Recro Pharma, Inc.
Form S-1/A
December 20, 2013
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As filed with the Securities and Exchange Commission on December 19, 2013

Registration Statement No. 333-191879

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

AMENDMENT No. 2

To

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

RECRO PHARMA, INC.

(Exact name of registrant as specified in its charter)

Pennsylvania (State or other jurisdiction of incorporation or organization)	2834 (Primary Standard Industrial Classification Code Number)	26-1523233 (I.R.S. Employer Identification Number)

490 Lapp Road

Malvern, PA 19355

(484) 395-2400

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Gerri A. Henwood

President and Chief Executive Officer

Recro Pharma, Inc.

490 Lapp Rd

Malvern, PA 19355

(484) 395-2400

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Justin P. Klein, Esq.	**Oded Har-Even, Esq.**
Katayun I. Jaffari, Esq.	**Howard E. Berkenblit, Esq.**
Ballard Spahr LLP	**Zysman, Aharoni, Gayer and**
1735 Market Street, 51st Floor	**Sullivan & Worcester LLP**
Philadelphia, PA 19103	**1633 Broadway**
(215) 665-8500	**New York, NY 10019**

(212) 660-3000

Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box: ¨

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

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

The registrant is an emerging growth company, as defined in Section 2(a) of the Securities Act. This registration statement complies with the requirements that apply to an issuer that is an emerging growth company.

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee(2)
Common Stock, $0.01 par value	$ 32,200,000	$ 4,147.36(3)

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Includes the offering price of shares that the underwriters have the option to purchase to cover over-allotments, if any.
(2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.
(3) Of which $3,606.40 were previously paid.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and we are not soliciting an offer to buy these securities in any state or jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION DATED DECEMBER 19, 2013

Shares

Common Stock

This is the initial public offering of Recro Pharma, Inc. s common stock. No public market currently exists for our common stock. We are offering all of the shares of common stock offered by this prospectus. We expect the public offering price to be between $ and $ per share.

We have applied to list our common stock on the NASDAQ Capital Market under the symbol REPH.

We are an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, will be subject to reduced public company reporting requirements.

Investing in our common stock involves a high degree of risk. Before buying any shares, you should carefully read the discussion of material risks of investing in our common stock in Risk Factors beginning on page 9 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	Total
Public offering price	$	$

Underwriting discounts and commissions [1]	$	$
Offering proceeds to us, before expenses	$	$

(1) The underwriters will receive compensation in addition to the underwriting discount. See Underwriting beginning on page 103.

The underwriters may also purchase up to an additional shares of our common stock at the public offering price, less the underwriting discounts and commissions payable by us, to cover over-allotments, if any, within 45 days from the date of this prospectus. If the underwriters exercise this option in full, the total underwriting discounts and commissions will be $ and our total proceeds, after deducting underwriting discounts and commissions but before expenses, will be $.

The underwriters are offering the common stock as set forth under Underwriting. Delivery of the shares will be made on or about , 2013.

Aegis Capital Corp

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Neither we nor the underwriters have 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. Neither we nor the underwriters take 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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PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, especially the Risk Factors section and our financial statements and the related notes appearing at the end of this prospectus, before making an investment decision. As used in this prospectus, unless the context otherwise requires, references to we, us, our, our company, Company and Recro 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 in the post-operative setting. Our lead product, an intranasal formulation of Dexmedetomidine, or Dex, has completed a placebo controlled trial demonstrating effective pain relief. We have studied various dosage forms of Dex in eight completed clinical studies, two of which were placebo controlled trials that demonstrated effective pain relief. As our product candidates are not opioid based drugs, we expect to overcome many of the side effects associated with commonly prescribed opioid based therapeutics, including addiction, constipation and respiratory distress while maintaining analgesic, or pain relieving, effect. We are ready to begin a Phase IIb trial with Dex in patients experiencing post-operative pain. We have completed a placebo-controlled Phase Ib trial in chronic lower back pain patients where Dex produced meaningful reduction in pain. We believe Dex will be an alternative pain medication to opioids for the more than 50 million surgical procedures that require post-operative pain medication. If approved, Dex would also be the first and only approved post-operative pain drug in its class of drugs.

Overview of Dex

Dex is a U.S. Food and Drug Administration, or FDA, approved and commercial injectable drug indicated for sedation in an intensive care unit, or ICU, setting sold by Hospira, Inc., or Hospira, in the United States under the brand name, Precedex®, and by Orion Farma Oy, a division of Orion Corporation, or Orion,in Europe under the brand name, Dexdor®. 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 our lead, proprietary intranasal formulation of Dex, or Dex-IN, which allows us to leverage the existing safety data from the NDA of Precedex® and Dexdor® in pursuing a program for a new drug application, 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 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.

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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 registration 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.

Product candidate	Indication	Stage	Commercial rights*
Dexmedetomidine			Worldwide, except Europe, Turkey and CIS
Dex-IN (intranasal)	Post-operative pain	Phase IIb	
	Cancer breakthrough pain	Phase II	
Dex-SL (sublingual)	Chronic pain	Phase II	
Fadolmidine			Worldwide, except Europe, Turkey and CIS
Intrathecal	Post-operative pain	Phase IIb	
Topical	Neuropathic pain	Phase I	

* Subject to regulatory approval in the appropriate jurisdictions and by the appropriate governmental authorities.

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Our Completed Clinical Trials of Dex

We have evaluated multiple formulations of Dex in eight completed studies in over 100 subjects, including two 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-11-010. Our most recently completed study 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 patients. The study compared single doses of placebo, 25mcg of Dex and 50 mcg of Dex, all administered using a single-use device.

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 our other 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 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.

Based upon the positive results from these two placebo controlled trials and our other completed clinical trials, we expect the next study of Dex-IN to be a Phase IIb clinical study in approximately 150 to 200 post-surgical patients.

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;

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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 Commonwealth of Independent States, or 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 section entitled Intellectual Property beginning on page 66 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 section entitled Risk Factors beginning on page 9 of this prospectus for a discussion of such risks.

Corporate Information

Our principal executive offices are located at 490 Lapp Road, Malvern, PA 19355, and our telephone number is (484) 395-2400. 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

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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 earliest 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 this offering; (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 us	shares
Common stock to be outstanding immediately after this offering	shares
Over-allotment option	The underwriters have an option for a period of 45 days to purchase up to additional shares of our common stock to cover over-allotments.
Use of proceeds	We intend to use the net proceeds from this offering to fund our continued development of Dex-IN, our lead product candidate, and to fund working capital needs and other general corporate purposes. See the section entitled Use of Proceeds beginning on page 39 of this prospectus for a more complete description of the intended use of proceeds from this offering.
Risk Factors	You should read the section entitled Risk Factors beginning on page 9 of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Proposed NASDAQ Capital Market symbol	REPH

The number of shares of our common stock outstanding after this offering is based on 389,000 actual shares of our common stock outstanding as of September 30, 2013, and (1) additional shares of our common stock issuable upon the automatic conversion of all outstanding shares of our Series A Redeemable Convertible Preferred Stock, including accrued dividends, upon the closing of this offering, and (2) additional shares of our common stock issuable upon the assumed conversion of all principal and accrued interest outstanding under our 8% Convertible Promissory Notes, including $195,300 of additional notes issued subsequent to September 30, 2013, upon the closing of this offering, assuming an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and assuming the conversion occurs on , 2013 (the expected closing date of this offering).

The number of shares of our common stock outstanding after this offering excludes:

- 837,000 shares of our common stock issuable upon the exercise of stock options outstanding as of September 30, 2013 at a weighted-average exercise price of $2.40 per share;

273,000 additional shares of our common stock available for future issuance as of September 30, 2013 under our 2008 Stock Option Plan; and

1,500,000 shares of our common stock available for future issuance under our 2013 Equity Incentive Plan.

Unless otherwise indicated, all information in this prospectus assumes:

the (1) additional shares of our common stock issuable upon the automatic conversion of all outstanding shares of our Series A Redeemable Convertible Preferred Stock, including accrued dividends, upon the closing of this offering, and (2) additional shares of our common stock issuable upon the assumed conversion of all principal and accrued interest outstanding under our 8% Convertible Promissory Notes, including $195,300 of additional notes issued subsequent to September 30, 2013, upon the closing of this offering, assuming an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and assuming the conversion occurs on , 2013 (the expected closing date of this offering);

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no exercise of the outstanding options described above; and

no exercise by the underwriters of their option to purchase up to additional shares of our common stock to cover over-allotments.

Summary Financial Data

The following tables summarize the financial data for the periods indicated. The summary statements of operations data for the years ended December 31, 2011 and 2012 have been derived from our audited financial statements included elsewhere in this prospectus. The statements of operations data for the nine months ended September 30, 2012 and 2013 and the period from November 15, 2007 (inception) through September 30, 2013 and the summary consolidated balance sheet data as of September 30, 2013 have been derived from our unaudited interim financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future and our interim period results are not necessarily indicative of the results for a full year. The summary financial data below should be read in conjunction with the information contained in Selected Financial Data, Management s Discussion and Analysis of Financial Condition and Results of Operations, the financial statements and notes thereto, and other financial information included elsewhere in this prospectus.

	Year ended December 31,		Nine Months Ended September 30,		Period from November 15, 2007 (inception) through September 30,
	2011	2012	2012	2013	2013
	(in thousands, except share and per share data)				
Statements of Operations Data:					
Operating expenses:					
Research and development	$ 1,828	$ 542	$ 505	$ 494	$ 11,939
General and administrative	485	339	239	444	1,902
Total operating expenses	2,313	881	744	938	13,841
Other income (expense):					
Interest income					4
Grant income		85			329
Interest expense	(558)	(740)	(542)	(636)	(2,274)
	(558)	(655)	(542)	(636)	(1,941)
Net loss	(2,871)	(1,536)	(1,286)	(1,574)	$ (15,782)
Accretion of redeemable convertible preferred stock	(383)	(413)	(299)	(327)	
	$ (3,254)	$ (1,949)	$ (1,585)	$ (1,901)	

Net loss applicable to common shareholders				
Basic and diluted net loss per common share	$ (8.36)	$ (5.01)	$ (4.08)	$ (4.89)
Weighted average basic and diluted common shares outstanding	389,000	389,000	389,000	389,000
Unaudited pro forma net loss(1)		$ (796)		$ (938)
Unaudited pro forma basic and diluted net loss per common share(1)		$		$
Unaudited pro forma weighted average basic and diluted common shares outstanding(1)				

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(1) See note 3(i) and 3(d) to our audited and unaudited financial statements appearing at the end of this prospectus for information regarding computation of unaudited pro forma basic and diluted net loss per common share and the unaudited pro forma weighted average basic and diluted common shares outstanding used in computing pro forma basic and diluted net loss per common share.

	As of September 30, 2013		
	Actual	Pro Forma(1) (unaudited) (in thousands)	Pro Forma As adjusted(1) (2)
Balance Sheet Data:			
Cash and cash equivalents	$ 20	$ 216	$
Working capital	(11,696)	(21)	
Total assets	291	487	
Convertible notes payable	11,480		
Series A redeemable convertible preferred stock	5,767		
Total shareholders equity (deficit)	(17,463)	(21)	

(1) Reflects (i) the automatic conversion of all of outstanding shares of our Series A Redeemable Convertible Preferred Stock, including accrued dividends, upon the closing of this offering, (ii) the receipt of gross proceeds of $195,300 from the issuance of additional 8% Convertible Promissory Notes and (iii) the assumed conversion of all principal and accrued interest outstanding under our 8% Convertible Promissory Notes, upon the closing of this offering, in each case assuming an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and assuming the conversion occurs on , 2013 (the expected closing date of this offering).

(2) Reflects the issuance and sale of shares of common stock in this offering at the initial public offering price of $ per share after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

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RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this prospectus, including our financial statements and the related notes and Management s Discussion and Analysis of Results of Operations and Financial Condition, before deciding to invest in our common stock. If any of the following risks actually occur, our business, prospects, operating results and financial condition could suffer materially, the trading price of our common stock could decline and you could 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 multiple formulations of our lead product candidate, Dex. In addition, we have another product candidate, Fado, in development. We have incurred significant net losses in each year since our inception in November 2007, including net losses of approximately $3.9 million, $2.9 million, $1.5 million and $1.6 million for fiscal years 2010, 2011, 2012 and for the nine months ended September 30, 2013, respectively. As of September 30, 2013, we had an accumulated deficit of $17.5 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.

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, 2013, we had negative working capital of approximately $11.7 million, and our audit report on our 2012 financial statements contains an explanatory paragraph stating that our recurring losses and negative cash flows from operations since inception raise substantial doubt about our ability to continue as a going concern. If we are unable to successfully complete this offering, we will need to seek alternative financing or operational plans to continue as a going concern. Even if the offering is successful, we may 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.

We estimate that the net proceeds from this offering will be approximately $ million, based on the initial offering price of $ per share, after deducting underwriting discounts and commissions and

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estimated offering expenses payable by us. We expect that the net proceeds from this offering and our existing cash and cash equivalents, together with interest, will be sufficient to fund our current operations into the second half of 2015. 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 the NDA 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.

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 post-operative pain;
- obtaining regulatory approval for Dex-IN for the treatment of post-operative 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 dosage forms and our other products, including Fado.

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

Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate unless we enter into a strategic 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.

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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 for you to use in evaluating the potential future success or viability of our business and any such evaluation of our business and prospects may not be accurate.

Our operating results may fluctuate significantly.

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

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

- variations in the level of expenses related to our development programs;
- the success of our clinical trials through all phases of clinical development;
- any delays in regulatory review and approval of product candidates in clinical development;
- potential side effects of our future products that could delay or prevent commercialization or cause an approved drug to be taken off the market;
- any intellectual property infringement lawsuit in which we may become involved;
- our ability to obtain and maintain patent protection;
- our ability to establish an effective sales and marketing infrastructure;
- our dependency on third-parties to supply and manufacture our product candidates and delivery devices;
- competition from existing products or new products that may emerge;

- regulatory developments affecting our products and product candidates, which are not limited to but could include the imposition of a Risk Evaluation and Mitigation Strategy, or REMS, program as a condition of approval;

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

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

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

Due to the various factors mentioned above, and others, the results of any prior quarterly period should not be relied upon as an indication of our future operating performance. If our quarterly operating results fall below 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.

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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 post-operative pain. We have completed two placebo-controlled clinical trials with two different dosage forms of Dex in chronic lower back pain subjects. We expect to initiate a Phase IIb clinical trial for Dex-IN in post-operative patients in the first half of 2014. Assuming completion of a successful clinical trial, we expect to complete two Phase III pivotal clinical trials with Dex-IN in post-operative pain. We intend to use these trials as a basis to submit an NDA for Dex-IN for treatment of post-operative 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.

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;

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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 payers, patients and the medical community; or

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.

We depend substantially on the successful completion of Phase IIb 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 IIb or III and, thus, we may never receive regulatory approval of our product candidates.

We have completed multiple clinical studies utilizing Dex-IN. However, we will conduct a Phase IIb clinical trial 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. Furthermore, while we have obtained positive safety and efficacy results for Dex-IN during our prior clinical trials, we cannot be certain that these results will be duplicated when our product candidates are tested in a larger number of patients in our Phase IIb and Phase III clinical trials.

To date, we have completed multiple clinical trials with Dex in chronic lower back pain. However, there is no certainty that the results we have seen in these studies and patient population will be similar in patients with post-operative pain in our future expected clinical trials. Accordingly, unexpected results could require us to redo clinical studies in the same or different patient populations or discontinue development of Dex-IN.

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. We expect to initiate a Phase IIb clinical trial in post-operative patients in the first half of 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 IIb 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 IIb 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;

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import delays;

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

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

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

delays in recruiting suitable patients to participate in a trial;

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

delays in having patients complete participation in a trial or return for post-treatment follow-up;

clinical sites dropping out of a trial to the detriment of enrollment;

time required to add new clinical sites;

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

delays or problems caused by third parties who market Dex for other indications.

If initiation or completion of the Phase IIb and Phase III trials are delayed for Dex-IN or other product candidates for any of the above reasons, our development costs may increase, our approval process could be delayed and our ability to commercialize Dex-IN or other product candidates could be materially harmed, which could have a material adverse effect on our business, financial condition or results of operations.

Our product candidates may cause adverse events or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

AEs caused by our product candidates could cause us, other reviewing entities, clinical study sites or regulatory authorities to interrupt, delay or halt clinical studies and could result in the denial of regulatory approval. Clinical studies conducted by us with Dex have generated some AEs, but no serious adverse events, or SAEs, as those terms are defined by the FDA in its regulations. For example, AEs have included higher incidences of somnolence and hypotension observed in patients receiving Dex over patients receiving placebo. If SAEs are observed in any of our clinical studies, our ability to obtain regulatory approval for our product candidates may be adversely impacted.

Further, if our products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including:

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

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates.

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Additional time may be required to obtain regulatory approval for Dex-IN, our lead product candidate, 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.

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.

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 issues, 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;

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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.

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

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

The FDA Amendments Act of 2007 implemented safety-related changes to product labeling and requires the adoption of REMS for certain products. Based on the FDA s actions with many products, our product candidates may require REMS. The REMS may include requirements for special labeling or medication guides for patients, special communication plans to health care professionals and restrictions on distribution and use. We cannot predict the specific scope or magnitude of REMS to be required as part of the FDA s approval of Dex-IN. Depending on the extent of the REMS requirements, our costs to commercialize Dex-IN may increase significantly and distribution restrictions could limit sales. Our other product candidates, if approved, may also require REMS programs that may increase our costs to commercialize these product candidates or limit sales.

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

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

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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 are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be adversely affected.

Risks Related to Our Reliance on Third Parties

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

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

- the inability to meet our product specifications and quality requirements consistently;
- a delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- a failure to comply with cGMP and similar foreign standards;
- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- the reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell our product candidates in a timely fashion, in sufficient

quantities or under acceptable terms;

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.

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

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

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing them successfully. Furthermore, if our suppliers fail to deliver the required quantities of product components on a timely basis and at reasonable prices, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

Manufacture of Dex-IN requires specialized equipment and expertise, the disruption of which may cause delays and increased costs.

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

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 impurities 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 System 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 Malvern Consulting Group, Inc., or MCG, and other third parties to ensure the proper and timely conduct of our clinical trials. While we have agreements governing their activities, we have limited influence over certain of these third parties actual performance. We have relied and plan to continue to rely upon third parties to monitor and manage data for our ongoing clinical programs for Dex and our other product candidates, as well as the execution of nonclinical studies. We control only certain aspects of our third parties activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the third parties does not relieve us of our regulatory responsibilities.

We and our contractors are required to comply with the FDA s 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 IIb 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

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result, our financial results and the commercial prospects for Dex-IN and any future product candidates that we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

Risks Related to Commercialization of Our Product Candidates

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

The degree of market acceptance of any of our product candidates will depend on a number of factors, including:

- demonstration of clinical safety and efficacy;
- the relative convenience, ease of administration and acceptance by physicians, patients and health care payors;
- the prevalence and severity of any AEs;
- limitations or warnings contained in the FDA-approved label for Dex-IN;
- availability of alternative treatments;
- pricing and cost-effectiveness;
- the effectiveness of our or any future collaborators sales and marketing strategies;
- our ability to convince hospitals to include Dex on their list of authorized products, referred to as formulary approval;
- our ability to obtain and maintain sufficient third party coverage or reimbursement; and
- the willingness of patients to pay out-of-pocket in the absence of third party coverage.

If Dex-IN or any product candidates are approved, but does not achieve an adequate level of acceptance by physicians, patients and health care payors, we may not generate sufficient revenue from Dex-IN or any product candidates and we may not become or remain profitable.

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

We currently do not have an organization for the sales, marketing and distribution of Dex-IN and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. We intend to enter into strategic partnerships with third parties to commercialize our product candidates outside of the United States. We will also consider the option to enter into strategic partnerships for our product candidates in the United States.

To date, we have not entered into any strategic partnerships for any of our product candidates. We face significant competition in seeking appropriate strategic partners, and these strategic partnerships can be intricate and time consuming to negotiate and document. We may not be able to negotiate strategic partnerships on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any strategic partnerships because of the numerous risks and uncertainties associated with establishing strategic partnerships. Our strategy for Dex-IN is to develop a hospital-directed sales force and/or collaborate with third parties to promote the product to healthcare professionals and third party payors in the United States. Our future collaboration partners, if any, may not dedicate sufficient resources to the commercialization of our product candidates or may otherwise fail in their commercialization due to factors beyond our control. If we are unable to establish effective

collaborations to enable the sale of our product candidates to healthcare professionals and in geographic regions, including the United States, that will not be covered by our own marketing and sales force, or if our potential future collaboration partners do not successfully commercialize our product candidates, our ability to generate revenues from product sales will be adversely affected.

If we are unable to negotiate a strategic partnership or obtain additional financial resources for our other product candidates, we may be forced to curtail the development of them, delay potential commercialization, reduce the scope of our sales or marketing activities or undertake development or commercialization activities at our own expense. In addition, without a partnership, we will bear all the risk related to the development of these other product candidates. If we elect to increase our expenditures to fund development or commercialization activities ourselves, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring our other product candidates to market or generate product revenue.

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

We are subject to intense competition and, if we are unable to compete effectively, our product candidates may not reach their commercial potential.

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

In the post-operative pain relief setting, we believe Dex-IN will be prescribed for moderate to severe pain, competing mostly with opioids such as morphine, oxycodone, hydrocodone and fentanyl. There are a number of pharmaceutical companies that currently market therapeutics in the pain relief area, including Johnson & Johnson, Purdue Pharma L.P., Endo Pharmaceuticals Inc., Cadence Pharmaceuticals Inc. and Pacira Pharmaceuticals, Inc. Purdue and Endo are the primary competitors in the manufacture, marketing and commercialization of opioid therapeutics. Cadence 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., 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, Meda AB, Kyowa Hakko, Insys Therapeutics Inc. and Archimedes Pharma Ltd. 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.

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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 post-operative pain or breakthrough pain could render Dex-IN non-competitive or obsolete. These and other risks may materially adversely affect our ability to attain or sustain profitable operations.

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

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

Furthermore, market acceptance and sales of Dex-IN, or any future product candidates that we develop, will depend on reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third party payors, such as private health insurers, hospitals and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. We cannot be sure that reimbursement will be available for Dex-IN, or any future product candidates. Also, reimbursement amounts may reduce the demand for, or the price of, our products. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize Dex-IN, or any future product candidates that we develop.

The availability of numerous generic pain medications may substantially reduce the likelihood of reimbursement for Dex-IN. We expect to experience pricing pressures in connection with the sale of Dex-IN and 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:

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different regulatory requirements for drug approvals in foreign countries;

reduced protection for intellectual property rights;

unexpected changes in tariffs, trade barriers and regulatory requirements;

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

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

foreign taxes, including withholding of payroll taxes;

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

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

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

business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

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

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

Physicians may not prescribe any of our product candidates if approved by the FDA, in which case we would not generate the revenues we anticipate. Market acceptance of any of our products or product candidates by physicians, patients, third-party payors and the medical community depends on, among other things:

our ability to provide acceptable evidence of safety and efficacy;

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

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

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

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

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

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

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;

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

pricing and cost effectiveness; and

the availability of adequate reimbursement by third parties.

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

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

Although we do not expect to commercialize our product candidates for several years, if and when we do, we will be subject to a variety of additional risks. In particular, upon commercialization of our product candidates, our relationships with third-party payors in the United States and elsewhere will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

In addition, over the past few years, several pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as: allegedly providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicaid for non-covered, off-label uses; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Most states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer s products from reimbursement under government programs, criminal fines and imprisonment.

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

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

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted, or whether the FDA or state regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of Dex-IN or any other product candidates, if any, 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

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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 listed under Management beginning on page 81 of this prospectus, 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 which will be effective upon the consummation of this offering. 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 and one of our largest vendors.

Our President and Chief Executive Officer, Gerri A. 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. Upon consummation of this offering, 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.

Currently, MCG performs services for only one company with a product in the pain space, other than our company, although such product is not currently competitive with our products because the indication being pursued by such company is for systemic treatment of neuropathies, and we do not anticipate pursuing systemic treatment of neuropathies.

We sublease our current office space 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. See also Transactions with Related Persons on page 92 of this prospectus.

Following the consummation of this offering, Mr. Garner will devote a small portion of his time to his consulting business. In addition, Mr. Garner has never served as a Chief Financial Officer of a public company.

Charles Garner has been providing investment banking, finance and related services to us since 2011 in his capacity as an independent contractor through Inverness Advisors LLC, or Inverness Advisors, and has served as a consultant to

the Company. Mr. Garner has signed an employment agreement to become our Chief Financial Officer effective upon consummation of this offering. Following the consummation of this offering, Mr. Garner will continue to devote a small portion of his time to his consulting business by providing investment banking,

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finance and related services to other companies and third parties. Mr. Garner has agreed not to provide any services to companies or third parties that could compete with us.

In addition, Mr. Garner has never served as a Chief Financial Officer of a public company. If Mr. Garner is unable to effectively serve as our Chief Financial Officer, our business may suffer. In addition, we may incur additional and substantial costs in order to replace Mr. Garner or to otherwise obtain the services customarily provided by a Chief Financial Officer.

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.

Subsequent to this offering, we will be a public company and, as such, we will 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, as well as rules implemented by the SEC, and the NASDAQ Capital Market, the stock exchange on which our common stock will be listed following this offering. 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 we initially expect to 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, 2013, we are the owner of record of one issued U.S. patent related to Fado and are the owner of record and are prosecuting four U.S. non-provisional patent applications, one pending international Patent Cooperation Treaty application and 34 foreign national patent applications related to either Dex or 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 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 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 licensed from Orion will expire in January 2014 and October 2016, respectively. 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

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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 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.

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

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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;
- 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.

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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 will depend 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 no research coverage by securities and industry analysts. If securities or industry analysts do not commence coverage of our company, the trading price for our stock would 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.

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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 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 and did not consummate this offering.

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 you sell your 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., can effectively determine or substantially influence the outcome of matters requiring shareholder approval.

As of November 1, 2013, SCP Vitalife Partners II, L.P. and SCP Vitalife Partners (Israel) II, L.P., or collectively SCP Vitalife, owned 1,875,000 shares of our Series A Redeemable Convertible Preferred Stock, representing approximately 79% of our outstanding common stock on an as-converted basis. In addition, SCP Vitalife holds an aggregate of $9,330,284 in aggregate principal amount of our 8% Convertible Promissory Notes. Upon consummation of this offering, assuming an initial public offering price of $ per share (the midpoint of the price range set forth on the cover page of this prospectus) and assuming the conversion occurs on , 2013 (the expected closing date of this offering), SCP Vitalife will own shares of our common stock, representing approximately % 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 your ability to influence certain corporate matters.

Following this proposed offering of our common stock, our directors and their affiliated entities, and our executive officers will beneficially own, in the aggregate, approximately % of our outstanding common stock. As a result, these shareholders are collectively able to significantly influence or control all 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. The concentration of ownership 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.

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The price of our common stock may fluctuate substantially.

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

- plans for, progress in and results from clinical trials of our product candidates generally;
- the commercial performance of any of our product candidates that receive marketing approval;
- FDA, state or international regulatory actions, including actions on regulatory applications for any of our product candidates;
- announcements of new products, services or technologies, commercial relationships, acquisitions or other events by us or our competitors;
- market conditions in the pharmaceutical and biotechnology sectors;
- fluctuations in stock market prices and trading volumes of similar companies;
- variations in our quarterly operating results;
- changes in accounting principles;
- litigation or public concern about the safety of our potential products;
- deviations in our operating results from the estimates of securities analysts;
- 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 you to sell your shares of our common stock.

Prior to this offering, there has been no public market for our common stock. Although we are applying to have our common stock listed on the NASDAQ Capital Market, an active trading market for our shares may never develop or be sustained following this offering. If an active market for our common stock does not develop, it may be difficult for you to sell shares you purchase in this offering without depressing the market price for the shares or at all. The initial public offering price for our common stock will be determined through negotiations with the underwriters and the negotiated price may not be indicative of the market price for our common stock after this offering. The initial public offering price may vary from the market price of our common stock after the offering. As a result of these and other factors, you may not be able to sell your shares of our common stock at or above the initial public offering price or at all. 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

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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.

Our management team may invest or spend the proceeds of this offering in ways with which you may not agree or in ways which may not yield a significant return, if any.

The net proceeds from this offering will be used to fund the research and development of our product candidates, and for other general corporate purposes. Because of the number and variability of factors that will determine our use of the proceeds from the offering, their ultimate use may vary substantially from their currently intended use. You will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. The net proceeds may be used for corporate purposes that do not increase our operating results or market value. Until the net proceeds are used, they may be placed in investments that do not produce significant income or investments that lose value. For a further description of our intended use of the proceeds of this offering, see Use of Proceeds on page 39 of this prospectus.

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 JOBS Act until the earliest to occur of (1) the last day of the fiscal year during which our total annual gross revenues equal or exceed $1 billion (subject to adjustment for inflation), (2) the last day of the fiscal year following the fifth anniversary of our initial public offering, (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 as 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

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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 stockholders 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.

All of our existing shareholders have entered into lock-up agreements with the underwriters in connection with this offering that restrict the shareholders ability to transfer shares of our common stock, options, warrants or our other securities for 180 days after the effectiveness of the registration statement of which this prospectus is a part. The lock-up agreements limit the number of shares of our common stock that may be sold immediately following the consummation of this offering. Subject to certain limitations, including sales volume limitations with respect to shares held by our affiliates, substantially all of our outstanding shares prior to this offering will become eligible for sale upon expiration of the lock-up period, as calculated and described in more detail in the section entitled Underwriting-Lock-Up Agreements. In addition, shares issued or issuable upon exercise of options and warrants vested as of the expiration of the lock-up period will be eligible for sale at that time. Sales of shares by these shareholders could have a material adverse effect on the trading 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, subject to the 180-day lock-up arrangement described above. 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.

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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 Phase IIb clinical trial of Dex-IN;
- 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 use of proceeds from this offering and 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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USE OF PROCEEDS

We estimate that our net proceeds from our issuance and sale of shares of our common stock in this offering will be approximately $ million, assuming an initial public offering price of $ per share, which is the midpoint of the price range listed on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their over-allotment option in full, we estimate that the net proceeds from this offering will be approximately $.

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share would increase (decrease) the net proceeds from this offering by approximately $, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds from this offering as follows:

- approximately $2.1 million for our planned Dex-IN post-operative pain Phase IIb trial following orthopedic surgery, specifically bunionectomy surgery;
- approximately $8.0 million for two Dex-IN post-operative pain Phase III pivotal trials, one following intra-abdominal surgery and one following orthopedic surgery;
- approximately $1.5 million for preclinical animal toxicology studies;
- approximately $5.0 million for human safety clinical trials and manufacturing work for Dex-IN, including the preparation of registration and stability batches and packaging of clinical materials; and
- the remainder to fund working capital needs and other general corporate purposes.

We expect the proceeds of the offering to enable our company to complete the post-operative pain Phase IIb orthopedic trial in bunionectomy patients, the post-operative pain Phase III pivotal trials, preclinical animal toxicology studies, and human safety clinical trials.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development efforts, the status of and results from clinical trials, as well as any collaborations that we may enter into with third parties for our product candidates, and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment grade, interest bearing instruments and U.S. government securities.

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.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of September 30, 2013:

on an actual basis;

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on a pro forma basis to give effect to:

- the issuance of shares of our common stock upon the closing of this offering as a result of the automatic conversion of our Series A Redeemable Convertible Preferred Stock, including accrued dividends, assuming the conversion occurs on , 2013 (the expected closing date of this offering),

- the issuance of shares of our common stock upon the closing of this offering as a result of the assumed conversion of all principal and accrued interest outstanding under our 8% Convertible Promissory Notes, including $195,300 of additional notes issued subsequent to September 30, 2013, assuming an initial public offering price of $ per share (the midpoint of the price range set forth on the cover page of this prospectus) and assuming the conversion occurs on , 2013 (the expected closing date of this offering); and

- on a pro forma as adjusted basis to give further effect to the issuance and sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range listed on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma and pro forma as adjusted information below is illustrative only, and our cash and cash equivalents and capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this information in conjunction with our financial statements and related notes appearing at the end of this prospectus and the Management s Discussion and Analysis of Financial Condition and Results of Operations section and other financial information contained in this prospectus.

	As of September 30, 2013		
	Actual	Pro Forma	Pro Forma As Adjusted
	(unaudited)		
	(in thousands, except share data)		
Cash and cash equivalents	$ 20	$ 216	$
Convertible notes payable	$ 11,480	$	$
Series A redeemable convertible preferred stock, $0.01 par value, Authorized 2,000,000 shares; 2,000,000 shares issued and outstanding actual	5,767		
Shareholders equity (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 389,000 shares issued and outstanding actual, shares issued and outstanding pro forma, and shares issued and	4	4	

outstanding pro forma as adjusted			
Additional paid-in capital		17,442	
Deficit accumulated during the development stage	(17,467)	(17,467)	
Total shareholders equity (deficit)	(17,463)	(21)	
Total capitalization	$ (216)	$ (21)	$

The table above excludes the following as of September 30, 2013:

837,000 shares of our common stock issuable upon the exercise of stock options outstanding as of September 30, 2013 at a weighted-average exercise price of $2.40 per share;

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273,000 additional shares of our common stock available for future issuance as of September 30, 2013 under our 2008 Stock Option Plan; and

1,500,000 shares of our common stock available for future issuance under our 2013 Equity Incentive Plan.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this initial public offering.

Our historical net tangible book value as of September 30, 2013 was $(17.5) million or $(44.89) per share of our common stock. Historical net tangible book value per share represents the amount of our total tangible assets less total liabilities, divided by the number of shares of our common stock outstanding.

Our pro forma net tangible book value as of September 30, 2013 was $(21,000), or $ per share of our common stock. Pro forma net tangible book value per share represents the amount of our total pro forma tangible assets less our pro forma total liabilities, divided by the pro forma number of shares of our common stock outstanding after giving effect to (1) the automatic conversion of all of our Series A Redeemable Convertible Preferred Stock, including accrued dividends, and (2) the assumed conversion of all principal and accrued interest outstanding under our 8% Convertible Promissory Notes, including $195,300 of additional notes issued subsequent to September 30, 2013, upon the closing of this offering, at 75% of the initial public offering price, into shares of our common stock, assuming an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and assuming the conversion occurs on , 2013 (the expected closing date of this offering).

After giving effect to our issuance and sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range listed on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2013 would have been $, or $ per share. This represents an immediate increase in pro forma net tangible book value per share of $ to existing shareholders and immediate dilution of $ in pro forma net tangible book value per share to new investors purchasing common stock in this offering.

Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Initial public offering price per share of common stock		$
Historical net tangible book value per share as of September 30, 2013	$ (44.89)	
Increase in net tangible book value per share attributable to proforma adjustments described above		
Pro forma net tangible book value per share as of September 30, 2013		

Increase in net tangible book value per share attributable to new investors	
Pro forma as adjusted net tangible book value per share after this offering	
Dilution per share to new investors	$

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A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range listed on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted net tangible book value by approximately $, our pro forma as adjusted net tangible book value per share by approximately and dilution per share to new investors by approximately $, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions.

If the underwriters exercise their over-allotment option or if any additional shares are issued in connection with outstanding options, you will experience further dilution.

The following table summarizes, on a pro forma as adjusted basis as of September 30, 2013, the total number of shares purchased from us, the total consideration paid, or to be paid, and the average price per share paid, or to be paid, by existing shareholders and by new investors in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range listed on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. As the table shows, new investors purchasing shares in this offering will pay an average price per share substantially higher than our existing shareholders paid.

	Shares Purchased		Total Consideration		Average Price per Share
	Number	Percent	Amount	Percent	
Existing shareholders		%	$	%	$
New investors					
Total		%	$	%	

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range listed on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors by $ and increase (decrease) the percentage of total consideration paid by new investors by approximately %, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same.

The table above excludes:

- 837,000 shares of our common stock issuable upon the exercise of stock options outstanding as of September 30, 2013 at a weighted-average exercise price of $2.40 per share;
- 273,000 additional shares of our common stock available for future issuance as of September 30, 2013 under our 2008 Stock Option Plan; and
- 1,500,000 shares of our common stock available for future issuance under our 2013 Equity Incentive Plan.

If the underwriters exercise their over-allotment option in full, the following will occur:

- the percentage of shares of our common stock held by existing shareholders will decrease to approximately % of the total number of shares of our common stock outstanding after this offering; and

- the number of shares of our common stock held by new investors will increase to , or approximately % of the total number of shares of our common stock outstanding after this offering.

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SELECTED FINANCIAL DATA

The following tables present our selected financial data for the periods indicated. The selected statements of operations data for the years ended December 31, 2011 and 2012 and the selected balance sheet data as of December 31, 2011 and 2012 have been derived from our audited financial statements included elsewhere in this prospectus. The statements of operations data for the nine months ended September 30, 2012 and 2013 and the period from November 15, 2007 (inception) through September 30, 2013 and the selected balance sheet data as of September 30, 2013 have been derived from our unaudited interim financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future and our interim period results are not necessarily indicative of our results for a full year. The selected financial data below should be read in conjunction with the information contained in Management s Discussion and Analysis of Financial Condition and Results of Operations, the financial statements and notes thereto, and other financial information included elsewhere in this prospectus.

	Year ended December 31,		Nine Months Ended September 30,		Period from November 15, 2007 (inception) through September 30,
	2011	2012	2012	2013	2013
	(in thousands, except share and per share data)				
Statements of Operations Data:					
Operating expenses:					
Research and development	$ 1,828	$ 542	$ 505	$ 494	$ 11,939
General and administrative	485	339	239	444	1,902
Total operating expenses	2,313	881	744	938	13,841
Other income (expense):					
Interest income					4
Grant income		85			329
Interest expense	(558)	(740)	(542)	(636)	(2,274)
	(558)	(655)	(542)	(636)	(1,941)
Net loss	(2,871)	(1,536)	(1,286)	(1,574)	$ (15,782)
Accretion of redeemable convertible preferred stock	(383)	(413)	(299)	(327)	
Net loss applicable to common shareholders	$ (3,254)	$ (1,949)	$ (1,585)	$ (1,901)	
Basic and diluted net loss per common share	$ (8.36)	$ (5.01)	$ (4.08)	$ (4.89)	
	389,000	389,000	389,000	389,000	

Weighted average basic and diluted common share outstanding		
Unaudited pro forma net loss(1)	$ (796)	$ (938)
Unaudited pro forma basic and diluted net loss per common share(1)	$	$
Unaudited pro forma weighted average basic and diluted common shares outstanding(1)		

(1) See note 3(i) and 3(d) to our audited and unaudited financial statements appearing at the end of this prospectus for information regarding computation of unaudited pro forma basic and diluted net loss per common share and the unaudited pro forma weighted average basic and diluted common shares outstanding used in computing pro forma basic and diluted net loss per common share.

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	As of December 31, 2011	2012	As of September 30, 2013
		(in thousands)	
Balance Sheet Data:			
Cash and cash equivalents	$ 8	$ 53	$ 20
Working capital	(8,588)	(10,123)	(11,696)
Total assets	26	154	291
Convertible notes payable	8,148	10,159	11,480
Series A redeemable convertible preferred stock	5,027	5,440	5,767
Total shareholders deficit	(13,612)	(15,562)	(17,463)

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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 Selected Financial Data and 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 in the post-operative setting. We have studied various dosage forms of Dex in eight completed clinical trials, including two placebo controlled trials that demonstrated effective pain relief. Dex, which is in a class of drugs called alpha-2 adrenergic agonists, is an FDA approved and commercial injectable drug sold by Hospira in the United States under the brand name Precedex® and by Orion in Europe under the brand name Dexdor®. As Dex is not an opioid based drug, we expect to overcome many of the side effects associated with commonly prescribed opioid based 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 post-operative pain, we may elect to pursue additional approvals for cancer breakthrough pain and/or non-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 in multiple dosage forms.

We are a development stage company with a limited operating history. We have funded our operations to date primarily from the private placement of convertible preferred stock and proceeds received from our convertible notes private placements. From inception through September 30, 2013, we have received net proceeds of $4.0 million from the sale of convertible preferred stock and $9.2 million from the sale of our convertible notes in private placements.

Since our inception in November 2007, we have not generated any revenue from the sale of our products and do not anticipate generating any revenues for the foreseeable future. We have incurred losses and generated negative cash flows from operations since inception. Our net losses were $1.5 million and $1.6 million for the year ended December 31, 2012 and the nine months ended September 30, 2013, respectively. As of September 30, 2013, we had an accumulated deficit of $17.5 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 Phase IIb, Phase III pivotal and safety trials. In addition, based on the availability of additional financial resources, subsequent to this offering, 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.

Since our inception, we have generally operated through agreements and contracts with third parties. We have entered into employment agreements, which will be effective upon consummation of the offering; see Management-Employment Agreements. Accordingly, operating results discussed below are likely not indicative of

results of the Company following the offering. Furthermore, upon closing of this offering, we expect to incur additional costs associated with operating as a public company. 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 contract research organizations, investigative sites and consultants that conduct our clinical trials and a substantial portion of our preclinical studies;
- the cost of acquiring and manufacturing clinical trial materials;
- 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;
- license fees for in-licensed product candidates and technology if the product candidate or technology has not reached technological feasibility and has no other alternative future use; and
- costs associated with non-clinical activities and regulatory approvals.

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 our founding, we have developed and evaluated a series of Dex product candidates through Phase I pharmacokinetic and placebo-controlled Phase Ib efficacy trials. Our current priority is the development of Dex-IN for post-operative pain. 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, patent costs and stock compensation expense. We currently rely on MCG, a related party, for a significant portion of our research and development activities (see the section entitled Transactions with Related Persons, beginning on page 92 of this prospectus). 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 entitled Risk Factors beginning on page 9 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, finance, business development, marketing, information technology, and legal 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 2013 will be higher than in 2012 and 2011. Once we complete this offering, 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 issued to our investor, SCP Vitalife. As of September 30, 2013, the outstanding principal balance and accrued interest of such notes was $11.5 million. To date, we have not paid any interest expense on these notes and do not expect to pay such interest as the accrued interest and principal balance on the notes is expected to be converted into common stock upon the consummation of this offering. Since the conversion price of our 8% Convertible Promissory Notes allows the note holders to convert at 75% of the initial offering price per share in the offering, we will record a non-cash charge of approximately $3.9 million upon the closing of the offering.

Net Operating Losses and Tax Carryforwards

As of December 31, 2012, we had approximately $8.5 million of federal net operating loss carryforwards. We also had federal and state research and development tax credit carryforwards of $347,000 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 consummation of this offering, 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 Code. 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

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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 liability to us.

Results of Operations

Comparison of the Nine Months Ended September 30, 2013 and 2012

	For the Nine Months Ended September 30,		Increase (Decrease)	
	2013	2012	$	%
	(amounts in thousands)			
Operating expenses:				
Research and development	$ 494	$ 505	$ (11)	(3)%
General and administrative	444	239	205	86%
Total operating expenses	938	744		
Other income (expense):				
Interest expense	(636)	(542)	94	17%
	(636)	(542)		
Net loss	$ (1,574)	$ (1,286)		

Research and Development. Our research and development expenses were $494,000 and $505,000 for the nine months ended September 30, 2013 and 2012, respectively. The decrease was primarily attributable to a decrease in clinical trial costs of $15,000 as the Phase Ib clinical trial for Dex-IN was substantially completed by the fourth quarter of 2011.

General and Administrative. Our general and administrative expenses were $444,000 and $239,000 for the nine months ended September 30, 2013 and 2012, respectively. This increase was mainly due to an increase of approximately $208,000 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.

Interest Expense. Interest expense was $636,000 and $542,000 for the nine months ended September 30, 2013 and 2012, respectively, which consisted of interest expense associated with our 8% Convertible Promissory Notes. The increase is due to the issuance of additional notes.

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Comparison of the Year Ended December 31, 2012 and the Year Ended December 31, 2011

	Year ended December 31,		Increase (Decrease)	
	2012	2011	$	%
	(amounts in thousands)			
Operating expenses:				
Research and development	$ 542	$ 1,828	$ (1,286)	(70)%
General and administrative	339	485	(146)	(30)%
Total operating expenses	881	2,313		
Other income (expense):				
Grant income	85		85	100%
Interest expense	(740)	(558)	182	33%
	(655)	(558)		
Net loss	$ (1,536)	$ (2,871)		

Research and Development. Our research and development expenses were $542,000 and $1.8 million for the years ended December 31, 2012 and 2011, respectively. This decrease was attributable to a decrease in clinical trial costs of $1.3 million as the Phase Ib clinical trial for Dex-IN was substantially completed by the fourth quarter of 2011.

General and Administrative. Our general and administrative expenses were $339,000 and $485,000 for the years ended December 31, 2012 and 2011, respectively. This decrease was mainly due to a decrease in marketing and business development costs, legal fees and travel expenses. Our expenses for the year ended December 31, 2011 included additional costs associated with our responsibility for the maintenance of the Fado patent for legal fees relating to our license agreement with Orion, expenses related to market research and assessment of our product candidates, and expenses resulting from a meeting with experts associated with the American Pain Association in 2011.

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 $740,000 in 2012 from $558,000 in 2011 as a result of additional borrowings.

Liquidity and Capital Resources

As of September 30, 2013 and December 31, 2012, we had $20,000 and $53,000, respectively, in cash and cash equivalents. We expect that the net proceeds from this offering and our existing cash and cash equivalents, together with interest, will be sufficient to fund our current operations into the second half of 2015. Since inception through September 30, 2013, we have financed our product development, operations and capital expenditures primarily from private sales of $4.0 million of our Series A Redeemable Convertible Preferred Stock and $9.2 million of our 8%

Convertible Promissory Notes.

Pursuant to our current articles of incorporation, the shares of our Series A Redeemable Convertible Preferred Stock may be converted at the election of the holder into shares of our common stock. The holders of all of our outstanding shares of Series A Redeemable Convertible Preferred Stock have notified us of their election to convert all of their shares of Series A Redeemable Convertible Preferred Stock, and all accrued dividends, into shares of our common stock, and the holders of our common stock effective contemporaneously with, and contingent upon, the consummation of this offering, and our board of directors have approved such

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conversion. Accordingly, upon closing of this offering, all outstanding shares of our Series A Redeemable Convertible Preferred Stock, including accrued dividends, will automatically convert into additional shares of common stock, assuming the conversion occurs on , 2013 (the expected closing date of this offering). Following the consummation of this offering, no shares of our Series A Redeemable Convertible Preferred Stock will be outstanding.

During 2012, 2011, 2010, and 2009, we issued $1.3 million, $2.0 million, $3.3 million and $2.0 million, respectively, of our convertible promissory notes. The convertible promissory notes bear interest at 8% per annum compounded quarterly and are due on demand. The convertible promissory notes accrue interest and may be converted at the election of the holders. The holders of all of our convertible promissory notes have notified us of their election to convert the outstanding aggregate principal amount and accrued interest of the convertible promissory notes into shares of our common stock effective contemporaneously with, and contingent upon, the consummation of this offering. Accordingly, upon consummation of this offering, the outstanding aggregate principal amount and accrued interest of the convertible promissory notes will convert into additional shares of our common stock at 75% of the initial price per share in this offering, assuming an initial public offering price of $ (the midpoint of the range set forth on the cover page of this prospectus) and assuming the conversion occurs on , 2013 (the expected closing date of this offering). Following the consummation of this offering, no convertible promissory notes will remain outstanding. As of September 30, 2013, $9.2 million of our convertible promissory notes were outstanding plus $2.3 million of accrued interest.

We will need to raise additional funds in order to continue our clinical trials beyond clinical trials of Dex-IN for post-operative pain, 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, we do not currently contemplate any acquisitions. If additional funds are required, we may raise such funds from time to time 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. 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.

We have incurred losses and negative cash flows from operations since inception and have a shareholders deficit of $17.5 million as of September 30, 2013. We anticipate incurring additional losses until such time, if ever, that we can generate significant sales from our products. We will need substantial additional financing to fund our operations and to commercially develop our product candidates. These factors raise substantial doubt about our ability to continue as a going concern. 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.

Sources and Uses of Cash

Cash used in operations was $668,000, $1.2 million and $2.2 million for the nine months ended September 30, 2013, and for the years 2012 and 2011, respectively, which represents our operating losses less our non-cash interest expense on our 8% Convertible Promissory Notes.

Cash provided by financing activities was $635,000, $1.3 million and $2.0 million for the nine months ended September 30, 2013, and years ended December 31, 2012 and 2011, respectively, from the issuance of 8% Convertible Promissory Notes to SCP Vitalife.

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

- the timing and expenses of trials prior to an NDA for Dex-IN;
- the timing and outcome of the FDA s review of an NDA for Dex-IN if our trials are successful;
- the extent to which the FDA may require us to perform additional clinical trials or pre-commercial manufacturing of Dex-IN;
- the timing and success of this offering;
- 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.

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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 approval, Orion will supply commercial quantities of bulk active pharmaceutical ingredient Dex for commercialization. For further information, see the section entitled, Business Intellectual Property beginning on page 66 of this prospectus.

We will pay milestone payments to Orion of up to 20.5 million Euros ($27.1 million as of December 31, 2012) 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 API agreement with Orion for the supply of Dex, which we believe provides fair and arm s-length pricing for the purchase of the Dex API that is produced in compliance with cGMP and which addresses certain circumstances related to the provision of qualified manufacturing facilities or alternatives.

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

We will pay milestone payments to Orion of up to 12.2 million Euros ($16.1 million as of December 31, 2012) based on regulatory filings and approval and on commercialized net sales levels. There are also royalty payments to be paid at varying percentages based on net sale levels.

Leases

We lease lab 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

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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 in the post-operative setting. As our product candidates are not opioid based drugs, we expect to overcome many of the side effects associated with commonly prescribed opioid based therapeutics, including addiction, constipation and respiratory distress, while maintaining analgesic, or pain relieving, effect. We have studied various dosage forms of Dex in eight completed clinical trials, including two placebo controlled trials that demonstrated effective pain relief. Dex is an FDA approved and commercial injectable drug sold by Hospira in the United States under the brand name Precedex® and by Orion in Europe under the brand name Dexdor®. Dex, which is in a class of drugs called alpha-2 adrenergic agonists, has demonstrated sedative, analgesic and anxiolytic properties in multiple preclinical and clinical studies, including the NDA studies for Precedex®. We are pursuing a Section 505(b)(2) regulatory strategy for our lead candidate, 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 post-operative pain, we may elect to pursue additional approvals for cancer breakthrough pain and/or non-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 all dosage forms.

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 post-operative pain;
- 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.

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

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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 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 Cephalon). 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.

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Dex Advantages over Opioids

We believe there is a clear unmet need for effective, well tolerated, non-opioid analgesics that can be used as a component of an effective pain management program. We are initially developing Dex-IN for post-operative pain following orthopedic and intra-abdominal surgeries. By evaluating Dex-IN in these trials, we believe that we will qualify for a label allowing for the treatment in post-operative pain. Based on the safety profile and labeling for the marketed Dex product, we believe our lead candidate has the potential to offer the following advantages over opioid analgesics:

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

Dex has not demonstrated habituative effects. Preclinical studies in monkeys and rats have showed that Dex has a weak potential for drug addiction and dependence. Based on these studies and the vast clinical experience with Dex, Dex is not classified as a controlled substance by the DEA.

Dex does not cause respiratory depression. Besides the addictive nature of opioids, we believe that medical practitioners are highly concerned with respiratory depression, which is a well-documented side effect of opioid use (all opioids including Fentanyl and Oxycodone). Respiratory depression is defined by decreased lung ventilation leading to increased carbon dioxide and can be life threatening. Dex has demonstrated through multiple clinical trials and patient use that it does not cause respiratory depression.

Dex is not associated with constipation, nausea, or vomiting. Unlike opioids, Dex s mechanism of action provides analgesic activity with very limited activity on the gastrointestinal tract thus limiting the unwanted side effects of constipation, nausea and vomiting. These opioid induced side effects can lead to poor pain management as patients often down dose or skip doses of their pain medication in order to avoid experiencing these side effects.

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

Patients utilizing Dex have been observed to be cognitively intact. We believe that patients utilizing opioid analgesics become cognitively impaired, impacting the patient s ability to perform routine mental and physical 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.

Pipeline

Recro filed the Dex-IN IND in the United States in February, 2011. The IND was filed for the indication for use in the management of breakthrough pain in cancer patients. The next step in developing the product for breakthrough pain in cancer patients would be to conduct a Phase II trial. This trial will not be commenced in the near term, but likely after further work has been completed on the DEX-IN for post-operative pain. As a result of switching the IND from cancer breakthrough pain to post-operative pain, it is possible that FDA would ask us to

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file an additional IND for cancer breakthrough pain at a later date. Recently, an IND amendment was filed to the DEX-IN IND and it has been agreed with FDA that the indication in the IND will be changed to the treatment of post-operative pain. Under this IND, we will conduct the planned post-operative pain studies. For DEX-SL, Recro filed an open IND under the indication of cancer breakthrough pain which we plan to amend for use of DEX-SL in pain management for a longer treatment period (such as chronic pain), at a later date. Studies with Fado have been conducted in Europe and therefore an IND has not yet been filed.

Upon consummation of this offering, we intend to develop Dex-IN for post-operative pain and file an NDA for such indication. If we obtain approval of Dex-IN for post-operative pain, we intend to develop Dex-IN for the second indication of cancer breakthrough pain. Our second development candidate, Fado, is another selective alpha-2 agonist which has been observed to be effective in a post-bunionectomy Phase II pain study and which we believe shows promise in neuropathic pain. Upon regulatory approval, our license with Orion and our ownership rights with respect to dosage forms for our product candidates will provide us with worldwide commercial rights related to our product candidates, except in Europe, Turkey and CIS.

Product candidate	**Indication**	**Stage**	**Commercial rights***
Dexmedetomidine			Worldwide, except Europe, Turkey and CIS
Dex-IN (intranasal)	Post-operative pain	Phase IIb	
	Cancer breakthrough pain	Phase II	
Dex-SL (sublingual)	Chronic pain	Phase II	
Fadolmidine			Worldwide, except Europe, Turkey and CIS
Intrathecal	Post-operative pain	Phase IIb	
Topical	Neuropathic pain	Phase I	

* Subject to regulatory approval in the appropriate jurisdictions and by the appropriate governmental authorities.

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. We believe that if we raise the full amount of this offering and assuming our trials meet our current expectations for costs and timing, then we should have sufficient funds to complete the Phase III program for Dex-IN. 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 IIb 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 either 24 or 48 hours as compared to placebo. We believe developing

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Dex-IN in the post-operative pain indication provides us the fastest and best path to building a specialty pharmaceutical company focused on the management of pain indications. Therefore, we are initially concentrating our management focus and resources on attaining this goal.

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

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

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

Dexmedetomidine Overview

Dex was developed in the 1990s by Abbott as a sedative in the intensive care unit setting. In 1999, Abbott received FDA approval to market IV Dex, trademarked Precedex® in the United States for ICU sedation. Hospira currently markets Dex in the United States. According to IMS, Precedex® had almost $140 million in sales in 2010. 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 1/10th 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®. According to IMS, Precedex® had almost $140 million in sales in 2010. 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 and amount to 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 multiple company-sponsored studies, including two Phase Ib placebo controlled studies, 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 Dex-IN and Dex-SL INDs, we have conducted eight completed studies, including two placebo-controlled studies, in over 100 subjects to evaluate the analgesic efficacy, safety and pharmacokinetics of Dex-IN and Dex-SL. Based upon the results of these trials, we believe that our formulations of Dex have demonstrated analgesic potential for moderate to severe pain.

REC-11-010

Our most recently completed study 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

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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 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.

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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.

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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.

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Dex-IN was well tolerated by patients in this study. 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. 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

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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.

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.

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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.

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 two aforementioned placebo controlled trials, 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

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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.

Next Anticipated Clinical Trial of Dex-IN

We expect the next study of Dex-IN to be a Phase IIb clinical trial in approximately 150 to 200 post-surgical patients. A Phase IIb clinical trial is a Phase II clinical trial in which the intended indication and dose selection for the product candidate are confirmed. The study is designed to assess the ability of Dex-IN to control moderate-to-severe post-operative pain over 48 to 72 hours compared to a placebo. The study will also assess tolerability and safety, including blood pressure and sedation observations. Top-line results are expected in second half of 2014. We expect to use the proceeds of this offering to complete the clinical trial. See the section entitled Use of Proceeds beginning on page 39 of this prospectus.

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 µg 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 beginning on page 29 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 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. 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. 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 ($27.1 million as of December 31, 2012) 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.

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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 cGMP 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 ($16.1 million as of

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December 31, 2012) 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.

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

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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 payers. We also expect to face competition in our efforts to identify appropriate collaborators or partners to help commercialize our product candidates in our target commercial markets.

In the post-operative pain relief setting, we believe patients are prescribed 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., Cadence Pharmaceuticals, Inc. and Pacira Pharmaceuticals, Inc. Purdue and Endo are the primary competitors in the manufacture, marketing and commercialization of opioid therapeutics. Cadence 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. 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., Meda AB, Kyowa Hakko, Insys Therapeutics, Inc. and Archimedes Pharma Ltd. All of these potential competitors have various formulations of fentanyl, a fast-acting opioid. We are not aware of any non-fentanyl related therapeutics in development for the treatment of cancer breakthrough pain.

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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 GCP 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 GCP 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.

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.

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. 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

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whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and operate profitably.

Other Healthcare Laws and Compliance Requirements

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

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

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

- the federal Health Insurance Portability and Accountability Act of 1996, 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; 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

Gerri Henwood is our President and Chief Executive Officer; Charles Garner, our Chief Financial Officer, Randall Mack is our Senior Vice President; Development; Diane Myers is our Senior Vice President, Regulatory and Quality; and Donna Nichols is our Corporate Controller. Upon consummation of this offering, we have no other officers or employees. We have negotiated and entered into employment agreements with Ms. Henwood, Mr. Garner, Mr. Mack, Ms. Myers and Ms. Nichols, which agreements will become effective upon consummation of this offering. For more information, see the section entitled Executive Compensation beginning on page 88 of this prospectus.

Our current employees are also employed by, and will continue following the consummation of the offering, to devote a small portion of their time to MCG and in the case of Mr. Garner, to a consulting business in which he is a principal. Ms. Henwood was, but no longer is, a venture partner with SCP. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We believe we have a good relationship with our employees.

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Facilities

Our principal executive offices are located at 490 Lapp Road, Malvern, PA 19355, where we occupy approximately 1,600 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. We have entered into an amended office services agreement to occupy approximately 4,000 square feet of laboratory and office space upon consummation of the offering.

Legal Proceedings

There are presently no pending legal proceedings to which we are a party or of which any of our property is the subject. From time to time and in the ordinary course of business, we are subject to various claims, charges and litigation. For example, we may be required to file infringement claims against third parties for the infringement of patents we obtain.

Although the outcome of potential litigation cannot be predicted with certainty and some lawsuits, claims or proceedings may be disposed of unfavorably to us, we do not believe the outcome of any such litigation, individually or in the aggregate, will have a material adverse effect on our financial condition, results of operations or cash flows.

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	61
Charles Garner	Chief Financial Officer / Chief Business Officer / Treasurer	38
Randall Mack	SVP, Development / Secretary	48
Diane Myers	SVP, Regulatory and Quality	50
Donna Nichols	Chief Accounting Officer / Corporate Controller	57
William L. Ashton	Director	62
Winston J. Churchill	Director	73
Abraham Ludomirski	Director	62
Wayne B. Weisman	Director / Chairman of the Board	57

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.

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.

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 October 1, 2013. 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 October 1, 2013. 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

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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 October 1, 2013. 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 a number of private company boards including the boards of Argo Medical Technologies Ltd., DIR Technologies, EndoSpan Ltd., FluidNet, LLC, and Echo360 Inc. He is the chairman of the boards of trustees of Young Scholars School and Young Scholars Frederick Douglass and Young Scholars Kenderton. He is also a 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.

As of the date of this prospectus, our board of directors recommended for election and our shareholders have elected the following nominees to our board of directors contingent and effective upon the consummation of this offering:

Name	Position	Age
Alfred Altomari	Director	54
Michael Berelowitz	Director	69

Alfred Altomari was elected to our board of directors contingent and effective upon the consummation of this offering. 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.

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Michael Berelowitz was elected to our board of directors contingent and effective upon the consummation of this offering. 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.

Board Composition and Independence

Our board of directors is currently authorized to have five members, and currently has five members. We expect that upon the closing of this offering, our board of directors will consist of directors. In accordance with the terms of our amended and restated articles of incorporation and third amended and restated bylaws that will become effective upon the closing of this offering, our board of directors will be divided into three classes, class I, class II and class III, with members of each class serving staggered three-year terms. Upon the closing of this offering, the members of the classes will be divided as follows:

- the class I directors will be Mr. Churchill and Mr. Weisman, and their term will expire at the annual meeting of shareholders to be held in 2014;
- the class II directors will be Dr. Ludomirski and Ms. Henwood, and their term will expire at the annual meeting of shareholders to be held in 2015; and
- the class III directors will be Mr. Altomari, Mr. Ashton, and Mr. Berelowitz, and their term will expire at the annual meeting of shareholders to be held in 2016.

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 that will go into effect immediately prior to the closing of this offering will 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.

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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 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, each to be effective upon the closing of this offering, under a charter that has been approved by our board. In addition, the composition of each committee will be effective upon the closing of this offering. 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

As of the closing of this offering, the members of our audit committee will be Mr. Altomari, Mr. Ashton and Mr. Berelowitz. Mr. Altomari will chair the audit committee. Upon the closing of this offering, our audit committee s responsibilities will include:

- appointing, approving the compensation of and assessing the independence of our independent registered public accounting firm;

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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

As of the closing of this offering, the members of our nominating and corporate governance committee will be Mr. Weisman, Mr. Berelowitz and Dr. Ludomirski, Mr. Berelowitz will chair the nominating and corporate governance committee. Upon the closing of this offering, our nominating and corporate governance committee s responsibilities will 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

As of the closing of this offering, the members of our compensation committee will be Mr. Altomari, Mr. Ashton and Mr. Churchill. Mr. Ashton will chair the compensation committee. Upon the closing of this offering, our compensation committee s responsibilities will include:

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

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

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persons performing similar functions. Upon completion of this offering, our code of business conduct and ethics will be available under the Investor Relations section of our website, www.recropharma.com.

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 2012, our only named executive officer was Gerri Henwood, our President and Chief Executive Officer.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt following the completion of this offering may differ materially from the currently planned programs summarized in this discussion.

Summary Compensation Table

The following table sets forth information concerning the compensation of our named executive officer during the fiscal years ended December 31, 2012:

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	Option Awards ($)	Non-Equity Incentive Plan Compensation ($)	Non-Qualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Gerri Henwood	2012								
President and Chief Executive Officer									

Ms. Henwood has received no compensation from the Company since inception. 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.

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, 2012.

	Option Awards					Stock Awards			
Name	Number of Securities Underlying Unexercised Options	Number of Securities Underlying Unexercised Options	Equity Incentive Plan Awards: Number of	Option Exercise Price ($)	Option Expiration Date	Number of Share or Units of Stock	Market Value of Shares of Units of	Equity Incentive Plan Awards: Number of Unearned	Equity Incentive Plan Awards: Market or Payout

	(#) Exercisable	(#) Unexercisable	Securities Underlying Unexercised Unearned Options (#)	That Have Not Vested (#)	Stock That Have Not Vested (#)	Shares, Units or Other Rights That Have Not Vested (#)	Value of Unearned Shares, Units or other Rights That Have Not Vested ($)
Gerri Henwood							

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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. Prior to this offering, we granted awards to our eligible participants under the 2008 Stock Option Plan. Following the consummation of this offering, we expect to grant awards to eligible participants under 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 1,110,000 shares of our common stock are reserved for issuance under the 2008 Stock Option Plan. As of September 30, 2013, under the 2008 Stock Option Plan, 837,000 shares of our common stock were subject to outstanding option awards and 273,000 shares of our common stock remained available for future issuance. Our board of directors has approved the grant of certain stock options to our officers, which grants are contingent and effective upon the consummation of this offering. After such grant, no shares of common stock will remain available for future issuance under the 2008 Stock Option Plan. See the section entitled Executive Compensation-Stock Option Grants to Executive Officers beginning on page 91 of this prospectus.

Administration. Our board of directors has administered the 2008 Stock Option Plan. Following the consummation of this offering, the 2008 Stock Option Plan will be administered by our compensation committee (except with respect to any award granted to non-employee directors, which will be 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 1,500,000 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) 500,000 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 3,500,000 shares. Effective upon consummation of this offering, under the 2013 Equity Incentive Plan, 179,566 shares of our common stock will be subject to outstanding option awards and 1,320,434 shares of our common stock remain available for future issuance.

Administration. The compensation committee of our board of directors will administer the 2013 Equity Incentive Plan (except with respect to any award granted to non-employee directors, which will be 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.

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

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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 3,500,000 shares will only be effective if approved by a majority of the outstanding voting stock of the Company.

Stock Option Grants to Executive Officers

Our board of directors has approved the grant of stock options to our officers. Such options will be granted contingent and effective upon the consummation of this offering and will be issued under our stock option plans. Upon consummation of this offering, Ms. Henwood, Mr. Garner, Mr. Mack, Ms. Myers, and Ms. Nichols will receive 150,000, 202,566, 50,000, 30,000, and 20,000 stock options, respectively. When granted, the exercise price of the stock options will be the initial public offering price. Such stock options vest monthly in equal proportions over a period of four years beginning on the date of grant. The stock options terminate on the earliest to occur of the following: (i) three months after termination of service with the Company for any reason other than death, disability or a termination for cause; (ii) one year after termination of service due to death or disability; (iii) the employee s termination for cause, including the breach by the employee of any non-competition agreement entered into with the Company or the unauthorized disclosure of any confidential or trade secret information of the Company; and (iv) the ten year anniversary of the date of grant.

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. Each of the employment agreements will become effective upon consummation of this offering.

The employment agreements provide for initial annual base salaries for each of our officers. Pursuant to the employment agreements, our officers will receive 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 may be 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 has considered a cash bonus opportunity for our officers with respect to services to our company during fiscal 2013. The board has considered 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, which the board will consider and determine during the first quarter of 2014.

Each of the employment agreements is for an initial term of one year and will automatically renew 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 (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 six 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 six months following the date of termination.

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

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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, change of control generally means (1) the sale or disposition of all or substantially all of the assets of the Company, (2) the merger or consolidation of the Company into any other entity, other than a merger or consolidation where the holders of shares of our common stock immediately prior to such merger or consolidation will hold at least a majority of the stock of the surviving company immediately after the merger or consolidation, (3) the acquisition by any person, group or entity of beneficial ownership of at least 50% of our outstanding shares of common stock, (4) the failure of a majority of our directors to serve for a period of 24 months, unless the election of each new director who was not a director at the beginning of such 24 month period was approved by a vote of at least two-thirds of the directors then in office who were directors at the beginning of such period, or (5) the approval by our shareholders of a plan of dissolution or liquidation. 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.

Director Compensation

As of the date of this offering, we have not paid any compensation to our directors. Following consummation of the offering, our directors will receive the following compensation:

- an annual retainer of $20,000 to each of our non-employee directors for service on our board of directors and an additional $20,000 to the chair of the board of directors;
- an annual payment of $7,500 to each member of the audit committee and an additional $7,500 to the chair of the audit committee, all members of which will be non-employee directors;
- an annual payment of $7,500 to each member of the compensation committee and an additional $7,500 for the chair of the compensation committee, all members of which will be non-employee directors;
- an annual payment of $3,500 to each member of the nominating and corporate governance committee and an additional $4,000 to the chair of the nominating and corporate governance committee, all members of which will be non-employee directors;
- an initial stock option grant of 20,000 shares of our common stock vesting in equal annual installments over three years to any newly elected director; and
- an annual stock option grant of 10,000 shares of our common stock vesting on the anniversary of the date of grant to any director continuing his or her service on the board of directors.

TRANSACTIONS WITH RELATED PERSONS

Since January 1, 2010, 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 will continue to provide a small portion of their time to, MCG following the consummation of the offering. 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,

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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 $1.1 million, $835,000, and $301,000 for the fiscal years ended December 31, 2010, 2011, and 2012, respectively, and $256,000 and $299,000 for the nine months ended September 30, 2012 and 2013, respectively.

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 $1.1 million, $835,000, and $253,000 for the fiscal years ended December 31, 2010, 2011, and 2012, respectively, and $263,000 for the nine months ended September 30, 2013. 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. 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. The square footage will increase to 3,786 upon the consummation of a qualified financing. For such purposes, a qualified financing constitutes equity investments, including without limitation a public offering from an investor or a group of investors, aggregating at least $20,000,000. Pursuant to the Office Services Agreement, we paid MCG $48,000 for the fiscal year ended December 31, 2012 and $36,000 for the nine months ended September 30, 2013.

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 $9.2 million, 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

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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 will terminate upon completion of this offering. The registration rights will continue following this offering 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 this offering 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 of which Mr. Churchill, a member of our board of directors, is the trustee, provided certain of our funding to date. Since 2009, in exchange for aggregate contributions to the Company of $250,000, we have issued an aggregate amount of 125,000 shares of our Series A Redeemable Convertible Preferred Stock to the trust.

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 paid Inverness Advisors $50,000 in 2011.

As described above, we have negotiated and entered into an employment agreement with Mr. Garner, which will become effective upon consummation of this offering. Pursuant to such employment agreement, Mr. Garner will serve as our Chief Financial Officer. For more information, see the section entitled Management-Employment Agreements beginning on page 91 of this prospectus.

Policies and Procedures for Related Person Transactions

Our board of directors has adopted a written related person transaction policy, to be effective upon the consummation of this offering, setting forth the policies and procedures for the review and approval or ratification of related-person transactions. This policy will cover, 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 Transactions with Related Persons 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 October 1, 2013, and as adjusted to reflect the sale of shares of common stock in this offering, by:

- our named executive officer;
- 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 October 1, 2013 is based on 2,389,000 shares of common stock outstanding. Percentage ownership after consummation of this offering is based on shares of common stock outstanding on , which gives effect to the conversion of all outstanding shares, including accrued dividends, of our Series A Redeemable Convertible Preferred Stock and all principal and accrued under our 8% Convertible Promissory Notes into shares of common stock. 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 October 1, 2013 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 Prior to Offering		Share Beneficially Owned After Offering	
Name of Beneficial Owner(1)	**Title of Class(2)**	**Number(3)**	**Percentage**	**Number(4)**	**Percentage**
5% or Greater Shareholders					
SCP Vitalife Partners II, L.P. 1200 Liberty Ridge Drive Suite 300 Wayne, PA 19087	Preferred Stock	1,405,531	58.8%		
SCP Vitalife Partners (Israel) II, L.P.	Preferred Stock	469,469	19.7%		

32B Habarzel St. Ramat Hachayal Tel Aviv 69710 Israel			
Churchill Trust 1200 Liberty Ridge Drive Suite 300 Wayne, PA 19087	Preferred Stock	125,000	5.2%
Thomas F. Henwood(5) c/o Malvern Consulting Group, Inc. 490 Lapp Road Malvern, PA 19355	Common Stock	375,000	15.7%

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Name of Beneficial Owner(1)	Title of Class(2)	Shares Beneficially Owned Prior to Offering Number(3)	Shares Beneficially Owned Prior to Offering Percentage	Share Beneficially Owned After Offering Number(4)	Share Beneficially Owned After Offering Percentage
Executive Officers and Directors					
Gerri Henwood(5)	Common Stock	375,000	15.7%		
William L. Ashton(6)	Common Stock	30,000	1.2%		
Winston J. Churchill(7)(8)	Preferred Stock	1,875,000	78.5%		
Abraham Ludomirski(9)	Preferred Stock	1,875,000	78.5%		
Wayne Weisman(10)	Preferred Stock	1,875,000	78.5%		
All executive officers and directors as a group (9 persons)	Preferred Stock	1,875,000	78.5%		
	Common Stock	684,000	25.4%		

* Less than 1%

(1) Upon consummation of this offering, each share of our Series A Redeemable Convertible Preferred Stock, including accrued dividends, will be converted into shares of our common stock.

(2) References to Preferred Stock refers to shares of our Series A Redeemable Convertible Preferred Stock.

(3) The amount of shares beneficially owned prior to the consummation of this offering does not include additional shares of our common stock that will be issued upon the conversion of all principal and accrued interest outstanding under our 8% Convertible Promissory Notes, assuming an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and assuming the conversion occurs on , 2013 (the expected closing date of this offering).

(4) The amount of shares beneficially owned after the consummation of this offering includes (i) additional shares of our common stock that will be issued upon the conversion of all principal and accrued interest outstanding under our 8% Convertible Promissory Notes and (ii) additional shares of our common stock that will be issued upon the conversion of all outstanding shares, including accrued dividends, of our Series A Redeemable Convertible Preferred Stock.

(5) Mr. Henwood holds 125,000 shares of our common stock. Ms. Henwood holds 250,000 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.

(6) Mr. Ashton holds exercisable stock options to purchase 30,000 shares of our common stock.

(7) Mr. Churchill has shared voting and investment power with respect to 1,875,000 shares of our Series A Redeemable Convertible Preferred Stock that are held by SCP Vitalife, of which he is a partner.

(8) Mr. Churchill disclaims beneficial ownership of 125,000 shares of our Series A Redeemable Convertible Preferred Stock that are held by the Churchill Trust for the benefit of his son and stock options to purchase 83,000 shares of our common stock held by his son.

(9) Dr. Ludomirski has shared voting and investment power with respect to 1,875,000 shares of our Series A Redeemable Convertible Preferred Stock that are held by SCP Vitalife, of which he is a partner.

(10) Mr. Weisman has shared voting and investment power with respect to 1,875,000 shares of our Series A Redeemable Convertible Preferred Stock that are held by SCP Vitalife, of which he is a partner.

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DESCRIPTION OF CAPITAL STOCK

General

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 that will be in effect upon the closing of this offering. We have filed copies of these documents with the SEC as exhibits to our registration statement, of which this prospectus forms a part. The description of the capital stock reflects changes to our capital structure that will occur upon the closing of this offering.

As of immediately prior to the consummation of this offering, there were issued and outstanding 2,000,000 shares of our Series A Redeemable Convertible Preferred Stock and $ in aggregate principal amount of our 8% Convertible Promissory Notes. Pursuant to our current articles of incorporation, the shares of our Series A Redeemable Convertible Preferred Stock may be converted at the option of the Company into shares of our common stock upon the occurrence of an underwritten public offering that results in net proceeds of not less than $20,000,000 and which reflects an enterprise value of at least $50,000,000. In addition, pursuant to our current articles of incorporation, the shares of our Series A Redeemable Convertible Preferred Stock may be converted at the election of the holders into shares of our common stock. Upon the election of a holder of shares of Series A Redeemable Convertible Preferred Stock, each share of Series A Redeemable Convertible Preferred Stock is convertible into one share of our common stock. Accrued dividends on shares of our Series A Redeemable Convertible Preferred Stock may be converted into shares of our common stock upon shareholder and board approval. The holders of all of our outstanding shares of Series A Redeemable Convertible Preferred Stock have notified us of their election to convert all of their shares of Series A Redeemable Convertible Preferred Stock, and all accrued dividends, into shares of our common stock, effective contemporaneously with, and contingent upon the consummation of this offering, and the holders of our common stock and our board of directors have approved such conversion.

As with the Series A Redeemable Convertible Preferred Stock, our 8% Convertible Promissory Notes may be converted at the election of the holders into shares of our Series A Redeemable Convertible Preferred Stock or shares of common stock to be issued by us in our next equity financing at 75% of the initial price per share of such offering. The holders of all of our 8% Convertible Promissory Notes have notified us of their election to convert the outstanding aggregate principal amount and accrued interest of all of their 8% Convertible Promissory Notes into shares of our common stock to be issued, effective contemporaneously with, and contingent upon, the consummation of this offering. As a result, upon consummation of this offering, the outstanding aggregate principal amount and accrued interest of our 8% Convertible Promissory Notes will be converted into shares of our common stock at 75% of the initial price per share in this offering.

Accordingly, pursuant to the terms of the Series A Redeemable Convertible Preferred Stock and our 8% Convertible Promissory Notes and the elections made by the holders of such shares and notes, effective upon the consummation of this offering, (1) all outstanding shares of our Series A Redeemable Convertible Preferred Stock, including accrued dividends, will convert into shares of our common stock, and (2) all principal and accrued interest on our 8% Convertible Promissory Notes will convert into shares of our common stock, in each case assuming an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and assuming the conversion occurs on , 2013 (the expected closing date of this offering). Following the consummation of this offering, no shares of our Series A Redeemable Convertible Preferred Stock or 8% Convertible Promissory Notes will remain outstanding.

Contemporaneously with the consummation of this offering, the Company will amend and restate its articles of incorporation and bylaws to make certain changes to its capital stock, including the elimination of the Series A Redeemable Convertible Preferred Stock. Pursuant to the Company s Amended and Restated Articles of Incorporation that will be effective upon the consummation of this offering, the Company s authorized capital stock will consist of 50,000,000 shares of common stock, par value of $0.01 per share, and 10,000,000 shares of

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preferred stock, par value $0.01 per share, to be designated from time to time by our board. Further, following the consummation of this offering and the effectiveness of such Amended and Restated Articles of Incorporation, the Company will have shares of common stock issued and outstanding and no shares of preferred stock will be issued and outstanding.

Common Stock

As of October 1, 2013, there were 389,000 shares of our common stock issued and outstanding and held of record by 3 shareholders. 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.

Preferred Stock

Upon consummation of the offering, our board of directors has the authority, without further action by our shareholders, to issue up to 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 October 1, 2013, options to purchase 837,000 shares of our common stock were outstanding under our 2008 Stock Option Plan, all of which were vested. As of October 1, 2013, there were no options to purchase shares of our common stock outstanding under our 2013 Equity Incentive Plan. Our board of directors has approved the grant of options to purchase an aggregate amount of 452,566 shares of our common stock to our officers, which grants are contingent and effective upon the closing of this offering. As a result, upon closing of this offering, options to

purchase 1,110,000 shares of our common stock will be outstanding under our 2008 Stock Option Plan, consisting of all shares reserved for issuance under such plan, and options to purchase 179,566 shares of our common stock will be outstanding under our 2013 Equity Incentive Plan. Accordingly, after such grant, no shares of our common stock will remain available for future issuance under our 2008 Stock

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Option Plan. See the section entitled Executive Compensation-Stock Option Grants to Executive Officers beginning on page 91 of this prospectus for more information.

Common Stock Warrants

We agreed to issue to the representative of the underwriters in this offering warrants to purchase up shares of our common stock, with a per share exercise price equal to 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 this offering.

Registration Rights

In addition to the registration rights granted with respect to the Representative s warrants described above, holders of our common stock issued upon conversion of our Series A Redeemable Convertible Preferred Stock immediately prior to the closing of this offering will be 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 section entitled Transactions with Related Persons, beginning on page 92 of this prospectus.

Demand Registration Rights. If at any time beginning 180 days after this offering 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 this offering 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.

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.

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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.

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 section entitled Management-Board Composition and Independence beginning on page 85 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.

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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 will be Broadridge Corporate Issuer Solutions, Inc.

Stock Market Listing

We have applied to have our shares of common stock listed for trading on the NASDAQ Capital Market under the symbol REPH. No assurance can be given that such listing will be approved.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock, and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options, or the anticipation of these sales, could materially and adversely affect market prices prevailing from time to time and could impair our ability to raise capital through sales of equity or equity-related securities.

As described below, only a limited number of shares of our common stock will be available for sale in the public market for a period of several months after completion of this offering due to contractual and legal restrictions on resale described below. Nevertheless, sales of a substantial number of shares of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could materially and adversely affect the prevailing market price of our common stock. Although we have applied to list our common stock on the NASDAQ Capital Market, we cannot assure you that there will be an active market for our common stock.

Upon the closing of this offering, we will have outstanding an aggregate of shares of our common stock, assuming (i) the underwriters do not exercise their over-allotment option, (ii) no options outstanding as of , 20 are exercised, (iii) additional shares of our common stock issuable upon the automatic conversion of our Series A Redeemable Convertible Preferred Stock, including accrued dividends, upon the closing of this offering, and (iv) additional shares of our common stock issuable upon the assumed conversion of all principal and accrued interest outstanding under our 8% Convertible Promissory Notes upon the closing of this offering, at 75% of the initial public offering price, into shares of our common stock, assuming an initial public offering price of $ per share, the midpoint of the price range set forth on the cover page of this prospectus, and assuming the conversion occurs on , 2013 (the expected closing date of this offering).

Of the shares to be outstanding immediately after the closing of this offering, we expect that the shares to be sold in this offering will be freely tradable without restriction under the Securities Act unless purchased by our affiliates, as that term is defined in Rule 144 under the Securities Act. The remaining shares of our common stock outstanding after this offering will be restricted securities under Rule 144,

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and we expect that substantially all of these restricted securities will be subject to the 180-day lock-up period under the lock-up agreements as described below. These restricted securities may be sold in the public market only if registered or pursuant to an exemption from registration, such as Rule 144 or Rule 701 under the Securities Act.

Rule 144

Affiliate Resales of Restricted Securities

In general, subject to the lock-up restrictions described below, beginning 90 days after the effective date of the registration statement, of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, who has beneficially owned shares of our common stock for at least six months would be entitled to sell in broker s transactions or certain riskless principal transactions or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering; or
- the average weekly trading volume in our common stock on the NASDAQ Capital Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of $50,000, the seller must file a notice on Form 144 with the SEC and the NASDAQ Capital Market concurrently with either the placing of a sale order with the broker or the execution directly with a market maker.

Non-Affiliate Resales of Restricted Securities

In general, subject to the lock-up restrictions described below, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the three months preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us.

If such person has held our shares for at least one year, such person can resell without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.

Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

Upon expiration of the 180-day lock-up period described below, approximately shares of our common stock will be eligible for sale under Rule 144, including shares eligible for resale immediately upon the closing of this offering as described above. We cannot estimate the number of shares of our common stock that our existing shareholders will elect to sell under Rule 144.

Rule 701

Rule 701 generally allows a shareholder who purchased shares of our common stock pursuant to a written compensatory plan or contract and who is not deemed to have been an affiliate of ours during the immediately preceding 90 days to sell these shares in reliance upon Rule 144, but without being required to comply with the current public information, holding period, volume limitation, or notice provisions of Rule 144. Rule 701 also permits affiliates of ours to sell their Rule 701 shares under Rule 144 without complying with the holding period

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requirements of Rule 144. All holders of Rule 701 shares, however, are required to wait until 90 days after the date of this prospectus before selling such shares pursuant to Rule 701 and until expiration of the 180-day lock-up period described below.

Subject to the 180-day lock-up period described below, approximately shares of our common stock will be eligible for sale in accordance with Rule 701.

Lock-Up Agreements

We, each of our directors and executive officers and holders of substantially all of our outstanding shares of common stock have agreed that, without the prior written consent of Aegis Capital Corp., we and they will not, subject to limited exceptions, during the period ending 180 days after the effectiveness of this registration statement of which this prospectus is a part:

- offer, sell, contract to sell, pledge, grant any option to purchase (except for options granted by the Company to our directors and officers), make any short sale or otherwise dispose of, engage in any hedging or other transactions, including, without limitation, any short sale or any purchase, sale or grant of any right (including without limitation any put or call option) with respect to, or with respect to any security that includes, relates to, or derives any significant part of its value from, any of our securities, or any securities convertible into or exercisable or exchangeable for, or any rights to purchase or otherwise acquire, any shares of our securities; or

- exercise or seek to exercise or effectuate in any manner any rights of any nature to register the sale, transfer or other disposition of any of our securities, or to otherwise participate as a selling security holder in any manner in any registration effected by us.

The lock-up restrictions and specified exceptions are described in more detail under Underwriting.

Stock Options

As of October 1, 2013, we had outstanding options to purchase 837,000 shares of our common stock, all of which were vested. In addition, upon consummation of this offering, we will issue options to purchase an aggregate amount of 452,566 shares of our common stock to our officers. As a result, upon consummation of this offering, we will have outstanding options to purchase 1,289,566 shares of our common stock. Following this offering, we intend to file one or more registration statements on Form S-8 under the Securities Act to register all of the shares of our common stock subject to outstanding options and options and other awards issued or issuable pursuant to our 2008 Stock Option Plan and our 2013 Equity Incentive Plan. See Executive Compensation Stock Option Plans and Executive Compensetion-Stock Option Grants to Executive Officers for additional information regarding these plans. Accordingly, shares of our common stock registered under the registration statements will be available for sale in the open market, subject to Rule 144 volume limitations applicable to affiliates, and subject to any vesting restrictions and lock-up agreements applicable to these shares.

UNDERWRITING

Aegis Capital Corp., or the Representative, is acting as the sole book-running manager of this offering and as the representative of the underwriters in this offering. We have entered into an underwriting agreement dated the date of

this prospectus with the Representative. Subject to the terms and conditions set forth in an underwriting agreement dated the date of this prospectus among us and the underwriters named below, we have

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agreed to sell to the underwriters, and each underwriter has severally agreed to purchase from us, the number of shares of common stock listed next to its name in the following table.

Underwriters	Number of Shares
Aegis Capital Corp.	$
Total	$

The underwriters are committed to purchase all the shares of common stock offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of nondefaulting underwriters may be increased or the offering may be terminated. The underwriters are not obligated to purchase the shares of common stock covered by the underwriters over-allotment option described below. The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer s certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Discounts and Commissions

The underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of $ per share. After the initial offering of the shares, the public offering price and other selling terms may be changed by the Representative.

The following table shows the public offering price, underwriting discounts and commissions and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their over-allotment option.

	Per Share	Without Option	With Option
Public offering price	$	$	$
Underwriting discounts and commissions paid by us (7%)			
Non-accountable expense allowance(1%)(1)			
Proceeds, before expenses, to us(2)			

(1) We have paid a $25,000 advance to the underwriters to be applied against the underwriters accountable expenses that will be paid by us to the underwriters in connection with this offering. The 1.0% non-accountable expense allowance granted to the underwriters will not include proceeds from the shares sold under the overallotment option.

(2)

In addition to the underwriting discounts and commissions and non-accountable expense allowance, we agreed to pay or reimburse the underwriters to cover certain out of pocket expenses of the underwriters in connection with this offering.

The total estimated expenses of the offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding underwriting discounts and commissions, are approximately $ and are payable by us.

Right of First Refusal

For a period of nine months from the date of effectiveness of the registration statement of which this prospectus is a part, we have agreed to grant to the Representative the right of first refusal to act as sole book-running manager for each and every future public and private equity and public debt offerings of the Company, or any successor to or any subsidiary of the Company.

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Representative s Warrants

We have also agreed to issue to the Representative or its designees, at the closing of this offering, warrants, or the Representative s Warrants, to purchase that number of our common stock equal to 4% of the aggregate number of shares sold in the offering. The Representative s Warrants will be exercisable at any time and from time to time, in whole or in part, during the 4-year period commencing one year from the date of effectiveness of this registration statement, at a price per share equal to 150.0% of the public offering price per share of common stock at the offering. The Representative s Warrants and the shares of common stock underlying the Representative s Warrants have been deemed compensation by the Financial Industry Regulatory Authority, or FINRA, and are, therefore, subject to a 180-day lock-up pursuant to Rule 5110(g)(1) of FINRA. The Representative (or permitted assignees under the Rule) will not sell, transfer, assign, pledge or hypothecate the Representative s Warrants or the shares of common stock underlying the Representative s Warrants, nor will it engage in any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the Representative s Warrants or the common stock underlying the Representative s Warrants for a period of 180 days after the effective date of the registration statement. The Representative s Warrants will provide for piggyback registration rights and customary anti-dilution provisions (for stock dividends and splits and recapitalizations) consistent with FINRA Rule 5110, and further, the number of shares underlying the Representative s Warrants shall be reduced if necessary to comply with FINRA rules or regulations.

Expenses

In addition to the underwriters discount and non-accountable expense allowance, we agreed to pay or reimburse the underwriters to cover certain out of pocket expenses of the underwriters in connection with this offering, in an amount of up to $_____. We have paid a $25,000 advance to the underwriters to be applied against the underwriters accountable expenses that will be paid by us to the underwriters in connection with this offering.

Over-Allotment Option

We have granted the underwriters an option to purchase up to additional shares of common stock at the public offering price, less underwriting discounts and commissions. The underwriters may exercise this option for 45 days from the date of this prospectus solely to cover sales of shares of common stock by the underwriters in excess of the total number of shares set forth in the table above. If any shares are purchased pursuant to this over-allotment option, the underwriters will purchase the additional shares in approximately the same proportion as shown in the table above. If any of these additional shares are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered. We will pay the expenses associated with the exercise of the over-allotment option.

Determination of Offering Price

Prior to this offering, there has been no public market for our common stock. The initial public offering price was negotiated between us and the Representative. Among the factors considered in these negotiations were:

- the prospects for our company and the industry in which we operate;
- our past and present financial and operating performance;

financial and operating information and market valuations of publicly traded companies engaged in activities similar to ours;

the prevailing conditions of U.S. securities markets at the time of this offering; and

other factors deemed relevant.

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Lock-Up Agreements

We, our officers and directors and holders of substantially all of our outstanding stock and options have entered into lock-up agreements with the underwriters. Under these agreements, we and these other individuals have agreed, subject to specified exceptions, not to sell or transfer any common stock, options, warrants, or other of our securities, during a period ending 180 days after the effectiveness of the registration statement of which this prospectus is a part, without first obtaining the written consent of Representative.

Specifically, we and these other individuals have agreed not to during a period ending 180 days after the date of this prospectus, without first obtaining the written consent of Representative:

- offer, sell, contract to sell, pledge, grant any option to purchase (except for options granted by the Company to our directors and officers), make any short sale or otherwise dispose of, engage in any hedging or other transactions, including, without limitation, any short sale or any purchase, sale or grant of any right (including without limitation any put or call option) with respect to, or with respect to any security that includes, relates to, or derives any significant part of its value from, any of our securities, or any securities convertible into or exercisable or exchangeable for, or any rights to purchase or otherwise acquire, any shares of our securities; or

- exercise or seek to exercise or effectuate in any manner any rights of any nature to register the sale, transfer or other disposition of any of our securities, or to otherwise participate as a selling security holder in any manner in any registration effected by us.

The restrictions described above do not apply to transfers below:

- as a bona fide gift or gifts;

- to any trust for the direct or indirect benefit of a security holder or the immediate family of a security holder;

- to any beneficiary of a security holder pursuant to a will or other testamentary document or applicable laws of descent;

- to any corporation, partnership, limited liability company or other entity all of the beneficial ownership interests of which are held by a security holder or the immediate family of a security holder;

- if the security holder is a corporation, partnership, limited liability company or other business entity, any transfers to any shareholder, partner or member of, or owner of a similar equity interest in, the security holder;

the exercise by a security holder of any stock options or warrants issued pursuant to our existing stock plans, including any exercise effected by the delivery of our securities; provided, that any securities received upon exercise of such options shall be subject to the terms of the lock-up agreement; or

of any of the following events: (1) an acquisition by an individual or legal entity or of effective control (whether through legal or beneficial ownership of our capital stock) of 100% of our voting securities; (2) we merge into or consolidate with any other entity, or any entity merges into or consolidates with us; or (3) we sell or transfer all or substantially all of our assets to another person; provided, that, in the case of each of the events set forth in clauses (1) through (3), our securities remain subject to the restrictions on transfer.

Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make for these liabilities.

NASDAQ Listing

We have applied to list our common stock on the NASDAQ Capital Market under the symbol REPH.

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Price Stabilization, Short Positions and Penalty Bids

In order to facilitate the offering of our common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of our common stock. In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in the offering. Covered short sales are sales made in an amount not greater than the underwriters option to purchase additional shares of common stock in the offering. The underwriters may close out any covered short position by either exercising their over-allotment option or purchasing shares of common stock in the open market. In determining the source of shares of common stock to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. Naked short sales are sales in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares of common stock in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

Similar to other purchase transactions, the underwriters purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As result, the price of our common stock may be higher than the price that might otherwise exist in the open market.

The underwriters have advised us that, pursuant to Regulation M under the Exchange Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of our common stock, including the imposition of penalty bids. This means that if the Representative purchases common stock in the open market in stabilizing transactions or to cover short sales, the Representative can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

The underwriters make no representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor the underwriters make any representation that the underwriters will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Offer, Sale and Distribution of Shares

A prospectus in electronic format may be made available on the websites maintained by one or more underwriters or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares of common stock to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the Representative and selling group members that may make Internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters websites and any information contained in any other website maintained by the underwriters is not part of this prospectus or the registration statement of which this prospectus forms a part.

Notice to Non-U.S. Investors

In relation to each member state of the European Economic Area that has implemented the Prospectus Directive, each of which we refer to as a relevant member state, with effect from and including the date on which

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the Prospectus Directive is implemented in that relevant member state, or the relevant implementation date, an offer of securities described in this prospectus may not be made to the public in that relevant member state other than:

- to legal entities that are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- to any legal entity that has two or more of (i) an average of at least 250 employees during the last financial year; (ii) a total balance sheet of more than 43,000,000 and (iii) an annual net turnover of more than 50,000,000, as shown in its last annual or consolidated accounts;
- to fewer than 100 natural or legal persons (other than qualified investors as defined in the Prospectus Directive) subject to obtaining the prior consent of the Representative for any such offer; or
- in any other circumstances that do not require the publication of a prospectus pursuant to Article 3 of the Prospectus Directive;

provided that no such offer of securities shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an offer of shares to the public in relation to any shares of common stock in any relevant member state means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe for the shares, as the same may be varied in that member state by any measure implementing the Prospectus Directive in that member state and the expression Prospectus Directive means Directive 2003/71/EC and includes any relevant implementing measure in each relevant member state.

Other Relationships

From time to time, certain of the underwriters and their affiliates have provided, and may provide in the future, various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which they have received and may continue to receive customary fees and commissions.

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 and for the underwriters by Zysman, Aharoni, Gayer and Sullivan & Worcester LLP, New York, New York.

EXPERTS

The financial statements of Recro Pharma, Inc. as of December 31, 2011 and 2012 and for the years then ended and for the period from November 15, 2007 (inception) through December 31, 2012 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,

2012 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.

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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.

Upon completion of this offering, 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. Upon completion of this offering, 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.

(A Development-Stage Company)

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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, 2011 and 2012, 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, 2012. 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, 2011 and 2012, 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, 2012 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

April 24, 2013

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RECRO PHARMA, INC.

(A Development-Stage Company)

Balance Sheets

	December 31, 2011	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 8,196	$ 53,346
Other receivables		85,000
Prepaid expenses	14,117	14,279
Total current assets	22,313	152,625
Equipment, net	3,385	1,447
Total assets	$ 25,698	$ 154,072
Liabilities and Shareholders Deficit		
Current liabilities:		
Convertible notes payable	$ 8,148,140	$ 10,158,505
Accounts payable	195,441	15,582
Accrued expenses	266,540	102,029
Total current liabilities	8,610,121	10,276,116
Total liabilities	8,610,121	10,276,116
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 $5,444,499 as of December 31, 2012)	5,027,210	5,439,833
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, 389,000 shares	3,890	3,890
Deficit accumulated during the development stage	(13,615,523)	(15,565,767)
Total shareholders deficit	(13,611,633)	(15,561,877)
Total liabilities and shareholders deficit	$ 25,698	$ 154,072

See accompanying notes to financial statements.

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RECRO PHARMA, INC.

(A Development-Stage Company)

Statements of Operations

	Year ended December 31,		Period from November 15, 2007 (inception) through December 31,
	2011	2012	2012
Operating expenses:			
Research and development	$ 1,828,301	$ 541,951	$ 11,445,033
General and administrative	485,257	339,255	1,457,910
Total operating expenses	2,313,558	881,206	12,902,943
Other income (expense):			
Interest income	301	35	4,274
Grant income (note 3)		85,000	329,479
Interest expense	(557,661)	(740,365)	(1,638,504)
	(557,360)	(655,330)	(1,304,751)
Net loss	(2,870,918)	(1,536,536)	$ (14,207,694)
Accretion of redeemable convertible preferred stock	(382,749)	(412,623)	
Net loss applicable to common shareholders	$ (3,253,667)	$ (1,949,159)	
Basic and diluted net loss per common share	$ (8.36)	$ (5.01)	
Weighted average basic and diluted common shares outstanding	389,000	389,000	
Unaudited pro forma net loss		$ (796,171)	
Unaudited pro forma basic and diluted net loss per common share		$	
Unaudited pro forma weighted average basic diluted common shares outstanding			

See accompanying notes to financial statements.

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RECRO PHARMA, INC.

(A Development-Stage Company)

Statements of Redeemable Convertible Preferred Stock and Shareholders Deficit

Period from November 15, 2007 (inception) through December 31, 2012

	Series A redeemable convertible preferred stock		Common stock		Shareholders Deficit		
	Shares	Amount	Shares	Amount	Additional paid-in capital	Deficit accumulated during the development stage	Total
Balance, November 15, 2007 (inception)		$		$	$	$	$
Net loss						(27,680)	(27,680)
Balance, December 31, 2007						(27,680)	(27,680)
Issuance of common stock			389,000	3,890	6,110		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			(6,110)	(33,368)	(39,478)
Net loss						(1,716,189)	(1,716,189)
Balance, December 31, 2008	750,000	1,494,396	389,000	3,890		(1,777,237)	(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	389,000	3,890		(6,101,607)	(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	389,000	3,890		(10,352,615)	(10,348,725)
Stock-based compensation income						(9,241)	(9,241)
		382,749				(382,749)	(382,749)

Accretion of Series A redeemable convertible preferred stock to redemption value							
Net loss						(2,870,918)	(2,870,918)
Balance, December 31, 2011	2,000,000	5,027,210	389,000	3,890		(13,615,523)	(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	389,000	$ 3,890	$	$ (15,565,767)	$ (15,561,877)

See accompanying notes to financial statements.

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RECRO PHARMA, INC.

(A Development-Stage Company)

Statements of Cash Flows

	Year ended December 31,		Period from November 15, 2007 (inception) through December 31,
	2011	2012	2012
Cash flows from operating activities:			
Net loss	$ (2,870,918)	$ (1,536,536)	$ (14,207,694)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	(9,241)	(1,085)	120,732
Non-cash interest expense	557,661	740,365	1,638,505
Depreciation expense	1,939	1,938	8,244
Acquired in-process research and development			1,448,680
Changes in operating assets and liabilities:			
Prepaid expenses	5,573	(162)	(14,279)
Other receivables		(85,000)	(85,000)
Accounts payable and accrued expenses	142,703	(344,370)	117,611
Net cash used in operating activities	(2,172,283)	(1,224,850)	(10,973,201)
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
Proceeds from issuance of common stock			10,000
Proceeds from notes payable	2,000,000	1,270,000	8,520,000
Borrowings from related parties			207,358
Repayments to related parties			(207,358)
Net cash provided by financing activities	2,000,000	1,270,000	12,484,918
Net increase (decrease) in cash and cash equivalents	(172,283)	45,150	53,346
Cash and cash equivalents, beginning of period	180,479	8,196	

Cash and cash equivalents, end of period	$ 8,196	$ 53,346	$ 53,346

See accompanying notes to financial statements.

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RECRO PHARMA, INC.

(A Development-Stage Company)

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 $15,561,877 and negative working capital as of December 31, 2012. 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 Policies

(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.

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RECRO PHARMA, INC.

(A Development-Stage Company)

Notes to Financial Statements

(b) Fair Value of Financial Instruments

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

(c) Cash and Cash Equivalents

The Company considers all highly liquid investments that have maturities of three months or less when acquired to be cash equivalents. Cash equivalents as of December 31, 2011 and 2012 consisted of money market mutual funds.

(d) 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. As of December 31, 2012, management believes that no revision of the remaining useful lives or write-down of long-lived assets is required.

Accumulated depreciation was $6,306 and $8,244 as of December 31, 2011 and 2012, respectively.

(e) 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.

(f) Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating

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RECRO PHARMA, INC.

(A Development-Stage Company)

Notes to Financial Statements

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.

(g) 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 postvesting 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.

(h) 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, 2012.

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RECRO PHARMA, INC.

(A Development-Stage Company)

Notes to Financial Statements

(i) 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, 2011 and 2012, as they would be anti-dilutive:

	December 31,	
	2011	**2012**
Redeemable convertible preferred stock	2,000,000	2,000,000
Shares issuable pursuant to redeemable convertible preferred stock accretion	520,602	722,250
Options outstanding	837,000	837,000
Convertible notes payable		

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 2,621,426 weighted average shares of common stock and the conversion of the convertible notes into weighted average shares of common stock upon the closing of the Company s planned Initial Public Offering (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.

(A Development-Stage Company)

Notes to Financial Statements

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

	Year ended December 31, 2012
Numerator:	
Net loss applicable to common shareholders	$ (1,949,159)
Effect of pro forma adjustments:	
Accretion of redeemable convertible preferred stock	412,623
Interest expense on convertible notes	740,365
Pro forma net loss applicable to common shareholders	$ (796,171)
Denominator:	
Weighted average common shares outstanding	389,000
Effect of pro forma adjustments:	
Conversion of redeemable convertible preferred stock	2,621,426
Conversion of convertible notes	
Shares used in computing unaudited pro forma weighted average basic and diluted common shares outstanding	
Unaudited pro forma basic and diluted net loss per common share	$

(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.

(A Development-Stage Company)

Notes to Financial Statements

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

	Fair value measurements at reporting date using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
At December 31, 2011:			
Assets:			
Money market mutual funds (included in cash and cash equivalents)	$ 8,196		
At December 31, 2012:			
Assets:			
Money market mutual funds (included in cash and cash equivalents)	$ 53,346		

(5) Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2011	2012
Clinical trial and related costs	$ 157,075	$ 11,216
Professional and consulting fees	106,341	87,998
Payroll and related costs	3,124	2,815
	$ 266,540	$ 102,029

(6) Convertible Notes Payable

In 2009, 2010, 2011, and 2012, the Company issued $2,000,000, $3,250,000, $2,000,000, and $1,270,000, 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, 2012, $8,520,000 of the Bridge Notes were outstanding plus $1,638,505 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 $3,392,276 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.

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(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 ($27.1 million as of December 31, 2012) 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 ($16.1 million as of December 31, 2012) 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 a share 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, 2012. As of December 31, 2012, there were $1,444,499 of cumulative undeclared Series A dividends. The financial statements as of, and for the years ended December 31, 2011 and 2012 include the effects of correcting the dividend accretion for the Series A from a daily to an annual compounding in accordance with the Company s Articles of Incorporation. The effects of the correction were immaterial.

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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 389,000 shares of common stock at $0.0257 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, 2012, no stock appreciation rights have been issued. Stock options are exercisable generally for a period of 10 years from the date of grant and generally vest over 4 years. Subsequent to adoption, the Plan has been amended to increase the authorized number of shares available for grant to 1,110,000 shares of common stock. As of December 31, 2012, 273,000 shares were available for future grants under the Plan.

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

	Years ended December 31,	
	2011	2012
Employee	$ 2,000	$ 2,000
Nonemployee	(11,241)	(3,085)
	$ (9,241)	$ (1,085)

During 2012 and 2011, 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 year ended December 31, 2012. The weighted average fair value of the options awarded to employees and nonemployees during 2011 was $0.11. The fair value of the options was estimated on the date of grant using a Black-Scholes option pricing model with the following assumptions:

	2011
Expected life	7 years
Expected volatility	68.0%
Risk-free interest rate	2.2%
Expected dividend yield	

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Notes to Financial Statements

The following table summarizes stock option activity under the Plan through December 31, 2012:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life
Balance, December 31, 2010	807,000	2.40	
Granted	30,000	2.40	
Exercised			
Canceled			
Balance, December 31, 2011	837,000	2.40	
Granted			
Exercised			
Canceled			
Balance, December 31, 2012	837,000	2.40	6 years
Options exercisable, December 31, 2012	837,000	2.40	6 years

In March 2009, options to purchase 50,000 shares of common stock were granted to an employee. In December 2008, options to purchase 757,000 shares of common stock were granted to nonemployees.

As of December 31, 2012, 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,	
	2011	2012
U.S. federal statutory income tax rate	34.0%	34.0%
State taxes, net of federal benefit	6.6%	6.6%
Permanent items	(7.9)%	(19.5)%
R&D credit	2.4%	1.1%

Change in valuation allowance	(35.1)%	(22.2)%
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,	
	2011	**2012**
Net operating loss carryforwards	$ 3,327,648	$ 3,459,513
Credits	329,244	346,552
Other temporary differences	1,451,559	1,642,940
Gross deferred tax asset	5,108,451	5,449,005
Deferred tax assets valuation allowance	(5,108,451)	(5,449,005)
	$	$

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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, 2011 and 2012.

The following table summarizes carryforwards of Federal net operating losses and tax credits as of December 31, 2012:

	Amount	Expiration	
Federal net operating losses	$ 8,520,966	2028	2032
Research and development credits	$ 346,552	2028	2032

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 MCG, a consulting company affiliated with the Company s acting 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 $834,796 and $252,532 of research and development expenses for MCG consulting fees in 2011 and 2012, respectively. As of December 31, 2011, $37,910 and $86,489 was recorded in accrued expenses and accounts payable, respectively, as amounts due to MCG. As of December 31, 2012, $11,216 and $11,682 was recorded in accrued expenses and accounts payable, respectively, as amounts due to MCG. In addition to fees for services, employees of MCG, certain of whom are related to the Company s acting Chief Executive Officer, received options to purchase 617,000 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 2012. The Company s acting Chief Executive Officer is 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 2012, the Company borrowed and repaid $108,000 from the Company s acting Chief Executive Officer and $99,358 from MCG.

(12) Subsequent Event

During April through December 2013, the Company issued an additional $880,584 of Bridge Notes in the aggregate.

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RECRO PHARMA, INC.

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Balance Sheets

(Unaudited)

	December 31, 2012	September 30, 2013	Pro Forma September 30, 2013
Assets			
Current assets:			
Cash and cash equivalents	$ 53,346	$ 20,403	$ 215,703
Other receivables	85,000		
Deferred offering costs		249,280	249,280
Prepaid expenses	14,279	21,573	21,573
Total current assets	152,625	291,256	486,556
Property and equipment, net	1,447	117	117
Total assets	$ 154,072	$ 291,373	$ 486,673
Liabilities and Shareholders Deficit			
Current liabilities:			
Convertible notes payable	$ 10,158,505	$ 11,480,128	$
Accounts payable	15,582	137,204	137,204
Accrued expenses	102,029	370,089	370,089
Total current liabilities	10,276,116	11,987,421	507,293
Total liabilities	10,276,116	11,987,421	507,293
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 $5,766,924 as of September 30, 2013)	5,439,833	5,766,924	
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, 389,000 shares at December 31, 2012 and September 30, 2013, shares September 30, 2013 pro forma	3,890	3,890	3,890

Additional paid-in capital			17,442,352
Deficit accumulated during the development stage	(15,565,767)	(17,466,862)	(17,466,862)
Total shareholders deficit	(15,561,877)	(17,462,972)	(20,620)
Total liabilities and shareholders deficit	$ 154,072	$ 291,373	$ 486,673

See accompanying notes to financial statements.

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RECRO PHARMA, INC.

(A Development-Stage Company)

Statements of Operations

(Unaudited)

	Nine Months Ended September 30,		Period from November 15, 2007 (inception) through September 30,
	2012	2013	2013
Operating expenses:			
Research and development	$ 505,653	$ 494,236	$ 11,939,269
General and administrative	238,701	443,470	1,901,380
Total operating expenses	744,354	937,706	13,840,649
Other income (expense):			
Interest income	34	41	4,315
Grant income			329,479
Interest expense	(542,219)	(636,339)	(2,274,843)
	(542,185)	(636,298)	(1,941,049)
Net loss	1,286,539	(1,574,004)	$ (15,781,698)
Accretion of redeemable convertible preferred stock	(298,889)	(327,091)	
Net loss applicable to common shareholders	$ (1,585,428)	$ (1,901,095)	
Basic and diluted net loss per common share	$ (4.08)	$ (4.89)	
Weighted average basic and diluted common shares outstanding	389,000	389,000	
Unaudited pro forma net loss		$ (937,665)	
Unaudited pro forma basic and diluted net loss per common share		$	
Unaudited pro forma weighted average basic and diluted common shares outstanding			

See accompanying notes to financial statements.

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RECRO PHARMA, INC.

(A Development-Stage Company)

Statements of Redeemable Convertible Preferred Stock and Shareholders Deficit

Nine Months Ended September 30, 2013

(Unaudited)

	Series A redeemable convertible preferred stock		Shareholders Deficit			
			Common stock		Deficit accumulated during the development	
	Shares	Amount	Shares	Amount	stage	Total
Balance, December 31, 2012	2,000,000	5,439,833	389,000	$ 3,890	$ (15,565,767)	$ (15,561,877)
Accretion of Series A redeemable convertible preferred stock to redemption value		327,091			(327,091)	(327,091)
Net loss					(1,574,004)	(1,574,004)
Balance, September 30, 2013	2,000,000	$ 5,766,924	389,000	$ 3,890	$ (17,466,862)	$ (17,462,972)

See accompanying notes to financial statements.

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RECRO PHARMA, INC.

(A Development-Stage Company)

Statements of Cash Flows

(Unaudited)

	Nine Months Ended September 30,	Period from November 15, 2007 (inception) through September 30, 2013