Recro Pharma, Inc.
Form 10-K
March 25, 2015
**Table of Contents**

**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, 2014**

¨ **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 $33,400,191.

As of March 18, 2015, there were 7,804,063 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 2015 annual meeting of shareholders to be filed no later than 120 days after the end of the registrant s fiscal year ended December 31, 2014.

Table of Contents

## TABLE OF CONTENTS

### Index

Table of Contents

## FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, patent applications and approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future financings and operations, our ongoing and planned development of Dex and other drug candidates, our ongoing and planned preclinical studies and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, expectations regarding clinical trial data, and future results of current and anticipated products are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

When used herein, the words anticipate, believe, estimate, upcoming, plan, target , intend and expect an expressions, as they relate to us or our management, are intended to identify such forward-looking statements. These forward-looking statements are based on information available to us as of the date of this Annual Report on Form 10-K and are subject to a number of risks, uncertainties, and other factors that could cause our actual results, performance, prospects, and opportunities to differ materially from those expressed in, or implied by, these forward-looking statements. We assume no obligation to update any such forward-looking statements.

As set forth under the section Risk Factors, some of the factors that we believe could cause actual results to differ from those anticipated or predicted include:

- the results and timing of the clinical trials of Dex-IN 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;

our ability to successfully implement our strategy;

our ability to close and integrate our pending acquisition of certain assets of Alkermes plc; and

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

New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Table of Contents

# PART I

## Item 1. Business

### Overview

We are a clinical stage specialty pharmaceutical company developing non-opioid therapeutics for the treatment of pain, initially for acute pain following surgery. Our lead product, an intranasal formulation of Dexmedetomidine, or Dex, has completed a placebo controlled trial demonstrating effective pain relief in chronic lower back pain patients. We have studied various dosage forms of Dex in nine completed clinical trials. Dex-IN, our proprietary intranasal formulation, is currently being studied in a Phase II clinical trial for acute pain following surgery. Dex, which is in a class of drugs called alpha-2 adrenergic agonists, is a Food and Drug Administration, or 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®. As Dex is not in the opioid class of drugs, we believe it will overcome many of the side effects associated with commonly prescribed opioid therapeutics, including addiction, constipation and respiratory distress while maintaining analgesic, or pain relieving, effect. We are pursuing a Section 505(b)(2) regulatory strategy for Dex-IN, which allows us to leverage the existing safety data from the new drug application, or NDA of Precedex® and Dexdor®. Following approval by the FDA for use in acute pain following surgery, we may elect to pursue an additional approval for cancer breakthrough pain.

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. We believe Fado also shows promise in neuropathic pain.

Upon regulatory approval, our license with Orion and our ownership rights with respect to dosage forms for Dex-IN and Dex-SL will provide us with worldwide commercial rights related to Dex, except in Europe, Turkey and the Commonwealth of Independent States, or CIS, 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, referred to as the Licensed Dosage Forms, but specifically excluding delivery vehicles for an administration by injection or infusion. Similarly, upon regulatory approval, our license with Orion and our ownership rights with respect to dosage forms for Fado will provide us with worldwide commercial rights related to Fado, except in Europe, Turkey and the CIS, for all indications in humans.

In summary, our product candidates for pain indications include:

- Dex-IN, a product candidate initially in development for the treatment of post-operative pain and for the treatment of cancer breakthrough pain, the next anticipated program after acute pain following surgery;
- Dex-SL, a product candidate we expect to develop for the treatment of chronic pain; and
- Fado, a product candidate used by injection into the spine for pain associated with surgery or certain types of chronic pain and which we intend to pursue as a topical product for local application to treat serious pain

associated with nerve damage to local tissues (neuropathies), especially of the lower extremities, which can occur in diabetic patients.

Table of Contents

**Pipeline**

**Pending Acquisition of Assets from Alkermes plc**

On March 7, 2015, we entered into a definitive agreement, or the Definitive Agreement, under which we will acquire assets from Alkermes plc, or Alkermes, including worldwide rights to IV/IM meloxicam, a proprietary, Phase III-ready, long-acting COX-2 NSAID for moderate to severe acute pain, as well as a contract manufacturing facility, royalty and formulation business in Gainesville, Georgia.

IV/IM meloxicam was designed using Alkermes NanoCrystal® platform, a technology that enables enhanced bioavailability of poorly water-soluble drug compounds. IV meloxicam has been administered in over 550 subjects in five studies and was well tolerated in doses up to 60mg. These studies demonstrated a consistent pharmacokinetic profile that resulted in analgesic efficacy for up to 24 hours. In the Phase II post-operative hysterectomy and dental pain studies, IV meloxicam provided highly statistically significant and clinically meaningful differences in multiple measurements of pain management, including a reduction in pain intensity, a reduction in time to pain relief and a reduction in the use of rescue medication.

The manufacturing facility to be acquired in Gainesville includes the manufacturing rights to Ritalin LA, Focalin XR, Verelan and Zohydro ER. The facility is DEA-licensed with approximately 87,000 sq. ft. and approximately 165 employees. Unaudited, carve-out revenues and earnings before interest, taxes, depreciation and amortization for the acquired assets were approximately $73.6 million and $26.5 million in 2014, respectively.

Under the terms of the agreement, we will pay Alkermes $50.0 million at closing and acquire the rights to IV/IM meloxicam and ownership of a current good manufacturing practice, or cGMP, manufacturing facility and related business located in Gainesville. Alkermes is entitled to receive 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, in each case, related to IV/IM meloxicam.

At closing, we will issue to Alkermes a seven-year warrant to purchase an aggregate of 350,000 shares of our common stock at an exercise price of two times the closing price. The $50.0 million up-front payment will be funded via a five-year senior secured term loan with an affiliate of OrbiMed, or OrbiMed, which carries interest at LIBOR plus 14.0%, with a 1.0% LIBOR floor. The acquisition is subject to customary closing conditions, including antitrust regulatory approval, and is anticipated to close in the second quarter of 2015.

Table of Contents

**Background**

We were incorporated in 2007 with the intention of pursuing products for non-opioid treatment of serious pain. Prior to the first round of financing by SCP Vitalife Partners II, L.P. and SCP Vitalife Partners (Israel) II, L.P., or SCP Vitalife, in late 2008, our company was funded by Gerri Henwood, our President and Chief Executive Officer. From late 2007 to 2008, Ms. Henwood pursued a license from Orion for Dex in multiple formulations for use associated with pain conditions. Our company initially targeted Dex because of Ms. Henwood s previous involvement with Abbott and Orion in the development of Dex for sedation of intensive care patients. Abbott subsequently spun-off Hospira, its Hospital Products Division, which included Abbott s rights to Dex. Dex had other attributes that we believed would be useful for managing serious pain as a non-opioid at substantially lower doses than those used to sedate patients on ventilators. We pursued discussions with Orion in the United States and Finland, which resulted in a definitive agreement between us and Orion.

Following the acquisition of the Dex license agreement, our company sought funding to allow initial drug product formulation for the sublingual dosage form, which was followed by clinical trials of the formulation for pain relief. Although Dex-SL proved effective for pain relief, our company decided to pursue a dose form with a faster onset for the first desired indication of post-operative pain and later for use in cancer breakthrough pain. Further investigations demonstrated that Dex-IN had a faster onset than Dex-SL, and our company proceeded to research the formulation and delivery methods of Dex-IN through clinical trials. We believe our studies support our development of Dex-IN for non-opioid treatment of post-operative pain.

**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 Drug Enforcement Administration, or 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 the Centers for Disease Control, or CDC, overdose deaths from prescription painkillers (defined by the CDC to mean opioid or narcotic pain relievers, including drugs such as Vicodin (hydrocodone), OxyContin (oxycodone), Opana (oxymorphone), and methadone) has increased significantly over the past 10 years. It notes the following trends:

Prescription painkiller overdoses killed nearly 15,000 people in the United States in 2008. This is more than 3 times the 4,000 people killed by these drugs in 1999.

In 2010, about 12 million Americans (age 12 or older) reported nonmedical use of prescription painkillers in the past year.

Nearly half a million emergency department visits in 2009 were due to people misusing or abusing prescription painkillers.

Nonmedical use of prescription painkillers costs health insurers up to $72.5 billion annually in direct health care costs.

We believe that Dex 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 issues associated with opioids.

Table of Contents

**Cancer Breakthrough Pain Market Overview**

In addition to post-operative 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.). In 2010, the combined sales for these fast acting opioids reached $519 million per IMS Health. However, because these therapeutics are opioids, they raise the same concerns discussed above. The acute nature of cancer breakthrough pain fits well with our first indication of post-operative pain which is typically acute in nature. Therefore, if Dex-IN demonstrates pain relief in the post-operative setting, we believe this pain relief will translate to cancer breakthrough pain. Following approval of our post-operative pain NDA, we expect to pursue further development regarding this indication.

**Dex Advantages over Opioids**

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 pain management program. We are initially developing Dex-IN for post-operative pain following orthopedic and intra-abdominal surgeries. By evaluating Dex-IN in these trials, we believe that we will qualify for a label allowing for the treatment in post-operative pain. Based on the safety profile and labeling for the marketed Dex product, we believe our lead candidate has the potential to offer the following advantages over opioid analgesics:

*Dex is not considered 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. Based on these studies and the vast clinical experience with Dex, Dex is not classified as a controlled substance by the DEA.

*Dex 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 is defined by decreased lung ventilation leading to increased carbon dioxide 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 associated with constipation, nausea, or vomiting*. Unlike opioids, 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. These opioid induced side effects can lead to poor pain management as patients often down dose or skip doses of their pain medication in order to avoid experiencing these side effects.

*Dex has been observed to lower morphine requirements while maintaining adequate pain management, as demonstrated by the NDA registration and independent studies.* Morphine is a common opioid analgesic utilized during and after surgery to help patients treat pain. The registration studies performed by Abbott and Orion and additional independent studies have demonstrated the ability of Dex to be morphine sparing. We believe the use of Dex could contribute to a decrease in morphine use thereby decreasing the harmful side effects of opioid usage.

*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

Table of Contents

tasks. Based upon published studies, patients utilizing Dex do not appear to experience cognitive impairment. We expect Dex to allow patients to participate in their normal daily activities while receiving adequate pain relief.

*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 may help with pain management.

**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 will target a broader group of prescribers and will likely require a partner. Our broader corporate strategy includes the following:

*Focus on developing Dex-IN for post-operative pain*. Our key goal is to file an NDA and receive FDA approval of Dex-IN for use in treating post-operative pain. Based on recent trials conducted by other companies for FDA-approved acute pain drugs, we believe that we will be required to complete two Phase III pivotal trials, one in patients with pain resulting from intra-abdominal surgery and one in patients with pain resulting from orthopedic surgery. Post-operative pain studies are normally performed in only one surgical condition to allow for a more homogenous patient population and to thereby permit an efficient comparison of the active drug effects and the placebo effects. The post-operative Phase II trial in bunionectomy patients is an example of a post-operative orthopedic trial that when combined with successful results from an intra-abdominal surgery study could result in a broad indication to treat post-operative pain that would not be limited to the specific surgeries performed. We believe that the primary efficacy endpoint will be the time-weighted sum of all of the pain intensity difference scores, or SPID, at 48 hours as compared to placebo. We believe developing Dex-IN in the post-operative pain indication provides us the fastest and best path to building a specialty pharmaceutical company focused on the management of pain indications. Therefore, we are initially concentrating our management focus and resources on attaining this goal.

*Develop our candidates through FDA approval to maximize their potential value*. Our management team has significant development and commercial experience. Therefore, we believe retaining development and commercialization rights of our candidates until a later stage will create significant value for our shareholders.

*Leverage our management development experience for other indications and product candidates*. If we have sufficient additional resources, we plan to progress Dex in other forms and/or for other therapeutic indications, including cancer breakthrough pain, and to develop Fado for post-operative and/or neuropathic pain.

*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.

**Dexmedetomidine Overview**

Dex was developed in the 1990s by Abbott as a sedative in the intensive care unit setting. In 1999, Abbott received FDA approval to market intravenous, or IV, Dex, trademarked Precedex® in the United States for intensive care unit, or ICU, sedation. Hospira currently markets Dex in the United States. In addition to its initial indication as a short

term sedative in the ICU, Hospira has received U.S. approval for Dex as a procedural sedative and has received approval in select regions outside the United States for longer term use of Dex. More recently, Orion received European approval to market Dex as an ICU sedative in the European Union, trademarked as Dexdor®.

Table of Contents

Dex is a selective alpha-2 adrenergic agonist that has demonstrated sedative, analgesic and anxiolytic properties. Alpha-2 agonists have been in clinical use since the mid-1960s when clonidine was introduced as an anti-hypertensive drug. While clonidine has demonstrated analgesic effects, it has not been widely used as an analgesic due to its hypotensive side effects. The Dex effect on alpha-2 sub receptors differs from clonodine, resulting in lower propensity to lower blood pressure. In our clinical trials completed to-date, we have observed some hypotensive activity but have not seen a clinically meaningful impact on hypotension.

Dex has an extensive history of safe intravenous use in acute and surgical settings, utilizing its sedative properties. We have formulated Dex at a significantly lower dose (perhaps as low as 1/10$^{th}$ for our intranasal product) than the currently recommended IV dosage levels. Under intravenous use, Dex is typically dosed in the range from 0.2 to 1mcg/kg/hr following a 1mcg/kg bolus over 10 minutes. An infusion of 0.7mcg/kg/hr is anticipated to maintain plasma concentrations of approximately 1.25ng/mL and may be titrated to desired level of sedation. Based upon our lower dose, we have seen minimal sedation to date in our clinical trials while still demonstrating an analgesic effect.

Dex Marketed Formulation: Demonstrated Efficacy and Safety in Multiple Studies

Dex has been approved in both the United States and the European Union as a sedative for use in intensive care patients or for procedural sedation based upon registration studies in 4,765 Dex-treated patients. Since we are pursuing a 505(b)(2) regulatory strategy, we have the ability to reference and access this patient data in support of our filings. In addition to these registration studies, Dex has demonstrated the following:

*Approved sedative with good safety profile.* Abbott obtained FDA approval for intravenous Dex in 1999. That product is currently marketed by Hospira under the brand name Precedex®. Hospira has received approval for long term use of Dex (defined as greater than 24 hours) in certain markets outside the United States. Additionally, in September 2011, Orion received marketing authorization in the European Union to market Dex, branded as Dexdor®, as an intensive care sedative.

*Studies and registration studies have shown Dex to be morphine sparing.* Opioids harmful side effects and addictive nature has been well documented in clinical trials and by patient usage. Morphine is a very potent opioid analgesic that is commonly used during and after surgical procedures to treat pain. We believe there is a large need for analgesics that either limit or reduce the need for opioids, including morphine. Studies have demonstrated that patients using Dex together with morphine can reduce the amount of morphine required to receive the same level of pain relief.

*Dex has been reported to relieve opioid-induced hyperalgesia*. Opioid-induced hyperalgesia, or increased sensitivity to pain, occurs when patients taking opioids to relieve their pain actually experience an increased level of pain. An article by M. Belgrade from the University of Minnesota describes how chronic opioid users with opioid induced hyperalgesia were treated with Dex in an attempt to improve pain control and reduce opioid use while avoiding opioid withdrawal. This report supports the proposition that patients experiencing hyperalgesia from morphine usage experienced better pain control when taking Dex together with a reduced amount of opioid medication.

*Analgesia has been demonstrated in multiple, independent studies for marketed Dex.* Alpha-2 agonists are well known for their analgesic potential. Specifically, clonidine, an alpha-2 agonist, has been reported in the literature to be effective for use in post-operative pain. Dex appears to be a more selective alpha-2 agonist than clonidine. Multiple studies evaluating Dex in various post-operative procedures demonstrated Dex s ability to reduce morphine consumption or delay the time to and amount of rescue therapy. Based on discussions with key opinion leaders in the pain area, we believe that reduced opioid requirements observed in some studies, along with direct analgesic effects observed in others, are indicative of Dex s analgesic effects.

*Recro sponsored studies have also demonstrated the potential of Dex to provide effective pain relief.* In two Recro sponsored Phase Ib placebo controlled studies in chronic lower back pain patients, Dex has demonstrated

Table of Contents

rapid and effective analgesia. One study utilizing Dex-IN demonstrated statistically significant improvement in pain symptoms within 30 minutes.

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 one Phase II placebo controlled studies, in over 200 subjects to evaluate the analgesic efficacy, safety and pharmacokinetics of Dex. We are currently conducting our second Phase II clinical trial of Dex-IN for acute pain following surgery. 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 October 2014, we commenced a Post Op Day 1 Phase II clinical trial of Dex-IN in the treatment of acute post-operative pain following bunionectomy surgery. Based upon the results of all these trials, we believe that our formulations of Dex have demonstrated analgesic potential for moderate to severe pain.

*REC-14-013*

Our current study utilizes Dex-IN in 200-250 patients initiating dosing of study medication on Post Op Day 1 following bunionectomy surgery. The Phase II trial is a randomized, multicenter, double-blind, placebo-controlled study to evaluate the efficacy and safety of Dex-IN. Patients are randomized to either a 50mcg dose of Dex-IN or a placebo intranasal dose given every 6 hours. Following the beginning of treatment, patients will remain under observation for 48 hours at study centers. Patients will be followed for 7 days after the initial dose of study medication. There will be an oral opioid rescue treatment available to patients in either treatment group, if required, to provide adequate pain relief. The primary efficacy endpoint of the trial is the summed pain intensity difference over 48 hours, or SPID48, starting treatment on Post Op Day 1. Additional efficacy endpoints include use of opioid rescue medication and opioid related side effects, and Patient Global Assessment, or PGA, of pain control. Top line results are expected mid-year 2015 and an interim analysis for sample size adjustment is planned when approximately half of the evaluable patients have been enrolled.

*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 adult subjects undergoing bunionectomy surgery with treatment beginning on Post Op Day 0. Subjects who met the eligibility criteria were randomized to either a 50mcg dose of Dex-IN, a 35mcg of Dex-IN or a placebo intranasal dose. Following the beginning of treatment, subjects remained under observation for 48 hours at study centers and, following the initial dose of study medication, patients were followed for 7 days. The primary efficacy endpoint of the trial was SPID48 starting on Post Op Day 0. Additional efficacy endpoints included use of rescue medication, PGA of pain control, opioid consumption and side effects of opioid use. While analgesia and a reduction in opioid use were observed in a subset of patients, 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 patients (three in the 50mcg Dex-IN treatment group and one in the 35mcg Dex-IN treatment group) discontinued due to symptomatic hypotension and one subject (35mcg Dex-IN) 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 (six in the 50mcg Dex IN treatment group) that had an adverse event of BP decreased. In addition, one patient in the Dex-IN 50mcg 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. Other key safety data of interest from the REC-13-012 trial are summarized in the table below.

Table of Contents

**Summary of Key Safety Data of Interest REC-13-012**

| Event | Dex-IN 50 mcg Group N (%) | Placebo Group N (%) |
|---|---|---|
| Drowsiness | 17 (53%) | 17 (53%) |
| Nausea | 8 (25%) | 14 (44%) |
| Vomiting | 2 (6%) | 6 (19%) |
| Dizziness | 3 (9%) | 5 (16%) |
| Nasal Irritation | 2 (6%) | 3 (9%) |
| Epistaxis | 2 (6%) | 3 (9%) |

**Fadolmidine Overview**

Our second novel compound 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 IT 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, altogether 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 anaesthesia in subjects undergoing bunionectomy surgery. Fado doses of 40, 60, 80, 100, 120, 140, 160, 180, 200, 220 and 240mcg were administered with 5mg of bupivacaine. At each dose level six subjects were randomized to receive combination treatment, and one subject to receive only isobaric bupivacaine 10mg. 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, they also reported less pain. All doses of Fado appeared to delay the onset of pain while doses of Fado greater than 120mcg also appeared to suppress pain.

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 10mg 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 when added to bupivacaine. These increases were dose-dependent.

**Intellectual Property**

We hold patent applications directed to the analgesia without significant sedation 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 difference 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 USPTO in issuing any patent. Additionally, we will seek patent term extension under the Hatch-Waxman Act when applicable. The extensions under U.S. law may extend patent protection beyond 2030.

Table of Contents

While our current focus is on seeking FDA approval for Dex-IN for the treatment of post-operative pain, we also have in development proprietary drug solutions for 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, topical, transdermal, intranasal, and sublingual platforms.

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. Our intellectual property portfolio currently consists of two families of patent applications, one for Dex and one for Fado. 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. For a more comprehensive discussion of the risks related to our intellectual property, please see Risk Factors Risks Related to Our Intellectual Property in the Risk Factors section of this Annual Report on Form 10-K.

Our success will depend significantly on our ability to:

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

We have taken steps to build and will continue to build proprietary positions for our product candidates and related technology in the United States and abroad.

We have 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) would have expired July 15, 2013; however, because Abbott/Hospira conducted pediatric trials, the patent term was extended to and 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, a pro-drug patent (U.S. Patent No. 7,759,496) 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 our product candidates. Our Dex patent portfolio comprises three families of patent applications.

A first 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 without significant sedation by administering to the oral mucosa of a mammal a unit dose of the active

Table of Contents

ingredient, or a pharmaceutically acceptable salt, in a pharmaceutically acceptable vehicle suitable for administration to the oral mucosa. 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.

A second family (U.S. Application Serial No. 13/520,959; which was also filed as a PCT application, International Application No. PCT/US11/20462) provides, among other things, methods of treating or preventing pain by applying to the skin of a mammal a composition comprising a dosage of the active ingredient, or a pharmaceutically acceptable salt or pro-drug thereof, in a pharmaceutically acceptable vehicle. The active ingredient, or salt or pro-drug thereof, is absorbed through the skin and produces analgesia without sedation. The second family also provides, among other things, methods of treating or preventing pain by applying to a skin membrane of a mammal a pharmaceutical composition comprising the active ingredient, or salt or pro-drug thereof, in a pharmaceutically acceptable vehicle. The active ingredient, or salt or pro-drug thereof, is absorbed through said skin and produces analgesia without sedation. The second family also provides methods of treating or preventing pain by administering to the skin of a mammal a systemically absorbed pharmaceutical composition comprising the active ingredient, or salt or pro-drug thereof, in an amount effective to treat or to prevent pain in the mammal upon administration. The pharmaceutical composition can provide a physiologically active amount of the active ingredient into the systemic circulatory system of the mammal at a rate that produces an analgesic effect without sedation within at least 6 hours of administration. The second family also provides, among other things, analgesic pharmaceutical compositions comprising the active ingredient, or salt or pro-drug thereof, in a pharmaceutically acceptable vehicle. The pharmaceutical composition is configured and adapted for topical administration to the mammal by applying the analgesic pharmaceutical composition to the skin of the mammal. The second family also provides an apparatus for treating or preventing pain. The apparatus can comprise an analgesic pharmaceutical composition comprising the active ingredient, or salt or pro-drug thereof, in a pharmaceutically acceptable vehicle, and a dispensing device that contains and dispenses the analgesic pharmaceutical composition.

A third 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 without significant sedation in a mammal by intranasally administering an intranasally effective amount of the active ingredient, or a pharmaceutically acceptable salt thereof, to the mammal. The intranasally effective amount of the active ingredient, or salt thereof, can produce a $C_{plasma}$ of about 0.1ng/ml within about 15 minutes to about 20 minutes of administration and can have an analgesic effect without significant sedation. The third family also provides methods of treating or preventing pain without significant sedation in an adult human by intranasally administering an intranasally effective amount of the active ingredient, or salt thereof, to the adult human. The intranasally effective amount of the active ingredient, or salt thereof, can act without producing significant sedation in the adult within a period of time of about two hours after administration and can have an analgesic effect within the period of time. The third 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 without significant sedation.

The three Dex patent application families are in various stages of prosecution, and no patent has been issued to date in the United States. The issuance of any patent from these applications is not a certainty. Unless and until our pending applications issue, their protective scope is impossible to determine. Further, there is only one patent application in connection with our lead candidate, 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.

Table of Contents

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 topical or transdermal Dex, if embodiments from the specification and/or present claims issued, the claims may cover: methods of treating or preventing pain without sedation via delivery of Dex to the skin; analgesic pharmaceutical compositions comprising Dex adapted to topical administration; and/or apparati for treating or preventing pain comprising a dispensing device 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

*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, the Licensed Dosage Forms, but specifically excluding delivery vehicles for administration by injection or infusion, in the United States, Canada and all other countries and territories worldwide other than Europe, the CIS, Turkey and their respective territories. 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 Euros ($24.9 million as of December 31, 2014) 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 a Licensed Dosage Form. Our royalty payments on net sales of Dex will be paid at varying percentages. Through December 31, 2014, no milestones have been achieved.

We are entitled to reference all regulatory filings made by Orion related to Dex, Dex products or the Dex 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 all territories other than Europe, the CIS and Turkey.

Table of Contents

The initial term of this license is 15 years from the first commercial sale in our allowed territories mentioned above. 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.

Dex-API

Recro and Orion are parties to a separate active pharmaceutical ingredient, or API, agreement, whereby Orion agrees to provide Recro 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 amounts agreed between Orion and our company. 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 by Orion are subject to regulatory approval. Upon commercialization, we will provide a rolling forecast of projected supply requirements to Orion, which will be updated on a quarterly basis for eight quarters. The first quarter of each rolling forecast will be a firm order for which we are financially responsible. The agreement contains provisions for shipping API product, receipt and acceptance, as well as back-up manufacturing, regulatory support, quality control, change control, recordkeeping, and inspection rights. Under the agreement, we may obtain API from other suppliers in certain circumstances, including Orion s failure to deliver API on more than one occasion in an 18-month period. The agreement also includes customary representations and warranties of the parties as well as an obligation for Orion to indemnify us for certain matters.

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.

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 United States, Canada and all other countries and territories worldwide other than Europe, the CIS (currently includes Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine and Uzbekistan), Turkey and their respective territories. 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 Euros ($14.8 million as of December 31, 2014) 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

15

Table of Contents

treatment of human subjects, in the territory, as defined in such agreement. Through December 31, 2014, no 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.

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 pain specialists, surgeons and anesthesiologists. 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 is Orion s Fermion Chemical Division. We currently rely on contract manufacturers to produce drug product for Dex and Fado for our clinical studies under cGMP, with oversight by our internal managers. Certain equipment specific to the pharmaceutical manufacturing process is leased by us and we are evaluating plans for commercial filling. 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 material additional costs.

Table of Contents

**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, or may 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. All contract manufacturers and component suppliers have been selected for their specific competencies in the manufacturing processes and materials that make up the Dex system. FDA regulations require that materials be produced under cGMPs or quality systems regulations, or QSR.

**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 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 acetaminophen, non-steroidal anti-inflammatory drugs, also known as 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 Dex will be prescribed for moderate to severe pain, competing mostly with opioids such as morphine, oxycodone and hydrocodone. 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, Depomed, Inc. 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.

Table of Contents

**Government Regulation**

Product Approval

Government authorities in the United States at the federal, state and local level, and other countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, export and import of products such as those we are developing. Our product candidates, including our formulations of 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 require 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

Table of Contents

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.

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 adverse events, or 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 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

Table of Contents

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.

*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

Table of Contents

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 patent 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 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.

Table of Contents

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 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 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 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.

Table of Contents

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.

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

Table of Contents

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.

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, increased the maximum civil monetary penalties for violations of HIPAA, granted enforcement authority to state attorneys general, and imposed 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 five full-time employees. None of our employees are covered by collective bargaining agreements and we consider relations with our employees to be good. Our current employees are also employed by, and will continue to devote a small portion of their time to, MCG, and in the case of Mr. Garner, he devotes a small portion of his time consulting for other companies and third parties by providing investment banking, finance and related services. Ms. Henwood was, but no longer is, a venture partner with SCP.

Table of Contents

## Item 1A. Risk Factors

## 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 are a development stage company with limited operating history. To date, we have focused primarily on developing our lead product candidate, Dex-IN. In addition, we have other product candidates, Dex-SL and Fado, in development. We have incurred significant net losses in each year since our inception in November 2007, including net losses of approximately $16.1 million for the year ended December 31, 2014, and $2.0 million and $1.5 million for fiscal years 2013 and 2012, respectively. As of December 31, 2014, we had an accumulated deficit of $34.1 million.

We have devoted most of our financial resources to research and development, including our non-clinical and formulation development activities, manufacturing and clinical trials. To date, we have financed our operations exclusively through the sale of debt and equity securities. The size of our future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenues. To date, none of our product candidates have been commercialized, and 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. We also expect an increase in our expenses associated with creating additional infrastructure to support operations as a public company. As a result of the foregoing, we expect to continue to incur significant and increasing losses and negative cash flows from operations for the foreseeable future.

***We have never generated any revenue and may never be profitable.***

Our ability to generate revenue and 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. Our ability to generate future revenues from product sales depends heavily on our success in:

- completing the clinical development of Dex-IN, initially for the treatment of acute pain following surgery;
- obtaining regulatory approval for Dex-IN for the treatment of acute pain;
- launching and commercializing Dex-IN through either building a specialty sales force or collaborating with third parties;
- obtaining and maintaining patent protection; and

completing the clinical development, obtaining regulatory approval, launching and commercializing other Dex product candidates and our other product candidate, Fado.

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

Table of Contents

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 our product candidates. 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 potential revenues we generate will fluctuate from quarter to quarter and year to year as a result of 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.

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

Table of Contents

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.***

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. As of December 31, 2014, we had working capital of approximately $18.9 million. We will need to raise additional funds to support our future operations, and such funding may not be available to us on acceptable terms, or at all.

On March 12, 2014, we closed the initial public offering, or 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. We expect our existing cash and cash equivalents, together with interest, will be sufficient to fund our current operations through March 31, 2016. 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 Dex-IN or otherwise enter into collaborations to launch and commercialize Dex-IN after receipt of FDA approval, if received, and, if we choose, to initiate clinical trials for additional uses of Dex-IN or for our other product candidates, including Fado. In any event, we will require additional capital to obtain regulatory approval for, and to commercialize, our product candidates.

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

- significantly delay, scale back or discontinue the development or commercialization of our product candidates;
- seek corporate partners for Dex-IN at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or
- relinquish or license, on unfavorable terms, our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing development and commercialization efforts, which will have a material adverse effect on our business, operating results and prospects.

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. Upon execution of the Purchase Agreement, we issued 96,463 shares of our common stock, or the Commitment Shares, to Aspire Capital in consideration for entering into the Purchase Agreement. 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 as described above. The number of shares that we may sell to Aspire Capital under the Purchase Agreement on any given day and during

Table of Contents

the term of the agreement is limited. Additionally, we and Aspire Capital may not affect any sales of shares of our common stock under the Purchase Agreement during the continuance of an event of default or on any trading day that the closing sale price of our common stock is less than $0.50 per share. Even if we are able to access the full $10.0 million under the Purchase Agreement, we will still need additional capital to fully implement our business, operating and development plans, as described above.

***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.***

In order to raise additional funds to support our operations, we may sell additional equity or debt securities, which would result in dilution to all of our shareholders or impose restrictive covenants that adversely impact our business. The incurrence of indebtedness would result in payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we are unable to expand our operations or otherwise capitalize on our business opportunities, our business, financial condition and results of operations could be materially adversely affected and we may not be able to meet our obligations.

**Risks Related to Clinical Development and Regulatory Approval**

***We depend substantially on the success of our product candidate, Dex-IN, which is 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 Dex-IN for use in treating acute pain following surgery. We have completed two Phase Ib placebo-controlled clinical trials with two different dosage forms of Dex in chronic lower back pain subjects. We closed our Post Op Day 0 Phase II clinical trial for Dex-IN in post-operative patients in the third quarter of 2014. Based upon the results of that trial, we commenced a Post Op Day 1 Phase II clinical trial of Dex-IN in post-operative patients in the fourth quarter of 2014. Assuming completion of a successful clinical trial, we expect to complete two Phase III pivotal clinical trials with Dex-IN in acute pain following surgery. We intend to use these trials as a basis to submit an NDA for Dex-IN for acute pain. 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 Dex-IN, generating revenues and achieving profitability. If this were to occur, we may be forced to abandon our development efforts for Dex-IN, which would have a material adverse effect on our business and could potentially cause us to cease operations. Because of the license from Orion, we expect to cross-reference the approved NDA for Dex in our 505(b)(2) NDA for Dex-IN. If the FDA disagrees with this strategy and determines we cannot pursue this pathway, we could incur significant time, resources, and delay, particularly if the FDA requires more clinical data than we expect.

***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 have completed multiple clinical studies utilizing Dex-IN. After an interim analysis in September 2014, we closed our first Phase II clinical trial of Dex-IN in the treatment of acute post-operative (Day 0) pain following bunionectomy surgery as the trial was not expected to reach statistical significance. We initiated a Post Op Day 1 Phase II clinical trial for Dex-IN in post-operative patients in October 2014, which will be completed before proceeding to Phase III, pivotal trials for Dex-IN. Our product candidates are subject to the risks of failure inherent in pharmaceutical

development. 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 study could cause the FDA to require that we repeat it or conduct additional clinical studies. 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.

Table of Contents

To date, we have completed multiple Phase Ib clinical trials with Dex in chronic lower back pain patients. However, there is no certainty that the results we have seen in these studies and patient population nor the trend toward analgesia in a subset of patients in our closed Day 0 Phase II clinical trial will be similar in patients with acute pain following surgery in our ongoing and future expected clinical trials. We cannot be certain that positive results will be duplicated when Dex-IN is tested in a larger number of patients in our Phase II and Phase III clinical trials. Unexpected results could require us to redo clinical studies in the same or different patient populations or discontinue clinical development of Dex-IN. If we are forced to discontinue development of Dex-IN because of unsuccessful clinical trials, we will not be able to commercialize Dex-IN, our lead product candidate, 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. In September 2014, we discontinued the REC-13-012 Post Op Day 0 Phase II clinical trial, as that was not expected to reach statistical significance, and we initiated a Post Op Day 1 Phase II clinical trial for Dex-IN in post-operative patients in October 2014. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients, or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including, but not limited to:

- inability to raise funding necessary to initiate or continue a trial;
- delays in the 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 the Phase II or any other 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 Dex for other indications.

Table of Contents

If completion of the Post Op Day 1 Phase II trial or initiation or completion of the Phase III trials are delayed for Dex-IN or other product candidates 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 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 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 by us with Dex have generated some AEs, but no serious adverse events, or SAEs, as those terms are defined by the FDA in its regulations. For example, AEs have included higher incidences of somnolence and hypotension observed in patients receiving Dex over patients receiving placebo. If SAEs are observed in any of our clinical studies, our ability to obtain regulatory approval for our product candidates may be adversely impacted. 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.

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

Our lead product candidate, 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, since 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 it could relate to possible device authorization by the FDA as well as a drug approval under an NDA. As

a result, product launch and commercialization may be delayed or may not occur, which could have an adverse effect on our business.

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

We cannot commercialize Dex-IN 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 Dex-IN. Additional delays may

Table of Contents

result if Dex-IN is taken before an FDA Advisory Committee which may recommend restrictions on approval or recommend non-approval. 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 Dex-IN and our other product candidates, we will still face extensive regulatory requirements and our products may face future development and 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-market surveillance. For example, the labeling ultimately approved for 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. 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-market 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.

Table of Contents

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 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 the 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 our product candidate, 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 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 clinical trial and to establish the proper dosage or dose frequency for Dex-IN before it approves this product candidate. The preparation of this additional data may be costly and may delay the approval of Dex-IN or any of our other product candidates for which we receive this request. If we cannot satisfy the FDA requirements, we might not be able to obtain marketing approval.

***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 Dex-IN. Depending on the extent of the REMS requirements, our costs to commercialize Dex-IN may increase significantly and distribution restrictions could limit sales. Our other product candidates, if approved, may also require REMS programs that may increase our costs to commercialize these product candidates or limit sales.

***We will need to obtain FDA approval of any proposed product trade names, and any failure or delay associated with such approval may adversely impact our business.***

Any trade name we intend to use for our product candidates will require approval from the FDA, regardless of whether we have secured a formal trademark registration from the United States Patent and Trademark Office,

Table of Contents

or USPTO. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names and/or medication or prescribing errors. The FDA may also object to any product name we submit if it believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product names, we may be required to adopt an alternative name for our product candidates. If we adopt an alternative name, we would lose the benefit of our existing trademark applications for such product candidate, and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

***Even if we obtain FDA approval for Dex-IN 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.

**Risks Related to Our Reliance on Third Parties**

***We rely on third party manufacturers to produce our preclinical and clinical drug supplies and delivery devices, and we intend to rely on third parties to produce commercial supplies of any approved product candidates.***

Reliance on third party manufacturers entails certain risks to which we would not be subject if we manufactured the pharmaceutical and device aspects of our product candidates ourselves, including, but not limited to:

- the inability to meet our product specifications and quality requirements consistently;
- a delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;

a failure to comply with cGMP and similar foreign standards;

the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;

termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;

the reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell our product candidates in a timely fashion, in sufficient quantities or under acceptable terms;

Table of Contents

- the lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;

- disruption of operations of our third party manufacturers or suppliers by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier;

- carrier disruptions or increased costs that are beyond our control; and/or

- the failure to deliver our products under specified storage conditions and in a timely manner.

Any of these events could lead to clinical study delays or failure to obtain regulatory approval or could impact our ability to successfully commercialize our products. Some of these events could be the basis for FDA action, including, but not limited to, clinical hold, corrective action, injunction, recall, seizure, or total or partial suspension of production.

***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.***

Orion is currently our sole source of the API for Dex. Although the API supply agreement that we have with Orion allows us to qualify and purchase API 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, Orion is the only established supplier of the Dex API.

We expect that the drug product (dosage form that is the final product) will be manufactured by a contract manufacturing organization, or CMO, but 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 Orion, the CMO or the device component suppliers is interrupted, there could be a significant disruption in commercial supply. The FDA, state regulatory authorities or other regulatory authorities outside of the United States may also require additional studies if a new supplier is 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.

These factors 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 product components on a timely basis and at reasonable prices, 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 Dex-IN requires 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 third party manufacturing facility or equipment may delay or impair our ability to complete our clinical trials or commercialize our product candidates and increase our costs.

Table of Contents

***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.

***We have limited experience in clinical manufacturing of Dex-IN and no experience with commercial manufacturing and do not own or operate a manufacturing facility.***

We have relied on contract manufacturers and secondary service providers to produce Dex-IN devices for clinical trials. As we do not own or operate a manufacturing facility, we currently outsource manufacturing of our products and filling and assembly of the Dex-IN sprayer to third parties and intend to continue to do so. We may encounter unanticipated problems in the scale-up that will result in delays in the manufacturing of the Dex-IN and/or the intranasal sprayer.

We do not currently have any commercial agreements with third party manufacturers for the manufacture of the drug product and the intranasal sprayer. We may not be able to enter into agreements for commercial manufacturing of Dex-IN and/or the intranasal sprayers with third party manufacturers, or may be unable to do so on acceptable terms. Any third party manufacturers that we engage will be subject to FDA regulations requiring that any materials produced meet cGMPs or QSR, and be subject to ongoing inspections by regulatory authorities. Failure by any of our suppliers to comply with applicable regulations may result in delays and interruptions to our product candidate supply while we seek to secure another supplier that meets all regulatory requirements.

Reliance on third party manufacturers entails risks to which we would not be subject if we manufactured the product candidates ourselves, including the possible breach of the manufacturing agreements by the third parties because of factors beyond our control, and the possibility of termination or nonrenewal of the agreements by the third parties because of our breach of the manufacturing agreement or based on their own business priorities.

***We rely on Malvern Consulting Group, Inc., an entity with which our management is affiliated, and other third parties to conduct, supervise and monitor our clinical studies, and if those third parties perform in an unsatisfactory manner, it may harm our business.***

We rely on MCG and other third parties to ensure the proper and timely conduct of our clinical trials. While we have agreements governing their activities, we have limited influence over certain of these third parties actual performance. We have relied and plan to continue to rely upon third parties to monitor and manage data for our ongoing clinical programs for Dex 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, legal, regulatory and scientific standards and our reliance on the 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. Upon inspection, the FDA may determine that our Phase II or Phase III clinical trials do not comply with cGCPs. In addition, our clinical trials for Dex-IN will require a sufficiently

Table of Contents

large number of test subjects to evaluate the safety and effectiveness of Dex-IN. 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.

Our contractors are not our employees, and we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and nonclinical programs. 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, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain 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 Dex-IN, or our other product candidates. As a result, our financial results and the commercial prospects for 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 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.***

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 relative convenience, ease of administration and acceptance by physicians, patients and health care payors;
- the prevalence and severity of any AEs;
- limitations or warnings contained in the FDA-approved label for Dex-IN;
- availability of 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 Dex 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.

If Dex-IN or any 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 from Dex-IN or any product candidates 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 Dex-IN, we may be unable to generate any revenue.***

We currently do not have an organization for the sales, marketing and distribution of Dex-IN 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

Table of Contents

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 our 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 Dex-IN is to develop a hospital-directed 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 relief setting, we believe Dex-IN 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, we are not aware of any other alpha-2 agonists compounds in development for acute pain following surgery. However, companies such as Adynxx, Inc., AcelRx Pharmaceuticals, Inc., Trevena, Inc. and Cara Therapeutics, Inc. are currently developing post-operative

pain therapeutics that could compete with us in the future.

Table of Contents

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 could render Dex-IN 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 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 formulary approval to allow us to sell our products into our target markets.

Furthermore, market acceptance and sales of 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 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 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 Dex-IN. We expect to experience pricing pressures in connection with the sale of Dex-IN and

Table of Contents

any other products that we develop, due to the trend toward managed healthcare and the increasing influence of health maintenance organizations. If we fail to successfully secure and maintain reimbursement coverage for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our business will be harmed.

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

If our product candidates are approved for commercialization, we intend to enter into agreements with third parties to market 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.

***The commercial success of our products and product candidates, if approved, depends upon attaining market acceptance by physicians, patients, third party payors and the medical community.***

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. Market acceptance of any of our products or product candidates by physicians, patients, third party payors and the medical community depends on, among other things:

our ability to provide acceptable evidence of safety and efficacy;

acceptance by physicians and patients of each product or product candidate as a safe and effective treatment;

perceived advantages of our products or product candidates over alternative treatments;

relative convenience and ease of administration of our products or product candidates compared to existing treatments;

any labeling restrictions placed upon each product or product candidate in connection with its approval;

the prevalence and severity of the adverse side effects of each of our products or product candidates;

the clinical indications for which each of our products or product candidates are approved, including any potential additional restrictions placed upon each product or product candidate in connection with its approval;

Table of Contents

prevalence of the disease or condition for which each product or product candidate is approved;

the cost of treatment in relation to alternative treatments, including generic products;

the extent to which each product or product candidate is approved for inclusion on formularies of hospitals and managed care organizations;

any negative publicity related to our or our competitors products or product candidates, including as a result of any related adverse side effects;

the effectiveness of our or any current or future collaborators sales, marketing and distribution strategies;

pricing and cost effectiveness; and

the availability of adequate reimbursement by third parties.

If our products or product candidates do not achieve an adequate level of acceptance by physicians, third party payors and patients, we may not generate sufficient revenues from these products or product candidates to become or remain profitable on a timely basis, if at all.

***Upon commercialization of any of our product candidates, we will become subject to a variety of additional risks applicable to companies engaged in the manufacture and 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 manufacturer 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 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 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 Dex-IN or any other product candidates, if any,

Table of Contents

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.

In early 2010, President Obama signed into law 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. Further, beginning in 2011, the new law imposes 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.

**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 each of our executive officers to spend a 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.

***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 rely on MCG, and other third parties to perform certain of our operational activities, and expect to continue to do so for the foreseeable future. However, as our company matures, we may choose to

Table of Contents

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 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. Some of our other employees, including Randall Mack, Diane Myers and Donna Nichols, are also employees of MCG. Such employees, including Ms. Henwood, will continue to devote a small portion of their time to MCG.

Such employees will provide services to, or on behalf of, MCG on an as needed basis. Although such employees have no obligation to devote a specified amount of time, we expect that Ms. Henwood and Ms. Nichols will devote up to 10% of their time to MCG, while Mr. Mack and Ms. Myers will devote approximately 10% to 20% of their time to MCG.

We sublease our facilities from MCG. MCG also provides services, including administrative, clinical development, regulatory and manufacturing fill 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 and could be doing so in competition with us. 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 Chief Financial Officer, Charles Garner continues to devote a small portion of his time to his consulting business.***

Mr. Garner became our Chief Financial Officer effective upon consummation of the IPO. Mr. Garner expects to continue to devote a small portion of his time consulting for other companies and third parties by providing investment banking, finance and related services. Mr. Garner has agreed not to provide any services to companies or third parties that could compete with us.

***We face potential product liability, 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. Product liability claims might be brought

Table of Contents

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;
- 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 $1.0 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 will 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 will 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 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 maintain director and officer liability insurance, and if we are able to obtain 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.

Table of Contents

***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 evaluated frequently. 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 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.

***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, 2014, 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, 2014, 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

Table of Contents

addition, we have recently received ownership from Orion 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 three Dex patent application families are in various stages of prosecution, and no patent in the United States has been issued to date. The issuance of any patent is not a certainty. Unless and until our pending applications issue, their protective scope is impossible to determine. Further, there is only one patent application in the United States in connection with our lead candidate, Dex-IN, which is also relatively early in the review process, which may take months to 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. 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.

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.

Recent 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 recently developed 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.

Table of Contents

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

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 in any dosage form for transdermal, transmucosal (including sublingual), topical, enteral or pulmonary (inhalational) delivery (collectively, referred to as the Licensed Dosage Forms), but specifically excluding delivery vehicles for administration by injection or infusion, in the United States, Canada and all other countries and territories worldwide other than Europe, the CIS, Turkey and their respective territories. 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 Company-licensed 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 all territories other than Europe, the CIS and Turkey. However, there is no guarantee that we would have the resources to exercise this right or, if we did, that we would be able to reach mutually agreeable terms with Orion.

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

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

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

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

If we were found by a court to have infringed a valid patent claim, we could be prevented from using the patented technology or be required to pay the owner of the patent for the right to license the patented technology. If we decide to pursue a license to one or more of these patents, we may not be able to obtain a license on commercially reasonable

terms, if at all, or the license we obtain may require us to pay substantial royalties or grant cross licenses to our patent rights. For example, if the relevant patent is owned by a competitor, that competitor may choose not to license patent rights to us. If we decide to develop alternative technology, we may not be able to do so in a timely or cost-effective manner, if at all.

Table of Contents

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-year 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.

***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 to date in the United States. The pharmaceutical patent situation outside 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;

Table of Contents

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 have, 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 might 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.

Table of Contents

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 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.

**Risks Relating to Our Securities**

***As a development stage company that is classified as a smaller reporting company and an emerging growth company, we may not be able to attract the attention of major brokerage firms.***

Additional risks may exist as a result of our being a development stage company that is classified as a smaller reporting company and an emerging growth company. Security analysts of major brokerage firms may not decide to cover our business or our stock. No assurance can be given that brokerage firms will want to provide analyst coverage of our business or our stock in the future, which may result in less liquidity and lower trading prices for our shareholders.

***If securities or industry analysts do not publish research or reports or 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 are subject to Sarbanes-Oxley, Dodd-Frank and the reporting requirements of federal securities laws, compliance with which can be expensive and time-consuming.***

We are subject to a variety of provisions under the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or Dodd-Frank Act, as well as the information and reporting requirements of the Exchange Act and other federal securities laws. The costs of compliance with the Sarbanes-Oxley Act and of preparing and filing annual and quarterly reports, proxy statements and other information with the SEC, the Dodd-Frank Act, and regulations promulgated under these statutes, will cause our expenses to be significantly higher than they would be if we had remained privately held.

***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

Table of Contents

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.

***Continued control by existing shareholders, SCP Vitalife Partners II, L.P. and SCP Vitalife Partners (Israel) II, L.P., or collectively SCP Vitalife, can effectively determine or substantially influence the outcome of matters requiring shareholder approval.***

As of December 31, 2014, SCP Vitalife owns 3,167,286 shares of our common stock, representing approximately 41.1% of our outstanding common stock.

As a result of such ownership, SCP Vitalife may have the ability to substantially influence matters submitted for approval by our shareholders by voting their shares, including the election of our board of directors. There is also the potential, through the election of members of our board of directors, that SCP Vitalife could substantially influence matters decided by our board of directors. This concentration of ownership may also have the effect of impeding a merger, consolidation, takeover or other business consolidation involving us, or discouraging a potential acquirer from making an offer for our shares, and could negatively affect the market price for our common stock or decrease any premium over market price that an acquirer might otherwise pay.

***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, 2014. As a result, these shareholders are collectively able to influence matters requiring approval of our shareholders, including the election of directors and approval of significant corporate transactions such as mergers, consolidations or the sale of all or substantially all of our assets. Such influence may delay, prevent or deter a change in control of our company even when such a change may be in the best interests of some shareholders, impede a merger, consolidation, takeover or other business combination involving us, or could deprive our shareholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might adversely affect the prevailing market price of our common stock.

***The price of our common stock may fluctuate substantially.***

The market price for our common stock is likely to be volatile. The market price of our common stock may fluctuate significantly in response to a number of factors, including:

- plans for, progress in and results from clinical trials of our product candidates generally;
- the commercial performance of any of our product candidates that receive marketing approval;
- FDA, state or international regulatory actions, including actions on regulatory applications for any of our product candidates;

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;

variations in our quarterly operating results;

changes in accounting principles;

litigation or public concern about the safety of our potential products;

deviations in our operating results from the estimates of securities analysts;

Table of Contents

additions or departures of key personnel;

sales of large blocks of our common stock, including sales by our executive officers, directors and significant shareholders;

any third-party coverage and reimbursement policies for our product candidates; and

discussion of us or our stock price in the financial or scientific press or in online investor communities.

The realization of any of the risks described in these Risk Factors could have a dramatic and material adverse impact on the market price of our common stock. In addition, class action litigation has often been instituted against companies whose securities have experienced periods of volatility. Any such litigation brought against us could result in substantial costs and a diversion of management attention, which could hurt our business, operating results and financial condition.

***We do not know whether a market will develop for our common stock or what the market price of our common stock will be and as a result it may be difficult for shareholders to sell their shares of our common stock.***

Our common stock is listed on the NASDAQ Capital Market. If an active market for our common stock does not develop, it may be difficult for shareholders to sell shares they purchase without depressing the market price for the shares or at all. As a result, shareholders may not be able to sell their shares of our common stock. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

***We could be subject to securities class action litigation.***

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management s attention and resources, which could harm our business.

***The recently enacted JOBS Act will allow 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);

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

Table of Contents

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. If we avail ourselves of certain exemptions from various reporting requirements, 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 by our existing shareholders 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.

We may ultimately sell all, some or none of the $10.0 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.

Table of Contents

**Risks Related to Our Pending Acquisition of Certain Assets from Alkermes plc**

***Completion of the acquisition of certain assets from Alkermes is subject to conditions and if these conditions are not satisfied or waived, the acquisition will not be completed.***

The obligations of ours and the seller to complete the transactions contemplated by the Definitive Agreement are subject to the satisfaction or waiver of a number of conditions, including the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and other customary closing conditions. If the closing conditions are not waived or satisfied by May 8, 2015, the non-breaching party may terminate the Definitive Agreement.

The failure to satisfy all of the required conditions could delay the completion of the acquisition for a significant period of time or prevent it from occurring. Any delay in completing the acquisition could cause us not to realize some or all of the benefits that we expect to achieve if the acquisition is successfully completed within its expected timeframe. There can be no assurance that the conditions to the closing of the acquisition will be satisfied or waived, or that the acquisition will be completed. The market price for our shares may reflect an assumption that the pending acquisition will occur, and the failure to complete the acquisition could result in a decline in our share price.

If closing of the acquisition has not occurred before April 21, 2015, the loan commitment from Orbimed will have terminated. In this event, we would not have the cash necessary to effect the agreed upon purchase price for the assets. There is no certainty that Orbimed or any other lender would provide a sufficient commitment to fund the up-front acquisition price after this date. Without this funding, we would not be able to close the acquisition, which could result in a decline of our share price.

***Integrating the acquired assets may be more difficult, costly or time consuming than expected and the anticipated benefits of the acquisition may not be realized.***

Until completion of the acquisition, Alkermes will continue to operate the assets that we will acquire pursuant to the Definitive Agreement independently. The success of the acquisition, including anticipated benefits, will depend, in part, on our ability to successfully combine and integrate the assets that we acquire from Alkermes with our business. It is possible that the pendency of the acquisition and/or the integration process could result in the loss of key employees, higher than expected costs, diversion of management attention, the disruption of ongoing businesses or inconsistencies in standards, controls, procedures and policies that adversely affect our ability to maintain relationships with customers, vendors and employees or to achieve the anticipated benefits and cost savings of the acquisition. If we experience difficulties with the integration process, the anticipated benefits of the acquisition may not be realized fully or at all, or may take longer to realize than expected. These integration challenges could have an adverse effect on us or the assets that we will acquire from Alkermes during this transition period and for an undetermined period after completion of the acquisition.

***If the acquisition of certain assets from Alkermes is completed, we will face new and additional risks in connection with the operation and integration of such assets, which may adversely affect our business, financial condition and results of operations.***

Upon consummation of the acquisition of the assets from Alkermes, our business will be transformed, including by becoming the operator of a manufacturing facility and by increasing our workforce with the addition of certain of Alkermes employees. As a result, our business will become subject to additional risks and uncertainties following the consummation of the acquisition. Such risks may be different from those currently applicable to our business. The risks to which we may be exposed include, but are not limited to, the following:

Increased costs and/or delayed timing of the Phase III clinical trials for meloxicam;

Inability of future meloxicam clinical trials to replicate past, positive clinical trials;

Commercial manufacturing and supply interruptions;

Table of Contents

Potential for declining revenues and profitability related to our customers products due to a variety of factors including increased market competition;

Governmental requirements for controlled substances;

Challenges or invalidation of existing intellectual property on manufactured products;

Capital requirements for the manufacturing facility beyond our current expectations;

Ability to successfully integrate and manage people and systems of the acquisition; and

Meeting required debt payments and operating under increased leverage and associated lending covenants.

We cannot anticipate all of the risks that will be applicable to our company following the consummation of the closing and cannot guarantee that we will be able to adequately address these risks. Such additional and different risk and uncertainties could have a material adverse effect on our business, financial condition and results of operations.

***In connection with the acquisition, we will incur significant indebtedness, which could adversely affect our business, including by decreasing our business flexibility.***

Prior to the acquisition, we had no outstanding indebtedness. In connection with, and contemporaneously with the closing of, the acquisition, we will enter into a five-year senior secured term loan with Orbimed. The anticipated incurrence of indebtedness in connection with the acquisition will be $50.0 million. Accordingly, we will have substantially increased indebtedness following completion of the acquisition in comparison to a recent historical basis, which could have the effect, among other things, of reducing our flexibility to respond to changing business and economic conditions and increasing our interest expense. We will also incur various costs and expenses associated with the financing. The amount of cash required to pay interest and/or principal upon maturity on our indebtedness following completion of the acquisition will increase the demands on our cash resources. The increased levels of indebtedness following completion of the acquisition could also reduce funds available for working capital, capital expenditures, acquisitions and other general corporate purposes and may create competitive disadvantages for us relative to other companies with lower debt levels. If we do not achieve the expected benefits from the acquisition, or if the financial performance of our company following the acquisition, does not meet current expectations, then our ability to service our indebtedness may be adversely impacted.

***Our debt obligations will include covenants that restrict our business, which may adversely affect us.***

The five-year senior secured term loan that we enter into with Orbimed in connection with our acquisition of assets from Alkermes will contain 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. The term loan will provide that the violation of any term, covenant or condition of the loan and other ancillary agreements will constitute an event of default. Accordingly, 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 operations.

***The acquisition will involve substantial costs.***

We have incurred, and expect to continue to incur, a number of non-recurring costs associated with the acquisition and integration of the acquired assets of Alkermes. The substantial majority of non-recurring expenses will be comprised of transaction and regulatory costs related to the acquisition. We also will incur transaction fees and costs related to formulating and implementing integration plans, including employment-related, information systems and other facility-related costs. We continue to assess the magnitude of these costs, and additional unanticipated costs may be incurred in the acquisition and the integration of the assets of Alkermes.

Table of Contents

***Uncertainties associated with the acquisition may cause a loss of key employees of the acquired assets, which could adversely affect the future business and operations of our company following the acquisition.***

The assets of Alkermes that we will acquire pursuant to the Definitive Agreement is dependent on the experience and industry knowledge of certain key employees to execute its business plans. Our company s results and operations after the acquisition will depend in part upon our ability to retain key employees of the acquired business. Current and prospective employees of the acquired business may experience uncertainty about their future roles within our company following the acquisition, which may materially adversely affect our ability to attract and retain key personnel during the pendency of the acquisition. Accordingly, no assurance can be given that the combined company will be able to retain key employees of the acquired business.

***The public resale by Alkermes and Orbimed of shares of our common stock subject to warrants issued in connection with the acquisition of the assets from Alkermes could have a negative effect on the trading price of our common stock.***

In connection with the acquisition of assets from Alkermes and the term loan with Orbimed, we expect to issue to Alkermes and Orbimed warrants to purchase (subject to certain vesting and other conditions) 350,000 and 3% of our outstanding, fully diluted shares of our common stock on closing of the acquisition, respectively. The exercise of such warrants will result in dilution of the ownership interests of existing shareholders.

At the time of the closing of the acquisition and the entry into the term loan, none of the shares subject to these warrants will be registered under the Securities Act, and such shares will only be able to be resold pursuant to an effective registration statement or an applicable exemption from registration (under both federal and state securities laws). However, once such shares may be resold, the sale of shares of our common stock issued in the acquisition or in connection with the term loan into the public markets may cause a decline in the trading price of our common stock.

## Item 1B. Unresolved Staff Comments

None.

## Item 2. Properties

Our principal executive offices are located at 490 Lapp Road, Malvern, PA 19355, where we occupy approximately 4,000 square feet of laboratory and office space. We have an office services agreement with MCG which includes the use of space as well as the use certain equipment and access to certain administrative services (for example, telephones, copy machines, kitchen facilities). Although certain of our employees are also employees of MCG, 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.

## Item 3. Legal Proceedings

We are not a party to any material litigation or proceeding and are not aware of any material litigation or proceeding, pending or threatened against us.

**Item 4. Mine Safety Disclosures**

Not applicable.

Table of Contents

## 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, 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 18, 2015, there were seven 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**

*Aspire Capital Transaction*

On February 2, 2015, we entered into a Purchase Agreement with Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase, at our election, up to an aggregate of $10.0 million of shares of our common stock, or the Purchase Shares, over the 24-month term of

the Purchase Agreement.

Upon execution of the Purchase Agreement, we issued 96,463 shares of our common stock to Aspire Capital in consideration for entering into the Purchase Agreement. The Purchase 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 volume weighted average price, or VWAP, purchase 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 volume weighted average price for such purchase date.

Table of Contents

The issuance of the Commitment Shares and all other shares of common stock that may be issued from time to time to Aspire Capital under the Purchase Agreement is exempt from registration under the Securities Act, pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(a)(2) of the Securities Act.

*8% Convertible Promissory Notes*

In each of calendar years 2011, 2012, 2013, and 2014, we sold an aggregate of $1,499,233, $952,013, $660,101, and $131,183, respectively, of our 8% Convertible Promissory Notes in private placements to SCP Vitalife Partners II, L.P., and $500,767, $317,987, $220,483, and $43,817, respectively, of our 8% Convertible Promissory Notes in private placements to SCP Vitalife Partners (Israel) II, L.P. The notes accrued interest at a rate of 8% compounded quarterly. The notes converted into shares of our common stock at the IPO. The notes were issued to SCP Vitalife Partners II, L.P. and SCP Vitalife Partners (Israel) II, L.P. in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(a)(2) of the Securities Act relative to transactions by an issuer not involving a public offering. All purchasers of the 8% Convertible Promissory Notes represented to us in connection with their purchase that they were accredited investors and were acquiring such notes for their own account for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

*Stock Option Grants*

From December 8, 2008 through March 2014, prior to our IPO and prior to the effectiveness of our registration statement on Form S-8, the Company granted stock options under our 2008 Stock Option Plan and our 2013 Equity Incentive Plan to purchase an aggregate of 334,800 shares of our common stock at a weighted-average exercise price of $6.00 per share to certain directors, employees and consultants. The stock options and the common stock issuable upon the exercise of such options were issued pursuant to written compensatory plans or arrangements with our directors, employee and consultants, in reliance on the exemption from the registration requirements of the Securities Act provided by Rule 701 promulgated under the Securities Act or the exemption set forth in Section 4(a)(2) under the Securities Act relative to transactions by an issuer not involving any public offering. All recipients either received adequate information about us or had access through our employment or other relationships to such information.

Table of Contents

**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, 2014 and 2013 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 year ended December 31, 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 financial statements and notes thereto, and other financial information included elsewhere in this Annual Report on Form 10-K.

| | Year ended December 31, | | |
|---|---|---|---|
| | 2014 | 2013 | 2012 |
| | (in thousands, except share and per share data) | | |
| **Statements of Operations Data:** | | | |
| Operating expenses: | | | |
| Research and development | $ 7,874 | $ 544 | $ 542 |
| General and administrative | 3,998 | 546 | 546 |
| Total operating expenses | 11,872 | 1,090 | 1,090 |
| Other income (expense): | | | |
| Interest income | 10 | | |
| Grant income | | | 85 |
| Interest expense | (4,272) | (868) | (740) |
| | (4,262) | (868) | (655) |
| Net loss | (16,134) | (1,958) | (1,536) |
| Accretion of redeemable convertible preferred stock | (1,270) | (440) | (413) |
| Net loss applicable to common shareholders | $ (17,404) | $ (2,398) | $ (1,949) |
| Basic and diluted net loss per common share | $ (2.79) | $ (15.41) | $ (12.53) |
| Weighted average basic and diluted common share outstanding | 6,238,581 | 155,600 | 155,600 |
| Unaudited pro forma net loss | $ (11,861) | | |
| Unaudited pro forma basic and diluted net loss per common share(1) | $ (1.73) | | |
| Unaudited pro forma weighted average basic and diluted common shares outstanding(1) | 6,861,570 | | |

(1) See Note 3(g) to our audited financial statements appearing at the end of this annual report for information regarding computation of unaudited pro forma basic and diluted net loss per common share and the unaudited pro

forma weighted average basic and diluted common shares outstanding used in computing pro forma basic and diluted net loss per common share.

| | As of December 31, | | |
|---|---|---|---|
| | 2014 | 2013 | 2012 |
| | | (in thousands) | |
| **Balance Sheet Data:** | | | |
| Cash and cash equivalents | $ 19,682 | $ 13 | $ 53 |
| Working capital | 18,929 | (12,080) | (10,123) |
| Total assets | 20,374 | 851 | 154 |
| Convertible notes payable | | 11,907 | 10,159 |
| Series A redeemable convertible preferred stock | | 5,880 | 5,440 |
| Total shareholders equity (deficit) | 18,929 | (17,960) | (15,562) |

Table of Contents

## 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 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 clinical stage specialty pharmaceutical company developing non-opioid therapeutics for the treatment of pain, initially for acute pain following surgery. Our lead product, Dex, has completed a placebo controlled trial demonstrating effective pain relief in chronic lower back pain patients. We have studied various dosage forms of Dex in nine completed clinical trials, including two placebo controlled chronic lower back pain trials that demonstrated effective pain relief. Dex-IN, our proprietary intranasal formulation of Dex, is currently being studied in a Phase II clinical trial for acute pain following surgery. Dex, which is in a class of drugs called alpha-2 adrenergic agonists, is a 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®. As Dex is not in the opioid class of drugs, we believe it will overcome many of the side effects associated with commonly prescribed opioid therapeutics, including addiction, constipation and respiratory distress while maintaining analgesic, or pain relieving, effect. If we are successful in obtaining approval of Dex-IN, our proprietary intranasal formulation of Dex, for acute pain, we may elect to pursue an additional approval for cancer breakthrough pain. Upon regulatory approval, our license with Orion and our ownership rights with respect to dosage forms for our product candidates will provide us worldwide commercial rights related to Dex, except in Europe, Turkey and the CIS, for use in the treatment of pain in humans.

We are a development stage company with a limited operating history. We have funded our operations to date primarily from proceeds received from a private placement of convertible preferred stock, convertible notes and an 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.

We have incurred losses and generated negative cash flows from operations since inception. As of December 31, 2014, we had an accumulated deficit of $34.1 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 Dex-IN, including completion of the ongoing Phase II Post Op Day 1, and planned Phase III pivotal and safety trials. After an interim analysis in September 2014, Recro closed its 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 October 2014, we commenced a Post Op Day 1 Phase II clinical trial of Dex-IN in the treatment of acute post-operative pain following bunionectomy surgery. In addition, based on the availability of additional financial resources, we plan to advance development of our proprietary formulations of Dex for additional indications and development of our second proprietary compound, Fado. Based upon additional financial resources and potential strategic interest, we may develop and commercialize our proprietary formulations of Dex ourselves or with a partner.

On March 7, 2015, we entered into a definitive agreement under which we will acquire assets from Alkermes, including worldwide rights to IV/IM meloxicam, a proprietary, Phase III-ready, long-acting COX-2 NSAID for moderate to severe acute pain, as well as a contract manufacturing facility, royalty and formulation business in Gainesville.

Table of Contents

Under the terms of the agreement, we will pay Alkermes $50.0 million at closing, and acquire the rights to IV/IM meloxicam and ownership of a cGMP manufacturing facility and related business located in Gainesville. Alkermes is entitled to receive 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, in each case, related to IV/IM meloxicam.

At closing, we will issue to Alkermes a seven-year warrant to purchase an aggregate of 350,000 shares of our common stock. The $50.0 million up-front payment will be funded via a five-year senior secured term loan with OrbiMed, which carries interest at LIBOR plus 14.0%, with a 1.0% LIBOR floor. The acquisition is subject to customary closing conditions, including antitrust regulatory approval, and is anticipated to close in the second quarter of 2015.

We expect that annual operating results of operations will fluctuate for the foreseeable future due to several factors including the outcome and extent of clinical trial activities and timing and extent of research and development efforts. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future.

**Financial Overview**

***Research and Development Expenses***

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

- expenses incurred under agreements with CROs, investigative sites and consultants that conduct our clinical trials and a substantial portion of our preclinical studies;
- the cost of acquiring and manufacturing clinical trial materials;
- the cost of manufacturing validation tests, if these materials are manufactured prior to obtaining regulatory approval;
- 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 pharmacokinetic and efficacy trials and a placebo controlled Phase II efficacy trial. Our current priority is the

development of Dex-IN for acute pain following surgery. Dex-IN is currently being evaluated in a Post Op Day 1 Phase II clinical trial. In addition to the development of Dex-IN, we intend to strategically invest in our product pipeline, including the development of other indications for Dex-IN as well as other formulations of Dex and Fado. 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 costs relate to clinical trial sites, analysis and testing of the product and patent costs. We currently rely on MCG, a related party, for a portion of our research and development activities. 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 varies substantially according to the type, complexity and novelty of the product candidate;

Table of Contents

the FDA and comparable agencies in foreign countries impose substantial requirements on the introduction of therapeutic pharmaceutical products, typically requiring lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures;

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. Data obtained from these activities also are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval;

the costs, timing and outcome of regulatory review of a product candidate are uncertain;

the emergence of competing technologies and products and other adverse market developments could impede our commercial efforts; and

the risks disclosed in the section titled Risk Factors of this report.

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, Dex-IN or any of our other product candidates will generate revenues and cash flows.

We expect our research and development costs related to Dex-IN to be substantial for the foreseeable future as we advance this product candidate through clinical trials, manufacturing scale-up and other pre-approval activities. 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. Other general and administrative expenses include professional fees for legal, including patent related expenses, consulting, auditing and tax services, and stock compensation expense.

Our general and administrative expenses in 2014 were higher than in 2013 as we had greater expenses relating to our operations as a public company, including increased payroll and increased consulting, legal and compliance, accounting, insurance and investor relations costs. We also expect that our patent costs will increase if our patents are issued, as the annuity fees will be higher than our current expenses and, if additional formulation technology is developed for our product candidates, patent expenses could increase further.

***Interest Expense***

Interest expense consisted of accrued interest on our 8% Convertible Promissory Notes, or Bridge Notes, issued to our investors SCP Vitalife. 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.

***Net Operating Losses and Tax Carryforwards***

As of December 31, 2014, we had approximately $16.8 million of federal net operating loss carryforwards. We also had federal and state research and development tax credit carryforwards of $729,012 available to offset

Table of Contents

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.

The closing of the IPO, together with private placements and other transactions that have occurred since our inception, may trigger, or may have already triggered, an ownership change pursuant to Section 382 of the Internal Revenue Code of 1986. If an ownership change is triggered, it will limit our ability to use some of our net operating loss carryforwards. In addition, since we will need to raise substantial additional funding to finance our operations, we may undergo further ownership changes in the future, which could further limit our ability to use net operating loss carryforwards. As a result, if we generate taxable income, our ability to use some of our net operating loss carryforwards to offset U.S. federal taxable income may be subject to limitations, which could result in increased future tax liabilities to us.

**Results of Operations**

***Comparison of the Years Ended December 31, 2014 and 2013***

| | Year ended December 31, | | Increase (Decrease) | |
|---|---|---|---|---|
| | 2014 | 2013 | $ | % |
| | (amounts in thousands) | | | |
| Operating expenses: | | | | |
| Research and development | $ 7,874 | $ 544 | $ 7,330 | 1,347% |
| General and administrative | 3,998 | 546 | 3,452 | 632% |
| Total operating expenses | 11,872 | 1,090 | | |
| Other income (expense): | | | | |
| Interest income (expense) | (4,262) | (868) | 3,394 | 391% |
| Net loss | $ (16,134) | $ (1,958) | | |

***Research and Development.*** Our research and development expenses were $7.9 million and $544,000 for the years ended December 31, 2014 and 2013, respectively. The increase was primarily due to our Phase II clinical trials, manufacturing costs, short-term preclinical studies and management s salaries and benefits which commenced with the proceeds from the IPO.

***General and Administrative.*** Our general and administrative expenses were $4.0 million and $546,000 for the years ended December 31, 2014 and 2013, respectively. This increase of $3.4 million was mainly due to management s salaries, benefits and stock-based compensation, increased consulting, legal and accounting fees and directors and officers insurance associated to becoming a public company.

***Interest Expense.*** Interest expense on our Bridge Notes was $192,000 and $868,000 for the years ended December 31, 2014 and 2013, respectively. 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.

**Liquidity and Capital Resources**

As of December 31, 2014 and 2013, we had $19.7 million and $13,000, respectively, in cash and cash equivalents. We expect that cash and cash equivalents, together with interest income, will be sufficient to fund our current operations through March 31, 2016. Since inception through December 31, 2014, we have financed our product development, operations and capital expenditures primarily from private sales of $4.0 million of our Series A Stock, $9.6 million of our Bridge Notes and $30.3 million from the IPO.

Table of Contents

We will need to raise additional funds in order to continue our clinical trials beyond clinical trials of Dex-IN for acute pain following surgery, 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 Purchase Agreement with Aspire Capital in 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 Agreement. On the execution of the Agreement, we issued 96,463 shares of its common stock to Aspire Capital. 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 VWAP purchase 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 volume weighted average price for such purchase date.

**Sources and Uses of Cash**

Cash used in operations was $10.9 million and $817,000 for the years ended December 31, 2014 and 2013, respectively, which represents our operating losses less our non-cash interest expense and beneficial conversion charge taken on our Bridge Notes upon the conversion of such Bridge Notes, including accrued interest, into common stock.

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 $30.4 million from the IPO and the issuance of $175,000 of Bridge Notes to SCP Vitalife. Cash provided by financing activities was $776,000 for the year ended December 31, 2013, from the issuance of 8% Convertible Promissory Notes to SCP Vitalife less cash paid for offering costs.

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

- the timing and expenses of trials prior to an NDA for Dex-IN;
- the timing and outcome of the FDA s review of an NDA for Dex-IN if our trials are successful;
- the extent to which regulatory requirements may necessitate performing additional preclinical studies, clinical trials or pre-commercial manufacturing of 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;

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.

Table of Contents

We might seek additional debt or equity financing or both 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**

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

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

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.

***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, as defined in such agreement, 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.

We will pay milestone payments to Orion of up to 20.5 million Euros ($24.9 million as of December 31, 2014) after regulatory approval of Dex dosage forms and upon achieving certain sales milestones. We will also pay Orion royalty payments on net sales of our products, which royalty payments will be paid at varying percentages. Through December 31, 2014, no milestones have been achieved.

We also have an API agreement with Orion for the supply of Dex, which we believe provides fair and arm s-length pricing for the purchase of the Dex API that is produced in compliance with cGMP, and which addresses certain circumstances related to the provision of qualified manufacturing facilities or alternatives.

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 have made products worldwide solely for purposes of commercialization.

Table of Contents

We will pay milestone payments to Orion of up to 12.2 million Euros ($14.8 million as of December 31, 2014) based on regulatory filings and approval and on commercialized net sales levels. We will also pay Orion royalty payments on net sales of our products, which royalty payments will be paid at varying percentages. Through December 31, 2014, no milestones have been achieved.

***Leases***

We lease our facilities space under an operating lease on a month-to-month basis with MCG, a related party.

**Off-Balance Sheet Arrangements**

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

**Critical Accounting Policies and Estimates**

Our management s discussion and analysis of our financial condition and results of operations are based on our 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. On an ongoing basis, we evaluate these estimates and judgments, including those described below. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities and amounts recorded as revenues and expenses that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates.

While a summary of significant accounting policies are more fully described in Note 3 to our financial statements appearing in this report, we believe that the following accounting policy is the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our financial statements.

We record our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing the related service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we will adjust the accrual accordingly. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates. We do not anticipate the future settlement of existing accruals to differ materially from our estimates.

**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, 2014, we had approximately $19.7 million invested in money market instruments. We believe our policy of investing in highly rated securities, whose liquidities are, at December 31, 2014, 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.

Table of Contents

**Item 8. Financial Statements and Supplementary Data**

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

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

None.

**Item 9A. Controls and Procedures**

**Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of December 31, 2014. We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2014, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

**Management s Annual Report on Internal Control Over Financial Reporting**

This Annual Report on Form 10-K does not include a report of management s assessment regarding internal control over financial reporting due to a transition period established by the rules of the SEC for newly public companies.

**Changes in Internal Control over Financial Reporting**

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

**Item 9B. Other Information**

None.

Table of Contents

## PART III

### Item 10. Directors, Executive Officers and Corporate Governance

Information required by this Item will be incorporated by reference to the similarly named section of the Company s Definitive Proxy Statement for its 2015 Annual Meeting of Shareholders.

### Item 11. Executive Compensation

Information required by this Item will be incorporated by reference to the similarly named section of the Company s Definitive Proxy Statement for its 2015 Annual Meeting of Shareholders.

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

The following table contains information about our equity compensation plans as of December 31, 2014.

**Equity Compensation Plan Information**

| Plan Category | Number of securities to be issued upon exercise of outstanding options | Weighted-average exercise price of outstanding options | 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 | 1,033,300 | $ 5.77 | 10,700 |
| Equity compensation plans not approved by security holders | | | |
| Total | 1,033,300 | $ 5.77 | 10,700 |

Other information required by this Item will be incorporated by reference to the similarly named section of the Company s Definitive Proxy Statement for its 2015 Annual Meeting of Shareholders.

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

Information required by this Item will be incorporated by reference to the similarly named section of the Company s Definitive Proxy Statement for its 2015 Annual Meeting of Shareholders.

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

Information required by this Item will be incorporated by reference to the similarly named section of the Company s Definitive Proxy Statement for its 2015 Annual Meeting of Shareholders.

Table of Contents

## PART IV

### Item 15. Exhibits, Financial Statement Schedules

(a)(1) Financial Statements.

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

Financial Statements

Report of Independent Registered Public Accounting Firm

Balance Sheets as of December 31, 2013 and 2014

Statements of Operations for the years ended December 31, 2013 and 2014

Statements of Redeemable Convertible Preferred Stock and Shareholders Equity (Deficit) for the years ended December 31, 2013 and 2014

Statements of Cash Flows for the years ended December 31, 2013 and 2014

(a)(2) 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

Table of Contents

**RECRO PHARMA, INC.**

**Index to Financial Statements**

Table of Contents

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Shareholders

Recro Pharma, Inc.:

We have audited the accompanying balance sheets of Recro Pharma, Inc. (the Company) as of December 31, 2013 and 2014, and the related statements of operations, redeemable convertible preferred stock and shareholders equity (deficit), and cash flows for the years then ended. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these 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 financial statements referred to above present fairly, in all material respects, the financial position of Recro Pharma, Inc. as of December 31, 2013 and 2014, and the results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

/s/ KPMG LLP

Philadelphia, Pennsylvania

March 25, 2015

Table of Contents

**RECRO PHARMA, INC.**

Balance Sheets

| | December 31, 2013 | December 31, 2014 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 12,828 | $ 19,682,430 |
| Other receivables | 38,418 | 89,604 |
| Deferred offering costs | 784,177 | |
| Prepaid expenses | 15,689 | 601,586 |
| Total current assets | 851,112 | 20,373,620 |
| Total assets | $ 851,112 | $ 20,373,620 |
| **Liabilities and Shareholders Equity (Deficit)** | | |
| Current liabilities: | | |
| Convertible notes payable | $ 11,907,198 | $ |
| Accounts payable | 434,244 | 869,919 |
| Accrued expenses | 589,532 | 575,112 |
| Total current liabilities | 12,930,974 | 1,445,031 |
| Total liabilities | 12,930,974 | 1,445,031 |
| Commitments (note 7) | | |
| Series A redeemable convertible preferred stock, $0.01 par value. Authorized, 2,000,000 shares; issued and outstanding, 2,000,000 shares | 5,880,037 | |
| Shareholders equity (deficit): | | |
| 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, 155,600 shares at December 31, 2013 and 7,707,600 shares at December 31, 2014 | 1,556 | 77,076 |
| Additional paid-in capital | | 52,947,126 |
| Accumulated deficit | (17,961,455) | (34,095,613) |
| Total shareholders equity (deficit) | (17,959,899) | 18,928,589 |
| Total liabilities and shareholders equity (deficit) | $ 851,112 | $ 20,373,620 |

See accompanying notes to financial statements.

F-3

Table of Contents

**RECRO PHARMA, INC.**

Statements of Operations

| | Year ended December 31, 2013 | 2014 |
|---|---|---|
| Operating expenses: | | |
| Research and development | $ 543,632 | $ 7,874,187 |
| General and administrative | 546,119 | 3,997,596 |
| Total operating expenses | 1,089,751 | 11,871,783 |
| Other income (expense): | | |
| Interest income | 42 | 10,544 |
| Interest expense | (868,109) | (4,272,919) |
| | (868,067) | (4,262,375) |
| Net loss | (1,957,818) | (16,134,158) |
| Accretion of redeemable convertible preferred stock | (440,204) | (1,270,057) |
| Net loss applicable to common shareholders | $ (2,398,022) | $ (17,404,215) |
| Basic and diluted net loss per common share | $ (15.41) | $ (2.79) |
| Weighted average basic and diluted common shares outstanding | 155,600 | 6,238,581 |
| Unaudited pro forma net loss | | $ (11,861,239) |
| Unaudited pro forma basic and diluted net loss per common share | | $ (1.73) |
| Unaudited pro forma weighted average basic and diluted common shares outstanding | | 6,861,570 |

See accompanying notes to financial statements.

Table of Contents

**RECRO PHARMA, INC.**

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

For the Years Ended December 31, 2013 and 2014

| | Series A Redeemable Convertible Preferred Stock | | Shareholders Equity (Deficit) | | | | |
|---|---|---|---|---|---|---|---|
| | | | Common Stock | | Additional paid | | |
| | Shares | Amount | Shares | Amount | in capital | Accumulated Deficit | Total |
| Balance, December 31, 2012 | 2,000,000 | $ 5,439,833 | 155,600 | $ 1,556 | $ | $ (15,563,433) | $ (15,561,877) |
| Accretion of Series A redeemable convertible preferred stock to redemption value | | 440,204 | | | | (440,204) | (440,204) |
| Net loss | | | | | | (1,957,818) | (1,957,818) |
| Balance, December 31, 2013 | 2,000,000 | 5,880,037 | 155,600 | 1,556 | | (17,961,455) | (17,959,899) |
| Accretion of Series A redeemable convertible preferred stock to redemption value | | 88,771 | | | (88,771) | | (88,771) |
| Deemed dividend on Series A | | 1,181,286 | | | (1,181,286) | | (1,181,286) |
| Sale of common stock in initial public offering, net of offering costs of $4,243,658 | | | 4,312,500 | 43,125 | 30,213,217 | | 30,256,342 |
| Stock-based compensation expense | | | | | 531,150 | | 531,150 |
| Conversion of Series A and | (2,000,000) | (7,150,094) | 1,193,762 | 11,938 | 7,138,156 | | 7,150,094 |

| | | | | | | |
|---|---|---|---|---|---|---|
| accrued dividends to common stock | | | | | | |
| Conversion of notes payable and accrued interest to common stock | | 2,045,738 | 20,457 | 12,253,970 | | 12,274,427 |
| Beneficial conversion upon conversion of notes payable (Note 6) | | | | 4,080,690 | | 4,080,690 |
| Net loss | | | | | (16,134,158) | (16,134,158) |
| Balance, December 31, 2014 | $ | 7,707,600 | $ 77,076 | $ 52,947,126 | $ (34,095,613) | $ 18,928,589 |

See accompanying notes to financial statements.

Table of Contents

**RECRO PHARMA, INC.**

Statements of Cash Flows

| | Year ended December 31, 2013 | 2014 |
|---|---|---|
| Cash flows from operating activities: | | |
| Net loss | $ (1,957,818) | $ (16,134,158) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation | | 531,150 |
| Non-cash interest expense | 868,109 | 4,272,919 |
| Depreciation expense | 1,447 | |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses | (1,410) | (585,897) |
| Other receivables | 46,582 | (51,186) |
| Accounts payable and accrued expenses | 226,465 | 1,100,955 |
| Net cash used in operating activities | (816,625) | (10,866,217) |
| Cash flows from financing activities: | | |
| Proceeds from issuance of common stock | | 30,360,819 |
| Offering costs | (104,477) | |
| Proceeds from notes payable | 880,584 | 175,000 |
| Net cash provided by financing activities | 776,107 | 30,535,819 |
| Net (decrease) increase in cash and cash equivalents | (40,518) | 19,669,602 |
| Cash and cash equivalents, beginning of year | 53,346 | 12,828 |
| Cash and cash equivalents, end of year | $ 12,828 | $ 19,682,430 |
| Supplemental disclosure of cash flow information: | | |
| Accretion of Series A and deemed dividend | $ 440,204 | $ 1,270,057 |
| Conversion of Series A and accrued dividends | $ | $ 7,150,094 |

See accompanying notes to financial statements.

Table of Contents

**RECRO PHARMA, INC.**

Notes to Financial Statements

**(1) Background**

Recro Pharma, Inc. (the Company) is a development-stage company that was incorporated in Pennsylvania as Recro Pharma I, Inc. on November 15, 2007 (inception). The Company changed its name to Recro Pharma, Inc. on August 31, 2008. The Company is a clinical stage specialty pharmaceutical company developing non-opioid therapeutics for the treatment of pain, initially for acute pain following surgery. The Company operates in one segment and has its principal offices in Malvern, Pennsylvania.

**(2) Development-Stage Risks and Liquidity**

The Company has incurred losses and negative cash flows from operations since inception and has an accumulated deficit of $34.1 million as of December 31, 2014. 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, 2016. 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) Use of Estimates***

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (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 expenses during the reporting period. Actual results could differ from such estimates.

***(b) Fair Value of Financial Instruments***

Management believes that the carrying amounts of the Company s financial instruments, including cash equivalents, accounts payable, and accrued expenses, approximate fair value due to the short-term nature of those instruments.

***(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, 2013 and 2014 consisted of money market mutual funds and government and agency bonds.

***(d) Research and Development***

Research and development costs 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

Table of Contents

**RECRO PHARMA, INC.**

Notes to Financial Statements

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.

***(e) 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.

***(f) 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-based awards requires the input of subjective assumptions, including the fair value of the Company s common stock prior to the Company s initial public offering (IPO) and for stock options, 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 no 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

Table of Contents

**RECRO PHARMA, INC.**

Notes to Financial Statements

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.

***(g) Net Loss Per Common Share***

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

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as of December 31, 2013 and 2014, as they would be anti-dilutive:

| | December 31, | |
|---|---|---|
| | **2013** | **2014** |
| Shares issuable upon conversion of redeemable convertible preferred stock | 800,000 | |
| Shares issuable pursuant to redeemable convertible preferred stock accretion | 376,008 | |
| Options outstanding | 334,800 | 1,033,300 |
| Convertible notes payable | 1,984,533 | |
| Warrants | | 150,000 |

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

The unaudited pro forma net loss per common share is computed using the weighted average number of common shares outstanding and reflects the conversion of all outstanding shares of the Company s Series A Redeemable Convertible Preferred Stock, or Series A Stock, including accrued dividends, into 230,484 weighted average shares of common stock and the conversion of the 8% Convertible Promissory Notes, or Bridge Notes, including accrued interest, into 392,505 weighted average shares of common stock as if they had occurred at the later of the beginning of the period or date of issuance. Accordingly, net loss applicable to common stockholders is adjusted to remove all preferred stock accretion and interest expense on the Bridge Notes. The Company believes the unaudited pro forma net loss per common share provides material information to investors, as the conversion of the Company s Series A Stock to common stock, including accrued dividends, and the conversion of the Bridge Notes, including accrued interest, occurred upon the closing of the Company s IPO in March 2014, and the disclosure of pro forma net loss per common share provides an indication of net loss per common share that is comparable to what will be reported by the Company as a public company following the closing of the IPO.

Table of Contents

**RECRO PHARMA, INC.**

Notes to Financial Statements

The following table summarizes the calculation of unaudited pro forma basic and diluted net loss per common share:

| | Year ended December 31, 2014 |
|---|---|
| Numerator: | |
| Net loss applicable to common shareholders | $ (17,404,215) |
| Effect of pro forma adjustments: | |
| Accretion of redeemable convertible preferred stock | 1,270,057 |
| Interest expense on convertible notes | 4,272,919 |
| Pro forma net loss applicable to common shareholders | $ (11,861,239) |
| Denominator: | |
| Weighted average common shares outstanding | 6,238,581 |
| Effect of pro forma adjustments: | |
| Conversion of redeemable convertible preferred stock | 230,484 |
| Conversion of convertible notes | 392,505 |
| Shares used in computing unaudited pro forma weighted average basic and diluted common shares outstanding | 6,861,570 |
| Unaudited pro forma basic and diluted net loss per common share | $ (1.73) |

***(h) Recent Accounting Pronouncements***

In June 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-10 *Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810*, Consolidation, which eliminates all incremental financial reporting requirements for development stage entities by removing Accounting Standards Codification (ASC) Topic 915, *Development Stage Entities, from the FASB Accounting Standards Codification*. ASC Topic 915 is removed effective for annual periods beginning after December 15, 2014 and early adoption is permitted. The Company adopted the ASU effective with the issuance of the June 30, 2014 financial statements.

**(4) 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)

Table of Contents

**RECRO PHARMA, INC.**

Notes to Financial Statements

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, 2013: | | | |
| Assets: | | | |
| Money market mutual funds (included in cash and cash equivalents) | $ 12,828 | | |
| At December 31, 2014: | | | |
| Assets: | | | |
| Money market mutual funds | $ 10,921,896 | | |
| Government and agency bonds | 8,663,044 | | |
| Cash equivalents | $ 19,584,940 | $ | $ |

**(5) Accrued Expenses**

Accrued expenses consist of the following:

| | December 31, | |
|---|---|---|
| | **2013** | **2014** |
| Clinical trial and related costs | $ 18,944 | $ 112,438 |
| Professional and consulting fees | 567,500 | 394,021 |
| Payroll and related costs | 3,088 | 24,677 |
| Other | | 43,976 |
| | $ 589,532 | $ 575,112 |

**(6) Convertible Notes Payable**

As of December 31, 2013, $9,400,584 of the Bridge Notes were outstanding plus $2,506,614 of accrued interest. In January 2014, the Company issued an additional $175,000 of Bridge Notes in the aggregate. The Bridge Notes bore interest at 8% per annum, compounded quarterly and were due on demand. During the years ended December 31, 2013 and 2014, the Company recorded $868,109 and $192,229 of interest expense, respectively, for the Bridge Notes. Upon the closing of the Company s IPO, $9,575,585 of Bridge Notes outstanding plus $2,698,842 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 IPO price per share. The Company determined that the Bridge Notes contained a contingent beneficial conversion feature (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 of the offering price. In accordance with that accounting guidance, the contingent BCF of $4,080,690 was recognized as additional interest expense when the Bridge Notes, including accrued interest, converted into shares of common stock.

Table of Contents

**RECRO PHARMA, INC.**

Notes to Financial Statements

**(7) 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 20,500,000 ($24.9 million as of December 31, 2014) 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 2013 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 12,200,000 ($14.8 million as of December 31, 2014) 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 2013 or 2014.

**(8) 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 January 27, 2014, the Company effected a 1-for-2.5 reverse stock split of the Company s common stock. All share and per share amounts included in these financial statements and notes thereto have been adjusted retroactively for all periods presented to give effect to the reverse stock split.

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 $34,500,000. In connection with the IPO, the Company paid $4,243,658 in underwriting discounts, commissions and offering costs resulting in net proceeds of $30,256,342. Also in connection with the IPO, all of the outstanding shares of the Company s Series A Stock, including accreted dividends, and Bridge Notes, including accrued interest, were converted into common stock.

***(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, 2014, 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

Table of Contents

**RECRO PHARMA, INC.**

Notes to Financial Statements

IPO. The holders of Series A Stock were entitled to receive cumulative dividends of 8%, compounded annually. As of December 31, 2013, there were $1,880,037 of cumulative undeclared Series A Stock dividends. 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, the Company has recorded a non-cash deemed dividend of $1,181,286 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 in the accompanying financial statements.

Upon the closing of the Company s IPO on March 12, 2014, the Series A Stock plus $1,968,808 of cumulative Series A Stock dividends were converted into 1,193,762 shares of common stock. After the IPO, there are no longer any shares of Series A Stock authorized or outstanding.

***(d) Warrants***

In connection with the closing of the Company s IPO on March 12, 2014, the Company issued to the designees of Aegis Capital Corporation, the representative of the underwriters for the IPO, warrants to purchase 150,000 shares of common stock. The warrants are exercisable for cash at a price of $12.00 per share. The warrants are exercisable by the holders at any time, in whole or in part, during the four-year period ending March 12, 2018.

**(9) 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, 2014, no stock appreciation rights have been issued. Subsequent to adoption, the Plan has been 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. Stock options are exercisable generally for a period of 10 years from the date of grant and generally vest over 4 years. As of December 31, 2014, 10,526 and 174 shares were 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 year ended December 31, 2014 was $3.55. The fair value of the options was estimated on the date of grant using a Black-Scholes option pricing model with the following assumptions:

| | **2014** |
|---|---|

| | |
|---|---|
| Expected life | 6.0 years |
| Expected volatility | 80.30% |
| Risk-free interest rate | 2.14-2.73% |
| Expected dividend yield | |

Stock-based compensation expense for the year ended December 31, 2014 was $531,150. There was no stock-based compensation expense for the year ended December 31, 2013.

Table of Contents

**RECRO PHARMA, INC.**

Notes to Financial Statements

The following table summarizes stock option activity during year ended December 31, 2014:

| | 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 | |
| Exercised | | | |
| Canceled | | | |
| Balance, December 31, 2014 | 1,033,300 | $ 5.77 | 7.83 years |
| Options exercisable, December 31, 2014 | 426,520 | $ 6.38 | 5.33 years |

Included in the table above are 70,500 performance-based options granted in December 2014 with an exercise price of $2.47 per share that vest 30% upon positive topline results from the Company s ongoing Phase II clinical trial, with the remaining portion of the performance-based options vesting monthly over a three-year period beginning on the date the performance conditions are satisfied.

In December 2014, the Company also granted 123,500 time-based options and 123,500 performance-based options to the Company s Chief Executive Officer with an exercise price of $2.47 per share that are subject to shareholder approval at the Company s 2015 annual meeting since there were insufficient shares available under the 2013 Plan. These options are excluded from the above table. The grant-date fair value of these options will be determined as of the date of shareholder approval.

As of December 31, 2014, there was $2,411,030 of unrecognized compensation expense related to unvested options that are expected to vest and will be expensed over a weighted average period of 3.59 years, which includes $121,260 of unrecognized compensation related to performance-based options.

**(10) Income Taxes**

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, | |
|---|---|---|
| | 2013 | 2014 |

| | | |
|---|---|---|
| U.S. federal statutory income tax rate | 34.0% | 34.0% |
| State taxes, net of federal benefit | 6.6% | 6.6% |
| Nondeductible expenses | (18.0)% | (10.8)% |
| Research and development credits | 0.7% | 2.3% |
| Change in valuation allowance | (23.3)% | (32.1)% |
| Effective income tax rate | % | % |

Table of Contents

**RECRO PHARMA, INC.**

Notes to Financial Statements

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

| | December 31, | |
|---|---|---|
| | 2013 | 2014 |
| Net operating loss carryforwards | $ 3,697,105 | $ 6,799,653 |
| Research and development credits | 359,980 | 729,012 |
| Capitalized start-up costs | 1,130,893 | 2,626,367 |
| Intangibles | 658,422 | 658,422 |
| Stock-based compensation | 49,009 | 264,621 |
| Other temporary differences | 9,446 | 9,135 |
| Gross deferred tax asset | 5,904,855 | 11,087,210 |
| Deferred tax assets valuation allowance | (5,904,855) | (11,087,210) |
| | $ | $ |

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. The Company believes that it is more likely than not that the Company s deferred income tax asset will not be realized in the immediate future. As such, there is a full valuation allowance against the net deferred tax assets as of December 31, 2013 and 2014.

The following table summarizes carryforwards of Federal net operating losses and tax credits as of December 31, 2014:

| | Amount | Expiration | |
|---|---|---|---|
| Federal net operating losses | $ 16,750,636 | 2028 | 2034 |
| Research and development credits | $ 729,012 | 2028 | 2034 |

Under the Tax Reform Act of 1986 (the Act), the utilization of a corporation s net operating loss and research and development tax credit carryforwards is limited following a greater than 50% change in ownership during a three-year period. Any unused annual limitation may be carried forward to future years for the balance of the carryforward period. The Company may have experienced ownership changes, as defined by the Act, as a result of past financings; accordingly, the Company s ability to utilize the aforementioned carryforwards may be limited. The Company has not yet determined whether or not ownership changes, as defined by the Act, have occurred. In addition, state net operating loss carryforwards may be further limited, including Pennsylvania, which has a limitation equal to the greater of 30.0% of taxable income after modifications and apportionment or $5,000,000 on state net operating losses

utilized in any one year.

The Company will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2014, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company s statements of operations. Due to net operating loss and tax credit carry forwards that remain unutilized, income tax returns for tax years from inception through 2013 remain subject to examination by the taxing jurisdictions.

**(11) Related Party Transactions**

In July 2008, the Company entered into an agreement with Malvern Consulting Group, Inc., or MCG, a consulting company affiliated with the Company s President and Chief Executive Officer. A new agreement

Table of Contents

**RECRO PHARMA, INC.**

Notes to Financial Statements

was signed in October 2013 under which MCG continues to provide consulting services to the Company, principally in the fields of clinical development, regulatory affairs, and quality assurance. MCG consulting fees for services are based on a flat fee and time worked at hourly rates for consultants. The Company recorded MCG consulting fees for research and development and general and administrative expenses of $319,980 and $483,435 for the year ended December 31, 2013 and 2014, respectively. As of December 31, 2014, $37,618 was recorded in accrued expenses as amounts due to MCG. As of December 31, 2013, $18,944 and $130,331 was recorded in accrued expenses and accounts payable, respectively, as an amount due to MCG. In addition to fees for services, employees of MCG, certain of whom are related to the Company s President and Chief Executive Officer, received options to purchase 246,800 shares of common stock during 2009. The Company also paid $48,000 in rental fees to MCG for a month to month lease for facilities space for the year ended December 31, 2013 and $100,695 for facilities space for the year ended December 31, 2014. The Company s Chief Executive Officer was affiliated with SCP Vitalife Venture Funds, or SCP. A representative of SCP serves as Chairman of the Company s board of directors and two other representatives of SCP are members of the board of directors.

**(12) Subsequent Event**

On February 2, 2015, the Company entered into a Purchase Agreement with Aspire Capital in which Aspire Capital is committed to purchase up to an aggregate of $10.0 million of shares of the Company s common stock over the 24 month term of the Agreement. On the execution of the Purchase Agreement, the Company issued 96,463 shares of its common stock to Aspire Capital.

On March 7, 2015, the Company entered into a definitive agreement under which we will acquire assets from Alkermes plc, or Alkermes, including worldwide rights to IV/IM meloxicam, a proprietary, Phase III-ready, long-acting COX-2 NSAID for moderate to severe acute pain, as well as a contract manufacturing facility, royalty and formulation business in Gainesville, Georgia.

Under the terms of the agreement, the Company will pay Alkermes $50.0 million at closing, and acquire the rights to IV/IM meloxicam and ownership of a cGMP manufacturing facility and related business located in Gainesville, Georgia. Alkermes is entitled to receive 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, in each case, related to IV/IM meloxicam.

At closing, the Company will issue to Alkermes a seven-year warrant to purchase an aggregate of 350,000 shares of the Company s common stock. The $50.0 million up-front payment will be funded via a five-year senior secured term loan with an affiliate of OrbiMed, which carries interest at LIBOR plus 14.0% with a 1.0% LIBOR floor. The acquisition is subject to customary closing conditions, including antitrust regulatory approval, and is anticipated to close in the second quarter of 2015.

Table of Contents

## SIGNATURES

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

Date: March 25, 2015

**RECRO PHARMA, INC.**

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

## POWER OF ATTORNEY

We, the undersigned officers and directors of Recro Pharma, Inc., hereby severally constitute and appoint Gerri A. Henwood and Charles Garner, our true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution in her or him for her or him and in her or his name, place and stead, and in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as full to all intents and purposes as she or he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or her or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

| Signature | Title | Date |
|---|---|---|
| /s/ Gerri A. Henwood | President, Chief Executive Officer and Director | March 25, 2015 |
| Gerri A. Henwood | (Principal Executive Officer) | |
| /s/ Charles Garner | Chief Financial Officer | March 25, 2015 |
| Charles Garner | (Principal Financial Officer) | |
| /s/ Donna Nichols | Chief Accounting Officer | March 25, 2015 |
| Donna Nichols | (Principal Accounting Officer) | |
| /s/ Alfred Altomari | Director | March 25, 2015 |
| Alfred Altomari | | |

| | | |
|---|---|---|
| /s/ William L. Ashton<br>William L. Ashton | Director | March 25, 2015 |
| /s/ Michael Berelowitz<br>Michael Berelowitz | Director | March 25, 2015 |
| /s/ Winston J. Churchill<br>Winston J. Churchill | Director | March 25, 2015 |
| /s/ Abraham Ludomirski<br>Abraham Ludomirski | Director | March 25, 2015 |
| /s/ Wayne B. Weisman<br>Wayne B. Weisman | Director | March 25, 2015 |

Table of Contents

## EXHIBIT INDEX

| Exhibit No. | Description | Method of Filing |
|---|---|---|
| 1.1 | Underwriting Agreement. | Incorporated herein by reference to Exhibit 1.1 to the Company s Registration Statement on Form S-1/A filed on February 11, 2014. |
| 2.1 | Purchase and Sale Agreement, dated March 7, 2015, by and among Recro Pharma, Inc., Recro Pharma LLC, Daravita Limited, Alkermes Pharma Ireland Limited and Eagle Holdings USA, Inc. | Incorporated herein by reference to Exhibit 2.1 to the Company s Current Report on Form 8-K filed on March 11, 2015. |
| 3.1 | Second Amended and Restated Articles of Incorporation of Recro Pharma, Inc. | Incorporated herein by reference to Exhibit 3.1 to the Company s Current Report on Form 8-K filed on March 13, 2014. |
| 3.2 | Third Amended and Restated Bylaws of Recro Pharma, Inc. | Incorporated herein by reference to Exhibit 3.2 to the Company s Current Report on Form 8-K filed on March 13, 2014. |
| 4.1 | Specimen certificate evidencing shares of common stock. | Incorporated herein by reference to Exhibit 4.1 to the Company s Registration Statement on Form S-1/A filed on December 20, 2013. |
| 4.2 | Investor Rights Agreement, dated September 4, 2008, by and among Recro Pharma, Inc., and the investors party thereto. | Incorporated herein by reference to Exhibit 4.2 to the Company s Registration Statement on Form S-1/A filed on November 29, 2013. |
| 4.3 | Registration Rights Agreement, dated February 2, 2015, between Recro Pharma, Inc. and Aspire Capital Fund, LLC. | Incorporated herein by reference to Exhibit 4.1 to the Company s Current Report on Form 8-K filed on February 3, 2015. |
| 4.4 | Form of Alkermes Warrant. | Incorporated herein by reference to Exhibit 4.1 to the Company s Current Report on Form 8-K filed on March 11, 2015. |
| 4.5 | Form of Orbimed Warrant. | Incorporated herein by reference to Exhibit 4.2 to the Company s Current Report on Form 8-K filed on March 11, 2015. |
| 10.1 | Dexmedetomidine License Agreement, dated August 22, 2008, by and among Recro Pharma, Inc. and Orion Corporation. | Incorporated herein by reference to Exhibit 10.1 to the Company s Registration Statement on Form S-1/A filed on November 29, 2013. |
| 10.2 | First Amendment to Dexmedetomidine License Agreement, dated January 17, 2009, by and between Recro Pharma, Inc., and Orion Corporation. | Incorporated herein by reference to Exhibit 10.2 to the Company s Registration Statement on Form S-1/A filed on November 29, 2013. |
| 10.3 | Dexmedetomidine API Supply Agreement, dated August 22, 2008, by and among Recro Pharma, Inc., | Incorporated herein by reference to Exhibit 10.3 to the Company s Registration Statement on |

| | | |
|---|---|---|
| | and Orion Corporation. | Form S-1/A filed on November 29, 2013. |
| 10.4 | Fadolmidine License Agreement, dated July 21, 2010, by and among Recro Pharma, Inc. and Orion Corporation. | Incorporated herein by reference to Exhibit 10.4 to the Company s Registration Statement on Form S-1/A filed on November 29, 2013. |
| 10.5 | Employment Agreement, dated October 8, 2013, between Recro Pharma, Inc. and Gerri Henwood. | Incorporated herein by reference to Exhibit 10.5 to the Company s Registration Statement on Form S-1/A filed on November 29, 2013. |

Table of Contents

| Exhibit No. | Description | Method of Filing |
|---|---|---|
| 10.6 | Employment Agreement, dated October 9, 2013, between Recro Pharma, Inc. and Charles Garner. | Incorporated herein by reference to Exhibit 10.6 to the Company s Registration Statement on Form S-1/A filed on November 29, 2013. |
| 10.7 | Employment Agreement, dated October 9, 2013, between Recro Pharma, Inc. and Randall Mack. | Incorporated herein by reference to Exhibit 10.7 to the Company s Registration Statement on Form S-1/A filed on November 29, 2013. |
| 10.8 | Employment Agreement, dated October 9, 2013, between Recro Pharma, Inc. and Diane Myers. | Incorporated herein by reference to Exhibit 10.8 to the Company s Registration Statement on Form S-1/A filed on November 29, 2013. |
| 10.9 | Employment Agreement, dated October 9, 2013, between Recro Pharma, Inc. and Donna Nichols. | Incorporated herein by reference to Exhibit 10.9 to the Company s Registration Statement on Form S-1/A filed on November 29, 2013. |
| 10.10 | Form of Amendment to the Employment Agreement of each of Gerri Henwood, Charles Garner, Randall Mack, Diane Myers and Donna Nichols. | Incorporated herein by reference to Exhibit 10.3 to the Company s Current Report on Form 8-K filed on December 19, 2014. |
| 10.11 | 2008 Stock Option Plan. | Incorporated herein by reference to Exhibit 10.10 to the Company s Registration Statement on Form S-1/A filed on November 29, 2013. |
| 10.12 | Form of 2008 Stock Option Plan Award Agreement. | Incorporated herein by reference to Exhibit 10.11 to the Company s Registration Statement on Form S-1/A filed on November 29, 2013. |
| 10.13 | 2013 Equity Incentive Plan. | Incorporated herein by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed on March 13, 2014. |
| 10.14 | Form of 2013 Equity Incentive Plan Award Agreement. | Filed herewith. |
| 10.15 | Master Consulting Services Agreement, dated October 10, 2013, by and between Recro Pharma, Inc. and Malvern Consulting Group, Inc. | Incorporated herein by reference to Exhibit 10.14 to the Company s Registration Statement on Form S-1/A filed on November 29, 2013. |
| 10.16 | Office Services Agreement, dated January 1, 2012, between Recro Pharma, Inc. and Malvern Consulting Group, Inc. | Incorporated herein by reference to Exhibit 10.15 to the Company s Registration Statement on Form S-1/A filed on November 29, 2013. |
| 10.17 | Amendment #1 to the Office Services Agreement, dated October 3, 2013, by and between Recro Pharma, Inc. and Malvern Consulting Group, Inc. | Incorporated herein by reference to Exhibit 10.16 to the Company s Registration Statement on Form S-1/A filed on November 29, 2013. |
| 10.18 | Common Stock Purchase Agreement, dated February 2, 2015, between Recro Pharma, Inc. and Aspire Capital Fund, LLC. | Incorporated herein by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed on February 3, 2015. |
| 10.19 | | |

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| | Credit Agreement, dated as of March 7, 2015, by and between Recro Pharma LLC and OrbiMed Royalty Opportunities II, LP. | Incorporated herein by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed on March 11, 2015. |
| 10.20 | Guarantee, dated as of March 7, 2015, by Recro Pharma, Inc. in favor of OrbiMed Royalty Opportunities II, LP. | Incorporated herein by reference to Exhibit 10.2 to the Company s Current Report on Form 8-K filed on March 11, 2015. |

Table of Contents

| Exhibit No. | Description | Method of Filing |
|---|---|---|
| 23.1 | Consent of KPMG LLP, Independent Registered Public Accounting Firm. | Filed herewith. |
| 31.1 | Rule 13a-14(a)/15d-14(a) certification of Gerri A. Henwood | Filed herewith. |
| 31.2 | Rule 13a-14(a)/15d-14(a) certification of Charles Garner | Filed herewith. |
| 31.3 | Rule 13a-14(a)/15d-14(a) certification of Donna Nichols | Filed herewith. |
| 32 | Section 1350 Certification | Filed herewith. |
| 101 INS | XBRL Instance Document | Filed herewith. |
| 101 SCH | XBRL Taxonomy Extension Schema | Filed herewith. |
| 101 CAL | XBRL Taxonomy Extension Calculation Linkbase | Filed herewith. |
| 101 DEF | XBRL Taxonomy Extension Definition Linkbase | Filed herewith. |
| 101 LAB | XBRL Taxonomy Extension Label Linkbase | Filed herewith. |

Management contract or compensatory plan or arrangement.
Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 406 under the Securities Act of 1933.