Recro Pharma, Inc.
Form 10-Q
May 13, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the Quarterly Period Ended: March 31, 2014

¨ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
Commission File Number: 001-36329

Recro Pharma, Inc.

(Exact name of registrant as specified in its charter)

Pennsylvania	**26-1523233**
(State or other jurisdiction of	**(I.R.S. Employer**

incorporation or organization)	Identification No.)
490 Lapp Road, Malvern, Pennsylvania	**19355**
(Address of principal executive offices)	**(Zip Code)**

(484) 395-2400

(Registrant s telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

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

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

As of April 30, 2014, there were 7,707,600 shares of common stock outstanding, par value $0.01 per share.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

RECRO PHARMA, INC.

(A Development-Stage Company)

Balance Sheets

(unaudited)

	March 31, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 29,905,016	$ 12,828
Other receivables	35,787	38,418
Prepaid expenses	287,279	15,689
Deferred offering costs		784,177
Total current assets	30,228,082	851,112
Total assets	$ 30,228,082	$ 851,112
Liabilities and Shareholders Equity (Deficit)		
Current liabilities:		
Convertible notes payable	$	$ 11,907,198
Accounts payable	32,435	434,244
Accrued expenses	792,406	589,532
Total current liabilities	824,841	12,930,974
Total liabilities	824,841	12,930,974
Series A redeemable convertible preferred stock, $0.01 par value. Authorized, 2,000,000 shares, issued and outstanding, 2,000,000 shares		5,880,037
Shareholders equity (deficit):		
Preferred stock, $0.01 par value. Authorized, 10,000,000 shares; none issued and outstanding		
Common stock, $0.01 par value. Authorized, 50,000,000 shares, issued and outstanding, 7,707,600 shares at March 31, 2014 and 155,600 shares at December 31, 2013	77,076	1,556
Additional paid-in-capital	52,433,949	

Deficit accumulated during the development stage	(23,107,784)	(17,961,455)
Total shareholders equity (deficit)	29,403,241	(17,959,899)
Total liabilities and shareholders equity (deficit)	$ 30,228,082	$ 851,112

See accompanying notes to unaudited financial statements.

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RECRO PHARMA, INC.

(A Development-Stage Company)

Statements of Operations

(unaudited)

	Three Months Ended March 31,		Period from November 15, 2007 (inception) through March 31,
	2014	2013	2014
Operating expenses:			
Research and development	$ 226,997	$ 113,973	$ 12,514,111
General and administrative	646,628	91,664	2,352,208
Total operating expenses	873,625	205,637	14,866,319
Other income (expense):			
Interest income	215	3	4,532
Grant income			329,479
Interest expense	(4,272,919)	(203,170)	(6,779,533)
	(4,272,704)	(203,167)	(6,445,522)
Net loss	(5,146,329)	(408,804)	$ (21,311,841)
Accretion of redeemable convertible preferred stock and deemed dividend	(1,270,057)	(104,283)	
Net loss applicable to common shareholders	$ (6,416,386)	$ (513,087)	
Basic and diluted net loss per common share	$ (3.67)	$ (3.30)	
Weighted average basic and diluted common shares outstanding	1,749,911	155,600	
Unaudited pro forma net loss	$ (873,410)		
Unaudited pro forma net loss per share	$ (0.20)		
	4,276,478		

Unaudited pro forma weighted average basic and diluted common shares outstanding	

See accompanying notes to unaudited financial statements.

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RECRO PHARMA, INC.

(A Development-Stage Company)

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

Three Months ended March 31, 2014

(unaudited)

	Series A Redeemable Convertible Preferred Stock		Shareholders Equity (Deficit)				
	Shares	Amount	Common stock Shares	Amount	Additional paid-in capital	Deficit accumulated during the development stage	Total
Balance, December 31, 2013	2,000,000	$ 5,880,037	155,600	$ 1,556	$	$ (17,961,455)	$ (17,959,899)
Accretion of Series A redeemable convertible preferred stock to redemption value		88,771			(88,771)		(88,771)
Sale of common stock in initial public offering net of offering costs of $4,245,158			4,312,500	43,125	30,211,717		30,254,842
Stock-based compensation expense					19,473		19,473
Deemed dividend on Series A		1,181,286			(1,181,286)		(1,181,286)
Conversion of Series A and accrued dividends to common	(2,000,000)	(7,150,094)	1,193,762	11,938	7,138,156		7,150,094
Conversion of notes payable and accrued			2,045,738	20,457	12,253,970		12,274,427

interest to common					
Beneficial conversion upon conversion of notes payable (Note 6)			4,080,690		4,080,690
Net loss				(5,146,329)	(5,146,329)
Balance, March 31, 2014	$ 7,707,600	$ 77,076	$ 52,433,949	$ (23,107,784)	$ 29,403,241

See accompanying notes to unaudited financial statements.

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RECRO PHARMA, INC.

(A Development-Stage Company)

Statements of Cash Flows

(unaudited)

	Three Months Ended March 31,		Period from November 15, 2007 (inception) through March 31,
	2014	**2013**	**2014**
Cash flows from operating activities:			
Net loss	$ (5,146,329)	$ (408,804)	$ (21,311,841)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	19,473		140,205
Noncash interest expense	4,272,919	203,170	6,779,533
Depreciation expense		485	9,691
Acquired in-process research and development			1,448,680
Changes in operating assets and liabilities:			
Prepaid expenses	(271,590)	(19,645)	(287,279)
Other receivables	2,631	85,000	(35,787)
Accounts payable and accrued expenses	306,949	89,404	651,025
Net cash used in operating activities	(815,947)	(50,390)	(12,605,773)
Cash flows from investing activities:			
Purchases of property and 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 initial public offering	30,533,135		30,428,658
Proceeds from issuance of common stock			10,000
Proceeds from notes payable	175,000		9,575,584
Borrowings from related parties			207,358
Repayments to related parties			(207,358)

Net cash provided by financing activities	30,708,135		43,969,160
Net increase (decrease) in cash and cash equivalents	29,892,188	(50,390)	29,905,016
Cash and cash equivalents, beginning of period	12,828	53,346	
Cash and cash equivalents, end of period	$ 29,905,016	$ 2,956	$ 29,905,016
Supplemental disclosure of cash flow information:			
Conversion of notes payable and accrued interest into common stock	$ 12,274,427		$ 12,274,427
Conversion of Series A and accrued dividends into common stock	$ 5,968,808		$ 5,968,808

See accompanying notes to unaudited financial statements.

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RECRO PHARMA, INC.

(A Development-Stage Company)

Notes to Unaudited Financial Statements

(1) Background

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

(2) Development-Stage Risks and Liquidity

The Company has incurred losses and negative cash flows from operations since inception and has an accumulated deficit of $23.1 million as of March 31, 2014. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its products currently in development. Substantial additional financing will be needed by the Company to fund its operations and to commercially develop its product candidates.

The Company s future operations are highly dependent on a combination of factors, including (i) the timely and successful completion of additional financing discussed above; (ii) the Company s ability to complete revenue-generating partnerships with pharmaceutical companies; (iii) the success of its research and development; (iv) the development of competitive therapies by other biotechnology and pharmaceutical companies, and, ultimately; (v) regulatory approval and market acceptance of the Company s proposed future products.

(3) Summary of Significant Accounting Policies

(a) ***Basis of Presentation***

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

The accompanying unaudited interim financial statements should be read in conjunction with the annual audited financial statements and related notes as of and for the year ended December 31, 2013 included in the Company s S-1 registration statements.

(b) ***Use of Estimates***

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

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

Basic and diluted net loss per common share is determined by dividing net loss applicable to common shareholders by the weighted average common shares during the period. For all periods presented, the outstanding 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.

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RECRO PHARMA, INC.

(A Development-Stage Company)

Notes to Unaudited Financial Statements

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

	March 31, 2014	December 31, 2013
Redeemable convertible preferred stock		800,000
Shares issuable pursuant to redeemable convertible preferred stock accretion		376,008
Options outstanding	635,826	334,800
Convertible notes payable		1,984,533

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

The unaudited pro forma net loss per common share is computed using the weighted average number of common shares outstanding and assumes the conversion of all outstanding shares of the Company s Series A Redeemable Convertible Preferred Stock, or Series A Stock, including accrued dividends, into 934,743 weighted average shares of common stock and the conversion of the 8% Convertible Promissory Notes, or the Bridge Notes, including accrued interest, into 1,591,824 weighted average shares of common stock as if they had occurred at the later of the beginning of the period or date of issuance. Accordingly, net loss applicable to common shareholders is adjusted to remove all preferred stock accretion. The Company believes the unaudited pro forma net loss per common share provides material information to investors, as the conversion of the Company s Series A Stock to common stock, including accrued dividends, and the conversion of Bridge Notes, including accrued interest, occurred upon the closing of the Company s initial public offering, or the IPO, in March 2014, and the disclosure of pro forma net loss per common share provides an indication of net loss per common share that is comparable to what will be reported by the Company as a public company following the IPO.

	Three Months Ended March 31, 2014
Numerator:	
Net loss applicable to common shareholders	$ (6,416,386)
Effect of pro forma adjustments:	
Accretion of redeemable convertible preferred stock	1,270,057
Interest expense on convertible notes	4,272,919
Pro forma net loss applicable to common shareholders	$ (873,410)

Denominator:		
Weighted average common shares outstanding		1,749,911
Effect of pro forma adjustments:		
Conversion of redeemable convertible preferred stock		934,743
Conversion of convertible notes		1,591,824
Shares used in computing unaudited pro forma weighted average basic and diluted common shares outstanding		4,276,478
Unaudited pro forma basic and diluted net loss per common share	$	(0.20)

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RECRO PHARMA, INC.

(A Development-Stage Company)

Notes to Unaudited Financial Statements

(4) Fair Value of Financial Instruments

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

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

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

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

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

	Fair value measurements at reporting date using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
At March 31, 2014:			
Assets:			
Money market mutual funds (included in cash and cash equivalents)	$ 29,905,016		
At December 31, 2013:			
Assets:			
Money market mutual funds (included in cash and cash equivalents)	$ 12,828		

(5) Accrued Expenses

Accrued expenses consist of the following:

	March 31, 2014	December 31, 2013
Clinical trial and related costs	$ 86,331	$ 18,944
Professional and consulting fees	374,051	567,500
Payroll and related costs	332,024	3,088
	$ 792,406	$ 589,532

(6) Convertible Notes Payable

As of December 31, 2013, $9,400,584 of the Bridge Notes were outstanding plus $2,506,615 of accrued interest. In January 2014, the Company issued an additional $175,000 of Bridge Notes in the aggregate. The Bridge Notes bore interest at 8% per annum, compounded quarterly and were due on demand. During the three months ended March 31, 2014 and 2013, the Company recorded $192,227 and $203,170 of interest expense for the Bridge Notes. Upon the closing of the Company s IPO, $9,575,584 of Bridge Notes outstanding plus $2,698,842 of accrued interest were converted into 2,045,738 shares of common stock. After the IPO, there are no Bridge Notes outstanding.

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RECRO PHARMA, INC.

(A Development-Stage Company)

Notes to Unaudited Financial Statements

The Bridge Notes, including accrued interest, were converted upon consummation of the IPO at seventy-five percent (75%) of the initial offering price per share. The Company determined that the Bridge Notes contained a contingent beneficial conversion feature, or BCF. The contingent BCF existed at the date of issuance of the Bridge Notes, which allowed the holders to purchase equity at a 25% discount to the offering price. In accordance with the accounting guidance on convertible instruments, the contingent BCF of $4,080,690 was recognized as additional interest expense when the Bridge Notes, including accrued interest, were converted into shares of common stock.

(7) Capital Structure

(a) *Common Stock*

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

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

On March 12, 2014 the Company completed an IPO in which the Company sold 4,312,500 shares of common stock at $8.00 per share resulting in gross proceeds of $34,500,000. In connection with the offering, the Company paid $4,245,158 in underwriting discounts, commissions and offering costs resulting in net proceeds of $30,254,842. Also in connection with the IPO, all of the outstanding shares of the Company s Series A Stock, including accreted dividends, and Bridge Notes, including accrued interest, were converted into common stock.

(b) *Preferred Stock*

The Company is authorized to issue 10,000,000 shares of preferred stock, with a par value of $0.01 per share. As of March 31, 2014, no preferred stock was issued or outstanding.

(c) *Series A Redeemable Convertible Preferred Stock*

The Company previously had outstanding 2,000,000 shares of Series A Stock. Each share of Series A Stock was mandatorily convertible into 0.4 shares of common stock upon closing of the Company s IPO. The Series A Stock holders were entitled to receive cumulative dividends of 8%, compounded annually. As of December 31, 2013, there were $1,880,037 of cumulative undeclared Series A Stock dividends. Upon conversion of the Series A Stock into common stock, cumulative undeclared dividends were convertible into a number of shares of common stock equal to the total amount of cumulative dividends divided by $2.00 (the Series A Stock issuance price) multiplied by 0.4 (the

Series A Stock conversion ratio). Based on the IPO price of $8.00, the Company has recorded a non-cash deemed dividend of $1,181,286 upon closing of the IPO which represents the fair value of the common stock issued for such dividends in excess of the amounts previously recognized as accretion on the Series A Stock in the accompanying financial statements.

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

(d) ***Warrants***

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

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(A Development-Stage Company)

Notes to Unaudited Financial Statements

(8) Stock-Based Compensation

The Company established the 2008 Stock Option Plan, or the 2008 Plan, which allows for the granting of common stock awards, stock appreciation rights, and incentive and nonqualified stock options to purchase shares of the Company s common stock to designated employees, nonemployee directors, and consultants and advisors. As of March 31, 2014, no stock appreciation rights have been issued. Subsequent to adoption, the 2008 Plan was amended to increase the authorized number of shares available for grant to 444,000 shares of common stock. In October 2013, the Company established the 2013 Equity Incentive Plan, or the 2013 Plan, which allows for the grant of stock options, stock appreciation rights and stock awards for a total of 600,000 shares of common stock. Stock options are exercisable generally for a period of 10 years from the date of grant and generally vest over four years. As of March 31, 2014, 408,174 shares are available for future grants under the 2013 Plan.

The weighted average grant-date fair value of the options awarded to employees during the three months ended March 31, 2014 was $6.21. The fair value of the options was estimated on the date of grant using a Black-Scholes option pricing model with the following assumptions:

	2014
Expected life	6.0 years
Expected volatility	80.30%
Risk-free interest rate	2.73%
Expected dividend yield	

Stock-based compensation expense for the three months ended March 31, 2014 was $19,473. There was no stock based compensation expense for the three months ended March 31, 2013.

The following table summarizes stock option activity during the three months ended March 31, 2014:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life
Balance, December 31, 2013	334,800	$ 6.00	
Granted	301,026	$ 8.00	
Exercised			
Canceled			
Balance, March 31, 2014	635,826	$ 6.95	7.5 years

Options exercisable, March 31, 2014	334,800	$ 6.00	5 years

As of March 31, 2014, there was $1,849,898 of unrecognized compensation expense related to unvested options that are expected to vest and will be expensed over a weighted average period of 4.0 years.

(9) Related-Party Transactions

In July 2008, the Company entered into an agreement with Malvern Consulting Group, Inc., or MCG, a consulting company affiliated with the Company s President and Chief Executive Officer. A new agreement was signed in October 2013 under which MCG continues to provide consulting services to the Company, principally in the fields of clinical development, regulatory affairs, and quality assurance. MCG consulting fees for services are based on a flat fee for two consultants and on time worked at hourly rates for other consultants. The Company recorded $84,737 and $60,936 of research and development expenses for MCG consulting fees for the three months ended March 31, 2014 and 2013, respectively. As of March 31, 2014, $97,523 and $9,428 was recorded in accrued expenses and accounts payable, respectively, as amounts due to MCG. As of December 31, 2013, $18,944 and $130,331 was recorded in accrued expenses and accounts payable, respectively, as amounts due to MCG. In addition to fees for services, employees of MCG, certain of whom are related to the Company s President and Chief Executive Officer, received options to purchase 246,800 shares of common stock during 2009. The Company also

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RECRO PHARMA, INC.

(A Development-Stage Company)

Notes to Unaudited Financial Statements

paid $12,000 in rental fees to MCG for a month to month lease for lab space for the three months ended March 31, 2013 and $15,484 for lab space and offices for the three months ended March 31, 2014. The Company s Chief Executive Officer was affiliated with SCP Vitalife Venture Funds, or SCP. A representative of SCP serves as Chairman of the Company s board of directors and another representative of SCP is a member of the board of directors.

From its inception through March 31, 2014, the Company borrowed and has repaid $108,000 from the Company s Chief Executive Officer and $99,358 from MCG.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes appearing elsewhere. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled Risk Factors included elsewhere in this prospectus.

Overview

We are a clinical stage specialty pharmaceutical company developing non-opioid therapeutics for the treatment of pain, initially for acute pain following surgery. Our lead product, 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 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, or Food and Drug Administration, approved and commercial injectable drug sold by Hospira, Inc. in the United States under the brand name Precedex® and by Orion Corporation, or Orion, in Europe under the brand name Dexdor®. As Dex is not in the opioid class of drugs, we believe it will overcome many of the side effects associated with commonly prescribed opioid therapeutics, including addiction, constipation and respiratory distress while maintaining analgesic, or pain relieving, effect. If we are successful in obtaining approval of Dex-IN, our proprietary intranasal formulation of Dex, for acute pain, we may elect to pursue an additional approval for cancer breakthrough pain. Upon regulatory approval, our license with Orion and our ownership rights with respect to dosage forms for our product candidates will provide us worldwide commercial rights related to Dex, except in Europe, Turkey and the Commonwealth of Independent States, or 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 proceeds received from a private placement of convertible preferred stock, convertible notes and an initial public offering, or IPO. On March 12, 2014, we announced the closing of the IPO of 4,312,500 shares of common stock, including the full exercise of the underwriters over-allotment at a public offering price of $8.00 per share. Total gross proceeds from the offering were $34.5 million before deducting underwriting discounts and commissions and other offering expenses payable by us resulting in net proceeds of $30.3 million.

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. As of March 31, 2014, we have an accumulated deficit of $23.1 million. Substantially all of our operating losses resulted from costs incurred in connection with our development programs, including our non-clinical and formulation development activities, manufacturing and clinical trials.

We expect to incur increasing expenses over the next several years, 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, we plan to advance development of our proprietary formulations of Dex for additional indications and development of our second proprietary compound, Fadolmidine, or 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 expect that quarterly and annual operating results of operations will fluctuate for the foreseeable future due to several factors including the outcome and extent of clinical trial activities and timing and extent of research and development efforts.

As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future.

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, or CROs, investigative sites and consultants that conduct our clinical trials and a substantial portion of our preclinical studies;

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- 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 inception, 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 acute pain following surgery. 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 Malvern Consulting Group, or MCG, a related party, for a significant portion of our research and development activities. Costs related to facilities, depreciation, and support are not charged to specific programs.

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

- the duration of clinical trials varies substantially according to the type, complexity and novelty of the product candidate;
- the FDA and comparable agencies in foreign countries impose substantial requirements on the introduction of therapeutic pharmaceutical products, typically requiring lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures;
- data obtained from nonclinical and clinical activities at any step in the testing process may be adverse and lead to discontinuation or redirection of development activity. Data obtained from these activities also are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval;

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

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

the risks disclosed in Part II, Item 1A entitled Risk Factors of this Form 10-Q.

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.

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

Interest Expense

Interest expense consists of accrued interest on our Bridge Notes issued to our investors, SCP Vitalife Partners II, L.P. and SCP Vitalife Partners (Israel) II, L.P., or collectively SCP Vitalife. Upon the closing of the IPO, these Bridge Notes, including accrued interest, were converted into shares of common stock. Since the conversion price of our Bridge Notes allowed the note holders to convert at 75% of the initial offering price per share in the IPO, we recorded a non-cash interest charge of approximately $4.1 million upon the closing of the IPO.

Net Operating Losses and Tax Carryforwards

As of December 31, 2013, we had approximately $9.1 million of federal net operating loss carryforwards. We also had federal and state research and development tax credit carryforwards of $360,000 available to offset future taxable income. U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. These federal and state net operating loss and federal and state tax credit carryforwards will begin to expire at various dates beginning in 2028, if not utilized. As a result, we may not be able to take full advantage of these carryforwards for federal and state tax purposes.

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

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Results of Operations

Comparison of the Three Months Ended March 31, 2014 and March 31, 2013

	Three Months Ended March 31,		Increase (Decrease)	
	2014	2013	$	%
	(amounts in thousands)			
Operating expenses:				
Research and development	$ 227	$ 114	113	99%
General and administrative	647	92	555	603%
Total operating expenses	874	206		
Other income (expense):				
Interest expense	(4,273)	(203)	4,070	2005%
Net loss	$ (5,147)	$ (409)		

Research and Development. Our research and development expenses were $227,000 and $114,000 for the three months ended March 31, 2014 and 2013, respectively. The increase was due to the commencement of management salaries, bonuses and benefits upon the closing of the IPO, and the planning for our Phase IIb trial.

General and Administrative. Our general and administrative expenses were $647,000 and $92,000 for the three months ended March 31, 2014 and 2013, respectively. This increase of $555,000 was mainly due to the commencement of management salaries, bonuses and benefits upon the closing of the IPO; increased consulting, legal and accounting fees due to costs associated with being a public company; and increased directors and officers insurance.

Interest Expense. Interest expense on our Bridge Notes was approximately $192,000 and $203,000 for the three months ended March 31, 2014 and 2013, respectively. Since the conversion price of our Bridge Notes allowed the note holders to convert at 75% of the initial offering price per share in the IPO, we recorded a non-cash interest charge of approximately $4.1 million upon the closing of the IPO.

Liquidity and Capital Resources

As of March 31, 2014 and December 31, 2013, we had $29,905,000 and $13,000, respectively, in cash and cash equivalents. We expect that the net proceeds from the IPO, together with interest, will be sufficient to fund our current operations through the end of 2015. Since inception through March 31, 2014, we have financed our product development, operations and capital expenditures primarily from private sales of $4.0 million of our Series A Stock, $9.6 million of our Bridge Notes and $30.3 million from the IPO.

We will need to raise additional funds in order to continue our clinical trials beyond clinical trials of Dex-IN for acute pain following surgery, to commercialize any product candidates or technologies and to enhance our sales and marketing efforts for additional products we may acquire. Insufficient funds may cause us to delay, reduce the scope of or eliminate one or more of our development, commercialization or expansion activities. Our future capital needs

and the adequacy of our available funds will depend on many factors, including the cost of clinical studies and other actions needed to obtain regulatory approval of our products in development. We do not currently contemplate any acquisitions. If additional funds are required, we may raise such funds through public or private sales of equity or debt securities or from bank or other loans or through strategic research and development, licensing and/or marketing arrangements from time to time. Financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could materially adversely impact our growth plans and our financial condition or results of operations. Additional equity financing, if available, may be dilutive to the holders of our common stock and may involve significant cash payment obligations and covenants that restrict our ability to operate our business.

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Sources and Uses of Cash

Cash used in operations was $816,000 and $50,000 for the three months ended March 31, 2014 and 2013, respectively, which represents our operating losses less our non-cash interest expense and beneficial conversion charge taken on our Bridge Notes upon the conversion of such Bridge Notes, including accrued interest, into common stock.

Cash provided by financing activities was $30.7 million for the three months ended March 31, 2014 as a result of successfully raising net proceeds of $30.3 million from the IPO, and the issuance of $175,000 of Bridge Notes to SCP Vitalife. Cash provided by financing activities was zero for the three months ended March 31, 2013.

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 New Drug Application, or 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 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 investigational new drug application, or IND, or an NDA) are successfully accomplished, as well meeting certain sales thresholds.

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We may also out-license products, for which we hold the rights, to other companies for commercialization in other territories, or at times, for other uses. If this happens, we would expect to be paid:

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

Orion

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

We will pay milestone payments to Orion of up to 20.5 million Euros ($28.2 million as of March 31, 2014) after regulatory approval of Dex dosage forms and upon achieving certain sales milestones. We will also pay Orion royalty payments on net sales of our products, which royalty payments will be paid at varying percentages.

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

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

We will pay milestone payments to Orion of up to 12.2 million Euros ($16.8 million as of March 31, 2014) based on regulatory filings and approval and on commercialized net sales levels. We will also pay Orion royalty payments on net sales of our products, which royalty payments will be paid at varying percentages.

Leases

We lease lab and office 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

The Company s significant accounting policies, which include management s best estimates and judgments, are included in Note 3 to the financial statements for the year ended December 31, 2013 included in the Company s registration statement on Form S-1. There have been no significant changes in the Company s critical accounting policies since December 31, 2013.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business. These market risks are principally limited to interest rate fluctuations. At March 31, 2014, we had approximately $29.9 million invested in money market instruments. We believe our policy of investing in highly rated securities, whose liquidities are, at March 31, 2014, all less than 90 days minimizes such risks. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10.0% change in interest rates would not have a material effect on the fair market value of our portfolio. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our investment portfolio. We do not enter into investments for trading or speculative purposes.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

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

Changes in Internal Control over Financial Reporting

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

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

None.

Item 1A. Risk Factors

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

We are a development stage company with limited operating history. To date, we have focused primarily on developing our lead product candidate, Dex-IN. In addition, we have other product candidates, Dex-SL and Fado, in development. We have incurred significant net losses in each year since our inception in November 2007, including net losses of approximately $409,000 for the three months ended March 31, 2013 and $5.1 million for the three months ended March 31, 2014. As of March 31, 2014, we had an accumulated deficit of $23.1 million.

We have devoted most of our financial resources to research and development, including our non-clinical and formulation development activities, manufacturing and clinical trials. To date, we have financed our operations exclusively through the sale of debt and equity securities. The size of our future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenues. To date, none of our product candidates have been commercialized, and if our product candidates are not successfully developed or commercialized, or if revenues are insufficient following marketing approval we will not achieve profitability and our business may fail. Even if we successfully obtain regulatory approval to market our product candidates in the United States, our revenues are also dependent upon the size of the markets outside of the United States, as well as our ability to obtain market approval and achieve commercial success.

We expect to continue to incur substantial and increased expenses as we expand our research and development activities and advance our clinical programs. We also expect an increase in our expenses associated with creating additional infrastructure to support operations as a public company. As a result of the foregoing, we expect to continue to incur significant and increasing losses and negative cash flows from operations for the foreseeable future.

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

Our ability to generate revenue and achieve profitability depends on our ability, alone or with collaborators, to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize our product candidates. We do not anticipate generating revenues from sales of our product candidates for the foreseeable future, if ever. Our ability to generate future revenues from product sales depends heavily on our success in:

- completing the clinical development of Dex-IN, initially for the treatment of acute pain following surgery;
- obtaining regulatory approval for Dex-IN for the treatment of acute pain;

launching and commercializing Dex-IN through either building a specialty sales force or collaborating with third parties;

obtaining and maintaining patent protection; and

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

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

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

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

We were incorporated in 2007. Since inception, our operations have been primarily limited to developing our technology and undertaking non-clinical studies and clinical trials for our product candidates. We have not yet obtained regulatory approval for any of our product candidates. Consequently, we have a very limited amount of information to use in evaluating the potential future success or viability of our business and any such evaluation of our business and prospects may not be accurate.

Our operating results may fluctuate significantly.

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

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

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

our dependency on third-parties to supply and manufacture our product candidates and delivery devices;

competition from existing products or new products that may emerge;

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

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.

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

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

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We expect our research and development expenses to substantially increase in connection with our ongoing activities, particularly as we advance our clinical programs. As of March 31, 2014, we had positive working capital of approximately $29.4 million. 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.

On March 12, 2014, we closed the IPO of 4,312,500 shares of common stock, including the full exercise of the underwriters over-allotment at a public offering price of $8.00 per share. Total gross proceeds from the offering were $34.5 million before deducting underwriting discounts and commissions and other offering expenses payable by us, resulting in net proceeds of $30.3 million. We expect our existing cash and cash equivalents, together with interest, will be sufficient to fund our current operations through the end 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 an NDA for Dex-IN or otherwise enter into collaborations to launch and commercialize Dex-IN after receipt of FDA approval, if received, and, if we choose, to initiate clinical trials for additional uses of Dex-IN or for our other product candidates, including Fado. In any event, we will require additional capital to obtain regulatory approval for, and to commercialize, our product candidates.

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

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

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

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.

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Risks Related to Clinical Development and Regulatory Approval

We depend substantially on the success of our product candidate, Dex-IN, which is still under clinical development, and which may not obtain regulatory approval or be successfully commercialized.

We have not marketed, distributed or sold any products. The success of our business depends primarily upon our ability to develop and commercialize Dex-IN for use in treating acute pain following surgery. We have completed two 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 second quarter of 2014. Assuming completion of a successful clinical trial, we expect to complete two Phase III pivotal clinical trials with Dex-IN in acute pain following surgery. We intend to use these trials as a basis to submit an NDA for Dex-IN for acute pain. There is no guarantee that our clinical trials will be completed, or if completed, will be successful. Any delay in obtaining, or inability to obtain, regulatory approval would prevent us from commercializing Dex-IN, generating revenues and achieving profitability. If this were to occur, we may be forced to abandon our development efforts for Dex-IN, which would have a material adverse effect on our business and could potentially cause us to cease operations. Because of the license from Orion, we expect to cross-reference the approved NDA for Dex in our 505(b)(2) NDA for Dex-IN. If the FDA disagrees with this strategy and determines we cannot pursue this pathway, we could incur significant time, resources, and delay, particularly if the FDA requires more clinical data than we expect.

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

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

- successfully complete our clinical trials;
- receive marketing approvals from the FDA and similar foreign regulatory authorities;
- obtain and maintain patent protection;
- produce, through a validated process, sufficiently large quantities of our product candidates to permit successful commercialization;
- establish commercial manufacturing arrangements with third-party manufacturers;
- build and maintain strong U.S.-based sales, distribution and marketing capabilities sufficient to launch commercial sales of our product candidates or build collaborations with third parties for the commercialization of our product candidates within the United States;

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

secure acceptance of our product candidates by physicians, health care 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.

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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 acute pain following surgery 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 second quarter 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;
- 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 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;

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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.

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

regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution in a form of a modified REMS;

regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;

we may be required to change the way the product is administered or conduct additional clinical studies;

we could be sued and held liable for harm caused to patients; and/or

our reputation may suffer.

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

Additional time may be required to obtain regulatory approval for Dex-IN, 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.

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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 cGMP and adherence to commitments made in the NDA. If we, or a regulatory authority, discover previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market, suspension of manufacturing, or other FDA action.

If we fail to comply with applicable regulatory requirements following approval of our product candidate, a regulatory authority may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or supplements to an NDA submitted by us;
- seize our product candidate; and/or

refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity in addition to the aforementioned potential regulatory actions. The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenues.

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.

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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 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;

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a failure to comply with cGMP and similar foreign standards;

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

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

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

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

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

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

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

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

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

Orion is currently our sole source of the active pharmaceutical ingredient, or API, for Dex. Although the API supply agreement that we have with Orion allows us to qualify and purchase API from an alternative supplier in certain circumstances, it would be time-consuming and expensive for us to do so, and there can be no assurance that an alternative supplier could be found. Currently, Orion is the only established supplier of the Dex API.

We expect that the drug product (dosage form that is the final product) will be manufactured by a 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.

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

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

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

As we scale up manufacturing of our product candidates and conduct required stability testing, product-packaging, equipment and process-related issues may require refinement or resolution in order to proceed with our planned clinical trials and to obtain regulatory approval for commercial marketing. We may identify 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 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.

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Our contractors are not our employees, and we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and nonclinical programs. These contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies, or other drug development activities that could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by our contractors, which may allow our potential competitors to access our proprietary technology. If our contractors do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize Dex-IN, or our other product candidates. As a result, our financial results and the commercial prospects for Dex-IN and any future product candidates that we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

Risks Related to Commercialization of Our Product Candidates

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

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

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

our ability to obtain and maintain sufficient third party coverage or reimbursement; and

the willingness of patients to pay out-of-pocket in the absence of third party coverage.

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

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

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

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

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

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

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

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

In the post-operative pain relief setting, we believe Dex-IN will be prescribed for moderate to severe pain, competing mostly with opioids such as morphine, oxycodone, hydrocodone and fentanyl. There are a number of pharmaceutical companies that currently market therapeutics in the pain relief area, including Johnson & Johnson, Purdue Pharma L.P., Endo Pharmaceuticals Inc., Mallinckrodt plc. and Pacira Pharmaceuticals, Inc. Purdue and Endo are the primary competitors in the manufacture, marketing and commercialization of opioid therapeutics. Mallinckrodt commercializes an injectable formulation of acetaminophen. Pacira commercializes an intraoperative formulation of bupivacaine, a sodium channel blocker. As far as potential competitors in development, we are not aware of any other alpha-2 agonists compounds in development for acute pain following surgery. However, companies such as Adynxx, Inc., AcelRx Pharmaceuticals, Inc., 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 Depomed, Inc. All of these potential competitors have various formulations of fentanyl, a fast-acting opioid. We are not aware of any non-fentanyl related therapeutics in development for the treatment of cancer breakthrough pain.

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

Many of our potential competitors have substantially greater:

- capital resources;

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

drug development, clinical trial and regulatory resources and experience;

sales and marketing resources and experience;

manufacturing and distribution resources and experience;

name recognition; and

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

Accordingly, our competitors may be more successful than we are in obtaining FDA approval for product candidates in the pain management and relief space and achieving widespread market acceptance of these products. Our competitors drugs or drug delivery systems may be more effective, have fewer AEs, be less expensive to develop and manufacture, or be more effectively marketed and sold than any product candidate we may commercialize. This may render our product candidates obsolete or non-competitive before we can recover our losses. We anticipate that we will face intense and increasing competition as new drugs enter the market and additional technologies become available in the pain management and relief space. These entities may also establish collaborative or licensing relationships with our competitors, which may adversely affect our competitive position. Finally, the development of different methods for the treatment of acute pain following surgery or breakthrough pain could render Dex-IN non-competitive or obsolete. These and other risks may materially adversely affect our ability to attain or sustain profitable operations.

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

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

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

The availability of numerous generic pain medications may substantially reduce the likelihood of reimbursement for Dex-IN. We expect to experience pricing pressures in connection with the sale of Dex-IN and any other products that we develop, due to the trend toward managed healthcare and the increasing influence of health maintenance organizations. If we fail to successfully secure and maintain reimbursement coverage for our products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our products and our

business will be harmed.

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

If our product candidates are approved for commercialization, we intend to enter into agreements with third parties to market Dex-IN or other product candidates outside the United States. We expect that we will be subject to additional risks related to entering into international business relationships, including:

different regulatory requirements for drug approvals in foreign countries;

reduced protection for intellectual property rights;

unexpected changes in tariffs, trade barriers and regulatory requirements;

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

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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;

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.

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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 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

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Reform Law until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Risks Related to Our Business Operations and Industry

Our future success depends on our ability to retain and have the full attention of our key executives as well as to attract, retain and motivate other qualified personnel.

We are highly dependent on the principal members of our executive team and, in particular, the services of Gerri A. Henwood, our President and Chief Executive Officer, the loss of whose services would adversely impact the achievement of our objectives. We have entered into employment agreements with each of our executive officers. We expect each of our executive officers to spend a small portion of their time engaged in the provision of services to other companies, including companies that are engaged in the development and commercialization of other pharmaceutical products. Recruiting and retaining qualified employees for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. In addition, failure to succeed in clinical studies may make it more challenging to recruit and retain qualified personnel. The inability to recruit or loss of the services of any executive or key employee could impede the progress of our research, development and commercialization objectives.

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

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

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

Our President and Chief Executive Officer, Ms. Henwood, owns a majority of the stock of MCG. Some of our other employees, including Randall Mack, Diane Myers and Donna Nichols, are also employees of MCG. Such employees,

including Ms. Henwood, will continue to devote a small portion of their time to MCG.

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

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 lab and 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.

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

Our Chief Financial Officer, Charles Garner continues to devote a small portion of his time to his consulting business. In addition, prior to the IPO, Mr. Garner had never served as a Chief Financial Officer of a public company.

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

In addition, prior to the IPO, Mr. Garner had 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.

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We will incur increased costs and demands upon our management as a result of complying with the laws and regulations affecting public companies, which could harm our operating results.

We are a public company and, as such, we have begun and will continue to incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. We will incur costs associated with current corporate governance requirements, including certain of the requirements under Section 404 and other provisions of the Sarbanes-Oxley Act of 2002, as well as rules implemented by the SEC, and the NASDAQ Capital Market, the stock exchange on which our common stock is listed . If we fail to comply with current corporate governance requirements, our business may be negatively affected, including by having our common stock delisted from the NASDAQ Capital Market.

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 March 31, 2014, 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 are licensed from Orion. The composition of matter patent for Dex expired in January 2014, and the composition of matter patent for Fado will expire in October 2016. If no additional patent protection is obtained, these patent expirations will impact our ability to prevent third parties from marketing generic equivalents.

The patent position of biotechnology and pharmaceutical companies, including us, generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after the first filing, or in some case at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the

patent laws in the United States and other countries may diminish the value of patents or narrow the scope of patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. On September 16, 2011, the Leahy Smith America Invents Act, or the Leahy Smith Act, was signed into law. The Leahy Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent Office recently developed new regulations and procedures to govern administration of the Leahy Smith Act, and many of the substantive changes to patent law associated with the Leahy Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy Smith Act will have on the operation of our business. However, the Leahy Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patent, all of which could have a material adverse effect on our business and financial condition.

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

The Company has an exclusive license from Orion for the development and, subsequent to approval, the commercialization, of Dex-IN for use in the treatment of pain in humans in any dosage form for transdermal, transmucosal (including sublingual), topical, enteral or pulmonary (inhalational) delivery (collectively, referred to as the Licensed Dosage Forms), but specifically excluding delivery vehicles for administration by injection or infusion, in the United States, Canada and all other countries and territories worldwide other than Europe, the CIS, Turkey and their respective territories. Orion retains the rights to develop and commercialize Dex for all uses and indications other than pain in humans and for use in combination products in that field, and we have granted Orion a license to use our clinical trial data, patents and know-how for such purpose; provided, however that Orion cannot undertake development activities in the United States, Australia or South Africa with respect to treatment of pain in humans in any Licensed Dosage Form until four years after our first product is granted regulatory approval in the United States. It is possible, therefore, that Orion may develop and commercialize competing products in the territories retained by it and/or combination products for Dex in the Company-licensed territory. We are unaware of any such programs at Orion at this time. We have a right of first refusal to commercialize any such product developed by Orion in all territories other than Europe, the CIS and Turkey. However, there is no guarantee that we would have the resources to exercise this right or, if we did, that we would be able to reach mutually agreeable terms with Orion.

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

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

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

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

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

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

In addition, because patent applications can take years to issue and are often afforded confidentiality for some period of time there may currently be pending applications, unknown to us, that later result in issued patents that could cover one or more of our products.

It is possible that we may in the future receive, particularly as a public company, communications from competitors and other companies alleging that we may be infringing their patents, trade secrets or other intellectual property rights, offering licenses to such intellectual property or threatening litigation. In addition to patent infringement claims, third parties may assert copyright, trademark or other proprietary rights against us. We may need to expend considerable resources to counter such claims and may not be able to be successful in our defense. Our business may suffer if a finding of infringement is established.

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Generic competitors can challenge the U.S. patents protecting our product candidates by filing an Abbreviated New Drug Application, or ANDA, or an NDA for a generic or a modified version of our product candidates and negatively affect our competitive position.

Separate and apart from the protection provided under the U.S. patent laws, drug candidates may be subject to the provisions of the Hatch-Waxman Act, which may provide drug candidates with either a three-year or five-year period of marketing exclusivity following receipt of FDA approval. The Hatch-Waxman Act prohibits the FDA from accepting the filing of an ANDA application (for a generic product) or a 505(b)(2) NDA (for a modified version of the product) for three years for active drug ingredients previously approved by the FDA or for five years for active drug ingredients not previously approved by the FDA.

There is an exception, however, for newly approved molecules that allows competitors to challenge a patent beginning four years into the five year exclusivity period by alleging that one or more of the patents listed in the FDA s list of approved drug products are invalid, unenforceable and/or not infringed and submitting an ANDA for a generic version of a drug candidate. This patent challenge is commonly known as a Paragraph IV certification. Within the past several years, the generic industry has aggressively pursued approvals of generic versions of innovator drugs at the earliest possible point in time.

If a generic company is able to successfully challenge the patents covering drug candidates by obtaining FDA approval for an ANDA, the generic company may choose to launch a generic version of a drug candidate. Any launch of a generic version of our drug candidates prior to the expiration of patent protection, will have a material adverse effect on our revenues and our results of operations.

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

The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States. The pharmaceutical patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents that may be issued from the applications we currently or may in the future own or license from third parties. Further, if any patent license we obtain is deemed invalid and/or unenforceable, it could impact our ability to commercialize or partner our technology.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- we were the first to make the inventions covered by each of our pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;

an individual or party will not challenge inventorship, that if successful, could have an adverse effect on our business;

any patents issued to us or our collaborators will provide a basis for commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties; or

the patents of others will not have an adverse effect on our business.

If we do not adequately protect our proprietary rights, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could materially harm our business, negatively affect our position in the marketplace, limit our ability to commercialize our product candidates and delay or render impossible our achievement of profitability.

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We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

In the future, we may rely on trade secrets to protect our proprietary know-how and technological advances, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection could enable competitors to use our proprietary information to develop products that compete with our products or cause additional, material adverse effects upon our competitive business position.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the United States Patent and Trademark Office and various foreign governmental patent agencies in several stages over the lifetime of the patents and/or applications.

We have systems in place to remind us to pay periodic maintenance fees, renewal fees, annuity fees and various other patent and application fees, and we employ an outside law firm to pay these fees. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ an outside law firm and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If this occurs, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property.

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

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

Risks Relating to Our Securities

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

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

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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 limited research coverage by securities and industry analysts. If additional securities or industry analysts do not commence coverage of our company, the trading price for our stock could be negatively impacted. In the event we obtain securities or industry analyst coverage, if one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

We are subject to Sarbanes-Oxley, Dodd-Frank and the reporting requirements of federal securities laws, compliance with which can be expensive and time-consuming.

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

We have never paid dividends on our common stock and do not intend to do so for the foreseeable future.

We have never paid dividends on our common stock and we do not anticipate that we will pay any dividends on our common stock for the foreseeable future. Accordingly, any return on an investment in our common stock will be realized, if at all, only when shareholders sell their shares. In addition, our failure to pay dividends may make our stock less attractive to investors, adversely impacting trading volume and price.

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

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

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

The concentration of our capital stock ownership with our directors and their affiliated entities and our executive officers will limit shareholders abilities to influence certain corporate matters.

Our directors and their affiliated entities, and our executive officers will beneficially own, in the aggregate, approximately 42.6% of our outstanding common stock as of March 31, 2014. As a result, these shareholders are collectively able to influence matters requiring approval of our shareholders, including the election of directors and

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

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The price of our common stock may fluctuate substantially.

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

- plans for, progress in and results from clinical trials of our product candidates generally;
- the commercial performance of any of our product candidates that receive marketing approval;
- FDA, state or international regulatory actions, including actions on regulatory applications for any of our product candidates;
- announcements of new products, services or technologies, commercial relationships, acquisitions or other events by us or our competitors;
- market conditions in the pharmaceutical and biotechnology sectors;
- fluctuations in stock market prices and trading volumes of similar companies;
- variations in our quarterly operating results;
- changes in accounting principles;
- litigation or public concern about the safety of our potential products;
- deviations in our operating results from the estimates of securities analysts;
- additions or departures of key personnel;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant shareholders;
- any third-party coverage and reimbursement policies for our product candidates; and

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

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

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

We could be subject to securities class action litigation.

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

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The recently enacted JOBS Act will allow us to postpone the date by which we must comply with certain laws and regulations and to reduce the amount of information provided in reports filed with the SEC.

We cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are and we will remain an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, until the earliest to occur of (1) the last day of the fiscal year during which our total annual gross revenues equal or exceed $1 billion (subject to adjustment for inflation), (2) the last day of the fiscal year following the fifth anniversary of our 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 we will not be required to:

- have an auditor report on our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act;
- comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor s report providing additional information about the audit and the financial statements (i.e., an auditor discussion and analysis);
- submit certain executive compensation matters to shareholder non-binding advisory votes;
- submit for shareholder approval golden parachute payments not previously approved; and
- disclose certain executive compensation related items such as the correlation between executive compensation and financial performance and comparisons of the Chief Executive Officer s compensation to median employee compensation, when such disclosure requirements are adopted.

In addition, Section 102(b)(1) of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the JOBS Act. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

We cannot predict if investors will find our common stock less attractive because we may rely on some of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. If we avail ourselves of certain exemptions from various reporting requirements, our reduced disclosure may make it more difficult for investors and securities analysts to evaluate us and may result in less investor confidence.

Sales of a substantial number of shares of our common stock in the public market by our existing 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 that restrict the shareholders ability to transfer shares of our common stock, options, warrants or our other securities before September 2, 2014, which is 180 days after the closing of the IPO. The lock-up agreements limit the number of shares of our common stock that may be sold. Subject to certain limitations, including sales volume limitations with respect to shares held by our affiliates, substantially all of our outstanding shares will become eligible for sale on September 2, 2014. 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.

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Certain holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Issuance of Securities

In connection with the closing of the Company s IPO on March 12, 2014, we issued to Aegis Capital Corporation, the representative of the underwriters for the offering, warrants to purchase 150,000 shares of our common stock. The warrants are exercisable for cash at a price of $12.00 per share. 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.

Upon the closing of the IPO on March 12, 2014, all shares of our then-outstanding Series A Redeemable Convertible Preferred Stock and all of our then-outstanding 8% Convertible Promissory Notes automatically converted into an aggregate of 3,239,500 shares of common stock. The issuance qualified for exemption under Section 3(a) (9) of the Securities Act.

In March 2014, we issued options exercisable for an aggregate of 301,026 shares of common stock at an exercise price of $8.00 to our executive officers and directors.

Unless otherwise stated, the sales of the above securities were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(a) (2) of the Securities Act (or Regulation D promulgated thereunder), or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or pursuant to benefit plans and contracts relating to compensation as provided under Rule 701.

Use of Proceeds

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

As of March 31, 2014, we have used approximately $0.5 million of the net proceeds for working capital and other general corporate purposes, a portion of which was paid to MCG, an affiliate of the Company. We believe that the net proceeds from the IPO and our existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our operations through the end of 2015, although there can be no assurance in that regard. No offering costs were paid directly or indirectly to any of our directors or officers or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

We cannot predict with certainty all of the particular uses for our current funds, or the amounts that we will actually spend on the uses described in our registration statement on Form S-1. The amounts and timing of our actual use of these funds will vary depending on numerous factors, including our ability to obtain additional financing, the relative

success and cost of our research, preclinical and clinical development programs. As a result, our management will have broad discretion in the application of these funds, and investors will be relying on our judgment regarding the application of the net proceeds of the offering.

Item 3. Defaults Upon Senior Securities.

None.

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Item 4. Mine and Safety Disclosures.
None.

Item 5. Other Information.
None.

Item 6. Exhibits.
(a) Exhibits required by Item 601 of Regulation S-K.

Exhibit Number	Description
31.1	Rule 13a-14(a)/15d-14(a) certification of Principal Executive Officer.
31.2	Rule 13a-14(a)/15d-14(a) certification of Principal Financial Officer.
31.3	Rule 13a-14(a)/15d-14(a) certification of Principal Accounting Officer.
32.1	Section 1350 certification, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Taxonomy Extension Definition Linkbase Document
101.LAB	Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

RECRO PHARMA, INC.

Date: May 12, 2014

By: /s/ Gerri A. Henwood
Gerri A. Henwood
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 12, 2014

By: /s/ Charles Garner
Charles Garner
Chief Financial Officer
(Principal Financial Officer)

Date: May 12, 2014

By: /s/ Donna Nichols
Donna Nichols
Chief Accounting Officer
(Principal Accounting Officer)

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