Recro Pharma, Inc.
Form 424B3
February 26, 2015
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Filed pursuant to Rule 424(b)(3)
Registration No. 333-201841

PROSPECTUS

2,500,000 Shares

Common Stock

This prospectus relates to the sale of up to 2,500,000 shares of our common stock by Aspire Capital Fund, LLC. Aspire Capital is also referred to in this prospectus as the selling shareholder. The prices at which the selling shareholder may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive proceeds from the sale of the shares by the selling shareholder. However, we may receive proceeds of up to $10.0 million from the sale of our common stock to the selling shareholder, pursuant to a common stock purchase agreement entered into with the selling shareholder on February 2, 2015.

The selling shareholder is an underwriter within the meaning of the Securities Act of 1933, as amended. We will pay the expenses of registering these shares, but all selling and other expenses incurred by the selling shareholder will be paid by the selling shareholder.

Our common stock trades on the NASDAQ Capital Market, or NASDAQ, under the ticker symbol REPH . On February 25, 2015, the last reported sale price per share of our common stock was $3.35 per share.

You should read this prospectus and any prospectus supplement, together with additional information described under the heading Where You Can Find More Information, carefully before you invest in any of our securities.

Investing in our securities involves a high degree of risk. See Risk Factors on page 8 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation

to the contrary is a criminal offense.

The date of this prospectus is February 26, 2015.

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We have not authorized anyone to provide any information other than that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, or can provide any assurance as to the reliability of, any other information that others may give you. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where such offers and sales are permitted. The information in this prospectus or any free writing prospectus is accurate only as of its date, regardless of its time of delivery or of any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity and market share, is based on information from our own management estimates and research, as well as from industry and general publications and research, surveys and studies conducted by third parties. Management estimates are derived from publicly available information, our knowledge of our industry and assumptions based on such information and knowledge, which we believe to be reasonable. In addition, assumptions and estimates of our and our industry s future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in Risk Factors. These and other factors could cause our future performance to differ materially from our assumptions and estimates. See Special Note Regarding Forward-Looking Statements.

This prospectus includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this prospectus appear without the ® and symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trademarks and tradenames.

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SUMMARY

This summary highlights certain information about us, this offering and selected information contained in the prospectus. This summary is not complete and does not contain all of the information that you should consider before deciding whether to invest in our common stock. For a more complete understanding of our company and this offering, we encourage you to read and consider the more detailed information in the prospectus, including Risk Factors and the financial statements and related notes. Unless we specify otherwise, all references in this prospectus to Recro, Recro Pharma, we, our, us, the Company, and our company refer to Recro Pharma, Inc.

Overview

Our Business

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, including two Phase Ib and one Phase II placebo controlled 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. If we are successful in obtaining approval of Dex-IN for post-operative 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 Commonwealth of Independent States, or CIS, for use in the treatment of pain in humans.

Overview of Dex

Dex is in a class of drugs called alpha-2 adrenergic agonists, which produce their effects by selectively activating the alpha-2 adrenergic receptors in the body and produce a broad range of effects depending on the specific drug and the alpha-receptors it activates, including anti-hypertensive, analgesic and sedative effects. In particular, Dex has demonstrated sedative, analgesic and anxiolytic properties in multiple preclinical and clinical studies, including the new drug application, or NDA, studies for Precedex®. We are currently pursuing a Section 505(b)(2) regulatory strategy for Dex-IN, which allows us to leverage the existing safety data from the NDA of Precedex® and Dexdor® in pursuing a program for a NDA for post-operative pain.

Post-Operative Pain Market

Based upon statistics from the National Center for Health Statistics, it is estimated that there are over 100 million surgeries performed in the United States each year. Of these surgeries, we believe at least 50 million procedures require post-operative pain medication. While opioids are generally considered the most effective and commonly prescribed treatment for post-operative pain, they are known to raise serious concerns due to addiction, respiratory depression and other side effects, including constipation, nausea, vomiting, tolerance and illicit use. Due to their addictive potential, opioids are regulated as controlled substances and are listed on Schedule II and III by the U.S.

Drug Enforcement Administration, or DEA. According to the Centers for Disease

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Control and Prevention, or CDC, overdose deaths from prescription painkillers have increased significantly over the past 10 years. Prescription painkillers, as defined by the CDC, refers to opioid or narcotic pain relievers, including drugs such as Vicodin® (hydrocodone), OxyContin® (oxycodone), Opana® (oxymorphone), and methadone.

All of these concerns limit the use of opioids and contribute to at least 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. Accordingly, we believe that physicians and third-party payors, including Medicare and Medicaid, are highly interested in new pain therapies that provide effective pain relief but overcome the concerns and issues associated with opioids.

Clinical and Competitive Advantages of Dex versus 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, such as relief of pain following orthopedic and intra-abdominal surgeries. Based on the 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 Schedule II nor Schedule III controlled substance as opioid therapeutics are designated;
- Dex has not demonstrated habituative effects, based upon the NDA studies for Precedex®;
- Dex does not cause respiratory depression, a well-documented side effect of opioid use;
- Dex is not associated with constipation, nausea, or vomiting, side effects commonly seen with opioid use, which can lead to poor pain management;
- Dex has been observed to lower morphine requirements while maintaining adequate pain management as demonstrated by the NDA and independent studies;
- Patients utilizing Dex have been observed to be cognitively intact, while patients utilizing opioid analgesics have been reported to become cognitively impaired; and
- Dex has demonstrated anxiolytic properties that help lessen anxiety, which may help with pain management.

We believe these advantages will translate well into pain indications, some of which we expect to pursue subsequent to receiving FDA approval for Dex-IN for post-operative pain.

Pipeline

Our lead product candidate is Dex-IN, our intranasal formulation of Dex. We are also evaluating multiple formulations of Dex to target a range of pain indications, including breakthrough cancer pain in addition to post-operative pain. In addition to Dex, we have a second alpha-2 agonist candidate under development, Fadolmidine, or Fado, which we believe shows significant promise in neuropathic pain.

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Our Completed Clinical Trials of Dex

We have evaluated multiple formulations of Dex in nine completed studies in over 200 subjects, including two Phase Ib and one Phase II placebo-controlled studies, described below, to evaluate the analgesic efficacy, safety and pharmacokinetics of Dex. Based upon the results of these trials, we believe that our formulations of Dex have demonstrated their potential as an analgesic for pain relief. We have chosen to develop Dex-IN over other formulations since it has a faster onset of action while still maintaining analgesic affect, which makes it best suited for post-operative pain and breakthrough pain.

Clinical Study REC-14-013. Our current study of Dex-IN is a Phase II clinical trial in approximately 200 to 250 post-surgical patients. The study is a randomized, multicenter, double-blind, placebo-controlled study to evaluate the efficacy and safety of Dex-IN in adult patients undergoing bunionectomy surgery, initiating dosing of study medication on post-operative day 1, or Post Op Day 1. 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. An interim analysis for sample size is planned when approximately half of evaluable patients have been enrolled. We expect to report top-line results by mid-year 2015.

Clinical Study REC-13-012. Our most recently completed study utilized Dex-IN in a double-blind, placebo-controlled study of post-operative patients undergoing bunionectomy surgery beginning on post-operative day 0, or Post Op Day 0. 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. Based on the observations from this study, the input of our advisors in post-operative pain and results observed in earlier Dex pain studies, we believe that an effective clinical strategy would be to study Dex-IN in the management of post-operative pain starting on Post Op Day 1 following bunionectomy surgery. As a result of this belief, we initiated our current study, REC-14-013.

Clinical Study REC-11-010. We previously completed a study utilizing Dex-IN in 24 chronic lower back pain patients. This design was a Phase Ib, randomized, double-blind, placebo-controlled, three-period, cross-over study evaluating the safety, efficacy, and pharmacokinetics of Dex-IN. The patients in this study included both chronic opioid users and opioid-naïve patients. The study compared single doses of placebo, 25mcg of Dex and 50mcg of Dex, all administered using a single-use device.

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Generally in this study, a dose of 50mcg of Dex resulted in a rapid onset of analgesia, reaching statistically significant improvement in pain symptoms within 30 minutes of administration and sustained improvement in pain symptoms for up to four hours. The 25mcg dose of Dex also resulted in improved pain symptoms, although it did not statistically differentiate itself from placebo. Doses of Dex were well tolerated in this study. Adverse events, or AEs, were generally mild in intensity and were consistent with the AE profile of Dex in previous studies via intranasal and other routes of administration. The most frequently reported AEs included somnolence, dizziness, nausea, headache, and hypotension. These AEs were not significant enough to cause any subjects to discontinue their participation in the study.

Clinical Study REC-09-003. We utilized a proprietary sublingual formulation of Dex, Dex-SL, in another completed, placebo-controlled study. This study design was a Phase Ib, double-blind, placebo-controlled, two-period, cross-over evaluation of the safety, efficacy, and pharmacokinetics of Dex-SL in 21 chronic lower back pain subjects. This study also included an open-label, repeat dose period to evaluate the safety of two sublingual Dex doses separated by six hours.

In this study, a 50mcg dose of Dex was administered as a spray under the tongue. Similar to our REC-11-010 trial, Dex-SL produced statistically significant improvement in pain symptoms by 60 minutes after administration for chronic lower back pain subjects. Dex-SL produced sustained improvement in pain symptoms for up to six hours after dosing compared to a placebo. AEs experienced in this study were typically mild in severity. In the single-dose, cross-over periods, the most frequently reported AEs were dizziness, nasal congestion and hypotension. In the repeat dosing period, the most frequently reported AEs were orthostatic hypotension, headache and dizziness.

Our Strategy

Our corporate strategy is to further develop our non-opioid therapeutic candidates for multiple pain indications. Our strategy includes:

- Focusing on the development of Dex-IN for post-operative pain;
- Developing our candidates through FDA approval and retaining U.S. rights to maximize their potential value;
- Leveraging our management s development experience for other indications and product candidates; and
- Entering into strategic partnerships to maximize the potential of our product candidates outside of the United States.

Our Intellectual Property

We have an exclusive license from Orion to commercialize Dex as therapeutically active ingredients for use in the treatment of pain in humans in any dosage form for a variety of delivery vehicles (except for administration by injection or infusion) in the United States, Canada and other countries and territories worldwide other than Europe, Turkey, and the CIS. We also have an exclusive license from Orion for Fado for use in humans in any dose form. Our intellectual property portfolio currently consists of two families: one for Dex and one for Fado. One focus of our

claims strategy is on formulation claims and method of treatment claims. The Dex patent application family includes three portfolios of pending patent applications, one for each of sublingual, topical/transdermal, and intranasal formulations of Dex. The Company s strategy, if successful in obtaining patent protection, could lead to protection of our product candidates through 2030 subject to any extensions or disclaimers. See the Business Intellectual Property section of this prospectus for more information.

Risks Associated with Our Business

Our business is subject to a number of risks of which you should be aware before making an investment decision. See the Risk Factors section of this prospectus for a discussion of such risks.

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Corporate Information

Our principal executive offices are located at 490 Lapp Road, Malvern, PA 19355, and our telephone number is (484) 395-2470. Our website address is *www.recropharma.com*. The information contained in, or accessible through, our website does not constitute part of this prospectus.

Implications of Being an Emerging Growth Company

We qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- requirement to provide only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced Management s Discussion and Analysis of Financial Condition and Results of Operations disclosure;
- reduced disclosure about our executive compensation arrangements;
- no non-binding advisory votes on executive compensation or golden parachute arrangements; and
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting under Section 404(b) of the Sarbanes Oxley Act of 2002.

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. This election allows us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

We may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earlier of (1) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more; (2) the last day of our fiscal year following the fifth anniversary of the date of the completion of our initial public offering of our common stock, or our IPO, which we completed March 12, 2014; (3) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (4) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission, or the SEC.

To the extent that we continue to qualify as a smaller reporting company, as such term is defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, after we cease to qualify as an emerging growth company, certain of the exemptions available to us as an emerging growth company may continue to be available to us as a smaller reporting company, including: (1) not being required to comply with the auditor attestation requirements of our internal control over financial reporting under Section 404(b) of the Sarbanes Oxley Act of 2002; (2) scaled executive compensation disclosures; and (3) the requirement to provide only two years of audited financial statements, instead of three years.

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The Offering

Common stock offered by the selling shareholder	Up to 2,500,000 shares
Common stock outstanding	7,707,600 shares (as of January 28, 2015)
Use of proceeds	The selling shareholder will receive all of the proceeds from the sale of the shares offered for sale by it under this prospectus. We will not receive proceeds from the sale of the shares by the selling shareholder. However, we may receive up to $10.0 million in proceeds from the sale of our common stock to the selling shareholder under the common stock purchase agreement described below. Any proceeds from the selling shareholder that we receive under the purchase agreement are expected be used for working capital and general corporate purposes.
NASDAQ Capital Market symbol	REPH
Risk Factors	Investing in our securities involves a high degree of risk. You should carefully review and consider the Risk Factors section of this prospectus for a discussion of factors to consider before deciding to invest in shares of our common stock.

The number of shares of our common stock outstanding excludes 1,033,300 shares of our common stock issuable upon the exercise of stock options outstanding as of January 28, 2015 at a weighted-average exercise price of $5.77 per share; 174 additional shares of our common stock available for future issuance as of January 28, 2015 under our 2008 Stock Option Plan; 10,526 shares of our common stock available for future issuance under our 2013 Equity Incentive Plan, not including 247,000 shares of common stock which are subject to shareholder approval; and 150,000 shares of our common stock issuable upon the exercise of outstanding warrants with an exercise price of $12.00 per share.

Unless otherwise indicated, all information in this prospectus assumes no exercise of the outstanding options or warrants described above.

On February 2, 2015, we entered into a common stock purchase agreement (referred to in this prospectus as the Purchase Agreement), with Aspire Capital Fund, LLC, an Illinois limited liability company (referred to in this prospectus as Aspire Capital or the selling shareholder), which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $10.0 million of our shares of common stock over the approximately 24-month term of the Purchase Agreement. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, we issued to Aspire Capital 96,463 shares of our common stock as a commitment fee (referred to in this prospectus as the Commitment Shares). Concurrently with entering into the Purchase Agreement, we also entered into a registration

rights agreement with Aspire Capital (referred to in this prospectus as the Registration Rights Agreement), in which we agreed to file one or more registration statements, including the registration statement of which this prospectus is a part, as permissible and necessary to register under the Securities Act of 1933, as amended, or the Securities Act, the sale of the shares of our common stock that have been and may be issued to Aspire Capital under the Purchase Agreement.

As of January 28, 2015, there were 7,707,600 shares of our common stock outstanding (4,386,114 shares held by non-affiliates). If all of the 2,500,000 shares of our common stock offered hereby were issued and

outstanding as of the date hereof, such shares would represent 24.5% of the total common stock outstanding or 36.3% of the non-affiliate shares of common stock outstanding as of the date hereof. The aggregate number of shares that we can issue to Aspire Capital under the Purchase Agreement may in no case exceed 1,540,749 shares of our common stock (which is equal to approximately 19.99% of the common stock outstanding on the date of the Purchase Agreement), unless (i) shareholder approval is obtained to issue more, in which case this 1,540,749 share limitation, will not apply, or (ii) shareholder approval has not been obtained and at any time the 1,540,749 share limitation is reached and at all times thereafter the average price paid for all shares issued under the Purchase Agreement (including the Commitment Shares) is equal to or greater than $2.81, the Minimum Price, a price equal to the closing sale price of our common stock on the business date of the execution of the Purchase Agreement; provided that at no point in time shall Aspire Capital (together with its affiliates) beneficially own more than 19.99% of our common stock.

Pursuant to the Purchase Agreement and the Registration Rights Agreement, we are registering 2,500,000 shares of our common stock under the Securities Act, which includes the Commitment Shares that have already been issued to Aspire Capital and 2,403,537 shares of common stock which we may issue to Aspire Capital after the date of this prospectus. All 2,500,000 shares of common stock are being offered pursuant to this prospectus. Under the Purchase Agreement, we have the right but not the obligation to issue more than the 2,500,000 shares of common stock included in this prospectus to Aspire Capital. On February 26, 2015, the conditions to the commencement under the Purchase Agreement were satisfied. As of the date hereof, we do not have any plans or intent to issue to Aspire Capital any shares of common stock in addition to the 2,500,000 shares of common stock offered hereby.

On any trading day on which the closing sale price of our common stock exceeds $0.50, we have the right, in our sole discretion, to present Aspire Capital with a purchase notice, each a Purchase Notice, directing Aspire Capital (as principal) to purchase up to 50,000 shares of our common stock per trading day, provided that the aggregate price of such purchase shall not exceed $500,000 per trading day, up to $10.0 million of our common stock in the aggregate at a per share price, or the Purchase Price, calculated by reference to the prevailing market price of our common stock (as more specifically described below).

In addition, on any date on which we submit a Purchase Notice for 50,000 shares to Aspire Capital and the closing sale price of our stock is equal to or greater than $0.50 per share of Common Stock , we also have the right, in our sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice, each, a VWAP Purchase Notice, directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the Company s common stock traded on the NASDAQ on the next trading day, or the VWAP Purchase Date, subject to a maximum number of shares we may determine, or the VWAP Purchase Share Volume Maximum and a minimum trading price, or the VWAP Minimum Price Threshold, (as more specifically described below). The purchase price per Purchase Share pursuant to such VWAP Purchase Notice, or the VWAP Purchase Price is calculated by reference to the prevailing market price of our common stock (as more specifically described below).

The Purchase Agreement provides that the Company and Aspire Capital shall not effect any sales under the Purchase Agreement on any purchase date where the closing sale price of our common stock is less than $0.50 per share, or the Floor Price. The Floor Price and the respective prices and share numbers in the preceding paragraphs shall be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction. There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Aspire Capital. Aspire Capital has no right to require any sales by us, but is obligated to make purchases from us as we direct in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future fundings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us.

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RISK FACTORS

You should carefully consider the following information about risks, together with the other information contained in this prospectus, before making an investment in our common stock. If any of the circumstances or events described below actually arises or occurs, our business, results of operations, cash flows and financial condition could be harmed. In any such case, the market price of our common stock could decline, and you may lose all or part of your investment.

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 $12.7 million for the nine months ended September 30, 2014, and $1.5 million and $2.0 million for fiscal years 2012 and 2013, respectively. As of September 30, 2014, we had an accumulated deficit of $30.6 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.

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Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to predict the timing or amount of increased expenses, and when, or if, we will be able to achieve or maintain profitability. For example, our expenses could increase beyond expectations if we are required by the FDA to perform studies in addition to those that we currently anticipate.

Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate unless we enter into a strategic partnership for the launch and commercialization of our product candidates. Even if we are able to generate revenues from the sale of our products, we may not become profitable and may need to obtain additional funding to continue operations.

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

We were incorporated in 2007. Since inception, our operations have been primarily limited to developing our technology and undertaking non-clinical studies and clinical trials for our product candidates. We have not yet obtained regulatory approval for any of 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;

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

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

- the level of market acceptance for any approved product candidates and underlying demand for that product and wholesalers buying patterns.

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

If we fail to obtain sufficient additional financing, we would be forced to delay, reduce or eliminate our product development programs.

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 September 30, 2014, we had working capital of approximately $22.2 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 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.

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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 the term of the agreement is limited. See The Aspire Capital Transaction section of this prospectus for additional information. 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

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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.

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 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;

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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.

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.

Adverse events, or 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 investigational new drug application, or 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.

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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 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.

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 current good manufacturing practices, or 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.

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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, 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;

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- 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;
- 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 active pharmaceutical ingredient, or 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 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.

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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.

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 quality systems regulations, 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

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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 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.

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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 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.

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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.

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.

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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 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;

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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;

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.

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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, 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 the Company.

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 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.

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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 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 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.

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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.

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.

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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 September 30, 2014, we are the owner of record of two issued U.S. patent related to Fado and four issued foreign patents to Dex. As of September 30, 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 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.

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

The Company has 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.

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.

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

The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged 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;
- 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.

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 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 September 30, 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 43.1% of our outstanding common stock as of September 30, 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;

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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;

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

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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;
- 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.

We are registering for sale the Commitment Shares that we have issued and 2,403,537 shares that we may sell to Aspire Capital under the Purchase Agreement. It is anticipated that shares registered in this offering will be sold over a period of up to approximately 24 months from the date of this prospectus. The number of shares ultimately offered for sale by Aspire Capital under this prospectus is dependent upon the number of shares we

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elect to sell to Aspire Capital under the Purchase Agreement. Depending upon market liquidity at the time, sales of shares of our common stock under the Purchase Agreement may cause the trading price of our common stock to decline.

Aspire Capital may ultimately purchase all, some or none of the $10.0 million of common stock that, together with the Commitment Shares, is the subject of this prospectus. 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 under the registration statement, of which this prospectus is a part, 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 in this offering, 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.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus, 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.

In some cases, you can identify forward-looking statements by terms such as may, will, should, expect, plan, anticipate, could, intend, target, project, contemplates, believes, estimates, predicts, potential or negative of these terms or other similar expressions. The forward-looking statements in this prospectus are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described under the sections in this prospectus entitled Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this prospectus. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment.

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 our 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; and

our ability to successfully implement our strategy.

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.

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THE ASPIRE CAPITAL TRANSACTION

General

On February 2, 2015, we entered into the Purchase Agreement which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $10.0 million of our shares of common stock over the term of the Purchase Agreement. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, we issued to Aspire Capital the Commitment Shares. Concurrently with entering into the Purchase Agreement, we also entered into the Registration Rights Agreement, in which we agreed to file one or more registration statements as permissible and necessary to register under the Securities Act, the sale of the shares of our common stock that have been and may be issued to Aspire Capital under the Purchase Agreement.

As of January 28, 2015, there were 7,707,600 shares of our common stock outstanding (4,386,114 shares held by non-affiliates). If all of such 2,500,000 shares of our common stock offered hereby were issued and outstanding as of the date hereof, such shares would represent 24.5% of the total common stock outstanding or 36.3% of the non-affiliate shares of common stock outstanding as of the date hereof. The aggregate number of shares that we can issue to Aspire Capital under the Purchase Agreement may in no case exceed 1,540,749 shares of our common stock (which is equal to approximately 19.99% of the common stock outstanding on the date of the Purchase Agreement), unless (i) shareholder approval is obtained to issue more, in which case this 1,540,749 share limitation, will not apply, or (ii) shareholder approval has not been obtained and at any time the 1,540,749 share limitation is reached and at all times thereafter the average price paid for all shares issued under the Purchase Agreement (including the Commitment Shares) is equal to or greater than $2.81, the Minimum Price, a price equal to the closing sale price of our common stock on the business date of the execution of the Purchase Agreement; provided that at no one point in time shall Aspire Capital (together with its affiliates) beneficially own more than 19.99% of our common stock.

Pursuant to the Purchase Agreement and the Registration Rights Agreement, we are registering 2,500,000 shares of our common stock under the Securities Act, which includes the Commitment Shares that have already been issued to Aspire Capital and 2,403,537 shares of common stock which we may issue to Aspire Capital after the date of this prospectus. All 2,500,000 shares of common stock are being offered pursuant to this prospectus. Under the Purchase Agreement, we have the right but not the obligation to issue more than the 2,500,000 shares of common stock included in this prospectus to Aspire Capital. On February 26, 2015, the conditions to the commencement under the Purchase Agreement were satisfied. As of the date hereof, we do not have any plans or intent to issue to Aspire Capital any shares of common stock in addition to the 2,500,000 shares of common stock offered hereby.

On any trading day on which the closing sale price of our common stock is not less than $0.50 per share, we have the right, in our sole discretion, to present Aspire Capital with a Purchase Notice, directing Aspire Capital (as principal) to purchase up to 50,000 shares of our common stock per business day, up to $10.0 million of our common stock in the aggregate at a Purchase Price calculated by reference to the prevailing market price of our common stock over the preceding 12-business day period (as more specifically described below).

In addition, on any date on which we submit a Purchase Notice to Aspire Capital for 50,000 Purchase Shares and out stock price is not less than $0.50 per share, we also have the right, in our sole discretion, to present Aspire Capital with a VWAP Purchase Notice directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the Company s common stock traded on the NASDAQ on the next trading day, subject to the VWAP Purchase Share Volume Maximum and the VWAP Minimum Price Threshold. The VWAP Purchase Price is calculated by reference to the prevailing market price of our common stock (as more specifically described below).

The Purchase Agreement provides that the Company and Aspire Capital shall not effect any sales under the Purchase Agreement on any purchase date where the closing sale price of our common stock is less than $0.50.

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There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Aspire Capital. Aspire Capital has no right to require any sales by us, but is obligated to make purchases from us as we direct in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future fundings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us. Aspire Capital may not assign its rights or obligations under the Purchase Agreement.

Purchase Of Shares Under The Purchase Agreement

Under the Purchase Agreement, on any trading day selected by us on which the closing sale price of our common stock exceeds $0.50 per share, we may direct Aspire Capital to purchase up to 50,000 shares of our common stock per trading day. The Purchase Price of such shares is equal to the lesser of:

- the lowest sale price of our common stock on the purchase date; or
- the arithmetic average of the three lowest closing sale prices for our common stock during the twelve consecutive trading days ending on the trading day immediately preceding the purchase date.

In addition, on any date on which we submit a Purchase Notice to Aspire Capital for purchase of 50,000 shares, we also have the right to direct Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the our common stock traded on the NASDAQ on the next trading day, subject to the VWAP Purchase Share Volume Maximum and the VWAP Minimum Price Threshold, which is equal to the greater of (a) 80% of the closing price of the Company s common stock on the business day immediately preceding the VWAP Purchase Date or (b) such higher price as set forth by the Company in the VWAP Purchase Notice. The VWAP Purchase Price of such shares is the lower of:

- the Closing Sale Price on the VWAP Purchase Date; or
- 95% of the volume-weighted average price for our common stock traded on the NASDAQ :
  - on the VWAP Purchase Date, if the aggregate shares to be purchased on that date have not exceeded the VWAP Purchase Share Volume Maximum or
  - during that portion of the VWAP Purchase Date until such time as the sooner to occur of (i) the time at which the aggregate shares traded on the NASDAQ exceed the VWAP Purchase Share Volume Maximum or (ii) the time at which the sale price of the Company s common stock falls below the VWAP Minimum Price Threshold.

The purchase price will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the trading day(s) used to compute the purchase price. We may deliver multiple

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

Minimum Share Price

Under the Purchase Agreement, we and Aspire Capital may not effect any sales of shares of our common stock under the Purchase Agreement on any trading day that the closing sale price of our common stock is less than $0.50 per share.

Events of Default

Generally, Aspire Capital may terminate the Purchase Agreement upon the occurrence of any of the following events of default:

the effectiveness of any registration statement that is required to be maintained effective pursuant to the terms of the Registration Rights Agreement between us and Aspire Capital lapses for any reason (including, without limitation, the issuance of a stop order) or is unavailable to Aspire Capital for sale

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of our shares of common stock, and such lapse or unavailability continues for a period of ten consecutive business days or for more than an aggregate of thirty business days in any 365-day period, which is not in connection with a post-effective amendment to any such registration statement; in connection with any post-effective amendment to such registration statement that is required to be declared effective by the SEC, such lapse or unavailability may continue for a period of no more than 30 consecutive business days, with an extension for up to an additional 30 days if we receive a comment letter from the SEC in connection with such post-effective amendment;

the suspension from trading or failure of our common stock to be listed on our principal market for a period of three consecutive business days;

the delisting of our common stock from the NASDAQ, and the Company s Common Stock is not immediately thereafter listed and traded on the New York Stock Exchange, the NYSE MKT, the Nasdaq Global Select Market, the Nasdaq Global Market, the Over-The-Counter Bulletin Board interdealer quotation system or either one of the OTCQB or the OTCQX market places of the OTC Markets Group, Inc.;

our transfer agent s failure to issue to Aspire Capital shares of our common stock which Aspire Capital is entitled to receive under the Purchase Agreement within five business days after an applicable purchase date;

any breach by us of the representations or warranties or covenants contained in the Purchase Agreement or any related agreements which could have a material adverse effect on us, subject to a cure period of five business days;

if we become insolvent or are generally unable to pay our debts as they become due; or

any participation or threatened participation in insolvency or bankruptcy proceedings by or against us.

Our Termination Rights

The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us.

No Short-Selling or Hedging by Aspire Capital

Aspire Capital has agreed that neither it nor any of its agents, representatives and affiliates shall engage in any direct or indirect short-selling or hedging of our common stock during any time prior to the termination of the Purchase Agreement.

Effect of Performance of the Purchase Agreement on Our Shareholders

The Purchase Agreement does not limit the ability of Aspire Capital to sell any or all of the 2,500,000 shares registered in this offering. It is anticipated that shares registered in this offering will be sold over a period of up to approximately 24 months from the date of this prospectus. The sale by Aspire Capital of a significant amount of

shares registered in this offering at any given time could cause the market price of our common stock to decline and/or to be highly volatile. Aspire Capital may ultimately purchase all, some or none of the 2,500,000 shares of common stock not yet issued but registered in this offering. After it has acquired such shares, it may sell all, some or none of such shares. Therefore, sales to Aspire Capital by us pursuant to the Purchase Agreement also may result in substantial dilution to the interests of other holders of our common stock. However, we have the right to control the timing and amount of any 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.

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Percentage of Outstanding Shares After Giving Effect to the Purchased Shares Issued to Aspire Capital

In connection with entering into the Purchase Agreement, we authorized the sale to Aspire Capital of up to $10.0 million of our shares of common stock. However, we estimate that we will sell no more the 2,500,000 shares to Aspire Capital under the Purchase Agreement (including of the 96,463 Commitment Shares), all of which are included in this offering. Subject to any required approval by our board of directors, we have the right but not the obligation to issue more than the 2,500,000 shares included in this prospectus to Aspire Capital under the Purchase Agreement. In the event we elect to issue more than 2,500,000 shares under the Purchase Agreement, we will be required to file a new registration statement and have it declared effective by the SEC. The number of shares ultimately offered for sale by Aspire Capital in this offering is dependent upon the number of shares purchased by Aspire Capital under the Purchase Agreement. The following table sets forth the number and percentage of outstanding shares to be held by Aspire Capital after giving effect to the sale of shares of common stock issued to Aspire Capital at varying purchase prices:

Assumed Average Purchase Price	Proceeds from the Sale of Shares to Aspire Capital Under the Purchase Agreement Registered in this Offering (in millions)	Number of Shares to be Issued in this Offering at the Assumed Average Purchase Price (in millions)(1)	Percentage of Outstanding Shares After Giving Effect to the Purchased Shares Issued to Aspire Capital(2)
$0.50	$ 0.7	1.4	16%
$1.00	$ 1.4	1.4	16%
$2.00	$ 2.9	1.4	16%
$3.00	$ 7.2	2.4	24%
$4.00	$ 9.6	2.4	24%
$6.00	$10.0	1.7	18%
$8.00	$10.0	1.3	14%

(1) Excludes the Commitment Shares issued under the Purchase Agreement between the Company and Aspire Capital.

(2) The denominator is based on 7,707,600 shares outstanding as of January 28, 2015, the Commitment Shares previously issued to Aspire Capital and the number of shares set forth in the adjacent column which we would have sold to Aspire Capital at the corresponding assumed purchase price set forth in the adjacent column. The numerator is based on the number of shares which we may issue to Aspire Capital under the Purchase Agreement at the corresponding assumed purchase price set forth in the adjacent column.

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USE OF PROCEEDS

This prospectus relates to shares of our common stock that may be offered and sold from time to time by Aspire Capital. We will not receive any proceeds upon the sale of shares by Aspire Capital. However, we may receive proceeds up to $10.0 million under the Purchase Agreement with Aspire Capital. The proceeds received from the sale of the shares under the Purchase Agreement will be used for working capital and general corporate purposes. This anticipated use of net proceeds from the sale of our common stock to Aspire Capital under the Purchase Agreement represents our intentions based upon our current plans and business conditions.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. There can be no guarantee that we will ever pay any dividends.

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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 this prospectus. 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 elsewhere in this prospectus.

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 September 30, 2014, we have an accumulated deficit of $30.6 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, principally 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, the Company 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.

We expect that quarterly and 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.

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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;

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 prospectus.

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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.

We expect that our general and administrative expenses in 2014 will be higher than in 2013. We expect to have 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 consists 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, 2013, we had approximately $9.1 million of federal net operating loss carryforwards. We also had federal and state research and development tax credit carryforwards of $360,000 available to offset future taxable income. U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. These federal and state net operating loss and federal and state tax credit carryforwards will begin to expire at various dates beginning in 2028, if not utilized. As a result, we may not be able to take full advantage of these carryforwards for federal and state tax purposes.

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.

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Results of Operations

Comparison of the Nine Months Ended September 30, 2014 and 2013:

	Nine Months Ended September 30,		Increase (Decrease)	
	2014	2013	$	%
	(amounts in thousands)			
Operating expenses:				
Research and Development	$ 5,619	$ 482	$ 5,137	1,066%
General and Administrative	2,768	456	2,312	507%
Total operating expenses	8,387	938		
Other income (expense):				
Interest income (expense)	(4,266)	(636)	3,630	571%
Net loss	$ (12,653)	$ (1,574)		

Research and Development. Our research and development expenses were $5.6 million and $482,000 for the nine months ended September 30, 2014 and 2013, respectively. The increase was primarily due to our Phase II clinical trial and associated manufacturing costs, short-term preclinical studies and management s salaries and benefits which commenced with becoming a public company.

General and Administrative. Our general and administrative expenses were $2.8 million and $456,000 for the nine months ended September 30, 2014 and 2013, respectively. The increase of $2.3 million was mainly due to the management s salaries, benefits and stock-based compensation; increased consulting, legal and accounting fees and increased directors and officers insurance associated with becoming a public company.

Interest Expense. Interest expense on our Bridge Notes was $192,000 and $636,000 for the nine months ended September 30, 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.

Comparison of the Year Ended December 31, 2013 and the Year Ended December 31, 2012

	Year ended December 31,		Increase (Decrease)	
	2013	2012	$	%
	(amounts in thousands)			
Operating expenses:				
Research and development	$ 544	$ 542	$ 2	%
General and administrative	546	339	207	61%

Total operating expenses	1,090	881		
Other income (expense):				
Grant income		85	(85)	(100)%
Interest expense	(868)	(740)	128	17%
	(868)	(655)		
Net loss	$ (1,958)	$ (1,536)		

Research and Development. Our research and development expenses were $544,000 and $542,000 for the years ended December 31, 2013 and 2012, respectively. These expenses have remained steady due to the end of the Phase Ib clinical trials for Dex-IN in 2011 and our preparing to begin Phase IIb.

General and Administrative. Our general and administrative expenses were $546,000 and $339,000 for the years ended December 31, 2013 and 2012, respectively. This increase was mainly due to an increase of

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approximately $215,000 in consulting, legal and accounting fees due to costs associated with our responsibility for the maintenance of our patents and patent applications and additional work performed in preparation of raising additional capital.

Grant Income. During 2012, we recognized $85,000 in grant income under a Commonwealth of Pennsylvania incentive program from the sale of tax credits.

Interest Expense. Interest expense on our 8% Convertible Promissory Notes increased to $868,000 in 2013 from $740,000 in 2012 as a result of additional borrowings.

Liquidity and Capital Resources

As of September 30, 2014 and December 31, 2013, we had $23.9 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 September 30, 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.

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.

Sources and Uses of Cash

Cash used in operations was $6.6 million and $668,000 for the nine months ended September 30, 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 used in operations was $817,000 and $1.2 million for the years 2013 and 2012, respectively, which represents our operating losses less our non-cash interest expense on our 8% Convertible Promissory Notes.

Cash provided by financing activities was $30.5 million for the nine months ended September 30, 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 for the nine months ended September 30, 2013 was from the issuance of $685,000 of Bridge Notes to SCP Vitalife less $50,000 used for offering costs. Cash provided by financing activities was $776,000 and $1.3 million for the years ended December 31, 2013 and 2012, respectively, 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;

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- 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.

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.

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We will pay milestone payments to Orion of up to 20.5 million Euros ($25.9 million as of September 30, 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.

We also have an active pharmaceutical ingredient, or 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 current good manufacturing practices, or 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.

We will pay milestone payments to Orion of up to 12.2 million Euros ($15.4 million as of September 30, 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.

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 at the end of this prospectus, 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.

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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, 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 FDA approved and commercial injectable drug sold by Hospira, Inc. in the United States under the brand name Precedex® and by 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 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, 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 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.

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Pipeline

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 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 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

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burden estimated to be at least $560 to $635 billion a year in medical costs and lost productivity. According to the 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.

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

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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 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.

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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 IV Dex, trademarked Precedex® in the United States for 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®.

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

Clinical Trial Overview

Under our 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 (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 50 mcg dose of Dex-IN, a 35 mcg 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

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efficacy endpoints included use of rescue medication, Patient Global Assessment (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 50 mcg Dex-IN treatment group and one in the 35 mcg Dex-IN treatment group) discontinued due to symptomatic hypotension and one subject (35 mcg 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 50 mcg Dex IN treatment group) that had an adverse event of BP decreased. In addition, one patient in the Dex-IN 50 mcg treatment group and two patients in the placebo treatment group had a heart rate of 50 bpm or below along with a notable change from baseline heart rate. Lastly, no clinically significant changes were seen in electrocardiograms in any treatment group, and there were no clinically significant changes in clinical laboratory studies. Other key safety data of interest from the REC-13-012 trial are summarized in the table below.

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%)

REC-11-010

We previously utilized Dex-IN in 24 chronic lower back pain patients. This design was a Phase Ib, randomized, double-blind, placebo-controlled, three-period, cross-over study evaluating the safety, efficacy, and pharmacokinetics of Dex-IN. The patients in this study included both chronic opioid users and opioid-naïve subjects. The study compared single doses of placebo, 25mcg of Dex-IN and 50mcg of Dex-IN, all administered using a single-use device. The efficacy assessments used in this study were pain intensity, or PI, and pain relief, or PR. PI is measured at various times up to 6 hours post-dosing by asking patients to rate their pain on an 11-point scale, where 0 is absence of pain and 10 is the worst possible pain. PR is measured at various times up to 60 minutes post-dosing by asking patients to rate their pain relief on a 5-point scale, where 0 is no relief and 4 is complete relief. The efficacy endpoints of this pilot study included the change from baseline in pain intensity, or PID, SPID, which is a time-weighted sum of all of the PID scores, pain relief from baseline, or PR, and total PR, which is a time-weighted sum of all of the PR scores, or TOTPAR. PID, SPID, PR and TOTPAR are FDA-recognized endpoints for acute pain clinical trials.

Generally in this study, a 50mcg dose of Dex-IN resulted in a rapid onset of analgesia, reaching statistically significant improvement in pain symptoms within 30 minutes of administration and sustained improvement in pain symptoms for up to four hours. While the 25mcg treatment arm experienced meaningful improvement in pain symptoms, the resulting difference from placebo was not statistically significant. However, we believe this lack of statistical significance is likely due to the unexpectedly high placebo response observed during the first dosing period.

Clinical trial results are considered statistically significant when the probability that the results observed are due to the drug s effects, rather than due to chance. Statistical significance is measured by the probability value, or p-value. P-value measures the probability of the same trial results occurring as a result of a drug effect, rather

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than randomly. A clinical trial result with a p-value of equal to or less than 0.05 means that the probability of the same trial results occurring as a result of the drug s effects are high (95% or greater), and the probability that the results occurring randomly or by chance is equal to or less than 5%; such results are generally considered to be statistically significant.

For mean PID from baseline, Dex-IN 25mcg and 50mcg doses resulted in numerically superior scores relative to placebo. These improvements were statistically significant ($p < 0.05$) for the 50mcg group at the 45, 60, 90 minute timepoints as well as the 2 hour timepoint. The figure below illustrates the PID relative to baseline and includes the p-values for the statistically significant measurements.

Pain Intensity Difference at

Specific Times Relative to Baseline

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The Dex-IN 50mcg dose also resulted in a statistically significant reduction in summed pain intensity difference over the initial one-hour time period, SPID-60. The SPID-60 was identified as the primary efficacy variable in this Phase Ib clinical trial. The figure below includes the p-values for the statistically significant measures.

Summed Pain Intensity Differences

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For the measurement of PR, the 50mcg dose resulted in statistically significant pain relief starting at 30 minutes, which was maintained throughout the time period where PR was collected. The following two figures illustrate the PR at various timepoints and the TOTPAR values, respectively, as well as the p-values for the statistically significant measurements.

Pain Relief at Specific Times Relative to Baseline

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Total Pain Relief over Time

Dex-IN was well tolerated by patients in this study. Adverse events, or AEs were generally mild in intensity, and were consistent with the AE profile of Dex in previous studies via intranasal and other routes of administration. The most frequently reported AEs included somnolence, dizziness, nausea, headache, and hypotension. These AEs were not significant enough to cause any patients to discontinue their participation in the study. Vital sign assessments of heart rate and blood pressure were consistently decreased by a greater amount than placebo, with the 50mcg dose of Dex having a greater effect than the 25mcg dose. Thus, more reports of asymptomatic hypotension were recorded with the 50mcg dose. Some observations of mild sedation were made within 60 minutes after dosing, and again, with greater frequency in the 50mcg dose group. Local effects of active doses were well tolerated. Mean nasal irritation scores did not exceed one on a scale from zero to ten (zero equated to no symptoms and ten equated to worse possible symptoms), and AEs related to nasal discomfort were infrequent. Given the demonstrated analgesic effects we observed and what we believe to be an acceptable side effect profile when average plasma concentrations are below 0.25ng/mL, we believe the ideal dose of Dex-IN to be between 20mcg to 40mcg.

REC-09-003

We utilized Dex-SL in our other completed, placebo-controlled study in chronic lower back pain patients. This study design was a Phase Ib, double-blind, placebo-controlled, two-period, cross-over, evaluation of the safety, efficacy, and pharmacokinetics of Dex-SL in 21 chronic lower back pain subjects. This study also included an open-label, repeat dose period to evaluate the safety of two sublingual Dex doses separated by six hours. In this study, a 50mcg dose of Dex-SL was administered as a spray under the tongue. The efficacy measure used in this study to measure the subject s PI was a visual analog scale which the patient scored. PI is measured at various times up to 6 hours post-dosing by asking patients to rate their pain on a visual analog scale, where 0 is absence of pain and 100 is the worst possible pain. Additionally, subjects reported a pain relief score for up to 1 hour, on a numerical scale where zero equates to no relief, and four equates to complete relief of pain symptoms. The additional efficacy endpoints of this pilot study included the PID and PR from baseline.

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Similarly to our Dex-IN trial, Dex-SL provided statistically significant improvement in pain symptoms compared to placebo by 60 minutes after administration, and sustained improvement in pain symptoms for up to six hours after dosing.

Specifically for mean PID from baseline, Dex-SL 50mcg doses resulted in numerically superior scores relative to placebo. These improvements were statistically significant ($p < 0.05$) for the 50mcg group at the 2 hour timepoint. The following figure illustrates the PID relative to baseline and the p-values for the statistically significant measurements.

Pain Intensity Difference at

Specific Times Relative to Baseline

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For the measurement of PR, the 50mcg doses resulted in statistically significant pain relief at 60 minutes. The following figure illustrates the PR at 30 and 60 minutes.

Pain Relief Relative to Baseline

AEs experienced in this study were typically mild in severity. In the single-dose, cross-over periods, the most frequently reported AEs were dizziness, nasal congestion and hypotension. In the repeated dosing period, with two doses six hours apart, the most frequently reported AEs were orthostatic or postural hypotension, headache and dizziness. Throughout the study, vital sign measurements were taken. In this study, larger changes in blood pressure were observed following administration of Dex-SL compared to placebo. The changes were usually transient and not associated with AEs. Sedation was monitored using the Ramsay Sedation Scale and Stanford Sleepiness Scale. Although changes in these scales were more common following the Dex-SL dosing, the mean changes were small and not clinically meaningful. We believe that Dex-SL is a good product candidate for subsequent development for non-opioid treatment of chronic pain following our focus on Dex-IN.

Other Completed Clinical Trials of Dex

In addition to the previously described studies, we have completed six studies evaluating the safety, tolerability, and pharmacokinetics of our proprietary intranasal, sublingual and transdermal/topical formulations of Dex in healthy volunteers. We have completed single and multi-dose pharmacokinetic studies demonstrating target plasma levels in the appropriate range for pain relief and onset of analgesic action for the intranasal dose form. In Study REC-11-008, seven 35mcg doses of Dex-IN separated by six hours were given into the same nostril of twelve subjects. AEs were generally mild in intensity, and consistent with the AE profile of Dex in previous studies via intranasal and other routes of administration. There was no evidence of an increase in the incidence of AE reports upon repeated dosing. Vital sign data was consistent with that observed in previous studies. The degree of post dose changes in vital signs was similar throughout the study with an apparent trend towards decreased magnitude of changes with repeated doses. Subject reported nasal irritation was not commonly reported, and mild when reported. Based on the studies completed to date, we believe our formulations of Dex in repeated doses were well-tolerated.

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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 240 mcg were administered with 5 mg of bupivacaine. At each dose level six subjects were randomized to receive combination treatment, and one subject to receive only isobaric bupivacaine 10 mg. In this study, Fado was shown to have beneficial effects. The time to first post-operative dose of rescue drug (patient controlled mini doses of morphine, called PCA) was longer with increasing Fado dose while total morphine use in the first ten hours was reduced. The subjects not only used less morphine, they also reported less pain. All doses of Fado appeared to delay the onset of pain while doses of Fado greater than 120 mcg also appeared to suppress pain.

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

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 prospectus.

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 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 0.1 ng/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.

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 ($25.9 million as of September 30, 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.

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.

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 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 current good manufacturing practices, or 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 ($15.4 million as of September 30, 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 treatment of human subjects, in the territory, as defined in such agreement.

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

the parties.

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

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

Sales and Marketing

Our current intent is to develop and commercialize our product candidates in the United States while out-licensing development and commercialization rights for other territories outside the United States for which we own the territorial rights. We believe the initial target audience for our product candidates will be specialty physicians, including 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.

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 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 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., 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.

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 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 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 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 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 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.

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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.

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.

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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.

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 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;

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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 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.

Facilities

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.

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.

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MANAGEMENT

Directors and Executive Officers

The following table sets forth the name, age and position of each of our executive officers and directors as of the date of this prospectus:

Name	Position	Age
Gerri Henwood	President, Chief Executive Officer and Director	62
Charles Garner	Chief Financial Officer / Chief Business Officer / Treasurer	39
Randall Mack	SVP, Development / Secretary	49
Diane Myers	SVP, Regulatory and Quality	51
Donna Nichols	Chief Accounting Officer / Corporate Controller	59
Alfred Altomari	Director	56
William L. Ashton	Director	64
Michael Berelowitz	Director	70
Winston J. Churchill	Director	74
Abraham Ludomirski	Director	63
Wayne B. Weisman	Director / Chairman of the Board	58

Gerri Henwood has served as our President and Chief Executive Officer and a director of the Company since our inception in 2008. From 2006 to 2013, Ms. Henwood served as the President of MCG. Ms. Henwood continues to spend a small portion of her time engaged in the provision of services for MCG to other companies, including companies that are engaged in the development and commercialization of other pharmaceutical products. Prior to this, Ms. Henwood was the President and Chief Executive Officer of Auxilium Pharmaceuticals, Inc., or Auxilium, a company she founded in late 1999. From 1985 to 1999, Ms. Henwood was the founder and Chief Executive Officer of IBAH, Inc., or IBAH, a contract research organization. IBAH reached a net revenue level of $150 million, as a NASDAQ traded company, before being acquired by Omnicare in 1998. Ms. Henwood began her career with Smith Kline & French, now part of GlaxoSmithKline plc, in the pharmaceutical management program. She rose through the ranks to be a brand manager, then the head of Regulatory and Medical Affairs for the U.S. business and then to the position of Group Director Marketing in the International Pharmaceutical Division. Ms. Henwood serves on the board of directors of Alkermes plc, a global biopharmaceutical company, and two private companies. Ms. Henwood holds a B.S. in Biology from Neumann University. As our founder and having served as a director since our inception, Ms. Henwood s extensive knowledge of our business and history, experience as a board member of multiple publicly-traded and privately-held companies, and expertise in developing, financing and providing strong executive leadership to numerous biopharmaceutical companies, as well as Ms. Henwood s strong background in clinical and product development and substantial knowledge of the pharmaceutical industry, contributed to our board of directors conclusion that she should serve as a director of our company.

Charles Garner was appointed as our Chief Financial Officer, Chief Business Officer and Treasurer in October 2013. From June 2011 to April 2013, Mr. Garner was an independent contractor to Inverness Advisers. In such capacity, Mr. Garner provided investment banking and financial advisory services to the Company as an independent contractor. From March 2010 to May 2011, Mr. Garner was a Director in the Merchant Banking Group of Burrill & Company, a diversified global financial services firm focused on the life sciences industry. From 2008 to May 2010, Mr. Garner was self-employed providing consulting and financial advisory services. From 1999 to 2008, Mr. Garner worked in the Healthcare Investment Banking Group of Deutsche Bank Securities. While with Deutsche Bank, Mr. Garner focused on assisting life sciences companies with financing and advisory transactions. He began his career

at PricewaterhouseCoopers in its Business Assurance Group. Mr. Garner received his Bachelors of Business Administration, high distinction, with a concentration in accounting and finance from the University of Michigan.

Randall Mack has served as our Senior Vice President, Development and Secretary since 2008. From 2008 to 2013, Mr. Mack served as Executive Vice President, Development for MCG. Mr. Mack continues to spend a

small portion of his time engaged in the provision of services for MCG to other companies, including companies that are engaged in the development and commercialization of other pharmaceutical products. From 2005 to 2008, Mr. Mack served as Vice President, Project Management and Operations at Adolor Corporation where he oversaw the development programs in the areas of opioid-induced bowel dysfunction and pain management. For more than 15 years, he also held positions of increasing responsibilities at Auxilium, Abbott Laboratories and Harris Laboratories. In these positions he was responsible for the conduct of over 400 clinical trials, the filing of 20 INDs and 4 NDAs. During his career he has authored more than 75 scientific articles, book chapters, abstracts and poster presentations in the areas of gastroenterology, urology, neuroscience and psychiatric disorders. Mr. Mack holds a B.S. in Biology and Chemistry from the University of Nebraska-Lincoln.

Diane Myers has served as our Senior Vice President, Regulatory and Quality since 2008. From 2008 to 2013, Ms. Myers served as Senior Vice President of Regulatory Affairs and Quality Assurance for MCG. Ms. Myers continues to spend a small portion of her time engaged in the provision of services for MCG to other companies, including companies that are engaged in the development and commercialization of other pharmaceutical products. From 2000 to 2008, Ms. Myers served as Vice President of Regulatory Affairs and Quality at Auxilium. In addition, for more than 15 years she held positions of increasing responsibility at GlaxoSmithKline plc in the Quality Control and Quality Assurance groups within the Biopharmaceutical Research and Development Division. Ms. Myers holds a B.S. in Biology from Neumann University. Ms. Myers is Ms. Henwood s sister.

Donna M. Nichols has been our Corporate Controller since 2009. Since March 2009, Ms. Nichols has served as an employee of MCG. Ms. Nichols continues to spend a small portion of her time engaged in the provision of services for MCG to other companies, including companies that are engaged in the development and commercialization of other pharmaceutical products. From 2004 to 2009, she served as Director of Accounting at Auxilium, and from 1996 to 2003, as Director of Financial Reporting at Adolor Corporation. In such prior roles, Ms. Nichols was responsible for the companies SEC financial reporting. Ms. Nichols holds a B.S. from Rider University and is a Certified Public Accountant.

Alfred Altomari was elected to our board of directors in March 2014 upon the consummation of our IPO. Mr. Altomari has served as President and Chief Executive Officer of Agile Therapeutics since October 2010. Mr. Altomari is also a member of the board of directors of Agile Therapeutics and prior to being named President and Chief Executive Officer, he served as Agile s Executive Chairman. From 2008 to September 2010, Mr. Altomari also served as a consultant. From 2003 to 2008, Mr. Altomari held multiple senior management positions at Barrier Therapeutics, Inc., including Chief Commercial Officer, Chief Operating Officer, and Chief Executive Officer. In 2008, in his role as Chief Executive Officer and as a member of Barrier s board of directors, Mr. Altomari completed the successful sale of Barrier to Stiefel Laboratories, which was subsequently acquired by GlaxoSmithKline plc. From 1982 to 2003, Mr. Altomari held numerous executive roles in general management, commercial operations, business development, product launch preparation, and finance with Johnson & Johnson. Mr. Altomari also serves on the board of directors of Insmed Incorporated. Mr. Altomari received an M.B.A. from Rider University and his B.S. from Drexel University. Mr. Altomari s extensive experience in the pharmaceutical industry, including the development, commercialization and launch of numerous pharmaceutical products, led to our board of directors conclusion that he should serve as a director of our company.

William L. Ashton has been a director of the Company since 2009. Since the beginning of 2013, Mr. Ashton has been a principal at Harrison Consulting Group, Inc., a privately-held biopharmaceutical consulting firm. From August 2009 to June 2013, Mr. Ashton was the senior vice president of external affairs reporting to the president and an assistant professor at the University of the Sciences in Philadelphia, Pennsylvania. From August 2005 to August 2009, Mr. Ashton was the founding Dean of the Mayes College of Healthcare Business and Policy. Mr. Ashton has 28 years experience in the biopharmaceutical industry. From 1989 to 2005, Mr. Ashton held a number of positions at Amgen

Inc., a biotechnology company, including vice president of U.S. sales and vice president of commercial and government affairs. Mr. Ashton currently serves on the boards of Galena

Biopharma, Inc. and Sucampo Pharmaceuticals, Inc. He is also a member of the board of the National Osteoporosis Foundation and Friends of the National Library of Medicine at the National Institutes of Health. Mr. Ashton holds a B.S., Education, from the California University of Pennsylvania and an M.A., Education, from the University of Pittsburgh. Mr. Ashton s extensive experience with pharmaceutical and biological products commercialization and reimbursement issues, his past advisory role during the early years of Auxilium, as well as his experience as a board member of privately-held companies and his scientific expertise contributed to our board of directors conclusion that he should serve as a director of our company.

Michael Berelowitz was elected to our board of directors in March 2014 upon the consummation of our IPO. Since 2011, Dr. Berelowitz has served as a biopharmaceutical consultant. From 2009 to 2011, Dr. Berelowitz was Senior Vice President and Head of Clinical Development and Medical Affairs in the Specialty Care Business Unit at Pfizer, Inc. From 1996 to 2009, he held various other roles at Pfizer, Inc., beginning as a Medical Director in the Diabetes Clinical Research team and then assuming positions of increasing responsibility. Prior to that, Dr. Berelowitz spent a number of years in academia. Dr. Berelowitz also serves on the board of directors of Oramed Pharmaceuticals Inc. Among his public activities, Dr. Berelowitz has served on the board of directors of the American Diabetes Association, the Clinical Initiatives Committee of the Endocrine Society, and has chaired the Task Force on Research of the New York State Council on Diabetes. He has also served on several editorial boards, including the Journal of Clinical Endocrinology and Metabolism and Endocrinology, Reviews in Endocrine and Metabolic Disorders and Clinical Diabetes. Dr. Berelowitz has authored and co-authored more than 100 peer-reviewed journal articles and book chapters in the areas of pituitary growth hormone regulation, diabetes and metabolic disorders. Dr. Berelowitz holds adjunct appointments as Professor of Medicine in the Divisions of Endocrinology and Metabolism at SUNY StonyBrook and Mt. Sinai School of Medicine in New York. Dr. Berelowitz s years of experience in management roles in the pharmaceuticals industry, as well as his vast skill and expertise in the fields of endocrinology and diabetes, led to our board of directors conclusion that he should as a director of our company.

Winston J. Churchill has been a director of the Company since 2008. Since 2007, Mr. Churchill has been a director of the corporate general partner of the common general partner of SCP Vitalife, which beneficially owns 79% of our outstanding stock as of January 31, 2014. He has also served as a managing member of SCP Vitalife Management Company, LLC, which pursuant to contract provides certain management services to the common general partner of SCP Vitalife. Mr. Churchill has also served since 1993 as the President of CIP Capital Management, Inc., the general partner of CIP Capital, L.P., an SBA-licensed private equity fund. Prior to that, Mr. Churchill was a managing partner of Bradford Associates, which managed private equity funds on behalf of Bessemer Securities Corporation and Bessemer Trust Company. From 1967 to 1983, Mr. Churchill practiced law at the Philadelphia firm of Saul Ewing, LLP, where he served as Chairman of the Banking and Financial Institutions Department, Chairman of the Finance Committee and was a member of the Executive Committee. Mr. Churchill is a director of Griffin Land & Nurseries, Inc., Innovative Solutions and Support, Inc., Cyalume Technologies Holdings, Inc., Amkor Technology, Inc. and of various SCP Vitalife portfolio companies. In addition, he serves as a director on the boards of a number of charities and as a trustee of educational institutions including the Gesu School and Scholar Academies and is a Trustee Fellow of Fordham University. From 1989 to 1993, Mr. Churchill served as Chairman of the Finance Committee of the Pennsylvania Public School Employees Retirement System. He was awarded a B.S. in Physics, summa cum laude, from Fordham University followed by an M.A. in Economics from Oxford University where he studied as a Rhodes Scholar, and a J.D. degree from Yale Law School. As a long time director of our company, Mr. Churchill s extensive knowledge of our business and history, experience as a board member of multiple publicly-traded and privately-held companies and expertise in developing, financing and providing strong executive leadership to numerous growing life science companies contributed to our board of directors conclusion that he should serve as a director of our company.

Abraham Ludomirski, M.D. has been a director of the Company since 2008. He is a director of the corporate general partner of the common general partner of SCP Vitalife, which collectively owns 79% of our outstanding stock as of

January 31, 2014. He is a managing member of SCP Vitalife Management Company, LLC and a

director of SCP Vitalife Management Company (Israel), Ltd, both of which by contract provide certain management services to the common general partner of SCP Vitalife. Previously, he founded in 2002 the Vitalife Life Sciences funds to invest in Israeli medical device technologies, and is a managing director of the limited liability company providing management services to these funds. He is also the Chairman of the board of directors of POCARED Diagnostics, Ltd., an Israeli high-tech company specializing in miniature electronics and optical and video systems, and serves on the boards of Sensible Medical Innovations Ltd., Trig Medical, Endospan Ltd., Vishay Intertechnology, Inc. and DIR Technologies. In addition to his general familiarity with corporate affairs and governance, Dr. Ludomorski s work in the high-tech venture capital and medical fields gives him a valuable perspective on investment in innovative technologies. Dr. Ludomirski earned his M.D. at the Sackler Tel-Aviv University Medical School, specializing in OBGYN and completed his fellowship at the University of Pennsylvania in maternal fetal medicine. As a long time director of our company, Dr. Ludomirski s extensive knowledge of our business and history, experience as a board member of multiple publicly-traded and privately-held companies and expertise in developing, financing and providing strong executive leadership to numerous growing life science companies contributed to our board of directors conclusion that he should serve as a director of our company.

Wayne B. Weisman has been a director of the Company and the chairman of our board of directors since 2008. Since 2007, Mr. Weisman has been a director of the corporate general partner of the common general partner of SCP Vitalife, which beneficially owns 79% of our outstanding stock as of January 31, 2014. He has also served as a managing member of SCP Vitalife Management Company, LLC, which by contract provides certain management services to the common general partner of SCP Vitalife. He has also led the activities of SCP Private Equity Partners II, L.P., a venture capital fund of which he and Mr. Churchill are principals, in the life sciences area; these activities include investments in the United States and Israel. He has also led several other technology investments for SCP Private Equity Partners II, L.P. He has been a member of the investment committee of the Vitalife Life Sciences funds since their inception in 2002 and has worked closely with these funds since then. Mr. Weisman has been a member of the board of directors of CIP Capital L.P., a small business investment company licensed by the U.S. Small Business Administration since its inception in 1991. From 1992 to 1994, Mr. Weisman was executive vice president and member of the board of a public drug delivery technology company. In addition, he also operated a management and financial advisory firm focusing on the reorganization and turnaround of troubled companies and began his career practicing reorganization law at a large Philadelphia law firm. Mr. Weisman possesses extensive experience in venture capital investing, particularly in the life sciences area. Mr. Weisman serves on the board of ReWalk Robotics Ltd. and on a number of private company boards including the boards of DIR Technologies, EndoSpan Ltd., Ivenix, LLC, and Echo360 Inc. He is the chairman of the boards of trustees of Young Scholars School, Young Scholars Frederick Douglass and Young Scholars Kenderton. He is also an advisory board member of the Philadelphia-Israel Chamber of Commerce and Mid-Atlantic Diamond Ventures, the venture forum of Temple University. Mr. Weisman holds a B.A. from the University of Pennsylvania, and a J.D. from the University of Michigan Law School. As a long time director of our company, Mr. Weisman s extensive knowledge of our business and history, experience as a board member of multiple publicly-traded and privately-held companies and expertise in developing, financing and providing strong executive leadership to numerous growing life science companies contributed to our board of directors conclusion that he should serve as a director of our company.

Board Composition and Independence

Our board of directors is currently authorized to have seven members, and currently has seven members. In accordance with the terms of our amended and restated articles of incorporation and third amended and restated bylaws, our board of directors is divided into three classes, class I, class II and class III, with members of each class serving staggered three-year terms. The members of the classes are divided as follows:

the class I directors are Mr. Churchill and Mr. Weisman, and their term will expire at the annual meeting of shareholders to be held in 2015;

the class II directors are Dr. Ludomirski and Ms. Henwood, and their term will expire at the annual meeting of shareholders to be held in 2016; and

the class III directors are Mr. Altomari, Mr. Ashton, and Dr. Berelowitz, and their term will expire at the annual meeting of shareholders to be held in 2017.

Upon the expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of shareholders in the year in which their term expires. Our amended and restated articles of incorporation provide that the authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control of our company.

Our board of directors has determined that all of our directors, except for Ms. Henwood, are independent directors, as defined under the rules of the NASDAQ Capital Market. In making such determination, the board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances that the board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director.

Other than Ms. Myers, our Senior Vice President, Regulatory and Quality, who is the sister of Ms. Henwood, there are no family relationships among any of our directors or executive officers.

Board Leadership Structure

Our board of directors is currently led by its chairman, Wayne Weisman. Our board of directors recognizes that it is important to determine an optimal board leadership structure to ensure the independent oversight of management as the company continues to grow. We separate the roles of chief executive officer and chairman of the board in recognition of the differences between the two roles. The chief executive officer is responsible for setting the strategic direction for the Company and the day-to-day leadership and performance of the company, while the chairman of the board of directors provides guidance to the chief executive officer and presides over meetings of the full board of directors. We believe that this separation of responsibilities provides a balanced approach to managing the board of directors and overseeing the company.

Our board of directors has concluded that our current leadership structure is appropriate at this time. However, our board of directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

Role of Board in Risk Oversight Process

Our board of directors has responsibility for the oversight of the Company s risk management processes and, either as a whole or through its committees, regularly discusses with management our major risk exposures, their potential impact on our business and the steps we take to manage them. The risk oversight process includes receiving regular reports from board committees and members of senior management to enable our board to understand the Company s risk identification, risk management and risk mitigation strategies with respect to areas of potential material risk, including operations, finance, legal, regulatory, strategic and reputational risk.

The audit committee reviews information regarding liquidity and operations, and oversees our management of financial risks. Periodically, the audit committee reviews our policies with respect to risk assessment, risk management, loss prevention and regulatory compliance. Oversight by the audit committee includes direct communication with our external auditors, and discussions with management regarding significant risk exposures and the actions management has taken to limit, monitor or control such exposures. The compensation committee is

responsible for assessing whether any of our compensation policies or programs has the potential to encourage excessive risk-taking. The nominating/corporate governance committee manages risks associated with the independence of the board, corporate disclosure practices, and potential conflicts of interest. While each

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committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire board is regularly informed through committee reports about such risks. Matters of significant strategic risk are considered by our board as a whole.

Board Committees and Independence

Our board of directors has established an audit committee, a nominating and corporate governance committee and a compensation committee, under charters that have been approved by our board. Our board of directors will only appoint members to the audit committee and the compensation committee that are independent as defined under the rules of the NASDAQ Capital Market and the independence requirements contemplated by Rule 10A-3 under the Exchange Act.

Audit Committee

The members of our audit committee are Mr. Altomari, Mr. Ashton and Dr. Berelowitz. Mr. Altomari chairs the audit committee. Our audit committee s responsibilities include:

- appointing, approving the compensation of and assessing the independence of our independent registered public accounting firm;
- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of reports from such firm;
- reviewing and discussing with management and the independent registered public accounting firm our annual and quarterly financial statements and related disclosures;
- monitoring our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;
- overseeing our risk assessment and risk management processes; and
- preparing the audit committee report required by SEC rules.

All audit and non-audit services, other than de minimis non-audit services, to be provided to us by our registered independent public accounting firm must be approved in advance by our audit committee.

Our board of directors has determined that Mr. Altomari is an audit committee financial expert as defined in applicable SEC rules.

Nominating and Corporate Governance Committee

The members of our nominating and corporate governance committee are Mr. Weisman, Dr. Berelowitz and Dr. Ludomirski. Dr. Berelowitz chairs the nominating and corporate governance committee. Our nominating and corporate governance committee s responsibilities include:

- identifying and recommending individuals for election to our board of directors;
- reviewing and making recommendations to our board of directors with respect to our board committee structure; and
- developing and recommending to our board corporate governance principles.

Compensation Committee

The members of our compensation committee are Mr. Altomari, Mr. Ashton and Mr. Churchill. Mr. Ashton chairs the compensation committee. Our compensation committee s responsibilities include:

- setting salary, bonus, stock options and other benefits for executive officers;

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reviewing and approving, consistent with the compensation philosophy adopted by the compensation committee, any annual incentive compensation plan for our chief executive officer and other executive officers, and evaluate the performance of the chief executive officer and other executive officers; and

overseeing and administering our cash and equity incentive plans.

Compensation Committee Interlocks and Insider Participation

None of our executive officers serves as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or our compensation committee. None of the members of our compensation committee has ever been one of our officers or employees.

Code of Business Conduct and Ethics

We have a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Our code of business conduct and ethics is available under the Investor Relations section of our website, www.recropharma.com.

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EXECUTIVE AND DIRECTOR COMPENSATION

Executive Compensation

This section discusses the material components of the executive compensation program for our executive officers who are named in the Summary Compensation Table below. In 2014, our named executive officers were Gerri Henwood, our President and Chief Executive Officer, Charles Garner, our Chief Financial Officer, Chief Business Officer, and Treasurer and Randall Mack, our Senior Vice President, Development, and Secretary. This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs.

Summary Compensation Table

The following table sets forth information concerning the compensation of our named executive officer during the fiscal years ended December 31, 2014 and December 31, 2013:

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)(2)	Total ($)
Gerri Henwood	2014	285,375(3)	205,000		993,840(4)			23,645	1,507,860
President and Chief Executive Officer	2013	125,000(3)							125,000
Charles Garner	2014	180,000	140,500		751,559			4,330	1,076,389
Chief Financial Officer	2013								
Randall Mack	2014	192,000	63,200		287,760			17,551	560,511
Senior Vice President, Development	2013								

(1) Reflects the grant date fair value determined in accordance with the Financial Accounting Standards Board Accounting Standards, Codification Topic 718, Compensation Stock Compensation, or ASC 718. The assumptions made in these valuations are included in Note 8 of the Notes to the Interim Financial Statements.

(2) Amounts shown represent payments made for medical, dental, life and disability premiums.

(3) Prior to March 2013, Ms. Henwood received no compensation from the Company. The salary received by Ms. Henwood during the fiscal year ended December 31, 2013 reflects amounts earned by Ms. Henwood for consulting services rendered to the Company from March 2013 through December 2013. During such period, the Company paid Ms. Henwood a monthly consulting fee of $12,500 in exchange for such consulting services. The Company ceased paying Ms. Henwood such consulting fee upon consummation of our IPO, at which point Ms. Henwood s employment agreement became effective and the Company began compensating Ms. Henwood in accordance with such agreement. See the Executive Compensation-Employment Agreements section of this prospectus for additional information regarding Ms. Henwood s employment agreement. Although we are party to a consulting agreement with MCG, pursuant to which MCG provides services to us, including administrative, clinical development, regulatory and manufacturing fill services, no payments to MCG by the Company have been

used to pay Ms. Henwood any compensation.

(4) Includes grant date fair value calculated as of December 17, 2014 for time and performance-based options to purchase shares of the Company s common stock that are subject to shareholder approval at the Company s 2015 Annual Meeting of Shareholders. Ms. Henwood volunteered to make her grants of stock options contingent upon shareholder approval of an increase in the shares available under the 2013 Equity Incentive Plan due to the insufficient number of shares available under the plan to make all of the grants approved by the compensation committee in December 2014. Under ASC 718, the grant date fair value will be determined as of the date of shareholder approval and may be higher or lower depending on the Company s share price as of that date. If shareholder approval for such increase is not received at the Company s next annual meeting, the stock options granted to Ms. Henwood on December 17, 2014 would be immediately forfeited.

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Outstanding Equity Awards at Fiscal End-Year

The following table summarizes the number of shares of common stock underlying outstanding equity incentive plan awards for each named executive officer as of December 31, 2014.

	Option Awards					Stock Awards			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)(1)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or other Rights That Have Not Vested ($)
Gerri Henwood	12,042	47,958		$ 8.00	3/12/2024				
	7,497	32,503		$ 7.00	4/8/2024				
		123,500(2)	123,500(2)	$ 2.47	12/17/2024				
Charles Garner	16,261	64,765		$ 8.00	3/12/2024				
	6,462	28,012		$ 7.00	4/8/2024				
		23,000	23,000	$ 2.47	12/17/2024				
Randall Mack	50,000			$ 6.00	12/8/2018				
	4,008	15,992		$ 8.00	3/12/2024				
	3,744	16,256		$ 7.00	4/8/2024				
		19,000	19,000	$ 2.47	12/17/2024				

(1) Reflects performance-based options.

(2) Reflects shares subject to shareholder approval at the Company s 2015 Annual Meeting of Shareholders. Ms. Henwood volunteered to make her grants of stock options contingent upon shareholder approval of an increase in the shares available under the 2013 Equity Incentive Plan due to the insufficient number of shares available under the plan to make all of the grants approved by the compensation committee in December 2014. If shareholder approval for such increase is not received at the Company s next annual meeting, the stock options granted to Ms. Henwood on December 17, 2014 would be immediately forfeited.

Stock Option Plans

The two stock option plans described in this section are the Company s 2008 Stock Option Plan and the 2013 Equity Incentive Plan.

2008 Stock Option Plan

Our 2008 Stock Option Plan was approved by our board of directors in December 2008 and by our shareholders in May 2009; subsequent increases in the plan were approved by our board and shareholders in June 2009.

Authorized Shares. A total of 440,000 shares of our common stock are reserved for issuance under the 2008 Stock Option Plan. As of January 28, 2015, under the 2008 Stock Option Plan, 443,826 shares of our common stock were subject to outstanding option awards and 174 shares of our common stock remained available for future issuance.

Administration. Our compensation committee administers the 2008 Stock Option Plan (except with respect to any award granted to non-employee directors, which is administered by our full board of directors). Subject to the terms of the 2008 Stock Option Plan, the administrator has the authority to select the persons to whom awards are to be made, to determine the type or types of awards to be granted to each person, determine the number of awards to grant, determine the number of shares to be subject to such awards, and the terms and conditions of such awards.

Eligibility. Awards under the 2008 Stock Option Plan may be granted to our employees or employees of our affiliates. Awards may also be made to our consultants and members of our board of directors. Only employees may be granted incentive stock options.

Awards. The 2008 Stock Option Plan provides for the grant of stock options, stock appreciation rights and stock awards. Each grant of stock options is set forth in a separate stock option agreement with the person receiving the grant, which agreement indicates the type, terms and conditions of the award. Awards of stock appreciation rights may be subject to a stock appreciation right agreement, which agreement will set forth any additional conditions, restrictions or limitations imposed on the grant of stock appreciation rights.

Extension of Time to Exercise Options. Our board of directors may extend the period of time that an option may be exercised by a person whose employment with the Company and its affiliates has terminated, provided that the time to exercise an option may not be extended beyond the original term of such option.

Change of Control. Under the 2008 Stock Option Plan, in the event of any dissolution or liquidation of the Company, the sale of all or substantially all of the Company s assets, the merger or consolidation of the Company, pursuant to which the shareholders of the Company immediately prior to such merger or consolidation would own less than 50% of the securities that are entitled to vote in the election of directors of the surviving entity, or the acquisition by any person or entity of 50% of the outstanding shares of common stock of the Company, our board of directors may take any action with respect to outstanding stock options that it determines is necessary or desirable. Such actions include the acceleration of the vesting period, exercisability, and the expiration or termination date of any stock options outstanding under the 2008 Stock Option Plan.

Amendment of the Plan. Our board of directors may amend the 2008 Stock Option Plan in such manner as it deems advisable. Notwithstanding the foregoing, any amendment that would change the individuals eligible to receive stock options under the 2008 Stock Option Plan, extend the expiration date of the 2008 Stock Option Plan, decrease the price of any incentive stock option or increase the maximum number of shares of common stock available for issuance under the 2008 Stock Option Plan will only be effective if approved by a majority of the outstanding voting stock of the Company.

2013 Equity Incentive Plan

Our 2013 Equity Incentive Plan was approved by our board of directors on October 8, 2013 and was subsequently approved by our shareholders pursuant to a written consent on October 14, 2013.

Authorized Shares. A total of 600,000 shares of our common stock are reserved for issuance under the 2013 Equity Incentive Plan. In addition, beginning in 2015, on January 31 of each year, the number of shares of common stock reserved for issuance under the 2013 Equity Incentive Plan may be increased by our board of directors, without the necessity of further approval from our shareholders, by an amount equal to the lower of (a) 200,000 shares or (b) four percent (4%) of the our issued and outstanding capital stock, or such lower amount as determined by the board of directors in its sole discretion; provided, however, that in no event shall the total number of shares exceed in the aggregate 1,400,000 shares. As of January 28, 2015, under the 2013 Equity Incentive Plan, 589,474 shares of our common stock are subject to outstanding option awards, not including 247,000 shares of common stock which are subject to shareholder approval, and 10,526 shares of our common stock remain available for future issuance.

Administration. The compensation committee of our board of directors administers the 2013 Equity Incentive Plan (except with respect to any award granted to non-employee directors, which is administered by our full board of directors). Subject to the terms and conditions of the 2013 Equity Incentive Plan, our compensation committee has the

authority to select the persons to whom awards are to be made, to determine the type or types of awards to be granted to each person, determine the number of awards to grant, determine the number of shares to be subject to such awards, and the terms and conditions of such awards.

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Eligibility. Awards under the 2013 Equity Incentive Plan may be granted to our employees or employees of our affiliates. Awards may also be made to our consultants and members of our board of directors. Only employees may be granted incentive stock options.

Awards. The 2013 Equity Incentive Plan provides for the grant of stock options, stock appreciation rights and stock awards. Each grant of stock options is set forth in a separate stock option agreement with the person receiving the grant, which agreement indicates the type, terms and conditions of the award. Awards of stock appreciation rights may be subject to a stock appreciation right agreement, which agreement will set forth any additional conditions, restrictions or limitations imposed on the grant of stock appreciation rights.

Extension of Time to Exercise Options. Our board of directors may extend the period of time that an option may be exercised by a person whose employment with the Company and its affiliates has terminated, provided that the time to exercise an option may not be extended beyond the original term of such option.

Change of Control. Under the 2013 Equity Incentive Plan, in the event of any dissolution or liquidation of the Company, the sale of all or substantially all of the Company s assets, the merger or consolidation of the Company, pursuant to which the shareholders of the Company immediately prior to such merger or consolidation would own less than 50% of the securities that are entitled to vote in the election of directors of the surviving entity, or the acquisition by any person or entity of 50% of the outstanding shares of common stock of the Company, our board of directors may take any action with respect to outstanding stock options that it determines is necessary or desirable. Such actions include the acceleration of the vesting period, exercisability, and the expiration or termination date of any stock options outstanding under the 2013 Equity Incentive Plan.

Amendment of the Plan. Our board of directors may amend the 2013 Equity Incentive Plan from time to time and in such manner as it deems advisable. Notwithstanding the foregoing, any amendment that would change the individuals eligible to receive stock options under the 2013 Equity Incentive Plan, extend the expiration date of the 2013 Equity Incentive Plan, or increase the maximum number of shares of common stock available for issuance under the 2013 Equity Incentive Plan above 1,400,000 shares will only be effective if approved by a majority of the outstanding voting stock of the Company.

Employment Agreements

We have entered into employment agreements with Gerri Henwood, our President and Chief Executive Officer, Charles Garner, our Chief Financial Officer and Chief Business Officer, Randall Mack, our Senior Vice President, Development, Diane Myers, our Senior Vice President, Regulatory and Quality, and Donna Nichols, our Chief Accounting Officer and Corporate Controller.

The employment agreements provide for initial annual base salaries for each of our officers. Pursuant to the employment agreements, our officers received the following initial base salaries: $320,000 for Ms. Henwood, $225,000 for Mr. Garner, $240,000 for Mr. Mack, $220,000 for Ms. Myers, and $180,000 for Ms. Nichols. Such salaries are reviewed and adjusted from time to time, in the discretion of our president and board of directors with respect to our officers, and in the discretion of our board of directors with respect to our president. In addition to base salaries, the employment agreements provide that each of our officers are eligible to participate in our company s incentive bonus program. Our board of directors and our compensation committee consider a cash bonus opportunity for our officers with respect to services to our company. The board and the compensation committee consider potential target cash bonuses to Ms. Henwood, Mr. Garner, Mr. Mack, Ms. Myers, and Ms. Nichols up to a maximum of 35%, 35%, 35%, 20% and 20%, respectively, of such respective officer s base salary dependent upon performance factors.

Each of the employment agreements is for an initial term of one year and automatically renews for one year periods, unless terminated by either party by delivery of 30 days written notice to the other party. Pursuant to each of the employment agreements, if we terminate an officer s employment without cause (as defined below) or such officer resigns for certain reasons described below within twelve months of a change of control

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(as defined below), such officer will be entitled to continue to receive such executive s base salary and health insurance benefits, at the Company s expense, for a period of 12 months following the date of termination. If an officer s employment is terminated as a result of such officer s death, such officer s estate will be entitled to continue to receive such executive s base salary for a period of 12 months following the date of termination. In addition, if the severance and other benefits provided in an executive officer s employment agreement or otherwise payable to an executive officer would be subject to excise tax under Section 280(G) of the Internal Revenue Code, then the executive officer s severance benefits will be either delivered in full or delivered as to such lesser extent that would result in no portion of the severance benefits being subject to such excise tax, whichever results in the receipt by the executive officer on an after-tax basis of the greatest portion of such total severance and other benefits.

For purposes of the employment agreements, cause generally means an officer s (1) commission of an act of fraud or dishonesty against the Company; (2) failure to substantially perform his or her duties or material violation of the employment agreement, which failure or violation continues for 30 days or more following written notice to such officer; (3) loss of any permit, license, accreditation or other authorization necessary for such officer to perform his or her duties; (4) conviction of a felony or a plea of no contest to a felony, or (5) conduct that is likely, in the judgment of our board of directors, to materially adversely affect the reputation of the Company.

For purposes of the employment agreements, a change of control shall be deemed to have occurred upon the happening of any of the following events: (1) the consummation of a plan of dissolution or liquidation of the Company; (2) the consummation of the sale or disposition of all or substantially all of the assets of the Company; (3) the consummation of a merger, consolidation or other shareholder-approved fundamental business transaction in which the Company is a participant with another entity where the shareholders of the Company, immediately prior to the referenced transaction, will not beneficially own, immediately after the referenced transaction, shares or other equity interests entitling such shareholders to more than 50% of all votes to which all equityholders of the surviving entity would be entitled in the election of directors; (4) the date any entity, person or group, (within the meaning of Section 13(d)(3) or Section 14(d)(2) of the Exchange Act), (other than (A) the Company or any of its subsidiaries or any employee benefit plan (or related trust) sponsored or maintained by the Company or any of its subsidiaries or (B) any person who, on the date the Plan is effective, is the beneficial owner of outstanding securities of the Company), shall have become the beneficial owner of, or shall have obtained voting control over, more than fifty percent (50%) of the outstanding shares of the Common Stock; or (5) the first day after the date hereof when directors are elected such that a majority of the Board shall have been members of the Board for less than twenty-four (24) months, unless the nomination for election of each new director who was not a director at the beginning of such twenty-four (24) month period was approved by a vote of at least two-thirds of the directors then still in office who were directors at the beginning of such period. An officer will receive the payments and benefits described above if they terminate within 12 months of a change of control and during such twelve month period the Company and/or its successor: (1) materially and adversely changes such officer s status, responsibilities or perquisites or (2) requires such officer to be principally based at any office or location more than 50 miles from such officer s principal office prior to the change of control.

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Director Compensation

Fiscal Year Ended December 31, 2014

Name	Fees Earned or Paid in Cash($)	Option Awards($)(1)	Total($)
Alfred Altomari	31,875	160,720	192,595
William L. Ashton	31,875	160,720	192,595
Michael Berelowitz	26,250	160,720	186,970
Winston Churchill	(2)	160,720	160,720
Abraham Ludomirski	(2)	160,720	160,720
Wayne B. Weisman	(2)	160,720	160,720

(1) Reflects the grant date fair value determined in accordance with ASC 718. The assumptions made in these valuations are included in Note 8 of the Notes to the Interim Financial Statements.

(2) The following fees that were earned by each of Mr. Churchill, Dr. Ludomirski, and Mr. Weisman, $20,625, $17,625, and $32,625, respectively, were paid to SCP Vitalife Partners II, L.P. pursuant to the partnership agreement between such partnership and Mr. Churchill, Dr. Ludomirski, and Mr. Weisman.

Our directors receive annual retainers and grants of stock option awards. Each non-employee director receives an annual retainer of $20,000, and chair of the board of directors receives an additional $20,000. Each chair of the audit and compensation committees receives an additional $15,000 and each other member of the audit and compensation committees receives an additional $7,500. The chair of the nominating and corporate governance committee receives an addition $7,500 and each other member of such committee receives an additional $3,500. The non-employee directors also receive initial and annual stock option awards.

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CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Since January 1, 2012, we have engaged in the following transactions with our directors, executive officers, holders of more than 5% of our voting securities, and affiliates or immediate family members of our directors, executive officers, and holders of more than 5% of our voting securities. We believe that all of these transactions were on terms as favorable as could have been obtained from unrelated third parties.

Relationship with Malvern Consulting Group, Inc.

Ms. Henwood, our President and Chief Executive Officer, owns a majority of the stock of MCG, a consulting firm. In addition, certain of our executive officers, Ms. Henwood, Mr. Mack, Ms. Myers, who is also Ms. Henwood s sister, and Ms. Nichols, have also been employed by, and continue to provide a small portion of their time to, MCG. Thomas F. Henwood, Ms. Henwood s husband, who is also a shareholder of our company, is a consultant for, and a shareholder of, MCG. In addition, Matthew Henwood, Ms. Henwood s son, is the President of, and a shareholder of, MCG. Certain other employees of MCG are immediate family members of Ms. Henwood, including Christopher Sharr, Ms. Henwood s brother, and Suzanne Sharr, Ms. Henwood s sister-in-law.

We currently rely on MCG to perform a significant amount of our operational activities. These activities include administrative, clinical development, regulatory and manufacturing related services. In addition, MCG leases us our current office space. In consideration for such services and sublease, as described below, we have recorded $301,000 and $368,000 for the fiscal years ended December 31, 2012 and 2013, respectively, and $402,000 for the nine months ended September 30, 2014.

We are party to a Master Consulting Services Agreement with MCG. Pursuant to the agreement, MCG provides us with certain consulting services, principally in the fields of clinical development, regulatory affairs, and quality assurances as an independent contractor in exchange for a fee that is determined at the time we request these services from MCG. The agreement will continue until terminated by either us or MCG upon: (1) 30 days written notice to the other party; (2) the material breach of the agreement or any work order, if the breach remains uncured for 30 days after written notice is delivered to the breaching party; or (3) the other party ceasing to actively conduct its business, admitting in writing its inability to pay debts as they become due, instituting proceedings for voluntary bankruptcy or otherwise being adjudicated to be bankrupt or insolvent. Under the agreement, each party has agreed to maintain the confidentiality of the other party s confidential information. During the term of the agreement, and for a period of one year thereafter, we and MCG have agreed not to recruit, solicit, employ or utilize the employees of the other party, unless otherwise agreed to in writing. In consideration for such services, we have recorded $253,000 and $320,000 for the fiscal years ended December 31, 2012 and 2013, respectively, and $402,000 for the nine months ended September 30, 2014. A portion of these amounts are used to pay a portion of the respective salaries of MCG employees that, as described above, include several immediate family members of Ms. Henwood.

In January 2012, we entered into an Office Services Agreement with MCG for the lease of an aggregate of 1,600 square feet of office and lab space located at 490 Lapp Road, Malvern, Pa 19355 which increased to approximately 3,800 square feet upon the consummation of the IPO. The agreement provides for the lease of lab space that contains a dedicated lab with bench and cabinet space, biosafety cabinet, scales, formulation and mixing equipment and a refrigerator. We also have available for use a server, copiers and general office support. Pursuant to the Office Services Agreement, we paid MCG $48,000 for the each fiscal year ended December 31, 2012 and 2013 and $72,000 for the nine months ended September 30, 2014.

Consulting Services of Ms. Henwood

Beginning in March 2013, we engaged Ms. Henwood to provide certain consulting services to our company. As part of such engagement, we paid Ms. Henwood a monthly fee of $12,500 in consideration for such services

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which concluded in March 2014 upon consummation of our IPO. Pursuant to such engagement, Ms. Henwood earned $125,000 during the fiscal year ended December 31, 2013 and $29,375 during the nine months ended September 30, 2014. See the Executive Compensation-Summary Compensation Table section of this prospectus for additional information.

SCP Vitalife Partners II, L.P. and SCP Vitalife Partners (Israel) II, L.P.

SCP Vitalife Partners II, L.P. and SCP Vitalife Partners (Israel) II, L.P. as defined as SCP Vitalife, are venture capital funds that provided substantially all of our funding to date. Since 2008, in exchange for contributions to the Company of $3.75 million, we have issued to SCP Vitalife an aggregate amount of 1,875,000 shares of our Series A Redeemable Convertible Preferred Stock; and for contributions to the Company of $9,575,584, we have issued to SCP Vitalife our 8% Convertible Promissory Notes. Ms. Henwood was a venture partner in SCP Vitalife Partners II, L.P. until April 2013; however, she maintains a financial interest in the fund by virtue of her prior investments. In addition, each of Mr. Churchill, Dr. Ludomirski and Mr. Weisman, members of our board of directors, are directors of the corporate general partner of the common general partner of SCP Vitalife Partners II, L.P. and SCP Vitalife Partners (Israel) II, L.P., and managing members of companies providing certain management services to them.

Investor Rights Agreement

We entered into an Investor Rights Agreement in September 2008 with SCP Vitalife. This agreement provides for certain rights relating to the registration of their shares of common stock issuable upon the conversion of their shares of Series A Redeemable Convertible Preferred Stock, certain rights relating to the purchase of future securities sold by us and certain additional covenants made by us. Except for the registration rights (including the related provisions pursuant to which we have agreed to indemnify the parties to the Investor Rights Agreement), all rights under this agreement terminated upon completion of our IPO. The registration rights continued following the consummation of our IPO and will terminate three years following the completion of an underwritten public offering of our common stock, which generates aggregate proceeds to us of at least $10,000,000, at a price per share of not less than four times the original purchase price of the shares of Series A Redeemable Convertible Preferred Stock, or for any particular holder with registration rights, at such time following our IPO when all securities held by that shareholder may be sold pursuant to Rule 144 under the Securities Act during any 90-day period. See Description of Capital Stock Registration Rights for additional information.

Churchill Trust

The Churchill Trust, a trust for the benefit of Justin Churchill, the son of Mr. Churchill, a member of our board of directors, provided certain of our funding to date. Since 2009, in exchange for aggregate contributions to the Company of $250,000, we issued an aggregate amount of 125,000 shares of our Series A Redeemable Convertible Preferred Stock to the trust which was converted to common stock at the IPO.

Advisor Services Provided by Inverness Advisors

In 2011, Charles Garner, in his capacity as an independent contractor for Inverness Advisors, provided investment banking, finance and related services to us. In consideration for such services, we recorded $50,000 for the fiscal year ended December 31, 2011, which amount was paid to Inverness Advisors.

As described above, we have entered into an employment agreement with Mr. Garner. Pursuant to such employment agreement, Mr. Garner serves as our Chief Financial Officer. For more information, see the Management-Employment Agreements section of this prospectus.

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Policies and Procedures for Related Person Transactions

Our board of directors has adopted a written related person transaction policy setting forth the policies and procedures for the review and approval or ratification of related-person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships in which we were or are to be a participant, where the amount involved exceeds $120,000 and a related person had or will have a direct or indirect material interest, including, without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm s length transaction and the extent of the related person s interest in the transaction. All of the transactions described in this Certain Relationships and Related Party Transactions section occurred prior to the adoption of this policy.

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PRINCIPAL SHAREHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock as of January 28, 2015 by:

- our named executive officers;
- each of our directors;
- all of our executive officers and directors as a group; and
- each person or group of affiliated persons known by us to beneficially own more than 5% of our common stock.

The number of shares beneficially owned by each shareholder is determined under rules issued by the SEC. Under these rules, beneficial ownership includes any shares as to which a person has sole or shared voting power or investment power. Percentage ownership as of January 28, 2015 is based on 7,707,600 shares of common stock outstanding. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options, warrants or other rights held by such person that are currently exercisable or will become exercisable within 60 days of January 28, 2015 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person.

Unless otherwise indicated, the address of each beneficial owner listed below is c/o Recro Pharma, Inc., 490 Lapp Road, Malvern, PA 19355. We believe that, based on information provided to us, each of the shareholders listed below has sole voting and investment power with respect to the shares beneficially owned by the shareholders unless noted otherwise, subject to community property laws where applicable.

	Shares Beneficially Owned	
Name of Beneficial Owner	**Number of Shares**	**Percentage**
5% or Greater Shareholders		
SCP Vitalife Partners II, L.P.(1) 1200 Liberty Ridge Drive Suite 300 Wayne, PA 19087	2,374,046	30.8%
Broadfin Capital, LLC(2) 300 Park Avenue New York, NY 10022	1,413,533	18.3%

SCP Vitalife Partners (Israel) II, L.P.(1) 32B Habarzel St. Ramat Hachayal Tel Aviv 69710 Israel	793,240	10.3%
Sabby Management, LLC(3) 10 Mountainview Road Upper Saddle River, NJ 07458	767,836	10.0%
Cormorant Asset Management, LLC(4) 100 High Street Boston, MA 02110	700,000	9.1%
Avet Capital Management, LLC(5) 1 Penn Plaza Suite 5320 New York, NY 10119	393,100	5.1%

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Name of Beneficial Owner	Shares Beneficially Owned Number of Shares	Percentage
Executive Officers and Directors		
Gerri Henwood(6)	175,788	2.2%
Charles Garner(7)	34,379	*
Randall Mack(8)	61,435	*
Albert Altomari(9)	7,012	*
William L. Ashton(10)	19,012	*
Michael Berelowitz(11)	7,012	*
Winston J. Churchill(12)(13)	3,174,298	41.1%
Abraham Ludomirski(14)	3,174,298	41.1%
Wayne Weisman(15)	3,174,298	41.1%
All executive officers and directors as a group (11 persons)(16)	3,570,285	44.9%

* Less than 1%.

(1) Based upon information set forth in the Schedule 13D filed on March 21, 2014 by SCP Vitalife Partners II, L.P (SCP Vitalife), SCP Vitalife Partners (Israel) II, L.P. (SCP Vitalife Israel), SCP Vitalife II Associates, L.P. (SCP Vitalife Associates), SCP Vitalife II GP, LTD (SCP Vitalife GP), Winston J. Churchill, Jeffrey Dykan, Abraham Ludomirski, and Wayne B. Weisman. (a) SCP Vitalife beneficially owns 2,374,046 shares of common stock and SCP Vitalife Israel beneficially owns 793,240 shares of common stock. As the general partner of SCP Vitalife and SCP Vitalife Israel, SCP Vitalife Associates may be deemed to beneficially own 3,167,286 shares of common stock. As the general partner of SCP Vitalife Associates, SCP Vitalife GP may be deemed to beneficially own 3,167,286 shares of common stock. As directors of SCP Vitalife GP, Messrs. Churchill, Dykan and Weisman and Dr. Ludomirski may be deemed to beneficially own 3,167,286 shares of common stock. (b) SCP Vitalife shares dispositive and voting power with respect to the 2,374,046 shares of common stock owned. SCP Vitalife Israel shares dispositive and voting power with respect to the 793,240 shares of common stock owned. SCP Vitalife Associates, SCP Vitalife GP, Messrs. Churchill, Dykan and Weisman and Dr. Ludomirski have shared dispositive and voting power with respect to the aggregate 3,167,286 shares of common stock owned by SCP Vitalife and SCP Vitalife Israel.

(2) Based upon information set forth in the Schedule 13G/A filed on February 17, 2015 by Broadfin Capital, LLC (Broadfin), Broadfin Healthcare Master Fund, Ltd. (Master Fund) and Kevin Kotler. Broadfin, Masterfund and Mr. Kotler have shared voting and dispositive power over 1,172,195 shares of common stock. Broadfin and Mr. Kotler each disclaim beneficial ownership of the share reported herein except to the extent of its or his pecuniary interest therein.

(3) Based upon information set forth in the Schedule 13G/A filed on January 12, 2015, by Sabby Healthcare Master Fund, Ltd. (Master Fund), Sabby Volatility Warrant Master Fund, Ltd. (Volatility), Sabby Management, LLC (Investment Manager) and Hal Mintz. (a) Master Fund and Volatility beneficially own 707,836 and 60,000 shares of common stock, respectively. (b) Investment Manager and Mr. Mintz each may be deemed to beneficially own 767,836 shares of common stock. Mr. Mintz is the manager of Investment Manager. Both Investment Manager and Mr. Mintz have shared voting and dispositive power with respect to the aggregate 767,836 shares of common stock owned by Master Fund and Volatility. Investment Manager and Mr. Mintz each disclaim beneficial ownership of the share reported herein except to the extent of its or his pecuniary interest therein.

(4) Based upon information set forth in the Schedule 13G/A filed on February 17, 2015 by Cormorant Global Healthcare Master Fund, LP (Cormorant), Cormorant Global Healthcare GP, LLC (General Partner), Cormorant Asset Management, LLC (Investment Manager) and Bihua Chen, and in the Form 13F filed on November 14, 2014 by Cormorant Asset Management, LLC. Cormorant Global Healthcare GP, LLC serves as the general partner and Cormorant Asset Management, LLC serves as the investment manager. Ms. Chen serves as the

managing member of General Partner and Investment Manager. Comorant, General Partner, Investment Manager and Ms. Chen share voting and dispositive power over all shares. Cormorant, General Partner, Investment Manager and Ms. Chen each disclaim beneficial ownership of the shares reported herein except to the extent of its or her pecuniary interest therein.

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(5) Based upon information set forth in the Schedule 13G filed on September 9, 2014 by Avet Capital Partners Master Fund, LP (Avet), Avet Capital Management, LLC (Investment Manager), Avet Capital GP, LLC (General Partner) and Norbert Gottesman. Avet is a private investment vehicle and directly owns 387,100 shares of common stock. Mr. Gottesman directly owns 6,000 shares of common stock. The Investment Manager is the investment manager to Avet. The General Partner is the general partner of Avet. Mr. Gottesman is Managing Member of the Investment Manager and the General Partner and is the Portfolio Manager for Avet. Investment Manager, General Partner and Mr. Gottesman may be deemed to beneficially own the shares owned directly by Avet. Investment Manager, General Partner and Mr. Gottesman each disclaim beneficial ownership with respect to the shares owned by Avet.

(6) Ms. Henwood holds 100,000 shares of our common stock and stock options to purchase 25,788 shares of our common stock that may be exercised within 60 days of January 28, 2015. Ms. Henwood s husband, Tom Henwood, holds 50,000 shares of our common stock. As spouses, Mr. and Ms. Henwood may be deemed to beneficially own the shares of our common stock that are held by the other spouse. Mr. and Ms. Henwood disclaim beneficial ownership of the shares of our common stock that are held by the other spouse

(7) Mr. Garner holds 3,000 shares of our common stock and stock options to purchase 31,379 shares of our common stock that may be exercised within 60 days of January 28, 2015.

(8) Mr. Mack holds stock options to purchase 61,435 shares of our common stock that may be exercised within 60 days of January 28, 2015.

(9) Mr. Altomari stock options to purchase 7,012 shares of our common stock that may be exercised within 60 days of January 28, 2015.

(10) Mr. Ashton holds exercisable stock options to purchase 19,012 shares of our common stock that may be exercised within 60 days of January 28, 2015.

(11) Dr. Berelowitz holds exercisable stock options to purchase 7,012 shares of our common stock that may be exercised within 60 days of January 28, 2015.

(12) Mr. Churchill holds exercisable stock options to purchase 7,012 shares of our common stock that may be exercised within 60 days of January 28, 2015. Mr. Churchill has shared voting and investment power with respect to 2,609,357 shares of our common stock that are held by SCP Vitalife, of which he is a partner.

(13) Mr. Churchill disclaims beneficial ownership of 50,000 shares of our common stock that are held by the Churchill Trust for the benefit of his son and stock options to purchase 33,200 shares of our common stock held by his son.

(14) Dr. Ludomirski holds exercisable stock options to purchase 7,012 shares of our common stock that may be exercised within 60 days of January 28, 2015. Dr. Ludomirski has shared voting and investment power with respect to 2,609,357 shares of our common stock that are held by SCP Vitalife, of which he is a partner.

(15) Mr. Weisman holds exercisable stock options to purchase 7,012 shares of our common stock that may be exercised within 60 days of January 28, 2015. Mr. Weisman has shared voting and investment power with respect to 2,609,357 shares of our common stock that are held by SCP Vitalife, of which he is a partner.

(16) Includes stock options to purchase 248,799 shares of our common stock that may be exercised within 60 days of January 28, 2015.

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DILUTION

If you acquire shares of our common stock from Aspire Capital in this offering, your ownership interest will be diluted to the extent of the difference between the public offering price per share of our common stock and the pro forma net tangible book value per share of our common stock after this offering. Our historical net tangible book value of common stock as of September 30, 2014 was $22.2 million, or $2.88 per share of common stock. Historical net tangible book value per share represents the amount of our total tangible assets less total liabilities, divided by the total number of shares of common stock outstanding.

After giving effect to (i) the issuance of the 96,463 Commitment Shares, and (ii) the sale of 1,444,286 shares of common stock (the maximum number of additional Purchase Shares that can be sold so as not to exceed 19.9% of our outstanding common stock on the date of the Purchase Agreement) in the aggregate amount of $10.0 million at an assumed offering price of $3.09 per share (the closing price of our common stock on January 28, 2015), and after deducting estimated offering expenses payable by us, our pro forma net tangible book value as of September 30, 2014 would have been $26.5 million, or $2.86 per share of common stock. This represents an immediate decrease in pro forma net tangible book value of $0.02 per share to our existing shareholders and an immediate dilution in pro forma net tangible book value of $0.23 per share to investors participating in this offering. The following table illustrates this per share dilution:

Assumed public offering price per share		$ 3.09
Historical net tangible book value per share as of September 30, 2014	$ 2.88	
Decrease in net tangible book value per share attributable to this offering	(0.02)	
Pro forma net tangible book value per share after this offering		2.86
Dilution per share to investors participating in this offering		$ 0.23

The shares sold in this offering, if any, in addition to the Commitment Shares, may be sold from time to time at various prices.

Each $1.00 increase (decrease) in the per share price at which we sell shares to Aspire Capital under the Purchase Agreement from the assumed offering price of $3.09 per share would increase (decrease) our pro forma net tangible book value by $1.4 million, our pro forma net tangible book value per share by $0.16 and dilution per share to new investors purchasing shares of common stock in this offering by $0.84, assuming that the number of shares of common stock offered, as set forth on the cover page of this prospectus, remains the same and after deducting estimated aggregate offering expenses payable by us. This information is supplied for illustrative purposes only.

The table and calculations set forth above are based on the number of shares of common stock outstanding as of September 30, 2014 and assumes no exercise of any outstanding options or warrants. To the extent that options or warrants are exercised, there will be further dilution to new investors.

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DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock and provisions of our articles of incorporation, bylaws and the Pennsylvania Business Corporation law are summaries and are qualified in their entirety by reference to the articles of incorporation and the bylaws. We have filed copies of these documents with the SEC as exhibits to our registration statement, of which this prospectus forms a part.

Pursuant to the Company s Second Amended and Restated Articles of Incorporation, the Company s authorized capital stock consists of 50,000,000 shares of common stock, par value of $0.01 per share, and 10,000,000 shares of preferred stock, par value $0.01 per share, to be designated from time to time by our board.

Market Information

Our common stock is listed on the NASDAQ Capital Market under the symbol REPH. The following table sets forth, for the periods indicated, the high and low sales prices for our common stock as reported on the NASDAQ Capital Market.

	High	Low
Year ending December 31, 2015		
First Quarter (through February 25, 2015)	$ 3.51	$ 2.80
Year ended December 31, 2014		
Fourth Quarter	$ 3.39	$ 2.36
Third Quarter	$ 8.10	$ 2.71
Second Quarter	$ 8.49	$ 5.01
First Quarter	$ 9.88	$ 7.00

The last reported sales price for our common stock on February 25, 2015 is set forth on the cover page of this prospectus. As of February 25, 2015, there were approximately 7 holders of record of our common stock.

Common Stock

As of January 28, 2015, there were 7,707,600 shares of our common stock issued and outstanding. Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of shareholders, including the election of directors, and do not have cumulative voting rights. Accordingly, the holders of a majority of the outstanding shares of common stock in person or represented by proxies in any election of directors can elect all of the directors standing for election, if they so choose, other than any directors that holders of any preferred stock that we may issue may be entitled to elect.

Subject to preferences that may be applicable to any then-outstanding shares of preferred stock, holders of our common stock are entitled to receive ratably dividends when, as, and if declared by our board of directors out of funds legally available therefore, subject to any preferential dividend rights of outstanding preferred stock. In the event of our liquidation, dissolution, or winding up, holders of our common stock will be entitled to ratably receive the net assets of our company available after the payments of all debts and other liabilities and subject to the prior rights of the holders of any then-outstanding shares of preferred stock.

Holders of our common stock have no preemptive, subscription, redemption or conversion rights. All outstanding shares of our common stock are, and the common stock to be outstanding upon completion of this offering, will be,

duly authorized, validly issued, fully paid and non- assessable. The rights and privileges of the holders of the common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

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Preferred Stock

Our board of directors has the authority, without further action by our shareholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the dividend, voting and other rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control and may adversely affect the market price of the common stock and the voting and other rights of the holders of our common stock. We have no current plans to issue any shares of preferred stock.

Stock Options

As of January 28, 2015, options to purchase 443,826 shares of our common stock were outstanding under our 2008 Stock Option Plan, 358,939 of which were vested. As of January 28, 2015, options to purchase 589,474 shares of our common stock, not including 247,000 options to purchase shares of our common stock subject to shareholder approval, were outstanding under our 2013 Equity Incentive Plan, 78,742 of which were vested.

Common Stock Warrants

We issued to the representatives of the underwriters in our IPO warrants to purchase up to 150,000 shares of our common stock, with a per share exercise price equal to $12.00, or 150% of the public offering price. The warrants provide for certain piggyback registration rights. The warrants are exercisable by the underwriters at any time, in whole or in part, during the four year period commencing one year after the closing of our IPO.

Registration Rights

In addition to the registration rights granted with respect to the representatives warrants described above, holders of our common stock that were issued upon conversion of our Series A Redeemable Convertible Preferred Stock immediately prior to the closing of our IPO are entitled to the following rights with respect to the registration of such shares for public resale under the Securities Act, pursuant to an Investor Rights Agreement by and among us and certain of our shareholders. The registration of shares of common stock as a result of the following rights being exercised would enable holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective. For more information, see the Certain Relationships and Related Party Transactions, section of this prospectus.

Demand Registration Rights. If at any time beginning 180 days after our IPO the holders of a majority of the registrable securities request in writing that we file a registration statement under the Securities Act for the registration of at least 20% of our common stock and any Series A Redeemable Convertible Preferred Stock convertible into common stock, then outstanding with an aggregate price of at least $20 million, we may be required to register their shares. We are obligated to effect no more than two registrations for the holders of registrable securities in response to these demand registration rights. If the holders requesting registration intend to distribute their shares by means of an underwriting, the underwriter of such offering will have the right to limit the numbers of shares to be underwritten on a pro rata basis for reasons related to the marketing of the shares.

Piggyback Registration Rights. If at any time after our IPO we propose to register any shares of our common stock under the Securities Act, subject to certain exceptions, the holders of registrable securities will be entitled to notice of the registration and the right to include their shares of registrable securities in the registration statement. If our proposed registration involves an underwriting, the underwriter of such offering will have the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares.

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Form S-3 Registration Rights. If at any time after we become entitled under the Securities Act to register our shares of common stock on Form S-3, holders of not less than 10% of the registrable securities then outstanding request in writing that we register their shares for public resale on Form S-3 and the reasonably anticipated price to the public is $10 million or more, we will be required to use commercially reasonable efforts to effect such registration; provided, however, that we will not be required to effect such a registration if (1) we certify in a certificate signed by our Chief Executive Officer that we intend to engage in a registered public offering within 90 days of receiving the Form S-3 request, or (2) we certify in a certificate signed by our Chief Executive Officer stating that in our good faith judgment, it would be detrimental to the Company for such registration on Form S-3 to be effected at such time, in which event we have the right to defer the filing of the Form S-3 registration statement for a period of not more than 120 days.

Expenses. Subject to certain exceptions, and other than underwriting discounts and selling commissions, we will be required to pay all expenses incurred by us related to any registration effected pursuant to the exercise of these registration rights. These expenses may include all registration and filing fees, printing expenses, fees and disbursements of our counsel, blue sky fees and expenses and the expenses of any special audits incident to or required by the registration.

Termination of Registration Rights. These registration rights terminate three years after the completion of an underwritten public offering of our common stock, which generates aggregate proceeds of at least $10,000,000, at a price per share of not less than four times the original purchase price of the shares of Series A Redeemable Convertible Preferred Stock. In addition, a holder s registration rights will expire if all registrable securities held by and issuable to such holder could be sold under Rule 144 of the Securities Act during any 90-day period.

Anti-Takeover Effects of Pennsylvania Law and Our Articles of Incorporation and Bylaws

Provisions of the Pennsylvania Business Corporation Law of 1988, or the PBCL, applicable to us provide, among other things, that:

- we may not engage in a business combination with an interested shareholder, generally defined as a holder of 20% of a corporation s voting stock, during the five-year period after the interested shareholder became such except under certain specified circumstances;

- holders of our common stock may object to a control transaction involving us (a control transaction is defined as the acquisition by a person or group of persons acting in concert of at least 20% of the outstanding voting stock of a corporation), and demand that they be paid a cash payment for the fair value of their shares from the controlling person or group; and

- any profit, as defined, realized by any person or group who is or was a controlling person or group with respect to us from the disposition of any equity securities of within 18 months after the person or group became a controlling person or group shall belong to and be recoverable by us.

Pennsylvania-chartered corporations may exempt themselves from these and other anti-takeover provisions. Our articles of incorporation do not provide for exemption from the applicability of these or other anti-takeover provisions in the PBCL.

The provisions noted above may have the effect of discouraging a future takeover attempt that is not approved by the board of directors of our company but which individual shareholders may consider to be in their best interests or in which shareholders may receive a substantial premium for their shares over the then current market price. As a result, shareholders who might wish to participate in such a transaction may not have an opportunity to do so. The provisions may also render the removal of our board of directors or management more difficult. Furthermore, such provisions could render our company being deemed less attractive to a potential acquiror and/or could result in our shareholders receiving a lesser amount of consideration for their shares of our common stock than otherwise could have been available either in the market generally and/or in a takeover.

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Staggered Board

Our bylaws divide our board of directors into three classes with staggered three-year terms. The classification of our board of directors could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our company. For more information on the composition of our board of directors, please see the Management-Board Composition and Independence section of this prospectus.

Shareholder Meetings

Our bylaws provide that a special meeting of shareholders may be called only by a majority of our board of directors.

Requirements for Advance Notification of Shareholder Nominations and Proposals

Our bylaws establish advance notice procedures with respect to shareholder proposals to be brought before a shareholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

No Shareholder Action by Written Consent

Our bylaws provide that shareholders may only act at a duly organized meeting. Accordingly, our shareholders may not take action by written consent without a meeting.

Removal of Directors

Our bylaws provide that no member of our board of directors may be removed from office by our shareholders upon the approval of 75% of the total voting power of all shares entitled to vote generally in the election of directors.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Broadridge Corporate Issuer Solutions, Inc.

Stock Market Listing

Our shares of common stock are listed for trading on the NASDAQ Capital Market under the symbol REPH.

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SELLING SHAREHOLDER

The selling shareholder may from time to time offer and sell any or all of the shares of our common stock set forth below pursuant to this prospectus. When we refer to the selling shareholder in this prospectus, we mean the entity listed in the table below, and its respective pledgees, donees, permitted transferees, assignees, successors and others who later come to hold any of the selling shareholder s interests in shares of our common stock other than through a public sale.

The following table sets forth, as of the date of this prospectus, the name of the selling shareholder for whom we are registering shares for sale to the public, the number of shares of common stock beneficially owned by the selling shareholder prior to this offering, the total number of shares of common stock that the selling shareholder may offer pursuant to this prospectus and the number of shares of common stock that the selling shareholder will beneficially own after this offering. Except as noted below, the selling shareholder does not have, or within the past three years has not had, any material relationship with us or any of our predecessors or affiliates and the selling shareholder is not or was not affiliated with registered broker-dealers.

Based on the information provided to us by the selling shareholder, assuming that the selling shareholder sells all of the shares of our common stock beneficially owned by it that have been registered by us and does not acquire any additional shares during the offering, the selling shareholder will not own any shares other than those appearing in the column entitled Beneficial Ownership After This Offering. We cannot advise you as to whether the selling shareholder will in fact sell any or all of such shares of common stock. In addition, the selling shareholder may have sold, transferred or otherwise disposed of, or may sell, transfer or otherwise dispose of, at any time and from time to time, the shares of our common stock in transactions exempt from the registration requirements of the Securities Act after the date on which it provided the information set forth in the table below.

			Beneficial Ownership After this Offering(1)	
Name	**Shares of Common Stock Owned Prior to this Offering**	**Shares of Common Stock Being Offered**	**Number of Shares**	**%**
Aspire Capital Fund, LLC(2)	146,463(3)	2,500,000	50,000	*

* Less than 1%.

(1) Assumes the sale of all shares of common stock registered pursuant to this prospectus, although the selling shareholder is under no obligation known to us to sell any shares of common stock at this time.

(2) Aspire Capital Partners LLC (Aspire Partners) is the Managing Member of Aspire Capital Fund LLC (Aspire Capital). SGM Holdings Corp (SGM) is the Managing Member of Aspire Partners. Mr. Steven G. Martin is the president and sole shareholder of SGM, as well as a principal of Aspire Partners. Mr. Erik J. Brown is the president and sole shareholder of Red Cedar Capital Corp (Red Cedar), which is a principal of Aspire Partners. Mr. Christos Komissopoulos is president and sole shareholder of Chrisko Investors Inc. (Chrisko), which is a principal of Aspire Partners. Each of Aspire Partners, SGM, Red Cedar, Chrisko, Mr. Martin, Mr. Brown, and Mr. Komissopoulos may be deemed to be a beneficial owner of common stock held by Aspire Capital. Each of

Aspire Partners, SGM, Red Cedar, Chrisko, Mr. Martin, Mr. Brown, and Mr. Komissopoulos disclaims beneficial ownership of the common stock held by Aspire Capital. Aspire Capital is not a licensed broker dealer nor is any of its affiliate a licensed broker dealer.

(3) As of the date hereof, 96,463 shares of our common stock have been acquired by Aspire Capital under the Purchase Agreement, consisting of shares we issued to Aspire Capital as a commitment fee. We may elect in our sole discretion to sell to Aspire Capital up to an additional 2,403,537 shares under the Purchase Agreement and included in this prospectus but Aspire Capital does not presently beneficially own those shares as determined in accordance with the rules of the SEC.

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PLAN OF DISTRIBUTION

The common stock offered by this prospectus is being offered by Aspire Capital, the selling shareholder. The common stock may be sold or distributed from time to time by the selling shareholder directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of the common stock offered by this prospectus may be effected in one or more of the following methods:

ordinary brokers transactions;

transactions involving cross or block trades;

through brokers, dealers, or underwriters who may act solely as agents;

at the market into an existing market for the common stock;

in other ways not involving market makers or established business markets, including direct sales to purchasers or sales effected through agents;

in privately negotiated transactions; or

any combination of the foregoing.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the registration or qualification requirement is available and complied with.

The selling shareholder may also sell shares of common stock under Rule 144 promulgated under the Securities Act, if available, rather than under this prospectus. In addition, the selling shareholder may transfer the shares of common stock by other means not described in this prospectus.

Brokers, dealers, underwriters, or agents participating in the distribution of the shares as agents may receive compensation in the form of commissions, discounts, or concessions from the selling shareholder and/or purchasers of the common stock for whom the broker-dealers may act as agent. Aspire Capital has informed us that each such broker-dealer will receive commissions from Aspire Capital which will not exceed customary brokerage commissions.

Aspire Capital is an underwriter within the meaning of the Securities Act.

Neither we nor Aspire Capital can presently estimate the amount of compensation that any agent will receive. We know of no existing arrangements between Aspire Capital, any other shareholder, broker, dealer, underwriter, or agent

relating to the sale or distribution of the shares offered by this prospectus. At the time a particular offer of shares is made, a prospectus supplement, if required, will be distributed that will set forth the names of any agents, underwriters, or dealers and any compensation from the selling shareholder, and any other required information. Pursuant to a requirement of the Financial Industry Regulatory Authority, or FINRA, the maximum commission or discount and other compensation to be received by any FINRA member or independent broker-dealer shall not be greater than eight percent (8%) of the gross proceeds received by us for the sale of any securities being registered pursuant to Rule 415 under the Securities Act.

We will pay all of the expenses incident to the registration, offering, and sale of the shares to the public other than commissions or discounts of underwriters, broker-dealers, or agents. We have agreed to indemnify Aspire Capital and certain other persons against certain liabilities in connection with the offering of shares of common stock offered hereby, including liabilities arising under the Securities Act or, if such indemnity is

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unavailable, to contribute amounts required to be paid in respect of such liabilities. Aspire Capital has agreed to indemnify us against liabilities under the Securities Act that may arise from certain written information furnished to us by Aspire Capital specifically for use in this prospectus or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons, we have been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is therefore, unenforceable.

Aspire Capital and its affiliates have agreed not to engage in any direct or indirect short selling or hedging of our common stock during the term of the Purchase Agreement.

We have advised Aspire Capital that while it is engaged in a distribution of the shares included in this prospectus it is required to comply with Regulation M promulgated under the Securities Exchange Act of 1934, as amended. With certain exceptions, Regulation M precludes the selling shareholder, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the shares offered hereby this prospectus.

We may suspend the sale of shares by Aspire Capital pursuant to this prospectus for certain periods of time for certain reasons, including if the prospectus is required to be supplemented or amended to include additional material information.

This offering will terminate on the date that all shares offered by this prospectus have been sold by Aspire Capital.

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LEGAL MATTERS

The validity of the issuance of the common stock offered by us in this offering will be passed upon for us by Ballard Spahr LLP, Philadelphia, Pennsylvania.

EXPERTS

The financial statements of Recro Pharma, Inc. as of December 31, 2012 and 2013 and for the years then ended and for the period from November 15, 2007 (inception) through December 31, 2013 have been included in this prospectus in reliance upon the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing. The audit report covering the December 31, 2013 financial statements contains an explanatory paragraph that states that the Company has incurred recurring losses and negative cash flows from operations since inception and has a net capital deficiency. Such matters raise substantial doubt about the Company s ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of that uncertainty.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock we are offering to sell. This prospectus, which constitutes part of the registration statement, does not include all of the information contained in the registration statement and the exhibits, schedules and amendments to the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and to the exhibits and schedules to the registration statement. Statements contained in this prospectus about the contents of any contract, agreement or other document are not necessarily complete, and, in each instance, we refer you to the copy of the contract, agreement or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You may read and copy the registration statement of which this prospectus is a part at the SEC s public reference room, which is located at 100 F Street, N.E., Room 1580, Washington, DC 20549. You can request copies of the registration statement by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the SEC s public reference room. In addition, the SEC maintains a website, which is located at www.sec.gov, that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC. You may access the registration statement of which this prospectus is a part at the SEC s website.

We will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. All documents filed with the SEC are available for inspection and copying at the public reference room and website of the SEC referred to above. We maintain a website at www.recropharma.com. You may access our reports, proxy statements and other information free of charge at this website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information on such website is not incorporated by reference and is not a part of this prospectus.

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RECRO PHARMA, INC.

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders

Recro Pharma, Inc.:

We have audited the accompanying balance sheets of Recro Pharma, Inc. (the Company) as of December 31, 2012 and 2013, and the related statements of operations, redeemable convertible preferred stock and shareholders deficit, and cash flows for the years then ended and the period from November 15, 2007 (inception) through December 31, 2013. 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, 2012 and 2013, and the results of its operations and its cash flows for the years then ended and the period from November 15, 2007 (inception) through December 31, 2013 in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in note 2 to the financial statements, the Company has incurred recurring losses and negative cash flows from operations since inception and has a net capital deficiency. Such matters raise substantial doubt about its ability to continue as a going concern. Management s plans in regard to these matters are also described in note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KPMG LLP

Philadelphia, Pennsylvania

February 10, 2014

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RECRO PHARMA, INC.

Balance Sheets

	December 31, 2012	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 53,346	$ 12,828
Other receivables	85,000	38,418
Deferred offering costs		784,177
Prepaid expenses	14,279	15,689
Total current assets	152,625	851,112
Equipment, net	1,447	
Total assets	$ 154,072	$ 851,112
Liabilities and Shareholders Deficit		
Current liabilities:		
Convertible notes payable	$ 10,158,505	$ 11,907,198
Accounts payable	15,582	434,244
Accrued expenses	102,029	589,532
Total current liabilities	10,276,116	12,930,974
Total liabilities	10,276,116	12,930,974
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 (liquidation value of $5,880,037 as of December 31, 2013)	5,439,833	5,880,037
Shareholders deficit:		
Preferred stock, $0.01 par value. Authorized, 2,000,000 shares; none issued and outstanding		
Common stock, $0.01 par value. Authorized, 5,000,000 shares; issued and outstanding, 155,600 shares at December 31, 2012 and 2013	1,556	1,556
Additional paid-in capital		
Deficit accumulated during the development stage	(15,563,433)	(17,961,455)
Total shareholders deficit	(15,561,877)	(17,959,899)
Total liabilities and shareholders deficit	$ 154,072	$ 851,112

See accompanying notes to financial statements.

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RECRO PHARMA, INC.

Statements of Operations

	Year ended December 31, 2012	2013	Period from November 15, 2007 (inception) through December 31, 2013
Operating expenses:			
Research and development	$ 541,951	$ 543,632	$ 12,287,114
General and administrative	339,255	546,119	1,705,580
Total operating expenses	881,206	1,089,751	13,992,694
Other income (expense):			
Interest income	35	42	4,317
Grant income (note 3)	85,000		329,479
Interest expense	(740,365)	(868,109)	(2,506,614)
	(655,330)	(868,067)	(2,172,818)
Net loss	(1,536,536)	(1,957,818)	$ (16,165,512)
Accretion of redeemable convertible preferred stock	(412,623)	(440,204)	
Net loss applicable to common shareholders	$ (1,949,159)	$ (2,398,022)	
Basic and diluted net loss per common share	$ (12.53)	$ (15.41)	
Weighted average basic and diluted common shares outstanding	155,600	155,600	
Unaudited pro forma net loss		$ (1,089,709)	
Unaudited pro forma basic and diluted net loss per common share		$ (0.35)	

Unaudited pro forma weighted average basic and diluted common shares outstanding	3,116,465

See accompanying notes to financial statements.

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RECRO PHARMA, INC.

Statements of Redeemable Convertible Preferred Stock and Shareholders Deficit

Period from November 15, 2007 (inception) through December 31, 2013

	Series A redeemable convertible preferred stock		Common Stock		Additional paid in capital	Deficit accumulated during the development stage	Total
	Shares	Amount	Shares	Amount			
Balance, November 15, 2007 (inception)		$		$	$	$	$
Net loss						(27,680)	(27,680)
Balance, December 31, 2007						(27,680)	(27,680)
Issuance of common stock			155,600	1,556	8,444		10,000
Sale of Series A redeemable convertible preferred stock, net of offering costs of $45,082	750,000	1,454,918					
Accretion of Series A redeemable convertible preferred stock to redemption value		39,478			(8,444)	(31,034)	(39,478)
Net loss						(1,716,189)	(1,716,189)
Balance, December 31, 2008	750,000	1,494,396	155,600	1,556		(1,774,903)	(1,773,347)
Sale of Series A redeemable convertible preferred stock	1,250,000	2,500,000					
Stock-based compensation expense					99,742		99,742

Accretion of Series A redeemable convertible preferred stock to redemption value		294,976			(99,742)	(195,234)	(294,976)
Net loss						(4,129,136)	(4,129,136)
Balance, December 31, 2009	2,000,000	4,289,372	155,600	1,556		(6,099,273)	(6,097,717)
Stock-based compensation expense					31,316		31,316
Accretion of Series A redeemable convertible preferred stock to redemption value		355,089			(31,316)	(323,773)	(355,089)
Net loss						(3,927,235)	(3,927,235)
Balance, December 31, 2010	2,000,000	4,644,461	155,600	1,556		(10,350,281)	(10,348,725)
Stock-based compensation income						(9,241)	(9,241)
Accretion of Series A redeemable convertible preferred stock to redemption value		382,749				(382,749)	(382,749)
Net loss						(2,870,918)	(2,870,918)
Balance, December 31, 2011	2,000,000	5,027,210	155,600	1,556		(13,613,189)	(13,611,633)
Stock-based compensation income						(1,085)	(1,085)
Accretion of Series A redeemable convertible preferred stock to redemption value		412,623				(412,623)	(412,623)
Net loss						(1,536,536)	(1,536,536)
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)

See accompanying notes to financial statements.

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RECRO PHARMA, INC.

Statements of Cash Flows

	Year ended December 31,		Period from November 15, 2007 (inception) through December 31,
	2012	2013	2013
Cash flows from operating activities:			
Net loss	$ (1,536,536)	$ (1,957,818)	$ (16,165,512)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	(1,085)		120,732
Non-cash interest expense	740,365	868,109	2,506,614
Depreciation expense	1,938	1,447	9,691
Acquired in-process research and development			1,448,680
Changes in operating assets and liabilities:			
Prepaid expenses	(162)	(1,410)	(15,689)
Other receivables	(85,000)	46,582	(38,418)
Accounts payable and accrued expenses	(344,370)	226,465	344,076
Net cash used in operating activities	(1,224,850)	(816,625)	(11,789,826)
Cash flows from investing activities:			
Purchases of equipment			(9,691)
Purchase of in-process research and development			(1,448,680)
Net cash used in investing activities			(1,458,371)
Cash flows from financing activities:			
Proceeds from issuance of Series A redeemable convertible stock			3,954,918
Offering costs		(104,477)	(104,477)
Proceeds from issuance of common stock			10,000
Proceeds from notes payable	1,270,000	880,584	9,400,584
Borrowings from related parties			207,358

Repayments to related parties			(207,358)
Net cash provided by financing activities	1,270,000	776,107	13,261,025
Net increase (decrease) in cash and cash equivalents	45,150	(40,518)	12,828
Cash and cash equivalents, beginning of period	8,196	53,346	
Cash and cash equivalents, end of period	$ 53,346	$ 12,828	$ 12,828

See accompanying notes to financial statements.

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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 specialty pharmaceutical company, which is developing solutions for managing serious pain and related conditions. 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 a shareholders deficit of $17,959,899 and negative working capital as of December 31, 2013. These factors raise substantial doubt about the Company s ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its products currently in development. Substantial additional financing will be needed by the Company to fund its operations and to commercially develop its product candidates. Management is currently evaluating different strategies to obtain the required funding for future operations. These strategies may include, but are not limited to: private placements of equity and/or debt, payments from potential strategic research and development, licensing and/or marketing arrangements with pharmaceutical companies, and public offerings of equity and/or debt securities. There can be no assurance that these future funding efforts will be successful.

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) Recapitalization

On January 27, 2014, the Company s board of directors approved a 1-for-2.5 reverse stock split of the Company s common stock. All references in the financial statements to the number of shares and per-share amounts of common stock have been retroactively restated to reflect the reverse stock split. In

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RECRO PHARMA, INC.

Notes to Financial Statements (Continued)

addition, the board of directors previously approved an increase in the authorized number of common shares to 50,000,000 and preferred shares to 10,000,000, which increase will become effective contemporaneously with the consummation of the Company s initial public offering (IPO).

(c) 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.

(d) 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, 2012 and 2013 consisted of money market mutual funds.

(e) Equipment

Equipment consists of office equipment and is recorded at cost. Equipment is depreciated on a straight-line basis over its estimated useful lives. The Company uses a life of five years for office equipment. Long-lived assets, such as equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, then an impairment charge is recognized for the amount by which the carrying value of the asset exceeds the fair value of the asset.

Accumulated depreciation was $8,244 and $9,691 as of December 31, 2012 and 2013, respectively.

(f) 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 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.

(g) 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

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RECRO PHARMA, INC.

Notes to Financial Statements (Continued)

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.

(h) 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 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 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.

(i) Grant Income

Grants received are recognized as income when the related work is performed and the qualifying research and development costs are incurred. In December 2012, the Company received approval from the State of Pennsylvania for a Keystone Innovation Zone Tax Credit. The Company has recognized $85,000 as grant income and a corresponding receivable at December 31, 2012, which was received in January 2013. During 2010, the Company received a grant for $244,479 under the Qualified Therapeutic Discovery Project Grants Program, a U.S. federal

government initiative, that is included in grant income on the statement of operations for the period from November 15, 2007 (inception) to December 31, 2013.

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RECRO PHARMA, INC.

Notes to Financial Statements (Continued)

(j) 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 Series A and common stock options 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, 2012 and 2013, as they would be anti-dilutive:

	December 31,	
	2012	**2013**
Shares issuable upon conversion of redeemable convertible preferred stock	800,000	800,000
Shares issuable pursuant to redeemable convertible preferred stock accretion	288,900	376,008
Options outstanding	334,800	334,800
Convertible notes payable	1,693,084	1,984,533

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 assumes the conversion of all outstanding shares of the Company s Series A including accrued dividends, into 1,132,454 weighted average shares of common stock and the conversion of the convertible notes into 1,828,411 weighted average shares of common stock upon the closing of the Company s planned IPO, 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. The Company believes the unaudited pro forma net loss per common share provides material information to investors, as the conversion of the Company s preferred stock to common stock, including accrued dividends, and the conversion of the convertible notes will occur upon the closing of an IPO, 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.

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RECRO PHARMA, INC.

Notes to Financial Statements (Continued)

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

	Year ended December 31, 2013
Numerator:	
Net loss applicable to common shareholders	$ (2,398,022)
Effect of pro forma adjustments:	
Accretion of redeemable convertible preferred stock	440,204
Interest expense on convertible notes	868,109
Pro forma net loss applicable to common shareholders	$ (1,089,709)
Denominator:	
Weighted average common shares outstanding	155,600
Effect of pro forma adjustments:	
Conversion of redeemable convertible preferred stock	1,132,454
Conversion of convertible notes	1,828,411
Shares used in computing unaudited pro forma weighted average basic and diluted common shares outstanding	3,116,465
Unaudited pro forma basic and diluted net loss per common share	$ (0.35)

(4) Fair Value of Financial Instruments

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

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities

Level 2: Significant other observable inputs other than Level 1 prices such as quoted prices in markets that are not active, or inputs that are observable, either directly or indirectly, for substantially the full term of the asset or liability

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity)

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RECRO PHARMA, INC.

Notes to Financial Statements (Continued)

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, 2012:			
Assets:			
Money market mutual funds (included in cash and cash equivalents)	$ 53,346		
At December 31, 2013:			
Assets:			
Money market mutual funds (included in cash and cash equivalents)	$ 12,828		

(5) Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2012	2013
Clinical trial and related costs	$ 11,216	$ 18,944
Professional and consulting fees	87,998	567,500
Payroll and related costs	2,815	3,088
	$ 102,029	$ 589,532

(6) Convertible Notes Payable

In 2009, 2010, 2011, 2012 and 2013, the Company issued $2,000,000, $3,250,000, $2,000,000, $1,270,000 and $880,584, respectively, of convertible promissory notes (the Bridge Notes). The Bridge Notes bear interest at 8% per

annum, compounded quarterly and are due on demand. The Bridge Notes and accrued interest may be converted at the election of the holder into shares of preferred stock to be issued by the Company in its next equity financing at seventy-five percent (75%) of the initial price per share of that offering.

As of December 31, 2013, $9,400,584 of the Bridge Notes were outstanding plus $2,506,614 of accrued interest. In addition, the Company amended the terms of the Bridge Notes to add an additional conversion feature that allows the holders to convert the Bridge Notes and accrued interest into shares of Series A redeemable preferred stock (Series A) at the lowest price per share paid for any shares of Series A (currently, $2.00 per share). In accordance with accounting guidance on certain convertible instruments, 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 since the Bridge Notes allow the holders to purchase equity at a 25% discount in the next round. In accordance with that accounting guidance, the contingent BCF of $3,969,066 is only recognized as additional interest expense if and when the Bridge Notes are converted into shares of the new series of preferred stock.

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RECRO PHARMA, INC.

Notes to Financial Statements (Continued)

(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 ($28.2 million as of December 31, 2013) 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.

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 ($16.8 million as of December 31, 2013) 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.

(8) Capital Structure

(a) Series A Redeemable Convertible Preferred Stock

In September and November 2008, the Company sold 750,000 shares of Series A at $2.00 per share for net proceeds of $1,454,918, after deducting offering costs of $45,082. In January through June 2009, the Company sold an additional 1,250,000 shares of Series A at $2.00 per share for gross proceeds of $2,500,000.

Each share of Series A is convertible into 0.4 shares of common stock (subject to certain antidilution adjustments) at any time at the option of the holder. The Series A is mandatorily convertible into common stock in the event of an initial public offering, as defined. Holders of the Series A have the number of votes equal to the number of common shares into which their stock is convertible. Holders of the Series A, voting as a class, are entitled to elect three members, or not less than a majority, of the board of directors. Approval of holders of a majority (greater than 50%) of the Series A shares is required for certain significant corporate events.

The Series A holders are entitled to receive cumulative dividends of 8%, compounded annually, if and when declared by the board of directors. No dividends have been declared through December 31, 2013. As of December 31, 2013, there were $1,880,037 of cumulative undeclared Series A dividends. Upon conversion of the Series A into common

stock, cumulative undeclared dividends are convertible into a number of shares of common stock equal to the total amount of cumulative dividends divided by $2.00 (the Series A issuance price) multiplied by 0.4 (the Series A conversion ratio). Based on an IPO price of $8.00 per share, the Company will record a non-cash deemed dividend of approximately $1.2 million upon the 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 in the accompanying financial statements.

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RECRO PHARMA, INC.

Notes to Financial Statements (Continued)

The Series A holders are entitled to a liquidation preference in an amount equal to $2.00 per share, plus any accumulated but unpaid dividends, in the event of a liquidation, dissolution, or winding up of the Company, or in the event the Company merges with or is acquired by another entity. Once the Series A liquidation preference has been paid, any remaining assets would be distributed pro rata to the Series A and common stockholders.

At any time after July 7, 2013, the holders of a majority (greater than 50%) of the Series A may require the Company to redeem the Series A for a price per share equal to $2.00, plus any accumulated but unpaid dividends, whether or not declared. The carrying value of the Series A will be accreted to its redemption value by a charge to additional paid-in capital, if any, then to accumulated deficit.

(b) Common Stock

In June 2008, the Company issued 155,600 shares of common stock at $0.0643 per share.

Holders of the common stock, voting as a class, are entitled to elect one member of the board of directors, provided that such director is reasonably acceptable to the holders of at least two-thirds of the shares of Series A.

(9) Stock-Based Compensation

The Company has established the 2008 Stock Option Plan (the 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, 2013, 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, which allows for the grant of stock options, stock appreciation rights and stock awards for a total of 600,000 shares of common stock. Effective upon the consummation of the IPO, options to purchase 181,026 shares of common stock will be granted with an exercise price equal to the purchase price in the Company s IPO of which 71,826 shares will be issued under the 2013 Equity Incentive Plan and the balance under the Plan. 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, 2013, 109,200 shares were available for future grants under the Plan and 600,000 shares were available under the 2013 Equity Incentive Plan.

Stock-based compensation expense (income) under the Plan was as follows:

	Year ended December 31, 2012
Employee	$ 2,000
Nonemployee	(3,085)

	$ (1,085)

During 2012, the Company recognized income related to nonemployee awards due to a decrease in the estimated fair value as those awards are revalued during the vesting period.

There were no stock option awards granted during the years ended December 31, 2012 and 2013.

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RECRO PHARMA, INC.

Notes to Financial Statements (Continued)

The following table summarizes stock option activity under the Plan through December 31, 2013:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life
Balance, December 31, 2011	334,800	$ 6.00	
Granted			
Exercised			
Canceled			
Balance, December 31, 2012	334,800	$ 6.00	
Granted			
Exercised			
Canceled			
Balance, December 31, 2013	334,800	$ 6.00	5 years
Options exercisable, December 31, 2013	334,800	$ 6.00	5 years

In March 2009, options to purchase 20,000 shares of common stock were granted to an employee. In December 2008, options to purchase 302,800 shares of common stock were granted to nonemployees.

As of December 31, 2013, all options are vested and there was no unrecognized compensation expense.

(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,	
	2012	2013
U.S. federal statutory income tax rate	34.0%	34.0%
State taxes, net of federal benefit	6.6%	6.6%
Permanent items	(19.5)%	(18.0)%
R&D credit	1.1%	0.7%
Change in valuation allowance	(22.2)%	(23.3)%

Effective income tax rate	%	%

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

	December 31,	
	2012	**2013**
Net operating loss carryforwards	$ 3,459,513	$ 3,697,105
Credits	346,552	359,980
Other temporary differences	1,642,940	1,847,770
Gross deferred tax asset	5,449,005	5,904,855
Deferred tax assets valuation allowance	(5,449,005)	(5,904,855)
	$	$

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RECRO PHARMA, INC.

Notes to Financial Statements (Continued)

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, 2012 and 2013.

The following table summarizes carryforwards of Federal net operating losses and tax credits as of December 31, 2013:

	Amount	Expiration	
Federal net operating losses	$ 9,106,169	2028	2033
Research and development credits	$ 359,980	2028	2033

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 20.0% of taxable income after modifications and apportionment or $3,000,000 on state net operating losses utilized in any one year.

(11) Related Party Transactions

In July 2008, the Company entered into an agreement with Malvern Consulting Group, Inc. (MCG), a consulting company affiliated with the Company s Chief Executive Officer. MCG provides consulting services to the Company, principally in the fields of clinical development, regulatory affairs, and quality assurance. MCG fees for services are based on time worked and the hourly rates of each consultant. The Company recorded $252,532 and $319,890 of research and development expenses for MCG consulting fees in 2012 and 2013, respectively. As of December 31, 2012, $11,216 and $11,682 was recorded in accrued expenses and accounts payable, respectively, 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 amounts due to MCG. In 2013, the Company recorded $125,000 of consulting fees for services provided by the Company s Chief Executive Officer. In addition to fees for services, employees of MCG, certain of whom are related to the Company s 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 lab space during 2013. The Company s Chief Executive Officer was affiliated with SCP Vitalife Venture Funds (SCP), which is an investor in the Series A, and represents SCP on the Company s board of directors. A representative of SCP serves as Chairman of the Company s board of directors.

From its inception through 2013, the Company borrowed and repaid $108,000 from the Company s Chief Executive Officer and $99,358 from MCG.

(12) Subsequent Event

During January 2014, the Company issued an additional $175,000 of Bridge Notes in the aggregate.

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RECRO PHARMA, INC.

Balance Sheets

(unaudited)

	September 30, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 23,904,128	$ 12,828
Other receivables	86,833	38,418
Prepaid expenses	133,694	15,689
Deferred offering costs		784,177
Total current assets	24,124,655	851,112
Total assets	$ 24,124,655	$ 851,112
Liabilities and Shareholders Equity (Deficit)		
Current liabilities:		
Convertible notes payable	$	$ 11,907,198
Accounts payable	682,187	434,244
Accrued expenses	1,236,171	589,532
Total current liabilities	1,918,358	12,930,974
Total liabilities	1,918,358	12,930,974
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, 7,707,600 shares at September 30, 2014 and 155,600 shares at December 31, 2013	77,076	1,556
Additional paid-in-capital	52,744,017	
Accumulated deficit	(30,614,796)	(17,961,455)
Total shareholders equity (deficit)	22,206,297	(17,959,899)
Total liabilities and shareholders equity (deficit)	$ 24,124,655	$ 851,112

See accompanying notes to unaudited financial statements.

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RECRO PHARMA, INC.

Statements of Operations

(unaudited)

	Nine Months Ended September 30,	
	2014	**2013**
Operating expenses:		
Research and development	$ 5,619,289	$ 481,736
General and administrative	2,768,260	455,970
Total operating expenses	8,387,549	937,706
Other income (expense):		
Interest income	7,127	41
Interest expense	(4,272,919)	(636,339)
	(4,265,792)	(636,298)
Net loss	(12,653,341)	(1,574,004)
Accretion of redeemable convertible preferred stock and deemed dividend	(1,270,057)	(327,091)
Net loss applicable to common shareholders	$ (13,923,398)	$ (1,901,095)
Basic and diluted net loss per common share	$ (2.42)	$ (12.22)
Weighted average basic and diluted common shares outstanding	5,743,527	155,600
Unaudited pro forma net loss	$ (8,380,422)	
Unaudited pro forma net loss per share	$ (1.27)	
Unaudited pro forma weighted average basic and diluted common shares outstanding	6,576,461	

See accompanying notes to unaudited financial statements.

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RECRO PHARMA, INC.

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

Nine Months Ended September 30, 2014

(unaudited)

	Series A Redeemable Convertible Preferred Stock		Shareholders Equity (Deficit)				
			Common stock		Additional paid-in	Accumulated	
	Shares	Amount	Shares	Amount	capital	deficit	Total
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)
Sale of common stock in initial public offering, net of offering costs of $4,245,158			4,312,500	43,125	30,211,717		30,254,842
Stock-based compensation expense					329,541		329,541
Deemed dividend on Series A		1,181,286			(1,181,286)		(1,181,286)
Conversion of Series A and accrued dividends to common	(2,000,000)	(7,150,094)	1,193,762	11,938	7,138,156		7,150,094
Conversion of notes payable and accrued interest to common			2,045,738	20,457	12,253,970		12,274,427
Beneficial conversion					4,080,690		4,080,690

upon conversion of notes payable (Note 6)						
Net loss					(12,653,341)	(12,653,341)
Balance, September 30, 2014	$	7,707,600	$ 77,076	$ 52,744,017	$ (30,614,796)	$ 22,206,297

See accompanying notes to unaudited financial statements.

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RECRO PHARMA, INC.

Statements of Cash Flows

(unaudited)

	Nine Months Ended September 30,	
	2014	**2013**
Cash flows from operating activities:		
Net loss	$ (12,653,341)	$ (1,574,004)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	329,541	
Noncash interest expense	4,272,919	636,339
Depreciation expense		1,331
Changes in operating assets and liabilities:		
Prepaid expenses	(118,005)	(7,294)
Other receivables	(48,415)	85,000
Accounts payable and accrued expenses	1,569,282	190,401
Net cash used in operating activities	(6,648,019)	(668,227)
Cash flows from financing activities:		
Proceeds from initial public offering	30,364,319	
Offering costs		(50,000)
Proceeds from notes payable	175,000	685,284
Net cash provided by financing activities	30,539,319	635,284
Net increase (decrease) in cash and cash equivalents	23,891,300	(32,943)
Cash and cash equivalents, beginning of period	12,828	53,346
Cash and cash equivalents, end of period	$ 23,904,128	$ 20,403
Supplemental disclosure of cash flow information		
Conversion of notes payable and accrued interest into common stock	$ 12,274,427	
Conversion of Series A and accrued dividends into common stock	$ 5,968,808	

See accompanying notes to unaudited financial statements.

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RECRO PHARMA, INC.

Notes to Unaudited Financial Statements

(1) Background

Recro Pharma, Inc., or the Company, 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 $30.6 million as of September 30, 2014. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its products currently in development. Substantial additional financing will be needed by the Company to fund its operations and to commercially develop its product candidates.

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 Policies

(a) Basis of Presentation

The accompanying unaudited interim financial statements of the Company have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP, for interim financial information. In the opinion of management, the accompanying financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company s financial position as September 30, 2014 and its results of operations and cash flows for the nine months ended September 30, 2014 and 2013. Operating results for the nine months ended September 30, 2014 are not necessarily indicative of the results that may be expected for the year ending December 31, 2014. The interim financial statements, presented herein, do not contain the required disclosures under U.S. GAAP for annual financial statements.

The accompanying unaudited interim financial statements should be read in conjunction with the annual audited financial statements and related notes as of and for the year ended December 31, 2013 included in this Registration Statement.

(b) Use of Estimates

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

(c) ***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

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RECRO PHARMA, INC.

Notes to Unaudited Financial Statements

outstanding 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 net loss per share are the same.

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as of September 30, 2014 and December 31, 2013, as they would be anti-dilutive:

	September 30, 2014	December 31, 2013
Redeemable convertible preferred stock		800,000
Shares issuable pursuant to redeemable convertible preferred stock accretion		376,008
Options outstanding	760,300	334,800
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 assumes the conversion of all outstanding shares of the Company s Series A Redeemable Convertible Preferred Stock, or Series A Stock, including accrued dividends, into 308,157 weighted average shares of common stock and the conversion of the 8% Convertible Promissory Notes, or the Bridge Notes, including accrued interest, into 524,777 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 shareholders is adjusted to remove all preferred stock accretion. 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 Bridge Notes, including accrued interest, occurred upon the closing of the Company s initial public offering, or the 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 IPO.

	Nine Months Ended September 30, 2014
Numerator:	
Net loss applicable to common shareholders	$ (13,923,398)
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	$	(8,380,422)
Denominator:		
Weighted average common shares outstanding		5,743,527
Effect of pro forma adjustments:		
Conversion of redeemable convertible preferred stock		308,157
Conversion of convertible notes		524,777
Shares used in computing unaudited pro forma weighted average basic and diluted common shares outstanding		6,576,461
Unaudited pro forma basic and diluted net loss per common share	$	(1.27)

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RECRO PHARMA, INC.

Notes to Unaudited Financial Statements

(d) 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:

(a) Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities

(b) 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

(c) 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)

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 September 30, 2014:			
Assets:			

Money market mutual funds (included in cash and cash equivalents)	$	23,904,128
At December 31, 2013:		
Assets:		
Money market mutual funds (included in cash and cash equivalents)	$	12,828

(5) Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2014	December 31, 2013
Clinical trial and related costs	$ 703,731	$ 18,944
Professional and consulting fees	220,374	567,500
Payroll and related costs	280,394	3,088
Other	31,672	
	$ 1,236,171	$ 589,532

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RECRO PHARMA, INC.

Notes to Unaudited Financial Statements

(6) Convertible Notes Payable

As of December 31, 2013, $9,400,584 of the Bridge Notes were outstanding plus $2,506,615 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 nine months ended September 30, 2014 and 2013, the Company recorded $192,229 and $636,339 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 initial offering price per share. The Company determined that the Bridge Notes contained a contingent beneficial conversion feature, or BCF. The contingent BCF existed at the date of issuance of the Bridge Notes, which allowed the holders to purchase equity at a 25% discount to the offering price. In accordance with the accounting guidance on convertible instruments, the contingent BCF of $4,080,690 was recognized as additional interest expense when the Bridge Notes, including accrued interest, were converted into shares of common stock.

(7) 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 $4,245,158 in underwriting discounts, commissions and offering costs resulting in net proceeds of $30,254,842. 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 September 30, 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 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

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RECRO PHARMA, INC.

Notes to Unaudited Financial Statements

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 outstanding or authorized.

(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 commencing one year after the closing of the IPO.

(8) 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 September 30, 2014, no stock appreciation rights have been issued. Subsequent to adoption, the 2008 Plan was amended to increase the authorized number of shares available for grant to 444,000 shares of common stock. In October 2013, the Company established the 2013 Equity Incentive Plan, or the 2013 Plan, which allows for the grant of stock options, stock appreciation rights and stock awards for a total of 600,000 shares of common stock. Stock options are exercisable generally for a period of 10 years from the date of grant and generally vest over four years. As of September 30, 2014, 283,526 shares and 174 shares are available for future grants under the 2013 Plan and 2008 Plan, respectively.

The weighted average grant-date fair value of the options awarded to employees during the nine months ended September 30, 2014 was $5.83. 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	2.69-2.73%
Expected dividend yield	

Stock-based compensation expense for the nine months ended September 30, 2014 was $329,541. There was no stock-based compensation expense for the nine months ended September 30, 2013.

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RECRO PHARMA, INC.

Notes to Unaudited Financial Statements

The following table summarizes stock option activity during the nine months ended September 30, 2014:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life
Balance, December 31, 2013	334,800	$ 6.00	
Granted	425,500	$ 7.71	
Exercised			
Canceled			
Balance, September 30, 2014	760,300	$ 6.96	7.3 years
Options exercisable, September 30, 2014	391,285	$ 6.25	5.2 years

As of September 30, 2014, there was $2,150,999 of unrecognized compensation expense related to unvested options that are expected to vest and will be expensed over a weighted average period of 3.5 years.

(9) 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 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 $330,431 and $262,834 for the nine months ended September 30, 2014 and 2013, respectively. As of September 30, 2014, $36,948 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 $36,000 in rental fees to MCG for a month to month lease for facilities space for the nine months ended September 30, 2013 and $72,291 for facilities space for the nine months ended September 30, 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.

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2,500,000 Shares

Common Stock

PROSPECTUS

February 26, 2015