintain the regulatory approval that is necessary to enable Actavis to distribute Verapamil in the United States. Actavis is responsible for distributing, marketing and promoting Verapamil in the United States. The License and Supply Agreement also contains certain restrictions in respect of manufacturing and selling competing products, although we are permitted to sell a branded version of Verapamil through a third party under the trade name Verelan®.

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Either party may terminate the License and Supply Agreement on an annual basis by serving the other with a written notice of termination 90 days prior to the contract anniversary date. Each party may also terminate the License and Supply Agreement in certain specified circumstances, including where their rates of return fall below certain specified thresholds. Actavis can terminate the License and Supply Agreement if we commit certain material breaches of contract, including failure to supply. If Actavis exercises this right, then it may elect to obtain a production license from us. In all other circumstances, we retain the right to use all technical and clinical data that has been generated under the License and Supply Agreement upon its termination.

Intellectual Property

We own and license patents and patent applications directed to the sale, use, manufacturing and formulating of injectable meloxicam. The patent protection for injectable meloxicam could lead to protection of injectable meloxicam through 2030, subject to any extensions or disclaimers. Additionally, we will seek, if appropriate, patent term extension under the Hatch-Waxman Act, when applicable. The extensions under U.S. law may extend patent protection beyond 2030.

We own patents and patent applications directed to the composition of, manufacturing of, and formulating of Zohydro ER®. The patent protection for Zohydro ER® could provide for protection of Zohydro ER® through 2034, subject to any extensions or disclaimers. Additionally, we will seek, if appropriate, patent term extension under the Hatch-Waxman Act, when applicable. The extensions under U.S. law may extend patent protection beyond 2034.

We hold patent applications directed to the analgesia indication and formulations of Dex, and we are progressing through the patent application process globally. We believe that the combination of the unique indication and formulations, as well as the significant dosing differences with the routes of administration, will allow us to, with the applications filed, protect our products from other Dex entrants to the analgesia field, regardless of formulation. Our strategy, if successful in obtaining patent protection, could lead to protection of our product candidates through 2030, subject to any extensions or disclaimers. The term may be extended due to patent term adjustment as a result of delays by the U.S. Patent and Trademark Office in issuing any patent. Additionally, we will seek, if appropriate, patent term extension under the Hatch-Waxman Act, when applicable. The extensions under U.S. law may extend patent protection beyond 2030.

Intellectual Property Protection

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.

As a result of the Gainesville Transaction, we are now the owners of patents (U.S. Patent Nos.: 6,228,398, 6,902,742 and 9,132,096) relating to Zohydro-ER®, which we license to our commercial partner, Pernix Therapeutics Holdings, Inc., or Pernix, in the United States. These patents have expiration dates of November 1, 2019, November 1, 2019, and September 12, 2034, respectively. 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. We cannot predict if the Canadian patent application will ever issue as a patent. We

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own patent applications and patents directed to nanoparticulate formulations of meloxicam that we expect to provide protection for injectable meloxicam, if injectable meloxicam gains marketing approval. The issued patents and any patents that may issue from various applications related to injectable meloxicam expire between 2016 and 2024, depending upon the application and patent.

Additionally, as part of the Gainesville Transaction, we acquired ownership of various controlled release formulation patents including patents in the United States, Canada, and Europe. These patents are scheduled to expire between 2019 and 2026.

We have in-licensed the Orion patent rights to Dex and Fado in the United States and internationally. For Dex, the composition of matter patent (U.S. Patent No. 4,910,214) expired in mid-January 2014. For Fado, the composition of matter patent (U.S. Patent No. 6,313,311) expires on October 2, 2016 with a possible patent term extension under the Hatch-Waxman Act. Also for Fado, we have a pro-drug patent (U.S. Patent No. 7,759,496) that expires on April 10, 2025. If no additional patent protection is obtained, these patent expirations will impact our ability to prevent third parties from marketing generic equivalents. We have also licensed additional method of use patents for both Dex and Fado from Orion. We are also pursuing patent protection for the specific formulations, dosage forms and methods of use of our product candidates.

Our Dex patent portfolio comprises three families of patent applications. A family (U.S. Application Serial No. 12/781,628; which was also filed as a PCT Application, International Application No. PCT/US10/35136) provides, among other things, methods of treating or preventing pain by administering to the oral mucosa of a mammal. The active ingredient, or salt, can be used to treat or prevent pain without significant sedation. The first family also provides, among other things, oral, transmucosal, analgesic pharmaceutical compositions comprising an oral, transmucosal pharmaceutically effective amount of the active ingredient, or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable vehicle. The pharmaceutically effective amount of the active ingredient treats or prevents pain without significant sedation. The first family also provides oral transmucosal dispensing devices comprising the analgesic pharmaceutical composition.

Another family (U.S. Application Serial No. 13/711,407; which was also filed as a PCT application, International Application No. PCT/US12/68988) provides, among other things, methods of treating or preventing pain by intranasally administering an intranasally effective amount of the active ingredient. This family also provides metered dose devices comprising a pharmaceutical composition comprising the active ingredient, or salt thereof. The metered dose devices can deliver a metered dose spray of the pharmaceutical composition intranasally that is analgesic in a mammal.

The Dex patent applications are in various stages of prosecution, and no patent has been issued to date in the United States. Unless and until our pending applications issue, their protective scope is impossible to determine. Further, there is only one patent application in connection with Dex-IN, which is also relatively early in the review process, which may take months or years, and there is no guarantee that the patent will issue. 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.

For the patent family regarding oral transmucosal Dex, if embodiments from the specification and/or present claims issued, the claims may cover: methods of treating or preventing pain without significant sedation via delivery of Dex to the oral mucosa; oral, transmucosal analgesic pharmaceutical compositions comprising Dex; and oral transmucosal dispensing devices containing Dex. For the patent family regarding Dex-IN, if embodiments from the specification and/or present claims issued, the claims may cover: methods of treating or preventing pain without significant sedation via delivering Dex intranasally; intranasal compositions comprising Dex; and/or metered dose devices

containing Dex.

If these patent applications are issued as patents, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, the resulting patent protection in the United States may last into 2030, subject to any disclaimers or extensions. We note that the patent laws of foreign countries differ from those in United States, and the degree of protection afforded by foreign patents may be different from the protection offered by United States patents.

In-Licensing Arrangements

Alkermes plc

As part of the Gainesville Transaction, we in-licensed, on a perpetual, royalty-free basis, technology relating to injectable meloxicam, from Alkermes. We have also licensed patents and applications relating to the formulations and manufacturing of injectable meloxicam, including the NanoCrystal™ technology. These patent applications are scheduled to expire between 2016 and 2030.

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Orion Corporation

Dexmedetomidine (Dex) License

In August 2008, we entered into 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, in the Territory. We have the right to sublicense the rights under this license at any time.

In consideration for this license, we are required to pay Orion lump sum payments on the achievement of certain developmental milestones and upon the achievement of certain commercial milestones. We will pay milestone payments to Orion of up to 20.5 million ($22.4 million as of December 31, 2015) after regulatory approval of Dex dosage forms and upon achieving certain sales milestones. Although we have a separate agreement for the license of Dex in Japan that provides for separate development and commercial milestones, we expect that development of Dex for Japan will require a local partner that would be required to make sure milestone payments are made. We are also required to pay Orion a royalty on net sales that, during the term, generally varies from 10% to 20%, depending on annual sales levels, and in some circumstances, such as in the event of the marketing of a generic competitor or a competing product being released by Orion or its licensees, could drop to low single digits, so long as Orion is not engaged in the use, manufacturing and/or commercialization of a pharmaceutical product containing Dex, medetomidine or detomidine as a therapeutically active ingredient for treatment of pain in humans in any dosage form for transdermal, transmucosal (including sublingual), topical, enteral or pulmonary (inhalational) delivery (collectively, referred to as the Licensed Dosage Forms). Our royalty payments on net sales of Dex will be paid at varying percentages. Through December 31, 2015, no such milestones have been achieved.

We are entitled to reference all regulatory filings made by Orion related to Dex, Dex products or the Dex active pharmaceutical ingredient, or API. Orion retained 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.

We have a right of first refusal to commercialize any such product developed by Orion in the Territory.

The initial term of this license is 15 years from the first commercial sale in the Territory. After the initial term, this license will be automatically extended for one or more periods of two years, unless either party provides written notice of termination at least six months prior to expiration. Each party has the right to terminate the agreement in connection with the bankruptcy, liquidation or dissolution of the other party or for a material breach that is uncured or without a reasonably acceptable plan to cure such breach within 90 days. In the event of termination, inventions created by Orion will remain Orion s property, and inventions created by us will remain our property. In the event that inventions are jointly created, the inventions will be the joint property of the parties.

Fadolmidine (Fado) License

In July 2010, we entered into 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 ($13.3 million as of December 31, 2015), 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%, so long as Orion is not engaged in the manufacture, use or sale of a competitive product containing Fado as a therapeutically active ingredient for treatment of human subjects, in the Territory, as defined in such agreement. Through December 31, 2015, no such milestones have been achieved.

We are entitled to reference data as well as information in prior Orion regulatory filings (European Union/Finland) made by Orion related to Fado. Orion retained the rights to develop and commercialize Fado in the European Union, the CIS and Turkey subject to the terms and conditions of the license agreement. In addition, Orion is entitled to receive a license-back to any intellectual property and data developed by us, and, in the event Orion sublicenses the use of such intellectual property and data, Orion would be required to pay us a portion of our costs incurred in developing Fado. In the event of termination, inventions created by Orion will remain Orion s property, and inventions created by us will remain our property. In the event that inventions are jointly created, the inventions will be the joint property of the parties.

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The term of the license agreement is 15 years from the first commercial sale of a product by us in any country in the Territory, as defined in such agreement. After the initial term, the license agreement will be automatically extended on the same terms and conditions for one or more successive three year periods, unless either party provides written notice six months prior to the expiration of the initial term or any renewal term.

Each party has the right to terminate the agreement in connection with the bankruptcy, liquidation or dissolution of the other party, for a material breach that is uncured or for which a reasonably acceptable plan to cure such breach has not been developed within 90 days of receipt of written notice, upon our failure to develop and commercialize Fado as determined by Orion, which failure remains uncured or for which a reasonably acceptable plan to cure such failure has not been developed within 90 days of receipt of written notice, or if we or our licensees contest the Orion patent rights.

Sales and Marketing

Our current intent is to develop and commercialize our product candidates in the United States while out-licensing development and commercialization rights for other territories outside the United States for which we own the territorial rights. We believe the initial target audience for our product candidates will be specialty physicians, including surgeons, anesthesiologists and pain specialists. Our management team has experience building and launching therapeutics to specialty physicians. 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.

Pharmaceutical Manufacturing and Supply

The source for Dex API is Orion s Fermion Chemical Division, and the source for bulk IV meloxicam formulation is Alkermes. We currently rely on contract manufacturers to produce drug product for IV meloxicam, Dex-In and Fado for our clinical studies 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.

Material Supply Agreements

Meloxicam

We are party to a Development, Manufacturing and Supply Agreement, or Supply Agreement, with Alkermes (through a subsidiary of Alkermes), pursuant to which Alkermes will provide (i) clinical and commercial bulk supplies of IV meloxicam formulation, and (ii) development services with respect to the Chemistry, Manufacturing and Controls section of an NDA for IV meloxicam. Pursuant to the Supply Agreement, Alkermes will supply us with such quantities of bulk IV meloxicam formulation as shall be reasonably required for the completion of clinical trials of IV 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 IV meloxicam formulation exclusively from Alkermes for a period of time. Sterile fill-finish of Meloxicam will be completed by a third party fill-finish facility. If the first commercial sale of 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 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.

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Dex API

We and Orion are parties to an API agreement, whereby Orion agrees to provide us API for the development and commercialization of the Dex and Fado product candidates.

During the development period 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. We have agreed with Orion on the specifications for the cGMP for API and the stability testing, storage, handling and agreed quality of the API, as well as a dispute resolution process, should differences arise in interpretation of data for the API.

The terms for commercial supply of Dex API by Orion are subject to regulatory approval. 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.

Device Manufacturing and Supply

The single unit dose intranasal sprayer for Dex 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, 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., Endo Pharmaceuticals, Inc., Mallinckrodt plc, and Pacira Pharmaceuticals, Inc. Purdue and Endo are the primary competitors 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. As far as potential competitors in development, we are not aware of any other alpha-2 agonists compounds in development for post-operative pain relief. However, companies such as Adynxx, Inc., AcelRx Pharmaceuticals, Inc., Heron Therapeutics, Inc., Trevena, Inc. and Cara Therapeutics, Inc. are currently developing post-operative pain therapeutics that could compete with us in the future.

In cancer breakthrough pain relief, we expect to compete against established companies, including Teva Pharmaceutical Industries, Ltd., BioDelivery Sciences International, Inc., Kyowa Hakko, Insys Therapeutics, Inc. and Depomed, Inc. All of these potential competitors have various formulations of fentanyl, a fast-acting opioid. We are not aware of any non-fentanyl related therapeutics in development for the treatment of cancer breakthrough pain.

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

Government Regulation

Product Approval

Governmental authorities in the United States at the federal, state and local level, and other in 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.

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 or judicial sanctions. These sanctions could include the FDA s refusal to approve pending applications, withdrawal of an approval, a clinical hold, 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 or any other actions. 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 according to Good Laboratory Practices regulations;
- submission to the FDA of an 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 inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP; 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 or non-compliance.

All clinical trials 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. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits. The IRB also 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.

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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 diseases 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. 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.

As an alternate path to FDA approval, particularly for modifications to drug products previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part

of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments, and it permits the submission of an NDA 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 interprets Section 505(b)(2) of the FDCA to permit the applicant to rely upon the FDA s previous findings of safety and effectiveness for an approved product. The FDA requires submission of information needed to support any changes to a previously approved drug, 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 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 submission of an NDA is subject to the payment of a substantial user fee; a waiver of such fee may be obtained under certain limited circumstances. For example, the agency will waive the application fee for the first human drug application that a small business or its affiliate submits for review.

In addition, under the Pediatric Research Equity Act of 2003, or PREA, which was reauthorized under the FDA Amendments Act of 2007, an NDA or supplement to an NDA 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 grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

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Section 505(b)(2) New Drug Applications. 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 Section 505(b)(2) application with respect to any patents for the approved product on which the application relies 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 application until all the listed patents claiming the referenced product have expired. Further, the FDA will also not approve, as applicable, a Section 505(b)(2) NDA application 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 referenced 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 referenced NDA for the previously approved 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 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 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) NDA that we submit.

We are pursuing a regulatory strategy pursuant to Section 505(b)(2) in connection with our NDA submissions for Dex-IN based on the expiration of the originator s patent. In the NDA submissions for our other product candidates, we intend to follow the development and approval pathway permitted under the FDCA that we believe will maximize their commercial opportunities.

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. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be re-submitted 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 a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve 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 on matters of importance that come before the agency. 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 is 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 of

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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 of 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. 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 specifics 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 as compensation 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. The patent term restoration period is generally 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. 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 the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active pharmaceutical ingredient, or active moiety, which 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. However, the FDCA will 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. Further, a Section 505(b)(2) application may be submitted after four years if it contains a Paragraph IV certification that a listed patent is invalid, unenforceable, or not infringed for the applicant s drug product. 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, if new clinical investigations that were conducted or sponsored by the applicant are determined by the FDA to be essential to the approval of the application. 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 changes of the approved drug product. The FDCA, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug or competitive product.

Pediatric exclusivity is another type of exclusivity in the United States. Pediatric exclusivity, if granted, provides an additional six months of exclusivity to be attached 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 protection 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. The current pediatric exclusivity provision was reauthorized in September 2007.

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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, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements. In September 2007, the FDA Amendments Act of 2007 was enacted, giving the FDA enhanced post-marketing authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA strictly regulates labeling, advertising, promotion and other types of information on 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. 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 generally 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 also 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, 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, injunctions or 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.

The 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 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 as Schedule I, II, III, IV or V substances, with Schedule II substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. Certain active ingredients are listed by the DEA as Schedule II and Schedule III under the CSA. Consequently, their manufacture, shipment and storage are subject to a high degree of oversight and regulation. 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 maintain 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

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substances and periodic reports made to the DEA, for example, distribution 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 to obtain authorization to destroy any controlled substance. In addition, special authorization and notification requirements apply to imports and exports.

Failure to maintain compliance with applicable requirements, particularly as manifested 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. In certain circumstances, violations could result in criminal proceedings.

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 clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. 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.

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 fiscal intermediaries and carriers that administer coverage and reimbursement for certain healthcare items and services furnished to the elderly and disabled. As required by Medicare contracting reform, CMS is transitioning from fiscal intermediaries and carriers to Medicare Administrative Contractors for fee-for-service Medicare. Medicaid is an insurance program for certain categories of patients whose income and assets fall below state defined levels and who are otherwise uninsured 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 payor has its own process and standards for determining whether it will cover and reimburse a procedure or particular 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.

The U.S. Congress and state legislatures may, from time to time, propose and adopt initiatives aimed at cost containment, which could impact our ability to sell our product candidates profitably. For example, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act and the associated reconciliation bill, which we refer to collectively as the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Health Care Reform Law revised the definition of average manufacturer price for reporting purposes, which could increase the amount of Medicaid drug rebates to states once the provision is effective. Further, beginning in 2011, the new law imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare practitioners. We will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our product candidates.

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The cost of pharmaceuticals continues to generate substantial governmental and third party payor interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Our results of operations could be adversely affected by current and future healthcare reforms.

Some third party payors also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers that use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and operate profitably.

Other Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the CMS, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments. These regulations include:

- the federal healthcare program anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other government reimbursement programs that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- 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 physician payments and other transfers of value and physician ownership and investment interests;

- the FDCA, which, among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples;

the federal Health Information Technology for Economic and Clinical Health Act, which made changes to HIPAA, including extending the reach of HIPAA beyond HIPAA covered entities, increasing the maximum civil monetary penalties for violations of HIPAA, granting enforcement authority to state attorneys general and imposing a breach notification requirement on HIPAA covered entities and business associates; and

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers, 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.

Employees

We currently have 186 full-time employees and 2 temporary employees. None of our employees are covered by collective bargaining agreements, and we consider relations with our employees to be good.

Item 1A. Risk Factors

You should carefully consider the following risk factors together with the other information contained in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes appearing in this report. We cannot assure you that any of the events discussed in the risk factors below will not occur. If any of the following risks actually occur, they may materially harm our business and our financial condition and results of operations. In this event, the market price of our common stock could decline and your investment could be lost. You should understand that it is not possible to predict or identify all such risks. Consequently, you should not consider the following to be a complete discussion of all potential risks or uncertainties.

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Risks Related to Our Finances and Capital Requirements

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

We have limited operating history. To date, we have focused primarily on developing injectable meloxicam and Dex-IN. In addition, we have other product candidates, Dex-SL and Fado, in development and may acquire or develop other product candidates in the future. We have incurred significant pre-tax losses in each year since our inception in November 2007, including pre-tax losses of approximately $12.5 million and $16.1 million for the years ended December 31, 2015 and 2014, respectively. As of December 31, 2015, we had an accumulated deficit of $31.1 million.

Until April 2015, we had devoted most of our financial resources to research and development, including our nonclinical and formulation development activities, product candidate manufacturing and clinical trials. Since April 2015, in addition to the continuation of the above activities for our product candidates, we have used revenue produced by our Gainesville manufacturing business to make payments under our credit facility with OrbiMed. Through December 31, 2015, we have financed our operations through the sale of debt and equity securities and a $50.0 million credit facility. We believe that the Gainesville manufacturing business s commercial 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 will depend, in part, on the rate of future expenditures and our ability to generate additional revenues. To date, none of our product candidates have been commercialized, and revenues generated by our manufacturing business do not cover our costs. 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.

We expect to continue to incur substantial and increased expenses as we expand our research and development activities and advance our clinical programs. As a result of the foregoing, we expect to continue to incur significant and increasing losses from operations for the foreseeable future.

We have only recently begun to generate revenue through our acquisition of the contract manufacturing facility, royalty and formulation business in the Gainesville Transaction but we may never be profitable.

Our ability to achieve profitability depends on our ability, alone or with collaborators, to successfully complete the development of, obtain the necessary regulatory approvals for and commercialize our product candidates. We do not anticipate generating revenues from sales of our product candidates for the foreseeable future, if ever. Although we generate revenue through our subsidiary s contract manufacturing, royalty and formulation business, such revenue 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 through either building a specialty sales force or collaborating with third parties; and

obtaining and maintaining patent protection.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, 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. For example, our expenses could increase beyond expectations if we are required by the FDA to perform studies in addition to those that we currently anticipate.

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 unless we enter into a strategic partnership for the launch and commercialization of our product candidates. 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

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our product candidates. In addition, our contract manufacturing business 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.

Our operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly and annual fluctuations. Prior to commercializing any of our product candidates, we expect that any expenses or revenues we generate will fluctuate from quarter to quarter and year to year as a result of (i) the timing and amount of development milestones and royalty revenues received or paid under our collaboration license agreements, as these revenues or payments from the arrangements are principally based on the achievement of clinical and commercial milestones outside of our control, and (ii) the revenues generated by our contract manufacturing business, which may fluctuate significantly.

If we commercialize one or more of our products, our operating results will be affected by numerous factors, including:

- 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;
- any intellectual property infringement lawsuit in which we may become involved;
- our ability to obtain and maintain patent protection;
- 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 products and product candidates, which are not limited to but could include the imposition of a Risk Evaluation and Mitigation Strategy, or REMS, program as a condition of approval;

our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements;

the achievement and timing of milestone payments under our existing collaboration and license agreements; 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.

If we fail to obtain sufficient additional financing, we would be forced to delay, reduce or eliminate our product development 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 substantially increase in connection with our ongoing activities, particularly as we advance our clinical programs. In addition, maintaining a world class cGMP pharmaceutical manufacturing facility is expensive. While our contract manufacturing business 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.

On February 2, 2015, we entered into a common stock purchase agreement, or the Purchase Agreement, with Aspire Capital Fund, LLC, or Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth in the Purchase Agreement, Aspire Capital is committed to purchase, at our election, up to an aggregate of $10.0 million of our shares of common stock over the approximately 24-month term of the Purchase Agreement. During the first quarter of 2016, we sold 93,940 shares of our common stock under the Purchase Agreement for proceeds of $560,000.

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We expect our existing cash and cash equivalents will be sufficient to fund our current operations through March 31, 2017. 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 file an NDA for injectable meloxicam, Dex-IN or other product candidates or otherwise enter into collaborations to launch and commercialize injectable meloxicam, Dex-IN or other product candidates after receipt of FDA approval, if received, and, if we choose, to initiate clinical trials for additional uses of injectable meloxicam, Dex-IN or other product candidates. The extent to which we utilize the Purchase Agreement with Aspire Capital as a source of funding will depend on a number of factors, including the prevailing market price of our common stock, the volume of trading in our common stock and the extent to which we are able to secure funds from other sources. The number of shares that we may sell to Aspire Capital under the Purchase Agreement on any given day and during the term of the agreement is limited. Even if we are able to access the remaining $9.4 million under the Purchase Agreement, we will still need additional capital to fully implement our business, operating and development plans.

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 corporate 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 manufacturing business.

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 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.

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

Prior to 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, 2015, we had an outstanding balance under the credit agreement of $33.7 million. Accordingly, we have substantially increased indebtedness following the acquisition in comparison to a recent historical basis. The credit agreement also 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. During the year ended December 31, 2015, we paid $16.3 million of the outstanding principal on our senior secured term loan from free cash flow generated by Gainesville.

Our indebtedness could have important consequences to you. 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;

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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; and

places us at a competitive disadvantage compared to our competitors that have less indebtedness.

Any of the above listed factors could materially adversely affect our business, financial condition, results of operations and cash flows. Our credit agreement with 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 agreements, and could have a material adverse effect on our business, financial condition and results of operation.

Further, subject to compliance with our credit agreement with OrbiMed, we have the ability to incur additional indebtedness, which would exacerbate the risks associated with our existing debt.

Risks Related to Clinical Development and Regulatory Approval

We depend substantially on the success of our product candidates, which are still under clinical development, and which may not obtain regulatory approval or be successfully commercialized.

We have not marketed, distributed or sold any products. The success of our business depends primarily upon our ability to develop and commercialize our product candidates. IV meloxicam, our lead product candidate, has successfully completed multiple Phase II clinical trials and is currently being studied in pivotal Phase III clinical trials for the management of acute post-operative pain. Based on feedback from the FDA, in January 2016, we initiated a Phase III program that includes two pivotal clinical trials, as well as other trials. We plan to pursue Dex-IN, as we discussed with the FDA, in peri-procedural pain. We intend to use these trials as a basis to submit an NDA for injectable meloxicam and Dex-IN. There is no guarantee that our clinical trials will be completed, or if completed, will be successful. Any delay in obtaining, or inability to obtain, regulatory approval would prevent us from commercializing each of injectable meloxicam, Dex-IN or our other product candidates, generating revenues from our product candidates and achieving profitability. If this were to occur, we may be forced to abandon our development efforts for injectable meloxicam, Dex-IN or our other product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations.

We depend substantially on the successful completion of Phase II and III clinical trials for our product candidates. The positive clinical results obtained for our product candidates in earlier clinical studies may not be repeated in Phase II or III and, thus, we may never receive regulatory approval of our product candidates.

We, or our predecessors, have completed multiple clinical studies utilizing IV meloxicam and Dex-IN. We are currently conducting Phase III clinical trials of IV meloxicam for the management of acute post-operative pain. We also intend to conduct further clinical trials for Dex-IN for the management of peri-procedural pain. Before obtaining regulatory approval for the commercial sale of any product candidate, we must successfully complete Phase III clinical trials. Negative or inconclusive results of a Phase III clinical trial could cause the FDA to require that we repeat it or conduct additional clinical trials. Any regulatory delays or request for additional clinical data will lead to new and costly expenditures and could cause delays in our drug development. There is no guarantee that our clinical

trials will be completed, or if completed, will be successful.

To date, we, or our predecessor, have completed multiple Phase II clinical trials with IV meloxicam and Dex-IN. However, there is no certainty that the results we have seen in these trials and in the patient population that we evaluated will be similar in our ongoing and future expected clinical trials. We cannot be certain that positive results will be duplicated when IV meloxicam is tested in larger number of patients or that Dex-IN will be successful when targeting peri-procedural pain. Unexpected results could require us to conduct additional clinical trials in the same or different patient populations or discontinue clinical development of injectable meloxicam or Dex-IN. If we are forced to discontinue development of injectable meloxicam, Dex-IN or any of our other product candidates because of unsuccessful clinical trials, we will not be able to commercialize injectable meloxicam, Dex-IN or our other product candidates, and our business, financial condition and results of operations may be materially adversely affected.

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:

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inability to raise funding necessary to initiate or continue a trial;

delays in a Phase II study required prior to Phase III initiation;

delays caused by toxicology studies required prior to Phase III initiation;

delays caused by unexpected results or unforeseen problems with any clinical trials;

delays in obtaining regulatory approval to commence a trial;

delays in reaching agreement with the FDA on final trial design or the scope of the development program;

import delays;

imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;

delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;

delays in obtaining required institutional review board approval at each site;

delays in recruiting suitable patients to participate in a trial;

delays in the testing, validation, manufacturing and delivery of the device components of our product candidates;

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;

delays by our contract manufacturers to produce and deliver a sufficient supply of clinical trial materials; or

delays or problems caused by third parties who market our product candidates for other indications.

If completion of the Phase III clinical trials for injectable meloxicam, the initiation of the clinical trials for Dex-IN in peri procedural pain or other clinical trials for our other product candidates is 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 injectable meloxicam, Dex-IN or other 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, Dex and other product candidates have generated some AEs, and in some cases serious adverse events, or SAEs, as those terms are defined by the FDA in its regulations. 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.

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After the completion of our clinical trials, we cannot predict whether or when we will obtain regulatory approval to commercialize injectable meloxicam, Dex-IN or other product candidates, and we cannot, therefore, predict the timing of any future revenue from injectable meloxicam, Dex-IN or other product candidates.

We cannot commercialize injectable meloxicam, Dex-IN or other product candidates until the appropriate regulatory authorities, such as the FDA, have reviewed and approved the product candidate. The regulatory authorities may not complete their review processes in a timely manner, or they may not provide regulatory approval for injectable meloxicam, Dex-IN or other product candidates. Additional delays may result if injectable meloxicam, Dex-IN or other product candidates are taken before an FDA Advisory Committee, which may recommend restrictions on approval or recommend that one or more product candidates not be approved. For example, our development timeline for Dex-IN has been delayed due to our decision, based on feedback from the FDA, not to pursue a Phase III program in post-operative pain and instead to study Dex-IN in peri-procedural pain. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical studies and the review process. Such delays or rejections could have an adverse effect on our business.

Even if we obtain regulatory approval, we cannot be certain that we will be able to successfully commercialize our product candidates, in which case we may be unable to generate sufficient revenues to sustain our business.

Our ability to successfully commercialize any of our products candidates will depend on, among other things, our ability to:

successfully complete our clinical trials;

receive marketing approvals from the FDA and similar foreign regulatory authorities;

obtain and maintain patent protection;

produce, through a validated process, sufficiently large quantities of our product candidates to permit successful commercialization;

establish commercial manufacturing arrangements with third-party manufacturers;

build and maintain strong U.S.-based sales, distribution and marketing capabilities sufficient to launch commercial sales of our product candidates or build collaborations with third parties for the commercialization of our product candidates within the United States;

establish collaborations with third parties for the commercialization of our product candidates in countries outside the United States, and such collaborators ability to obtain regulatory and reimbursement approvals in such countries;

secure acceptance of our product candidates by physicians, health care payors, patients and the medical community; and

manage our spending as costs and expenses increase due to commercialization and clinical trials.

There are no guarantees that we will be successful in completing these tasks. If we are unable to successfully complete these tasks, we may not be able to commercialize any of our product candidates in a timely manner, or at all, in which case we may be unable to generate sufficient revenues to sustain and grow our business. In addition, if we experience unanticipated delays or problems, development costs could substantially increase and our business, financial condition and results of operations will be adversely affected.

Even if we obtain regulatory approval for injectable meloxicam, Dex-IN and our other 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, the FDA and state regulatory authorities 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. For example, the labeling ultimately approved for injectable meloxicam, Dex-IN and our other product candidates will likely include restrictions regarding, among other items, the number of doses to be dispensed or the number of permissible distribution routes, until we have satisfied all FDA requests for additional data to support broader usage. Injectable meloxicam, Dex-IN and our other 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.

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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 for compliance with cGMP regulations and adherence to commitments made in the NDA. 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.

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 or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or supplements to an NDA submitted by us;
- seize our product candidate; and/or
- refuse to allow us to enter into supply contracts, including government contracts.

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.

The FDA may require us to provide more dosing data regarding injectable meloxicam, Dex-IN or our other product candidates.

The FDA may require us to provide additional dosing data beyond current data and data from our Phase II and Phase III clinical trials and to establish the proper dosage or dose frequency for injectable meloxicam or Dex-IN before it approves any of these product candidates. The preparation of this additional data may be costly and may delay the approval of injectable meloxicam, Dex-IN or any of our other product candidates for which we receive this request. If we cannot satisfy the FDA requirements, we may not be able to obtain marketing approval.

Injectable meloxicam, Dex-IN and our other product candidates may require REMS, which may significantly increase our costs.

The FDA Amendments Act of 2007 implemented safety-related changes to product labeling and requires the adoption of REMS for certain products. Based on the FDA s actions with many products, our product candidates 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, Dex-IN or our other product candidates. Depending on the extent of the REMS requirements, our costs to commercialize injectable meloxicam, Dex-IN or our other product candidates may increase significantly and distribution restrictions could limit sales.

Even if we obtain FDA approval for injectable meloxicam, Dex-IN 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 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.

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Additional time may be required to obtain regulatory approval for Dex-IN because the FDA may consider it a drug/device combination.

Dex-IN may be considered by the FDA to be a drug/device combination. While we have filed an IND for Dex-IN, we cannot guarantee that the FDA will not require a separate device review. There are a number of drugs such as Zecuity® and Sprix® that employ a device that have received approval as drugs. The third-party device we intend to use has previously received a device authorization. We have not taken any action, and although we plan to address such matter with the FDA in the future, we do not have a targeted date to do so, because we believe our device will be treated similarly to such other drugs. Because we cannot guarantee this result, however, we may experience delays in regulatory approval for Dex-IN due to potential uncertainties in the approval process, in particular as the FDA may require device authorization by NDA approval. As a result, product launch and commercialization may be delayed or may not occur, which could have an adverse effect on our business.

Risks Related to Our Reliance on Third Parties

We rely on limited sources of supply for the drug component of 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. Orion is currently our sole source of the API for Dex. Although the supply agreements that we have with Alkermes and Orion 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. Currently, Alkermes and Orion are the only established suppliers of bulk injectable meloxicam formulation and Dex API, respectively.

We expect that the drug product (dosage form that is the final product) for Dex-IN will be manufactured by a contract manufacturing organization, or CMO. There are only a small number of manufacturers with the capability to produce the Dex-IN product and fill the intranasal sprayers that are needed for the product. We expect to enter into an agreement with an intranasal delivery device company that will supply the components of the intranasal sprayer to the CMO for filling after they have made the formulated drug product. Currently, there is only one supplier for the filled and finished intranasal sprayer that we intend to use.

If supply from our suppliers, any CMO or any device component supplier is interrupted, there could be a significant disruption in commercial or clinical supply of injectable meloxicam, Dex-IN or our other product candidates. The FDA, state regulatory authorities or other regulatory authorities outside of the United States may also require additional studies if any new suppliers are relied upon for commercial production. In addition, failure of our suppliers or vendors to comply with applicable regulations may result in delays and interruptions to our product candidate supply while we seek to secure other suppliers that meet all regulatory requirements.

Any interruption in the supply of injectable meloxicam, Dex-IN or our other product candidates could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing them successfully. Furthermore, if our suppliers fail to deliver the required quantities of the drug component of our product candidates on a timely basis and at all, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

Manufacture of injectable meloxicam, Dex-IN and our other product candidates require specialized equipment and expertise, the disruption of which may cause delays and increased costs.

There are a limited number of machines and facilities that can accommodate our filling and assembly process, and for certain parts of the process, we need to use dedicated or disposable equipment throughout development and commercial manufacturing. If this equipment breaks down or needs to be repaired or replaced, it may cause significant disruption in clinical or commercial supply, which could result in delay in the process of obtaining approval for or sale of our products. Any problems with our existing manufacturing facility or equipment may delay or impair our ability to complete our clinical trials or commercialize our product candidates and increase our costs.

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

As we scale up manufacturing of our 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.

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We use third parties, including Malvern Consulting Group, Inc., an entity with which our management is affiliated, 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, including Malvern Consulting Group, Inc., or MCG, to provide certain manufacturing and operational support. We use other third parties 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, Dex-IN 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 current good clinical practices, or cGCPs, which are regulations and guidelines enforced by the FDA for all of our product candidates in clinical development. The FDA enforces 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, Dex-IN or 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, Dex-IN, or our other product candidates. As a result, our financial results and the commercial prospects for injectable meloxicam, Dex-IN 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

The commercial success of injectable meloxicam, Dex-IN 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;

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, Dex-IN and our other product candidates on their list of authorized products, referred to as formulary approval;

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.

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If injectable meloxicam, Dex-IN 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.

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

We currently do not have an organization for the sales, marketing and distribution of injectable meloxicam, Dex-IN or our other product candidates, and the cost of establishing and maintaining 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 and Dex-IN 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.

If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

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 and peri-procedural pain relief setting, we believe injectable meloxicam will be prescribed for moderate to severe pain, competing mostly with opioids such as morphine, oxycodone, hydrocodone and fentanyl. There are a number of pharmaceutical companies that currently market therapeutics in the pain relief area, including Johnson & Johnson, Purdue Pharma L.P., Endo Pharmaceuticals Inc., Mallinckrodt plc. and Pacira Pharmaceuticals, Inc. Purdue and Endo are the primary competitors 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. As far as potential competitors in development of product candidates for peri-procedural pain, such as Dex-IN, we are not aware of any other alpha-2 agonists compounds in development for this area. However, companies such as Adynxx, Inc., AcelRx Pharmaceuticals, Inc., Heron Therapeutics, Inc., Trevena, Inc. and Cara Therapeutics, Inc. are currently developing post-operative pain therapeutics that could compete with us in the future.

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In cancer breakthrough pain relief, we expect to compete against established companies, including Teva Pharmaceutical Industries Ltd, BioDelivery Sciences International, Inc., Kyowa Hakko, Insys Therapeutics Inc. and Depomed, Inc. All of these potential competitors have various formulations of fentanyl, a fast-acting opioid. We are not aware of any non-fentanyl related therapeutics in development for the treatment of cancer breakthrough pain.

It is possible that any of these competitors could develop or improve technologies or products that would render our product candidates obsolete or non-competitive, which could adversely affect our revenue potential. Key competitive factors affecting the commercial success of our product candidates are likely to be efficacy, safety profile, reliability, convenience of dosing, price and reimbursement.

Many of our potential competitors have substantially greater:

capital resources;

research and development resources and experience, including personnel and technology;

drug development, clinical trial and regulatory resources and experience;

sales and marketing resources and experience;

manufacturing and distribution resources and experience;

name recognition; and

resources, experience and expertise in prosecution and enforcement of intellectual property rights.

Accordingly, our competitors may be more successful than we are in obtaining FDA approval for product candidates in the pain management and relief space and achieving widespread market acceptance of these products. Our competitors drugs or drug delivery systems may be more effective, have fewer AEs, be less expensive to develop and manufacture or be more effectively marketed and sold than any product candidate we may commercialize. This may render our product candidates obsolete or non-competitive before we can recover our losses. 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. These entities may also establish collaborative or licensing relationships with our competitors, which may adversely affect our competitive position. Finally, the development of different methods for the treatment of acute pain following surgery or breakthrough pain, or of peri-procedural pain, could render injectable meloxicam or Dex-IN, respectively, 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, Dex-IN 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, Dex-IN, 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, Dex-IN, 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, Dex-IN, or any future product candidates that we develop.

The availability of numerous generic pain medications may substantially reduce the likelihood of reimbursement for injectable meloxicam, Dex-IN or our other product candidates. We expect to experience pricing pressures in connection with the sale of injectable meloxicam, Dex-IN 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.

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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, Dex-IN or other product candidates outside the United States. We expect that we will be subject to additional risks related to entering into international business relationships, including:

different regulatory requirements for drug approvals in foreign countries;

reduced protection for intellectual property rights;

unexpected changes in tariffs, trade barriers and regulatory requirements;

economic weakness, including inflation, or political instability in particular foreign economies and markets;

compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

foreign taxes, including withholding of payroll taxes;

foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;

workforce uncertainty in countries where labor unrest is more common than in the United States;

production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; 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.

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Upon commercialization of any of our product candidates, we will become subject to a variety of additional risks applicable to companies engaged in the distribution of pharmaceuticals.

Although we do not expect to commercialize our product candidates for several years, if and when we do, we will be subject to a variety of additional risks. In particular, upon commercialization of our product candidates, our relationships with 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 criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

In addition, over the past few years, several pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged 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; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Most states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a company s products from reimbursement under government programs, criminal fines and imprisonment.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialization of injectable meloxicam, Dex, or any of our future products, and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for injectable meloxicam, Dex-IN, or any of our future products, restrict or regulate post-approval activities and affect our ability to profitably sell our product candidate, assuming we obtain marketing approval.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted, or whether the FDA or state regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of injectable meloxicam, Dex-IN or any other product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In the United States, the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own

reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or Affordable Care Act, among other things, imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also contains substantial provisions 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 the healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms, any of which could negatively impact our business. A significant number of provisions are not yet, or have only recently become effective, but the Affordable Care Act is likely to continue the downward pressure on pharmaceutical and medical device pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Risks Related to Our Commercial Manufacturing Business

Revenues from our 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 manufacturing business is currently dependent on our relationships with our commercial partners. We currently have five key commercial partners: Novartis Pharma AG (Ritalin LA®, Focalin XR®), Actavis (generic

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Verapamil), Kremers Urban Pharmaceuticals, Inc. (Verelan PM®), Pernix Therapeutics Holdings, Inc. (Zohydro ER®) and Paladin Labs Inc. (Kodessa/Zohydro ER®). 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 or otherwise significantly reduces their purchasing volume our revenues could be adversely affected. We also work with companies to develop and manufacture development stage products.

Manufacturing revenues 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 Gainesville, 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, which 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, 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 and pharmaceutical wholesalers to provide the raw materials needed for the manufacture of our commercial 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.

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.

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We and our third-party suppliers 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 manufacturing business, 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 manufacturing business 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 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 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 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. We expect some of our executive officers to spend a very small portion of their time engaged in the provision of services to other companies, including companies that are engaged in the development and commercialization of other pharmaceutical products. 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.

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We may need to significantly expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations and cause additional costs to us.

We currently use third parties, including MCG, to perform certain of our operational activities, and we expect to continue to do so for the foreseeable future. However, as our company matures, we may choose to expand our employee base to increase our managerial, scientific and engineering, operational, sales, marketing, financial and other resources and to hire more consultants and contractors. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. 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. Our possible growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize injectable meloxicam, Dex-IN, and our other product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Our President and Chief Executive Officer, Gerri A. Henwood, is also the majority shareholder of MCG, our landlord.

Our President and Chief Executive Officer, Ms. Henwood, owns a majority of the stock of MCG. Ms. Henwood continues to devote a very small portion of her time to MCG. Ms. Henwood provides services to, or on behalf of, MCG on an as needed basis. Although Ms. Henwood has no obligation to devote a specified amount of time to MCG, we expect that Ms. Henwood will devote up to 5% of her time to MCG.

We sublease our facilities from MCG. MCG also provides certain services, including administrative, regulatory and manufacturing services, to us that are important to our success and programs. We have a Sublease and a Consulting Services Agreement in effect with MCG that we believe is on arm s length terms. However, upon expiration or earlier termination (for breach or otherwise) of these agreements, there is no guarantee that MCG will continue to make the current space available to us and/or to perform the current services or that it will do so on terms that meet our needs.

MCG also provides services to third parties, including other companies that are developing and commercializing pharmaceutical products. Because Ms. Henwood has ownership of MCG and operational control of our company, she could be in a conflicted situation between us and MCG and, therefore, may not be able to advance our interests to the extent that they would be in conflict with those of MCG.

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 contract research organizations, or CROs, may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these employees could include intentional, reckless and/or negligent conduct or unauthorized activity that violates: (1) FDA or DEA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA; (2) manufacturing standards; (3) federal and state healthcare fraud and abuse laws and regulations; or (4) laws that require the true, complete and accurate reporting of financial information

or data. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. Any incidents or any other conduct that leads to an employee receiving an FDA debarment could result in a loss of business from our partners and severe reputational harm. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business, operating results and financial condition.

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

The use of our product candidates in clinical studies and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. In addition, our manufacturing business exposes us to potential toxic tort and other

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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 $10.0 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 have begun and will continue to 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.

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.

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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.

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, 2015, we own and license patents and patent applications directed to the sale, use, manufacturing and formulating of injectable meloxicam. The patent protection for injectable meloxicam could lead to protection of injectable meloxicam through 2030, subject to any extensions or disclaimers. As of December 31, 2015, we own three patents relating to Zohydro-ER®, which have expiration dates of November 1, 2019, November 1, 2019, 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, 2015, we are the owner of record of two issued U.S. patents related to Fado and four issued foreign patents to Dex. As of December 31, 2015, we are also the owner of record and are prosecuting four U.S. non-provisional patent applications and 52 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 will expire 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.

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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.

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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 Abbreviated New Drug Application, or 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 are currently involved in Paragraph IV litigations in the United States involving our patents in respect of Zohydro ER®. These litigations may be expensive, distracting to management and protracted and 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®. We intend to vigorously prosecute our application that is involved in this interference. 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.

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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.

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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 45.9% of our outstanding common stock as of December 31, 2015. As a result, these shareholders are collectively able to influence matters

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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 and we will remain an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, until the earliest to occur of (1) the last day of the fiscal year during which our total annual gross revenues equal or exceed $1 billion (subject to adjustment for inflation), (2) the last day of the fiscal year following the fifth anniversary of our IPO, (3) the date on which we have, during the previous three-year period, issued more than $1 billion in non-convertible debt, or (4) the date on which we are deemed a large accelerated filer under the Exchange Act.

For so long as we remain an emerging growth company we will not be required to:

have an auditor report on our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act;

comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor s report providing additional information about the audit and the financial statements (i.e., an auditor discussion and analysis);

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submit certain executive compensation matters to shareholder non-binding advisory votes;

submit for shareholder approval golden parachute payments not previously approved; and

disclose certain executive compensation related items such as the correlation between executive compensation and financial performance and comparisons of the Chief Executive Officer s compensation to median employee compensation, when such disclosure requirements are adopted.

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.

The sale of our common stock to Aspire Capital may cause substantial dilution to our existing shareholders and the sale of the shares of common stock acquired by Aspire Capital could cause the price of our common stock to decline.

On February 2, 2015, we entered into a Purchase Agreement with Aspire Capital, in which Aspire Capital is committed to purchase, at our election, up to an aggregate of $10.0 million shares of our common stock over the 24-month term of the Agreement.

During the first quarter of 2016, we sold 93,940 shares of our common stock under the Purchase Agreement for $560,000. We may ultimately sell all, some or none of the remaining $9.4 million of common stock to Aspire Capital, and Aspire Capital may sell all, some or none of our shares that it holds or comes to hold under the Purchase Agreement. Sales by Aspire Capital of shares acquired pursuant to the Purchase Agreement may result in dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock by

Aspire Capital, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of sales of our shares to Aspire Capital, and the Purchase Agreement may be terminated by us at any time at our discretion without any penalty or cost to us.

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 7,300 square feet of laboratory, office, warehouse and GMP packaging space. We have an office services agreement with Malvern Consulting Group, or MCG, a consulting company affiliated with our Chief Executive Officer, which includes the use of space as well as the use of certain equipment and access to certain administrative services (for example, telephones, copy machines, and kitchen facilities). We believe that this agreement is on arm s length terms and is adequate for our current needs. The agreement is on a quarter to quarter basis.

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We own and operate an 87,000 square foot, DEA-licensed manufacturing facility in Gainesville, Georgia that makes five commercial products and receives royalties associated with the sales of these products. The campus includes an additional 10,000 square feet, which is comprised of administrative space and certain utilities areas.

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® is subject to five 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, another two of which were filed in November 2015, 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.

Under our license agreement with Pernix, we have the right to control the enforcement of 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. We intend to vigorously enforce the intellectual property rights relating to Zohydro ER®, but we cannot predict the outcome of these matters or guarantee the outcome of any litigation or interference.

Item 4. Mine Safety Disclosures

Not applicable.

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PART II

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

Market Information

Our common stock has been traded on the NASDAQ Capital Market since March 12, 2014, under the symbol REPH. Prior to such time, there was no public market for our common stock. The following table sets forth the high and low sales price of our common stock, as reported by the NASDAQ Capital Market for the period indicated:

	High	Low
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
Year Ended December 31, 2014		
Fourth Quarter	$ 3.39	$ 2.36
Third Quarter	$ 8.10	$ 2.71
Second Quarter	$ 8.49	$ 5.01
First Quarter (beginning March 12, 2014)	$ 9.88	$ 7.00

Holders of Common Stock

As of March 21, 2016, there were 10 holders of record of our common stock.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock and do not anticipate paying any cash dividends in the foreseeable future. We expect to retain available cash to finance ongoing operations and the potential growth of our business. Any future determination to pay dividends on our common stock will be at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

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

Except as previously reported in our current reports of Form 8-K filed with the SEC on July 8, 2015, April 16, 2015, March 11, 2015 and February 3, 2015, and our quarterly report on Form 10-Q filed with the SEC on November 13, 2015, there were no unregistered sales of equity securities during the period.

Use of Proceeds

On March 6, 2014, our registration statement on Form S-1 (File No. 333-191879) was declared effective by the SEC for our IPO of common stock. Aegis Capital Corporation acted as the sole book-running manager and Brean Capital, LLC acted as co-manager for the offering. At the closing of the IPO on March 12, 2014, we sold 4,312,000 shares of common stock, which includes the full exercise of the underwriters over-allotment, at an IPO price of $8.00 per share and received gross proceeds of $34.5 million, which results in net proceeds to us of approximately $30.3 million after deducting underwriting discounts, commissions and related offering costs.

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As of December 31, 2015, we have used all of the net proceeds from the IPO for our injectable meloxicam and Dex Phase II clinical trials, manufacturing costs, short term preclinical studies, working capital and other general corporate purposes, a portion of which was paid to MCG, an affiliate of the Company.

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, 2015 and 2014 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, 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,			
	2015	2014	2013	2012
	(in thousands, except share and per share data)			
Consolidated Statements of Operations Data:				
Revenue:				
Manufacturing, royalty and profit sharing revenue	$ 49,284	$	$	$
Research and development revenue	2,668			
Total revenue	51,952			
Operating expenses:				
Cost of sales (excluding amortization of intangible assets)	28,054			
Research and development	12,281	7,874	544	542
General and administrative	13,017	3,998	546	339
Amortization of intangible assets	1,884			
Change in warrant valuation	(1,560)			
Change in contingent consideration valuation	5,246			
Total operating expenses	58,922	11,872	1,090	881
Operating loss	(6,970)	(11,872)	(1,090)	(881)
Other income (expense):				
Interest income	12	11		
Grant income				85
Interest expense	(5,560)	(4,273)	(868)	(740)
Loss before income taxes	(12,518)	(16,134)	(1,958)	(1,536)
Income tax benefit	15,551			
Net income (loss)	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	$ 3,033	$ (17,404)	$ (2,398)	$ (1,949)
Basic net income (loss) per common share	$ 0.36	$ (2.79)	$ (15.41)	$ (12.53)
Diluted net income (loss) per common share	$ 0.21	$ (2.79)	$ (15.41)	$ (12.53)
Weighted average basic common shares outstanding	8,491,025	6,238,581	155,600	155,600
Weighted average diluted common shares outstanding	8,749,234	6,238,581	155,600	155,600

	As of December 31,			
	2015	2014	2013	2012
	(in thousands)			
Consolidated Balance Sheet Data:				
Cash and cash equivalents	$ 19,779	$ 19,682	$ 13	$ 53
Working capital	29,189	18,928	(12,080)	(10,123)
Total assets	138,697	20,374	851	154
Debt	29,760			
Convertible notes payable			11,907	10,159
Series A redeemable convertible preferred stock			5,880	5,440
Total shareholders equity (deficit)	40,350	18,928	(17,960)	(15,562)

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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 revenue-generating, specialty pharmaceutical company focused on products for hospitals and ambulatory care settings, that is currently developing non-opioid products for treatment of serious acute pain. Our lead product candidate is a proprietary injectable form of meloxicam. Meloxicam is a long-acting preferential COX-2 inhibitor and the oral form of meloxicam has been marketed by Boehringer Ingelheim Pharmaceuticals, Inc. since the 1990s as Mobic®. Intravenous, or IV, meloxicam has successfully completed multiple Phase II clinical trials in the treatment of moderate to severe pain. We believe injectable 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. Based on feedback from the U.S. Food and Drug Administration, or FDA, we have initiated a Phase III program that includes two pivotal clinical trials, as well as other trials. We expect to enroll a total of approximately 1,100 patients in these trials. One pivotal clinical trial, which began dosing in January 2016, is designed to demonstrate pain relief over a 24-hour period in a soft tissue, post-operative pain model (abdominoplasty), and the other pivotal clinical trial, for which we announced first patient dosing in February 2016, is designed to demonstrate pain relief over a 48-hour period in a hard tissue, post-operative pain model (bunionectomy). Our pipeline also includes Dex-IN, a proprietary intranasal formulation of dexmedetomidine, or Dex, which successfully completed a Phase II clinical trial in post-operative pain. We recently met with the FDA to obtain feedback on the Phase II efficacy and safety data, and for our proposed DEX-IN clinical development program. Based on feedback from the FDA regarding DEX-IN s benefit-risk profile, specifically its efficacy and blood pressure effects, which was demonstrated in post-operative pain, and the subsequent requirements for a post-operative pain clinical program, we have determined not to pursue Dex-IN in post-operative pain due to time, cost and associated risk. We plan to pursue DEX-IN, as discussed with the FDA, in peri-procedural pain. Dex is a selective alpha-2 adrenergic agonist that has demonstrated analgesic properties in multiple studies. If approved, Dex-IN would also be the first and only approved peri-procedural pain drug in its class of drugs. As our product candidates are not in the opioid class of drugs, we believe they will overcome many of the issues associated with commonly prescribed opioid therapeutics, including addiction, misuse/diversion, respiratory distress and constipation while maintaining analgesic, or pain relieving, effect.

We currently own and operate an 87,000 square foot, DEA-licensed manufacturing facility that makes five commercial products and receives royalties associated with the sales of these products. We manufacture the following products for our commercial partners: Ritalin LA®, Focalin XR®, Verelan PM®, generic Verapamil and Zohydro ER®, as well as development stage products. The campus includes an additional 10,000 square feet, which is comprised of administrative space and certain utilities areas.

We have a limited operating history. We have funded our operations to date primarily from proceeds received from private placements of convertible preferred stock, convertible notes and common stock and our initial public offering of common stock, or IPO. On March 12, 2014, we announced the closing of the IPO of 4,312,500 shares of common stock, including the full exercise of the underwriters over-allotment, at a public offering price of $8.00 per share. Total gross proceeds from the IPO were $34.5 million before deducting underwriting discounts and commissions and other offering expenses payable by us resulting in net proceeds of $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 of $11.60

per share, for net proceeds of approximately $14.8 million. 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.

We have incurred losses from operations since inception. As of December 31, 2015, we had an accumulated deficit of $31.1 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 expect to incur increasing expenses over the next several years to develop injectable meloxicam and Dex, including a planned Phase III pivotal and safety trials for injectable meloxicam and Phase II dose-ranging trials for Dex-IN. Based upon additional financial resources, we may develop and commercialize our proprietary formulations of injectable meloxicam and Dex.

We expect that annual 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 our acquisition from Alkermes plc, or Alkermes, of certain assets, including the worldwide rights to injectable meloxicam and the contract manufacturing facility, royalty and formulation business in Gainesville, Georgia, now

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operating through our subsidiary, Recro Gainesville LLC, or Gainesville. We refer to the acquisition herein as the Gainesville Transaction. The Gainesville Transaction transformed our business through the addition of a revenue-generating business and increase in our workforce as a result of the addition of the Gainesville employees.

The consideration paid in connection with the Gainesville Transaction consisted of $50.0 million, 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 $120.0 million in milestone payments upon the achievement of certain regulatory and net sales milestones and royalties on 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 Royalty Opportunities II, LP, or 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 year ended December 31, 2015, we recognized revenues in four categories: manufacturing revenue, royalty, profit sharing and research and development revenue.

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 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.

Research and Development Expenses

Research and development expenses currently consist of costs incurred in connection with the development of injectable meloxicam and Dex in different delivery forms. These expenses consist primarily of:

expenses incurred under agreements with contact research organizations, or CROs, investigative sites and consultants that conduct our clinical trials and 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 activities and regulatory approvals; and

salaries and related costs for personnel in research and development functions.

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.

Since inception, we have developed and evaluated a series of Dex product candidates through Phase I and Phase II trials. IV meloxicam has been successfully evaluated in multiple Phase II clinical trials and, based on feedback from the FDA at the end of

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Phase II meeting, in January 2016, we initiated a Phase III program that includes two pivotal clinical trials, as well as other trials. Dex-IN completed a Phase II bunionectomy study in 2015, and, based on feedback from the FDA, we intend to pursue a program in peri-procedural pain for Dex-IN. The commitment of funding for each subsequent stage of our development programs is dependent upon, among other things, the receipt of successful clinical data.

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, including MCG, a related party, 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 United States Food and Drug Administration, or 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, 2015.

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 clinical trials, manufacturing scale-up and other pre-approval activities. We also expect to have expenses as we initiate the Dex-IN Phase II clinical trials in peri-procedural pain and related work, as well as for our 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 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.

Our general and administrative expenses in 2015 were higher than in 2014. We expect to continue to have greater expenses relating to our operations as a public company and our acquisition of Gainesville, including increased headcount and increased salary, consulting, legal and compliance, accounting, insurance and investor relations costs. We also expect that our patent costs will increase due to the acquisition of new patents 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.

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Amortization of Intangible Assets

We recognize amortization expense related to the intangible asset for our contract manufacturing relationships on a straight-line basis over an estimated useful life of six years. The intangible asset related to injectable meloxicam represents in-process research and development, or IPR&D, which is considered an indefinite-lived intangible asset that is assessed for impairment annually or more frequently if impairment indicators exist.

Change in Fair Value of Contingent Consideration

In connection with the acquisition of injectable meloxicam in the Gainesville Transaction, we are required to pay milestone payments on the achievement of certain regulatory and net sales milestones and royalties on future net product sales of between 10% and 12%. 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.

Interest Expense

Interest expense for the year ended December 31, 2015 was a result of interest expense incurred on our senior secured term loan with OrbiMed. The interest rate under the credit agreement with OrbiMed is equal to LIBOR plus 14.0%, with a 1.0% floor. Interest expense for the year ended December 31, 2014 related to our previously outstanding Bridge Notes. Upon the closing of the IPO, these Bridge Notes, including accrued interest, were converted into shares of common stock. Since the conversion price of our Bridge Notes allowed the note holders to convert at 75% of the initial offering price per share in the IPO, we recorded a non-cash interest charge of approximately $4.1 million upon the closing of the IPO in 2014.

Net Operating Losses and Tax Carryforwards

As of December 31, 2015, we had approximately $13.0 million of federal net operating loss carryforwards. We also had federal and state research and development tax credit carryforwards of $1.3 million available to offset future taxable income. U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. 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 and 2014 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.

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Results of Operations

Comparison of the Years Ended December 31, 2015 and 2014

	Year ended December 31,	
	2015	2014
	(amounts in thousands)	
Revenue:		
Manufacturing, royalty and profit sharing revenue	$ 49,284	$
Research and development revenue	2,668	
Total revenues	51,952	
Operating expenses:		
Cost of sales (excluding amortization of intangible assets)	28,054	
Research and development	12,281	7,874
General and administrative	13,017	3,998
Amortization of intangible assets	1,884	
Change in warrant valuation	(1,560)	
Change in contingent consideration valuation	5,246	
Total operating expenses	58,922	11,872
Other income (expense):		
Interest income (expense)	(5,548)	(4,262)
Loss before income taxes	(12,518)	(16,134)
Income tax benefit	15,551	
Net income (loss)	$ 3,033	$ (16,134)

Revenue and costs of sales. As a result of the Gainesville Transaction and our subsequent operation of the manufacturing business through Gainesville, revenue for the year ended December 31, 2015 increased to $52.0 million and cost of sales increased to $28.1 million.

Research and Development. Our research and development expenses were $12.3 million and $7.9 million for the years ended December 31, 2015 and 2014, respectively. The increase of $4.4 million and 56% from December 31, 2014 was primarily due to an increase of $4.7 million in our injectable meloxicam clinical expenses, $2.8 million in research and development costs incurred at our Gainesville facility, which are primarily related to process development, regulatory affairs and development analytical work and $0.8 million in personnel costs offset by a $3.8 million reduction of clinical trial, manufacturing and supply costs for the Dex Phase II clinical trial.

General and Administrative. Our general and administrative expenses were $13.0 million and $4.0 million for the years ended December 31, 2015 and 2014, respectively. This increase of $9.0 million and 226% from December 31, 2014 was due to $1.1 million in costs associated with the Gainesville transaction, an increase of $3.6 million in management s salaries to market compensation rates, benefits and stock-based compensation, which includes

severance costs and expenses related to modifying equity awards due to our chief financial officer s departure and $3.4 million in increased consulting and legal fees associated with being a public company and acquisition of our Gainesville facility.

Amortization of Intangible Assets. Amortization expense was $1.9 million for year ended December 31, 2015, exclusively related to the amortization of our royalties and contract manufacturing relationships intangible asset over its six year estimated useful life.

Interest Expense. Interest expense was $5.5 million during the year ended December 31, 2015, as a result of our interest expense incurred on our OrbiMed senior secured term loan and amortization of financing costs. The interest rate under the credit agreement with OrbiMed is equal to LIBOR plus 14.0%, with a 1.0% LIBOR floor. For the year ended December 31, 2014, interest expense of $0.2 million was recorded on our Bridge Notes. Since the conversion price of our Bridge Notes allowed the note holders to convert at 75% of the initial offering price per share in the IPO, we recorded a non-cash interest charge of approximately $4.1 million upon the closing of the IPO.

Income Tax Benefit. During 2015, in connection with an international corporate restructuring, management determined that it was more likely than not that we would realize our deferred tax assets associated with our U.S. operations. Accordingly, we have recorded a benefit of $15.6 million associated with the release of our prior year valuation allowance against deferred tax assets and recorded a benefit associated with our current year loss from U.S. operations.

Liquidity and Capital Resources

As of December 31, 2015 and 2014, we had $19.8 million and $19.7 million, respectively, in cash and cash equivalents. We expect that cash and cash equivalents, along with excess cashflow from the Gainesville manufacturing business not subject to prepayment under the terms of our credit facility with OrbiMed, will be sufficient to fund our current operations through March 31, 2017. On July 7, 2015, we closed a private placement of shares of our common stock in which we received net proceeds of $14.8

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million. Since inception through December 31, 2015, we have financed our product development, operations and capital expenditures primarily from the private placement, private sales of $4.0 million of our Series A Stock, $9.6 million of our Bridge Notes and $15 million of our common stock, as well as $30.3 million from the IPO. Revenues from the Gainesville manufacturing business are used to fund operations and capital expenditures at the Gainesville facility.

We will need to raise additional funds in order 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. If additional funds are required, we may raise such funds through public or private sales of equity or debt securities or from bank or other loans or through strategic research and development, licensing and/or marketing arrangements 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 February 2, 2015, we 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 our election, up to an aggregate of $10.0 million of shares of our common stock over the 24-month term of the Purchase Agreement. The shares may be sold by us to Aspire Capital on any business day we select in two ways: (1) through a regular purchase of up to 50,000 shares at a known price based on the market price of our common stock prior to the time of each sale, and (2) through a purchase at a volume weighted average price, or VWAP, of a number of shares up to 30% of the volume traded on the purchase date at a price equal to the lessor of the closing sale price or 95% of the VWAP for such purchase date. During the first quarter of 2016, we sold 93,940 shares to Aspire Capital under the Purchase Agreement for proceeds of $560,000.

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 (as defined in the credit agreement); and (ii) after the 36 month anniversary of the closing of the credit agreement, payment of an Exit Fee Amount (as defined in the credit agreement). In the event that there shall be Excess Cash Flow (as defined in the credit agreement) for any fiscal quarter, OrbiMed has the option to require us to prepay the unpaid principal amount of the loan in an aggregate principal amount equal to the Excess Cash Flow, or any lesser amount requested by OrbiMed, provided that no payments under this option shall be subject to the premiums or exit fees due. The interest rate under the credit agreement is a rate per annum equal to 14.0% plus the greater of: (i) the LIBO Rate (as defined in the credit agreement) and (ii) 1.0%. In addition, the credit agreement 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. As of December 31, 2015, we paid $16.3 million of the outstanding principal on our senior secured term loan from free cash flow generated during the second and third quarters of 2015 by Gainesville. In February 2016, we

paid an additional $2.6 million of the outstanding principal on our senior secured term loan from free cash flow generated during the fourth quarter of 2015 by Gainesville.

Sources and Uses of Cash

Cash provided by operations was $8.5 million for the year ended December 31, 2015 and $10.9 million used in operations for the year ended 2014 which represents our operating losses less our stock-based compensation, depreciation, non-cash interest expense, changes in fair value of warrants and contingent consideration, amortization of intangibles and beneficial conversion charge taken on our Bridge Notes upon the conversion of such Bridge Notes, including accrued interest, into common stock.

Cash used in investing activities was $55.1 million for year ended December 31, 2015, as a result of the Gainesville Transaction and purchase of property and equipment at the plant in Gainesville.

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. Cash provided by financing activities was $30.5 million for the year ended December 31, 2014 as a result of successfully raising net proceeds of $30.3 million from the IPO and the issuance of $0.2 million of Bridge Notes.

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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 a New Drug Application, or NDA, for injectable meloxicam and Dex-IN;
- the timing and outcome of the FDA s review of an NDA for injectable meloxicam and Dex-IN if our trials are successful;
- the extent to which the FDA may require us to perform additional preclinical studies, clinical trials or pre-commercial manufacturing of injectable meloxicam and Dex-IN;
- 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;
- 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 current Good Manufacturing Practice, or 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, 2015. 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 investigational new drug application, or IND, or an NDA) are successfully accomplished, as well meeting certain sales thresholds.

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. If this happens, we would expect to be paid:

- an up-front payment made at or shortly after signing a partnering agreement;
- royalties as a percentage of net sales of the product;
- milestone payments that may be made on completion of a phase of a clinical program, or regulatory approval in a given territory; and
- a payment or payments made upon achievement of a certain level of sales in a given year.

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Alkermes

Pursuant to the purchase and sale agreement governing the Gainesville Transaction, we agreed to pay to Alkermes up to $120 million in milestone payments upon the achievement of certain regulatory and net sales milestones related to injectable meloxicam and royalties on future product sales of injectable meloxicam between 10% and 12%.

In July 2015, we also entered into a Development, Manufacturing and Supply Agreement, or Supply Agreement, with Alkermes (through a subsidiary of Alkermes), pursuant to which Alkermes 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 a 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. We have elected to have Alkermes supply our initial commercial requirements of bulk injectable meloxicam formulation. During the term of the Supply Agreement, we will purchase our clinical and commercial supplies of bulk injectable meloxicam formulation exclusively from Alkermes for a period of time.

Orion

In August 2008, we entered into a License Agreement with Orion for non-injectable Dex. Under the Dexmedetomidine License Agreement, we were granted an exclusive license under Orion Know-How and Cygnus/Farmos Patent to commercialize products in the Territory, and to use, research, develop and have made products worldwide solely for purposes of commercialization. We also entered into a Supply Agreement with Orion pursuant to which Orion will supply us with development quantities of Dex at no cost. Upon receipt of regulatory approval, Orion will supply commercial quantities of bulk active pharmaceutical ingredient Dex for commercialization.

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

There are milestone payments and royalty rates associated with both the Dex and Fado programs. Through December 31, 2015, no milestones have been achieved.

Leases

We lease our Malvern facility space under an operating lease on a month-to-month basis with MCG, a related party. Our Gainesville facility leases space for additional equipment and documentation storage.

Capital Expenditures and Materials

As of December 31, 2015, we had $4.0 million of non-cancellable commitments at the Gainesville facility for capital expenditures and material and services.

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. In the event that there shall be Excess Cash Flow (as defined in the credit agreement) for any fiscal quarter, OrbiMed has the option to require us to prepay the unpaid principal amount of the loan in an aggregate principal amount equal to the Excess Cash Flow, or any lesser amount requested by OrbiMed. As of December 31, 2015, we paid $16.3 million of the outstanding principal on our senior secured term loan from free cash flow generated during the second and third quarters of 2015 by Gainesville. In February 2016, we paid an additional $2.6 million of the outstanding principal on our senior secured term loan from free cash flow generated during the fourth quarter of 2015 by Gainesville.

Off-Balance Sheet Arrangements

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

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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 As a result of the Gainesville Transaction, 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 As a result of the Gainesville Transaction, we will be 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 Gainesville, 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, 2015 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 manufacturing, packaging 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.

Manufacturing and packaging service 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, our customer agreements have royalties and/or profit sharing payments, computed on the net product sales of our 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.

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.

Based on available objective evidence at December 31, 2015, we reversed the valuation allowance recorded against all of our prior year deferred tax assets in the United States, resulting in a tax benefit of $11.1 million. Management determined that a valuation allowance was no longer needed on these deferred tax assets based on an assessment of the relative impact of all positive and negative evidence that existed at December 31, 2015, including our international corporate restructuring, forecast of future sources of taxable income exclusive of reversing temporary differences, and significant risks and uncertainties related to our business. 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, 2015, we had approximately $15.3 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, 2015, 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.

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.

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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 accounting officer (performing the functions of a 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, 2015. 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 Securities and Exchange Commission s, or 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, 2015, our principal executive officer and principal accounting 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, 2015. 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, 2015, 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.

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Item 9B. Other Information

None.

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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 2016 Annual Meeting of Shareholders (the Proxy Statement) under the headings Proposal No. 1 Election of Class II Directors, Executive Officers, Section 16(a) Beneficial Ownership Reporting Compliance, and Governance of the Company 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 Executive 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 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	1,909,194	$ 7.29	830,821
Equity compensation plans not approved by security holders	133,000(2)	$ 10.83	(3)
Total	2,042,194	$ 7.00	830,821

(1) Represents the weighted-average exercise price of outstanding stock options and does not include restricted stock units.
(2) 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.
(3) 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 Voting Stock Ownership of Directors, Named Executive Officers and Certain Beneficial Owners and Executive 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 Governance of the Company 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 Proposal No. 2 Ratification of Independent Registered Public Accounting Firm for the 2016 Fiscal Year, 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.

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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, 2015 and 2014

Consolidated Statements of Operations for the years ended December 31, 2015 and 2014

Consolidated Statements of Redeemable Convertible Preferred Stock and Shareholders Equity (Deficit) for the years ended December 31, 2015 and 2014

Consolidated Statements of Cash Flows for the years ended December 31, 2015 and 2014

(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

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RECRO PHARMA, INC. AND SUBSIDIARIES

Index to Consolidated Financial Statements

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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, 2015 and 2014, and the related consolidated statements of operations, redeemable convertible preferred stock and shareholders equity (deficit), 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 misstatements. 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, 2015 and 2014, 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 24, 2016

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RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

(amounts in thousands, except share and per share data)	December 31, 2015	2014
Assets		
Current assets:		
Cash and cash equivalents	$ 19,779	$ 19,682
Accounts receivable	8,580	
Other receivables	36	90
Inventory	8,982	
Prepaid expenses	757	602
Deferred equity costs	542	
Total current assets	38,676	20,374
Property, plant and equipment, net	37,922	
Deferred income taxes	15,637	
Intangible assets, net	40,016	
Goodwill	6,446	
Total assets	$ 138,697	$ 20,374
Liabilities and Shareholders Equity		
Current liabilities:		
Accounts payable	$ 1,553	$ 870
Accrued expenses	3,418	576
Current portion of long-term debt	4,516	
Total current liabilities	9,487	1,446
Long-term debt	25,244	
Warrants	3,770	
Contingent consideration	59,846	
Total liabilities	98,347	1,446
Commitments and Contingencies (Note 12)		
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, 9,224,315 shares at December 31, 2015 and 7,707,600 shares at December 31, 2014	92	77
Additional paid-in capital	71,321	52,947
Accumulated deficit	(31,063)	(34,096)
Total shareholders equity	40,350	18,928

Total liabilities and shareholders equity	$ 138,697	$ 20,374

See accompanying notes to consolidated financial statements.

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RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Operations

(amounts in thousands, except share and per share data)	Year ended December 31, 2015	2014
Revenue:		
Manufacturing, royalty and profit sharing revenue	$ 49,284	$
Research and development revenue	2,668	
Total revenues	51,952	
Operating expenses:		
Cost of sales (excluding amortization of intangible assets)	28,054	
Research and development	12,281	7,874
General and administrative	13,017	3,998
Amortization of intangible assets	1,884	
Change in warrant valuation	(1,560)	
Change in contingent consideration valuation	5,246	
Total operating expenses	58,922	11,872
Operating loss	(6,970)	(11,872)
Other income (expense):		
Interest income	12	11
Interest expense	(5,560)	(4,273)
Loss before income taxes	(12,518)	(16,134)
Income tax benefit	15,551	
Net income (loss)	3,033	(16,134)
Accretion of redeemable convertible preferred stock		(1,270)
Net income (loss) applicable to common shareholders	$ 3,033	$ (17,404)
Basic net income (loss) per common share	$ 0.36	$ (2.79)
Diluted net income (loss) per common share	$ 0.21	$ (2.79)
Weighted average basic common shares outstanding	8,491,025	6,238,581
Weighted average diluted common shares outstanding	8,749,234	6,238,581

See accompanying notes to consolidated financial statements.

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RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Redeemable Convertible Preferred Stock and Shareholders Equity (Deficit)

For the Years Ended December 31, 2015 and 2014

(amounts in thousands, except share data)	Series A Redeemable Convertible Preferred Stock		Shareholders Equity (Deficit)				
			Common Stock		Additional paid in		
	Shares	Amount	Shares	Amount	capital	Accumulated Deficit	Total
Balance, December 31, 2013	2,000,000	$ 5,880	155,600	$ 2	$	$ (17,962)	$ (17,960)
Accretion of Series A redeemable convertible preferred stock to redemption value		89			(89)		(89)
Deemed dividend on Series A		1,181			(1,181)		(1,181)
Sale of common stock in initial public offering, net of offering costs of $4,243,658			4,312,500	43	30,213		30,256
Stock-based compensation expense					531		531
Conversion of Series A and accrued dividends to common stock	(2,000,000)	(7,150)	1,193,762	12	7,138		7,150
Conversion of notes payable and accrued interest to common stock			2,045,738	20	12,254		12,274
Beneficial conversion upon conversion of notes payable (Note 10)					4,081		4,081
Net loss						(16,134)	(16,134)
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
			2,941				

Cashless warrant exercises						
Net income					3,033	3,033
Balance, December 31, 2015	$	9,224,315	$ 92	$ 71,321	$ (31,063)	$ 40,350

See accompanying notes to consolidated financial statements.

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RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

(amounts in thousands)	Year ended December 31, 2015	2014
Cash flows from operating activities:		
Net income (loss)	$ 3,033	$ (16,134)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Stock-based compensation	3,064	531
Non-cash interest expense	668	4,273
Depreciation expense	4,120	
Amortization	1,884	
Change in warrant valuation	(1,560)	
Change in contingent consideration valuation	5,246	
Deferred income taxes	(15,637)	
Changes in operating assets and liabilities, net of effect of acquisition:		
Inventory	1,271	
Prepaid expenses	225	(587)
Accounts receivable and other receivables	3,992	(51)
Accounts payable and accrued expenses	2,152	1,101
Net cash provided by (used in) operating activities	8,458	(10,867)
Cash flows from investing activities:		
Acquisition of Gainesville, net of cash acquired	(52,690)	
Purchase of property and equipment	(2,411)	
Net cash used in investing activities	(55,101)	
Cash flows from financing activities:		
Proceeds from initial public offering		30,361
Proceeds from private placement, net of offering costs	14,812	
Proceeds from long-term debt	50,000	175
Payment on long-term debt	(16,329)	
Payment of debt issuance costs	(1,718)	
Payment of deferred equity costs	(253)	
Proceeds from option exercise	228	
Net cash provided by financing activities	46,740	30,536
Net increase in cash and cash equivalents	97	19,669
Cash and cash equivalents, beginning of year	19,682	13
Cash and cash equivalents, end of year	$ 19,779	$ 19,682

Supplemental disclosure of cash flow information:				
Common stock issued in connection with equity facility	$	285	$	
Conversion of notes payable and accrued interest into common stock	$		$	1,270
Conversion of Series A and accrued dividends into common stock	$		$	7,150
Cash paid for interest	$	4,892	$	
Purchase of property, plant and equipment included in accrued expenses	$	208	$	

See accompanying notes to consolidated financial statements.

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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 (inception). The Company is a revenue-generating, specialty pharmaceutical company currently developing non-opioid products for treatment of serious acute pain which may be useful in hospital and ambulatory surgery centers. 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 operating through the Company s subsidiary, Recro Gainesville, LLC or Gainesville. The acquisition is referred to herein as the Gainesville Transaction. Gainesville develops and manufactures innovative pharmaceutical products that deliver clinically meaningful benefits to patients, using its proprietary delivery technologies for pharmaceutical companies who commercialize or plan to commercialize these products.

(2) Development-Stage Risks and Liquidity

The Company has incurred losses from operations since inception and has an accumulated deficit of $31,063 as of December 31, 2015. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its products currently in development. Management believes that cash and cash equivalents will be sufficient to fund the Company s current operations through March 31, 2017. Substantial additional financing will be needed by the Company to fund its operations and to commercially develop its product candidates.

The Company s future operations are highly dependent on a combination of factors, including (i) the timely and successful completion of additional financing discussed above; (ii) the Company s ability to complete revenue-generating partnerships with pharmaceutical companies; (iii) the success of its research and development; (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.

(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.

(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, 2015 and 2014 consisted of money market mutual funds and government and agency bonds.

(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. Also included in inventory are raw materials used in the production of clinical products, which will be charged to research and development expense when consumed.

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RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

(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: four 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.

The Company performs its annual goodwill impairment test as of November 30th. As a result of the impairment test, the Company determined that there was no impairment to goodwill for the year ended December 31, 2015.

Intangible assets include the Company s royalties and contract manufacturing relationships intangible asset as well as an in-process research and development (IPR&D) asset. The royalties and contract manufacturing relationships intangible asset is considered a definite-lived intangible asset and are 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.

(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.

Manufacturing and packaging service 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.

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RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

(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, 2015 and these five customers represent approximately 95.4% of the Company s 2015 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 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 in-process research and development 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.

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, if applicable, on all tax exposures for which reserves have been established. Interest and 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.

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RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

(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 2014, the outstanding stock options and warrants have been excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive.

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as of December 31, 2015 and 2014, as they would be anti-dilutive:

	December 31,	
	2015	**2014**
Options and restricted stock units outstanding	1,153,950	1,033,300
Warrants	490,000	150,000

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

	2015	**2014**
Basic Earnings Per Share		
Net income (loss)	$ 3,033	$ (17,404)
Common stock outstanding (weighted average)	8,491,025	6,238,581
Basic net income (loss) per share	$ 0.36	$ (2.79)
Diluted Earnings Per Share		
Net income (loss)	$ 3,033	$ (17,404)
Add change in warrant valuation	(1,174)	
Diluted net income (loss)	$ 1,859	$ (17,404)
Common stock outstanding (weighted average)	8,491,025	6,238,581
Add shares from outstanding warrants and stock options	258,209	
Common stock equivalents	8,749,234	6,238,581
Diluted net income (loss) per share	$ 0.21	$ (2.79)

(n) Recent Accounting Pronouncements

In November 2015, the Financial Accounting Standards Board, or 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 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 (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 April 2015, the FASB issued updated guidance on the presentation requirements for debt issuance costs and debt discount and premium. The update requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the updated guidance. The updated guidance is effective for annual and interim periods beginning after December 15, 2015 and early adoption is permitted for financial statements that have not been previously issued. The Company adopted this guidance during the year ended December 31, 2015.

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 Company is currently evaluating the effect that this guidance may have on its consolidated financial statements.

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RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

(4) Acquisition of Gainesville 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 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 $120.0 million in milestone payments upon the achievement of certain regulatory and net sales milestones and royalties on 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 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 is a preliminary estimate of the purchase price 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 new drug application (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 Gainesville results of operations have been included in the consolidated statement of operations beginning April 10, 2015.

The following is a preliminary estimate of the assets acquired and the liabilities assumed in connection with the Gainesville Transaction, reconciled to the estimated 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

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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 in-process research and development 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 years ended December 31, 2015 and 2014 (assuming the closing of the Gainesville Transaction had occurred on January 1, 2014) are as follows:

	2015	2014
Revenue	$ 71,684	$ 40,866
Net income (loss)	6,016	(3,440)

(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)

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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, 2014:			
Assets:			
Money market mutual funds	$ 10,922	$	$
Government and agency bonds	8,663		
Cash equivalents	$ 19,585	$	$
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

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, 2014	$	$
Additions	5,330	54,600
Remeasurement	(1,560)	5,246
Balance at December 31, 2015	$ 3,770	$ 59,846

(6) Inventory

Inventory consists of the following:

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

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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, 2015
Land	$ 3,263
Building and improvements	16,367
Furniture, office and computer equipment	2,888
Vehicles	30
Manufacturing equipment	19,504
	42,052
Less: accumulated depreciation and amortization	4,130
Property, plant and equipment, net	$ 37,922

Depreciation expense for the year ended December 31, 2015 was $ 4,120.

(8) Intangible Assets

The following represents the balance of the intangible assets at December 31, 2015:

	Cost	Accumulated Amortization	Net Intangible Assets
Royalties and contract manufacturing relationships:	$ 15,500	$ 1,884	$ 13,616
In-process research and development	26,400		26,400
Total	$ 41,900	$ 1,884	$ 40,016

Amortization expense for the year ended December 31, 2015 was $1,884. The amortization expense for the next five years will be $2,583 per year.

(9) Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2015	2014
Clinical trial and related costs	$ 1,364	$ 112
Professional and consulting fees	863	394
Payroll and related costs	697	25
Income tax payable	86	
Other	408	45
	$ 3,418	$ 576

(10) Convertible Notes Payable

Upon the closing of the Company s initial public offering, or IPO, on March 12, 2014, $9,576 of 8% Convertible Promissory Notes, or Bridge Notes, outstanding plus $2,699 of accrued interest were converted into 2,045,738 shares of common stock. After the IPO, there are no Bridge Notes outstanding.

The Bridge Notes, including accrued interest, were converted upon consummation of the IPO at seventy-five percent (75%) of the initial offering price per share. The Company determined that the Bridge Notes contained a contingent beneficial conversion feature, or contingent BCF. The contingent BCF existed at the date of issuance of the Bridge Notes, which allowed the holders to purchase equity at a 25% discount to the offering price. In accordance with the accounting guidance on convertible instruments, the contingent BCF of $4,081 was recognized as additional interest expense when the Bridge Notes, including accrued interest, were converted into shares of common stock.

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RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

(11) 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, which carries interest at 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, 2015, 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 $3,911 as of December 31, 2015. As of December 31, 2015, the long-term debt balance is comprised of the following:

Principal balance outstanding	$ 33,671
Unamortized deferred issuance costs	(3,911)
	$ 29,760
Current portion	(4,516)
	$ 25,244

The credit agreement contains a provision that allows OrbiMed, at its option, the right to require the Company to prepay the principal balance outstanding under the loan based on quarterly Excess Cash Flows, of Gainesville, as defined in the credit agreement. The Company has estimated the amount of the Excess Cash Flow payments that could be payable within one year of December 31, 2015 upon request of OrbiMed and has classified that amount as a current debt in the accompanying consolidated balance sheet.

(12) 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 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 ($22.4 million as of December 31, 2015) 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 2015 or 2014.

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 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.

The Company will pay up to an additional 12,200 ($13.3 million as of December 31, 2015) 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 2015 or 2014.

As of December 31, 2015, the Company had $3,950 of non-cancellable commitments at the Gainesville facility for capital expenditures and material and services.

(b) Litigation

The Company is involved, from time to time, in various claims and legal proceedings arising in the ordinary course of its business. 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, 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® is subject to five 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, another two of which were filed in November 2015, 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.

Under our license agreement with Pernix, we have the right to control the enforcement of 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. We intend to vigorously enforce the intellectual property rights relating to Zohydro ER®, but we cannot predict the outcome of these matters or guarantee the outcome of any litigation or interference.

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RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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(13) 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.

(b) 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, 2015, no preferred stock was issued or outstanding.

(c) Series A Redeemable Convertible Preferred Stock

The Company previously had outstanding 2,000,000 shares of Series A Stock. Each share of Series A Stock was automatically converted into 0.4 shares of common stock upon closing of the Company s IPO. The holders of Series A Stock were entitled to receive cumulative dividends of 8%, compounded annually. Upon conversion of the Series A Stock into common stock, cumulative undeclared dividends were convertible into a number of shares of common stock equal to the total amount of cumulative dividends divided by $2.00 (the Series A Stock issuance price) multiplied by 0.4 (the Series A Stock conversion ratio). Based on the IPO price of $8.00 per share of common stock, the Company recorded a non-cash deemed dividend of $1,181 upon closing of the IPO which represents the fair value of the common stock issued for such dividends in excess of the amounts previously recognized as accretion on the Series A Stock.

(d) Warrants

As of December 31, 2015, 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.

(e) 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 the first quarter of 2016, the Company sold 93,940 shares of common stock under the Purchase Agreement for $560.

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

(14) 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, 2015, 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 which increased the aggregate amount of shares available for issuance to 2,000,000. In December 2015, per the Evergreen provision of the plan, shares were increased by 461,215 which represents 5% of outstanding common stock. The total number of options in the 2013 plan as of December 31, 2015 is 2,461,215.

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, 2015, 963,647 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, 2015 and 2014 was $8.10 and $3.55, 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:

	2015	2014
Range of expected option life	6-7 years	6 years
Expected volatility	77.39%	80.30%
Risk-free interest rate	2.06-2.51%	2.14-2.73%
Expected dividend yield		

The following table summarizes stock option activity during the year ended December 31, 2015:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life
Balance, December 31, 2013	334,800	$ 6.00	
Granted	698,500	5.66	
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	7.8 years
Vested	862,754	$	5.55	5.7 years
Vested and expected to vest	2,017,769	$	6.82	7.8 years

In December 2015, the Company granted 105,300 performance-based stock options and 32,200 performance-based restricted stock units, or RSUs, which are based on attaining clinical and operational goals during 2016. The RSUs are excluded from the table above.

Included in the table above are 133,000 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).

Stock-based compensation expense for the years ended December 31, 2015 and 2014 was $3,064 and $531, respectively.

As of December 31, 2015, there was $8,279 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 3.4 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, 2015, the aggregate intrinsic value of the vested and unvested options was $3,084 and $2,032, respectively.

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(15) Income Taxes

The components of loss before income taxes are as follows:

	Year ended December 31,	
	2015	**2014**
Domestic	$ (10,002)	$ (16,134)
Foreign	(2,516)	
Loss before income taxes	$ (12,518)	$ (16,134)

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

	Year ended December 31,	
	2015	**2014**
Current:		
Federal	$ 83	$
State and local	3	
Foreign		
	86	
Deferred:		
Federal	$ (13,418)	
State and local	(2,219)	
Foreign		
	(15,637)	
	$ (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,	
	2015	2014
U.S. federal statutory income tax rate	34.0%	34.0%
Foreign tax rate differential	(4.3)%	%
State taxes, net of federal benefit	2.6%	6.6%
Nondeductible expenses	4.2%	(10.8)%
Research and development credits	1.7%	2.3%
Change in valuation allowance	86.1%	(32.1)%
Effective income tax rate	124.3%	%

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

	December 31,	
	2015	2014
Net operating loss carryforwards	$ 5,754	$ 6,800
Research and development credits	1,343	729
Capitalized start-up costs	2,590	2,626
Intangibles	597	658
Contingent consideration	1,932	
Stock-based compensation	1,256	265
Other temporary differences	2,480	9
Gross deferred tax asset	15,952	11,087
Valuation allowance	(315)	(11,087)
Net deferred tax asset	$ 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. As such, there is a full valuation allowance against the net deferred tax assets associated with foreign operations as of December 31, 2015.