Recro Pharma, Inc.
Form 10-Q
August 14, 2015
Table of Contents

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: June 30, 2015

¨ **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) 395-2470

(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 x No ¨

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

Indicate by check mark 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 August 14, 2015, there were 9,221,374 shares of common stock, par value $0.01 per share, outstanding.

Table of Contents

TABLE OF CONTENTS

Index

PART I. FINANCIAL INFORMATION	3
Item 1. Financial Statements	3
Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations	15
Item 3. Quantitative and Qualitative Disclosures About Market Risk	24
Item 4. Controls and Procedures	24
PART II. OTHER INFORMATION	24
Item 1. Legal Proceedings	24
Item 1A. Risk Factors	25
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	31
Item 3. Defaults Upon Senior Securities	31
Item 4. Mine Safety Disclosures	31
Item 5. Other Information	31
Item 6. Exhibits	31
SIGNATURES	33

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

(unaudited)

(amounts in thousands, except share and per share data)	June 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 15,687	$ 19,682
Accounts receivable	15,024	
Other receivables	22	90
Inventory	9,610	
Prepaid expenses	1,478	602
Deferred equity costs	589	
Total current assets	42,410	20,374
Property, plant and equipment, net	39,352	
Intangible assets, net	41,308	
Goodwill	6,744	
Total assets	$ 129,814	$ 20,374
Liabilities and Shareholders Equity		
Current liabilities:		
Accounts payable	$ 767	$ 871
Accrued expenses	5,888	575
Current portion of long-term debt	9,123	
Total current liabilities	15,778	1,446
Long-term debt	36,495	
Warrants	6,213	
Contingent consideration	56,600	
Total liabilities	115,086	1,446
Shareholders equity		
Preferred stock, $0.01 par value. Authorized, 10,000,000 shares; none issued and outstanding		

Common stock, $0.01 par value. Authorized, 50,000,000 shares, issued and outstanding, 7,842,063 shares at June 30, 2015 and 7,707,600 shares at December 31, 2014		78		77
Additional paid-in capital		54,196		52,947
Accumulated deficit		(39,546)		(34,096)
Total shareholders equity		14,728		18,928
Total liabilities and shareholders equity	$	129,814	$	20,374

See accompanying notes to unaudited consolidated financial statements.

Table of Contents

RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Operations

(unaudited)

(amounts in thousands, except share and per share data)	Three Months Ended June 30, 2015	Three Months Ended June 30, 2014	Six Months Ended June 30, 2015	Six Months Ended June 30, 2014
Revenue:				
Manufacturing, royalty and profit sharing revenue	$ 16,704	$	$ 16,704	$
Research and development revenue	1,956		1,956	
Total revenue	18,660		18,660	
Operating expenses:				
Cost of sales (excluding amortization of intangible assets)	9,395		9,395	
Research and development	2,821	1,837	4,575	2,064
General and administrative	2,597	959	4,986	1,606
Amortization of intangible assets	592		592	
Change in warrant valuation	882		882	
Change in contingent consideration valuation	2,000		2,000	
Total operating expenses	18,287	2,796	22,430	3,670
Operating income (loss)	373	(2,796)	(3,770)	(3,670)
Other income (expense):				
Interest income	4	2	8	3
Interest expense	(1,688)		(1,688)	(4,273)
Net loss	(1,311)	(2,794)	(5,450)	(7,940)
Accretion of redeemable convertible preferred stock and deemed dividend				(1,270)
Net loss applicable to common shareholders	$ (1,311)	$ (2,794)	$ (5,450)	$ (9,210)
Basic and diluted net loss per common share	$ (0.17)	$ (0.36)	$ (0.70)	$ (1.94)
Weighted average basic and diluted common shares outstanding	7,829,536	7,707,600	7,799,282	4,745,213

See accompanying notes to unaudited consolidated financial statements.

Table of Contents

RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statement of Shareholders Equity

Six Months Ended June 30, 2015

(unaudited)

(amounts in thousands, except share and per share data)	Common stock Shares	Amount	Additional paid-in capital	Accumulated deficit	Total
Balance, December 31, 2014	7,707,600	$ 77	$ 52,947	$ (34,096)	$ 18,928
Shares issued in equity financing facility	96,463	1	284		285
Stock option exercise	38,000		228		228
Stock-based compensation expense			737		737
Net loss				(5,450)	(5,450)
Balance, June 30, 2015	7,842,063	$ 78	$ 54,196	$ (39,546)	$ 14,728

See accompanying notes to unaudited consolidated financial statements.

Table of Contents

RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

(unaudited)

(amounts in thousands, except share and per share data)	Six Months Ended June 30, 2015	2014
Cash flows from operating activities:		
Net loss	$ (5,450)	$ (7,940)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Stock-based compensation	737	175
Depreciation expense	1,269	
Noncash interest expense	211	4,273
Amortization	592	
Change in warrant valuation	882	
Change in contingent consideration valuation	2,000	
Changes in operating assets and liabilities, net of effect of acquisition:		
Inventory	345	
Prepaid expenses	(496)	(254)
Accounts receivables and other receivables	(2,436)	38
Accounts payable and accrued expenses	4,046	988
Net cash provided by (used in) operating activities	1,700	(2,720)
Cash flows from investing activities:		
Acquisition of Gainesville, net of cash acquired	(52,690)	
Purchase of property and equipment	(1,197)	
Net cash used in investing activities	(53,887)	
Cash flows from financing activities:		
Proceeds from initial public offering		30,364
Proceeds from long-term debt	50,000	175
Payment of debt issuance costs	(1,732)	
Payment of deferred equity costs	(304)	
Proceeds from option exercise	228	
Net cash provided by financing activities	48,192	30,539
Net increase (decrease) in cash and cash equivalents	(3,995)	27,819
Cash and cash equivalents, beginning of period	19,682	13
Cash and cash equivalents, end of period	$ 15,687	$ 27,832

Supplemental disclosure of cash flow information:		
Common stock issued in connection with equity facility	$ 285	
Conversion of notes payable and accrued interest into common stock		$ 12,274
Conversion of Series A and accrued dividends into common stock		$ 5,969

See accompanying notes to unaudited consolidated financial statements.

Table of Contents

RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements

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

(1) Background

Recro Pharma, Inc., or the Company, was incorporated in Pennsylvania on November 15, 2007 (inception). The Company is a revenue generating specialty pharmaceutical company developing multiple non-opioid therapeutics for the treatment of acute post operative pain. On April 10, 2015, the Company acquired from Alkermes plc, or Alkermes, worldwide rights to IV/IM meloxicam, a proprietary, Phase III-ready, long-acting preferential COX-2 inhibitor for the treatment of moderate to severe acute pain, as well as a contract manufacturing facility, royalty and formulation business in Gainesville, Georgia operating through the Company s subsidiary, Recro Gainesville, LLC or Gainesville. The acquisition is referred to herein as the Gainesville Transaction. Gainesville develops and manufactures innovative pharmaceutical products that deliver clinically meaningful benefits to patients, using its proprietary delivery technologies in collaboration with pharmaceutical companies.

(2) Development-Stage Risks and Liquidity

The Company has incurred losses since inception and has an accumulated deficit of $39,546 as of June 30, 2015. 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 revenue generated by its contract manufacturing business; (iii) the Company s ability to complete revenue-generating partnerships with pharmaceutical companies; (iv) the success of its research and development; (v) the development of competitive therapies by other biotechnology and pharmaceutical companies, and, ultimately; (vi) regulatory approval and commercial success of the Company s proposed future products.

(3) Summary of Significant Accounting Principles

(a) Basis of Presentation and Principles of Consolidation

The accompanying unaudited interim consolidated financial statements of the Company and its subsidiaries have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP, for interim financial information. The Company s consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated. 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 of June 30, 2015 and its results of operations and cash flows for the three and six months ended June 30, 2015 and 2014. Operating results for the six months ended June 30, 2015 are not necessarily indicative of the results that may be expected for the year ending December 31, 2015. The consolidated interim financial statements, presented herein, do not contain the required disclosures under U.S. GAAP for annual financial statements.

The accompanying unaudited interim consolidated 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, 2014 included in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2014, or the Form 10-K.

(b) Use of Estimates

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

(c) Inventory

Inventory is stated at the lower of cost or market value. Cost is determined using the first-in, first-out method. Included in inventory are raw materials used in production of commercial products. Also included in inventory are raw materials used in the production of clinical products, which do not have alternative future uses and are charged to research and development expenses when consumed.

(d) Revenue Recognition

The Company generates revenues from manufacturing and packaging services for multiple pharmaceutical companies. The agreements that the Company has with its commercial partners provide for manufacturing revenues, royalties and/or profit sharing components.

Table of Contents

RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements

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

Manufacturing and packaging service revenue is recognized upon shipment of the product in accordance with the terms of the contract, which specify when transfer of title and risk of loss occurs. After the Company has evidence of an arrangement, the price is determinable and there is a reasonable expectation regarding payment, the Company recognizes revenue.

In addition to manufacturing and packaging revenue, the customer agreements have royalties and/or profit sharing payments, computed on the net product sales of the partner. Royalty and profit sharing revenues are generally recognized when a partner sells the product to its customers, which could be in a different accounting period than the period in which the Company sold that product to the partner, and are based on a percentage of the partner s net sales or gross profits on sales of the product as specified in the underlying agreement.

Revenues related to research and development are generally recognized as the related services or activities are performed, in accordance with the contract terms. To the extent that the agreements specify services are to be performed on a fixed basis, revenues are recognized consistent with the pattern of the work performed.

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

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as of June 30, 2015 and December 31, 2014, as they would be anti-dilutive:

	June 30, 2015	December 31, 2014
Options outstanding	1,501,500	1,033,300
Warrants	794,928	150,000

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

(f) Recent Accounting Pronouncements

In April 2015, the Financial Accounting Standards Board, or FASB, issued updated guidance on the presentation requirements for debt issuance costs and debt discount and premium. The update requires that debt issuance costs

related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the updated guidance. The updated guidance is effective for annual and interim periods beginning after December 15, 2015 and early adoption is permitted for financial statements that have not been previously issued. The Company adopted this guidance during the three and six month period ended June 30, 2015.

In May 2014, the FASB issued updated guidance regarding the accounting for and disclosures of revenue recognition, with an effective date for annual and interim periods beginning after December 15, 2016. The update provides a single comprehensive model for accounting for revenue from contracts with customers. The model requires that revenue recognized reflect the actual consideration to which the entity expects to be entitled in exchange for the goods or services defined in the contract, including in situations with multiple performance obligations. In July 2015, the FASB deferred the effective date by one year. The guidance will be effective for annual and interim periods beginning after December 15, 2017. The Company is currently evaluating the effect that this guidance may have on its consolidated financial statements.

(4) Acquisition of Gainesville and Meloxicam

On April 10, 2015, the Company completed the Gainesville Transaction. The consideration paid in connection with the Acquisition consisted of $50.0 million at closing, a $4.0 working capital adjustment and a seven-year warrant to purchase 350,000 shares of the Company s common stock at an exercise price of $19.46 per share. In addition, the Company may be required to pay up to an additional $120.0 million in milestone payments upon the achievement of certain regulatory and net sales milestones and royalties on future product net sales related to IV/IM meloxicam. Under the acquisition method of accounting, the consideration paid and the fair value of the contingent consideration and royalties are allocated to the fair value of the assets acquired and liabilities assumed. The contingent consideration obligation is remeasured each reporting date with changes in fair value recognized as a period charge within the statement of operations (see note 6 for further information regarding fair value).

Table of Contents

RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements

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

The following is a preliminary estimate of the purchase price for the Gainesville Transaction:

	Estimated Fair Value
Purchase price agreement	$ 50,000
Fair value of warrants	2,470
Fair value of contingent consideration	54,600
Working capital adjustment	4,010
	$ 111,080

The contingent consideration consists of three separate components. The first component consists of two potential payments, which will be payable upon the submission of the new drug application (NDA) for meloxicam, and the related regulatory approval, respectively. The second component consists of three potential payments, based on the achievement of specified annual revenue targets. The third component consists of a royalty payment for a defined term on future meloxicam net sales.

The fair value of the first contingent consideration component recognized on the acquisition date was estimated by applying a risk adjusted discount rate to the probability adjusted contingent payments and the expected approval dates. The fair value of the second contingent consideration component recognized on the acquisition date was estimated by applying a risk adjusted discount rate to the potential payments resulting from probability weighted revenue projections and expected revenue target attainment dates. The fair value of the third contingent consideration component recognized on the acquisition date was estimated by applying a risk adjusted discount rate to the potential payments resulting from probability weighted revenue projections and the defined royalty percentage.

These fair values are based on significant inputs not observable in the market, which are referred to in the guidance as Level 3 inputs. The contingent consideration components are classified as liabilities and are subject to the recognition of subsequent changes in fair value through the results of operations.

The Gainesville results of operations have been included in the consolidated statement of operations beginning April 10, 2015.

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

	Amount
Accounts receivable	$ 12,519
Inventory	9,955
Prepaid expenses	380
Property, plant and equipment	39,424
Intangible assets	41,900
Goodwill	6,744
Total assets acquired	110,922
Accounts payable and accrued expenses	1,162
Warrants	2,470
Contingent consideration	54,600
Total liabilities assumed	58,232
Cash paid, net of $1,320 of cash acquired	$ 52,690

Table of Contents

RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements

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

The fair value of the property, plant and equipment and their weighted-average useful lives are as follows:

	Estimated Fair Value	Estimated Useful Life
Buildings and improvements	$ 16,371	35 years
Land	3,263	N/A
Furniture, office & computer equipment	2,510	4-5 years
Vehicles	30	2 years
Manufacturing equipment	17,250	6-7 years
	$ 39,424	

The estimated fair value of property, plant and equipment was determined using the cost and sales approaches.

The fair value of the identifiable intangible assets and their weighted-average useful lives are as follows:

	Estimated Fair Value	Weighted Average Estimated Useful Life
Royalties and contract manufacturing relationships	15,500	6
In-process research and development	26,400	N/A
Total intangible assets	41,900	

The in-process research and development asset and customer relationships were valued using the multi-period excess earnings method, which is an income approach in which excess earnings are the earnings remaining after deducting the market rates of return on the estimated values of contributory assets, including debt-free net working capital, tangible and intangible assets. The excess earnings are thereby calculated for each quarter of a multi-quarter projection period discounted to a present value utilizing an appropriate discount rate for the subject asset. Amortization expense was $592 for the three and six months ended June 30, 2015.

(5) Unaudited Pro Forma Results of Operations

The unaudited pro forma combined results of operations for the three and six months ended June 30, 2015 (assuming the closing of the Gainesville Transaction had occurred on January 1, 2015) are as follows:

	Three Months Ended June 30, 2015	Six Months Ended June 30, 2015
Net revenue	$ 20,339	$ 39,705
Net loss	(2,056)	(2,119)

(6) Fair Value of Financial Instruments

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

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

Table of Contents

RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements

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

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

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

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)
($ in thousands)			
At December 31, 2014:			
Assets:			
Money market mutual funds (included in cash and cash equivalents)	$ 10,922		
Government and agency bonds	8,663		
Cash equivalents	$ 19,585		
At June 30, 2015:			
Assets:			
Money market accounts (included in cash and cash equivalents)	$ 4,468		
Government and agency bonds	4,257		
Cash equivalents	$ 8,725		

Liabilities:	
Warrants	$ 6,213
Contingent consideration	56,600
	$ 62,813

The reconciliation of the contingent consideration and warrants measured at fair value on a recurring basis significant using unobservable inputs (Level 3) is as follows:

	Warrants	Contingent Consideration
Balance at December 31, 2014	$	$
Additions	5,331	54,600
Remeasurement	882	2,000
Balance at June 30, 2015	$ 6,213	$ 56,600

(7) Inventory

Inventory consists of the following:

	June 30, 2015
Raw materials	$ 2,974
Work in process	2,447
Finished goods	4,189
	$ 9,610

Table of Contents

RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements

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

(8) Accrued Expenses

Accrued expenses consist of the following:

	June 30, 2015	December 31, 2014
Clinical trial and related costs	$ 429	$ 112
Professional and consulting fees	1,180	394
Payroll and related costs	1,740	25
Interest on notes payable	1,688	
Other	851	44
	$ 5,888	$ 575

(9) Convertible Notes Payable

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

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

(10) Long-Term Debt

The Company financed the Gainesville Transaction via a $50,000 five-year senior secured term loan, entered into on April 10, 2015, with OrbiMed Royalty Opportunities II, LP, or OrbiMed, which carries interest at LIBOR plus 14.0% with a 1.0% floor. Our obligations under the senior term loan are secured by substantially all of the Company s assets.

There are certain usual and customary affirmative and negative covenants, as well as financial covenants that the Company will need to fulfill on a monthly and quarterly basis. As of June 30, 2015, the Company was in compliance with the covenants.

The Company issued to OrbiMed warrants to purchase 294,928 shares of common stock, with an exercise price of $3.28 per share. The warrants are exercisable through April 10, 2022. The initial fair value of the warrants of $2,861 was recorded as debt issuance costs.

Debt issuance costs related to the term loan of $4,593, including the initial warrant fair value of $2,861, are being amortized to interest expense over the five year term of the loan and netted with the loan principal amount. The unamortized balance of debt issuance costs is $4,382 as of June 30, 2015.

As of June 30, 2015, the long-term debt balance is comprised of the following:

Principal balance outstanding	$50,000
Deferred issuance costs	(4,382)
	$ 45,618
Current portion	(9,123)
	$ 36,495

The credit agreement contains a provision that allows OrbiMed, at its option, the right to require the Company to prepay the principal balance outstanding under the loan based on quarterly Excess Cash Flows, of Gainesville, as defined in the credit agreement. The Company has estimated the amount of the Excess Cash Flow payments that could be payable within one year of June 30, 2015 upon request of OrbiMed and has classified that amount as a current debt in the accompanying consolidated balance sheet.

(11) 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.

Table of Contents

RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements

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

On March 12, 2014 the Company completed an IPO in which the Company sold 4,312,500 shares of common stock at $8.00 per share resulting in gross proceeds of $34,500. In connection with the IPO, the Company paid $4,244 in underwriting discounts, commissions and offering costs resulting in net proceeds of $30,256. Also in connection with the IPO, all of the outstanding shares of the Company s Series A Redeemable Convertible Preferred Stock, or Series A Stock, including accreted dividends, and Bridge Notes, including accrued interest, were converted into common stock.

(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 June 30, 2015, no preferred stock was issued or outstanding.

(c) Series A Redeemable Convertible Preferred Stock

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

(d) Warrants

As of June 30, 2015, the Company had the following warrants outstanding to purchase shares of the Company s common stock:

Number of Shares	Exercise Price per Share	Expiration Date
150,000	$12.00	March 2018
350,000	$19.46	April 2022
294,928	$ 3.28	April 2022

The warrant to purchase 350,000 shares is liability classified since it contains a contingent net cash settlement feature. The warrant to purchase 294,928 shares is liability classified since it contains an anti-dilution provision. The fair value of both warrants will be remeasured through settlement or expiration with changes in fair value recognized as a period

charge within the statement of operations.

(e) Common Stock Purchase Agreement

On February 2, 2015, the Company entered into a Common Stock Purchase Agreement, or the Purchase Agreement, with Aspire Capital Fund, LLC, or Aspire Capital, pursuant to which Aspire Capital is committed to purchase, at the Company s election, up to an aggregate of $10,000 of shares of the Company s common stock over the 24 month term of the Purchase Agreement. On the execution of the Purchase Agreement, the Company issued 96,463 shares of common stock to Aspire Capital with a fair value of $285, as consideration for entering in the Purchase Agreement. In addition, the Company incurred $229 of costs in connection with the Aspire Capital facility, which, along with the fair value of the common stock has been recorded as deferred equity costs.

(12) 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 June 30, 2015, no stock appreciation rights have been issued. Subsequent to adoption, the 2008 Plan was amended to increase the authorized number of shares available for grant to 444,000 shares of common stock. In October 2013, the Company established the 2013 Equity Incentive Plan, or the 2013 Plan, which allows for the grant of stock options, stock appreciation rights and stock awards for a total of 600,000 shares of common stock. In June 2015, the Company s shareholders approved the Amended and Restated Equity Incentive Plan which increased the aggregate amount of shares available for issuance to 2,000,000.

Table of Contents

RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements

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

Stock options are exercisable generally for a period of 10 years from the date of grant and generally vest over four years. As of June 30, 2015, 904,326 shares and 174 shares are available for future grants under the 2013 Plan and 2008 Plan, respectively.

Stock-based compensation expense for the six months ended June 30, 2015 and 2014 was $737 and $175, respectively, and for the three months ended June 30, 2015 and 2014 was $504 and $155, respectively.

The following table summarizes stock option activity during the six months ended June 30, 2015:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life
Balance, December 31, 2014	1,033,300	$ 5.77	
Granted	506,200	6.92	
Exercised	(38,000)	6.00	
Canceled			
Balance, June 30, 2015	1,501,500	$ 5.79	8.18 years
Options exercisable, June 30, 2015	464,671	$ 6.43	5.62 years

Included in the table above are 194,000 performance-based options granted in December 2014 with an exercise price of $2.47 per share, 30% of these stock options vested in July 2015 based upon the achievement of positive topline results from the Company s completed Dex Phase II clinical trial was met. The remaining portion of the performance-based options vest monthly over a three-year period beginning on July 24, 2015.

As of June 30, 2015, there was $6,818, of unrecognized compensation expense related to unvested options that are expected to vest and will be expensed over a weighted average period of 3.4 years, which includes $1,495 of unrecognized compensation related to performance-based options.

(13) Related Party Transactions

In July 2008, the Company entered into an agreement with Malvern Consulting Group, Inc., or MCG, a consulting company affiliated with the Company s President and Chief Executive Officer. A new agreement was signed in October 2013 under which MCG continues to provide consulting services to the Company, principally in the fields of clinical development, regulatory affairs, and quality assurance. MCG consulting fees for services are based on a flat fee and time worked at hourly rates for consultants. The Company recorded MCG consulting fees for research and

development and general and administrative expenses of $129 and $123 for the three months ended June 30, 2015 and 2014, respectively and $237 and $208 for the six months ended June 30, 2015 and 2014, respectively. As of June 30, 2015, $47 and $53 are recorded in accounts payable and accrued expenses, 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 paid $57 in rental fees to MCG for a month to month lease for facilities space for the six months ended June 30, 2015 and $44 for facilities space for the six months ended June 30, 2014.

(14) Subsequent Event

On July 1, 2015, the Company entered into a Securities Purchase Agreement, or Purchase Agreement, with certain accredited investors, or the Investors, pursuant to which the Company agreed to issue and sell to the Investors in a private placement, or Private Placement, an aggregate of 1,379,311 shares of common stock, at a price per share of $11.60, for net proceeds of approximately $14,956. The Private Placement closed on July 7, 2015. The Company agreed to pay the placement agents a fee equal to 6.0% of the aggregate gross proceeds from the Private Placement, plus reimbursement of certain expenses. The Company intends to use the net proceeds from the Private Placement to further fund the clinical development of the Company s product candidates and for general corporate purposes. The Purchase Agreement requires the Company to file a registration statement with the Securities and Exchange Commission to register the resale of the shares within 45 days of the closing.

Table of Contents

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

The following Management s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with interim unaudited financial statements contained in Part I, Item 1 of this quarterly report, and the audited financial statements and notes thereto for the year ended December 31, 2014 and the related Management s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our annual report on Form 10-K filed with the SEC on March 25, 2015. As used in this report, unless the context suggests otherwise, we, us, our, the Company or Recro refer to Recro Pharma, Inc. and its consolidated subsidiaries.

Cautionary Note Regarding Forward-Looking Statements

This quarterly report on Form 10-Q contains forward-looking statements. We may in some cases, use terms such as may, will, should, expect, plan, anticipate, could, intend, target, project, contemplates, believ potential or continue or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements.

These forward-looking statements in this quarterly report on Form 10-Q include, among other things, statements about:

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

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

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

Any forward-looking statements that we make in this Quarterly Report speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Quarterly Report or to reflect the occurrence of unanticipated events. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless expressed as such, and should only be viewed as historical data.

You should also read carefully the factors described in the Risk Factors in this Quarterly Report and in our annual report on Form 10-K filed with the SEC on March 25, 2015, to better understand significant risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements in this report and you should not place undue reliance on any forward-looking statements.

Overview

We are a revenue generating specialty pharmaceutical company developing multiple non-opioid therapeutics for the treatment of pain, initially for acute post operative pain. We have two product candidates in mid to late stage clinical trials for the management of acute post operative pain. Intravenous and intramuscular, or IV/IM, meloxicam, a proprietary, long-acting preferential COX-2 inhibitor for moderate to severe acute pain has successfully completed multiple Phase II clinical trials and we are ready to begin pivotal Phase III clinical trials. We believe IV/IM meloxicam compares favorably to competitive therapies in onset of pain relief,

Table of Contents

duration of pain relief and time to peak analgesic effect. Dex-IN, a proprietary intranasal formulation of dexmedetomidine, or Dex, successfully completed a Phase II clinical trial and is also ready to begin Phase III clinical trials. Dex is a selective alpha-2 adrenergic agonist that has demonstrated analgesic properties in multiple studies. If approved, Dex-IN would also be the first and only approved acute post operative pain drug in its class of drugs. As our product candidates are not in the opioid class of drugs, we believe they will overcome many of the issues associated with commonly prescribed opioid therapeutics, including addiction, misuse/diversion, respiratory distress, and constipation while maintaining analgesic, or pain relieving, effect.

We currently own and operate an 87,000 square foot, DEA-licensed facility that manufactures five commercial products and receives royalties associated with the sales of these products. We manufacture the following products for our commercial partners: Ritalin LA®, Focalin XR®, Verelan PM®, generic Verapamil and Zohydro ER®.

We have a limited operating history. We have funded our operations to date primarily from proceeds received from private placements of convertible preferred stock, convertible notes and common stock and our initial public offering of common stock, or IPO. On March 12, 2014, we announced the closing of the IPO of 4,312,500 shares of common stock, including the full exercise of the underwriters over-allotment, at a public offering price of $8.00 per share. Total gross proceeds from the IPO were $34.5 million before deducting underwriting discounts and commissions and other offering expenses payable by us resulting in net proceeds of $30.4 million. We have incurred losses and generated negative cash flows from operations since inception. As of June 30, 2015, we had an accumulated deficit of $39.5 million. Substantially all of our operating losses resulted from costs incurred in connection with our development programs, including our non-clinical and formulation development activities, manufacturing and clinical trials. We expect to incur increasing expenses over the next several years to develop IV/IM meloxicam and Dex-IN, including planned Phase III pivotal and safety trials for Dex-IN and IV/IM meloxicam. Based upon additional financial resources, we may develop and commercialize our proprietary formulations of meloxicam and Dex.

We expect that annual operating results of operations will fluctuate for the foreseeable future due to several factors. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future.

On April 10, 2015, we completed our acquisition from Alkermes plc, or Alkermes, of certain assets, including the worldwide rights to IV/IM meloxicam and the contract manufacturing facility, royalty and formulation business in Gainesville, Georgia, now operating through our subsidiary, Recro Gainesville LLC, or Gainesville. We refer to the acquisition herein as the Gainesville Transaction. The Gainesville Transaction transformed our business through the addition of a revenue-generating business and increase in our workforce as a result of the addition of the Gainesville employees.

Under the terms of the purchase and sale agreement with Alkermes, we paid Alkermes $52.0 million at closing, as adjusted for working capital. Alkermes is entitled to receive up to an additional $120.0 million in milestone payments upon the achievement of certain regulatory and net sales milestones and royalties on future product net sales, in each case, related to IV/IM meloxicam. Upon closing, we issued to Alkermes a warrant to purchase an aggregate of 350,000 shares of our common stock at an exercise price of $19.46 per share. The $52.0 million up-front payment was funded with $50.0 million in borrowings under a credit agreement that we entered into with OrbiMed Royalty Opportunities II, LP, or OrbiMed, and cash on hand. The interest rate under the credit agreement is equal to LIBOR plus 14.0%, with a 1.0% LIBOR floor. Pursuant to the credit agreement, we issued OrbiMed a warrant to purchase an aggregate of 294,928 shares of our common stock at an exercise price of $3.28 per share, subject to certain adjustments.

Financial Overview

Revenues

During the three and six months ended June 30, 2015 and 2014, we recognized revenues in four categories: manufacturing revenue, royalty, profit sharing and research and development revenue.

Manufacturing revenues We recognize manufacturing revenues from the sale of products we manufacture for our commercial partners. Manufacturing revenues are recognized when persuasive evidence of an arrangement exists, shipment has occurred and title to the product and associated risk of loss has passed to the customer, the sales price is fixed or determinable and collectability is reasonably assured.

Royalty revenues We recognize royalty revenues related to the sale of products by our commercial partners that incorporate our technologies. Royalties are earned under the terms of a license agreement in the period the products are sold by a commercial partner and collectability is reasonably assured.

Profit sharing revenue We recognize revenue from profit sharing related to the sale of certain of our manufactured products by our commercial partners. Profit sharing revenue is earned under the terms of a license agreement in the period the products are sold and expenses are incurred by our commercial partner and collectability is reasonably assured.

Table of Contents

Research and development revenue Research and development revenue consists of funding that compensates us for formulation, pre-clinical and clinical testing under research and development arrangements with commercial partners. We generally bill our commercial partners under research and development arrangements using a full-time equivalent, or FTE, or hourly rate, plus direct external costs, if any.

Research and Development Expenses

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

- expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and a substantial portion of our preclinical studies;
- the cost of acquiring and manufacturing clinical trial materials;
- the cost of manufacturing validation tests, if these materials are manufactured prior to obtaining regulatory approval;
- costs related to facilities, depreciation and other allocated expenses;
- costs related to on-going process development and analytical controls associated with commercial manufacturing;
- costs associated with non-clinical activities and regulatory approvals; and
- salaries and related costs for personnel in research and development functions.

We expense research and development costs as incurred. Advanced payments for goods and services that will be used in future research and development activities are initially recorded as prepaid expenses and expensed as the activity is performed or when the goods have been received.

Since inception, we have developed and evaluated a series of Dex product candidates through Phase I pharmacokinetic and efficacy trials and placebo controlled Phase II efficacy trial. Our current clinical priorities are the development of Dex-IN and IV/IM meloxicam for acute pain following surgery. Dex-IN recently completed a Phase II bunionectomy study and is ready to begin Phase III clinical trials. IV/IM meloxicam has also successfully completed multiple Phase II clinical trials for and is ready to begin pivotal Phase III clinical trials. In addition to the development of Dex-IN and IV/IM meloxicam, we intend to strategically invest in our product pipeline, including Fadolmidine, or Fado, a second alpha-2 agonist candidate that we believe shows promise in neuropathic pain . The commitment of funding for each subsequent stage of our development programs is dependent upon, among other things, the receipt of successful clinical data.

The majority of our external research and development costs relate to clinical trials, analysis and testing of the product and patent costs. We currently rely on MCG, a related party, for a portion of our research and development activities. Costs related to facilities, depreciation, and support are not charged to specific programs.

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

- the duration of clinical trials, which varies substantially according to the type, complexity and novelty of the product candidate;

- the imposition by the United States Food and Drug Administration, or FDA, and comparable agencies in foreign countries of substantial requirements on the introduction of therapeutic pharmaceutical products, which may require lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures;

- the possibility that data obtained from nonclinical and clinical activities at any step in the testing process may be adverse and lead to discontinuation or redirection of development activity or may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval;

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

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

- the risks disclosed in the section titled Risk Factors of this quarterly report and our Annual Report on Form 10-K for the fiscal year ended December 31, 2014.

Table of Contents

Development timelines, probability of success and development costs vary widely. As a result of the uncertainties discussed above, we anticipate that we will make determinations as to which additional programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical data of each product candidate, as well as ongoing assessments of such product candidate s commercial potential. Accordingly, we cannot currently estimate with any degree of certainty the amount of time or costs that we will be required to expend in the future on our product candidates to complete current or future clinical or pre-commercial stages prior to their regulatory approval, if such approval is ever granted. As a result of these uncertainties surrounding the timing and outcome of any approvals, we are currently unable to estimate precisely when, if ever, any of our other product candidates will generate revenues and cash flows.

We expect our research and development costs related to IV/IM meloxicam and Dex-IN to be substantial for the foreseeable future as we advance these product candidates through clinical trials, manufacturing scale-up and other pre-approval activities. We may elect to seek out collaborative relationships in order to provide us with a diversified revenue stream and to help facilitate the development and commercialization of our product candidate pipeline.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive and finance functions. General and administrative expenses also include professional fees for legal, including patent related expenses, consulting, auditing and tax services, and stock compensation expense.

Our general and administrative expenses in 2015 will be higher than in 2014. We expect to continue 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 due to the acquisition of new patents through the Gainesville Transaction and, in addition, due to the higher annuity fees that will be due on patents that are issued. In addition, if additional formulation technology is developed for our product candidates, patent expenses could increase further.

Amortization of Intangible Assets

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

Change in Fair Value of Contingent Consideration

In connection with the acquisition of IV/IM meloxicam in the Gainesville Transaction, we are required to pay milestone payments on the achievement of certain regulatory and net sales milestones and royalties on future net product sales between 10% and 12%. The estimated fair value of the initial $54.6 million payment obligation was recorded as part of the purchase price for the Gainesville Transaction. Each reporting period, we revalue this estimated obligation with changes in fair value recognized as a non-cash operating expense or income.

Interest Expense

Interest expense for the three and six months ended June 30, 2015 consists of interest expense incurred on our senior secured term loan with OrbiMed. Interest expense for the three and six months ended June 30, 2014 related to our previously outstanding Bridge Notes. Upon the closing of the IPO, these Bridge Notes, including accrued interest,

were converted into shares of common stock. Since the conversion price of our Bridge Notes allowed the note holders to convert at 75% of the initial offering price per share in the IPO, we recorded a non-cash interest charge of approximately $4.1 million upon the closing of the IPO.

Net Operating Losses and Tax Carryforwards

As of December 31, 2014, we had approximately $16.8 million of federal net operating loss carryforwards. We also had federal and state research and development tax credit carryforwards of $0.7 million available to offset future taxable income. U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. These federal and state net operating loss and federal and state tax credit carryforwards will begin to expire at various dates beginning in 2028, if not utilized. As a result, we may not be able to take full advantage of these carryforwards for federal and state tax purposes.

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

Table of Contents

need to raise substantial additional funding to finance our operations, we may undergo further ownership changes in the future, which could further limit our ability to use net operating loss carryforwards. As a result, if we generate taxable income, our ability to use some of our net operating loss carryforwards to offset U.S. federal taxable income may be subject to limitations, which could result in increased future tax liabilities to us.

Results of Operations

Comparison of the Three Months Ended June 30, 2015 and 2014:

	Three months ended June 30,	
	2015	**2014**
	(amounts in thousands)	
Revenue:		
Manufacturing, royalty and profit sharing revenue	$ 16,704	$
Research and development revenue	1,956	
Total revenues	18,660	
Operating expenses:		
Costs of sales (excluding amortization of intangible assets)	9,395	
Research and development	2,821	1,837
General and administrative	2,597	959
Amortization of intangible assets	592	
Change in warrant valuation	882	
Change in contingent consideration valuation	2,000	
Total operating expenses	18,287	2,796
Other income (expense):		
Interest income (expense)	(1,684)	2
Net loss	$ (1,311)	$ (2,794)

Revenue and costs of sales. As a result of the Gainesville Transaction and our subsequent operation of the manufacturing business through Gainesville, revenue for the three months ended June 30, 2015 increased to $18.7 million and cost of sales increased to $9.4 million.

Research and Development. Our research and development expenses were $2.8 million and $1.8 million for the three months ended June 30, 2015 and 2014, respectively, an increase of $1.0 million and 54% from June 30, 2014, primarily due to $0.9 million of research and development costs incurred at our Gainesville facility. These incremental costs are primarily related to process development, regulatory affairs and research and development analytical work at Gainesville.

General and Administrative. Our general and administrative expenses were $2.6 million and $1.0 million for the three months ended June 30, 2015 and 2014, respectively, an increase of $1.6 million and 160% from June 30, 2014, due to

costs associated with the Gainesville Transaction, management s salaries, benefits and stock-based compensation, and increased consulting and legal fees associated with being a public company.

Amortization of Intangible Assets. Amortization expense was $0.6 million for the three months ended June 30, 2015 exclusively related to the amortization of our royalties and intangible asset over its six year estimated useful life.

Interest Expense. Interest expense was $1.7 million during the three months ended June 30, 2015. Interest expense consists of interest expense incurred on our OrbiMed senior secured term loan. The interest rate under the credit agreement with OrbiMed is equal to LIBOR plus 14.0%, with a 1.0% LIBOR floor.

Table of Contents

Comparison of the Six Months Ended June 30, 2015 and 2014:

	Six months ended June 30,	
	2015	**2014**
	(amounts in thousands)	
Revenue:		
Manufacturing, royalty and profit sharing revenue	$ 16,704	$
Research and development revenue	1,956	
Total revenues	18,660	
Operating expenses:		
Costs of sales (excluding amortization of intangible assets)	9,395	
Research and development	4,575	2,064
General and administrative	4,986	1,606
Amortization of intangible assets	592	
Change in warrant valuation	882	
Change in contingent consideration valuation	2,000	
Total operating expenses	22,430	3,670
Other income (expense):		
Interest income (expense)	(1,680)	(4,270)
Net loss	$ (5,450)	$ (7,940)

Revenue and costs of sales. As a result of the Gainesville Transaction and our subsequent operation of the manufacturing business through Gainesville, revenue for the six months ended June 30, 2015 increased to $18.7 million and cost of sales increased to $9.4 million.

Research and Development. Our research and development expenses were $4.6 million and $2.1 million for the six months ended June 30, 2015 and 2014, respectively, an increase of $2.5 million and 122% from June 30, 2014, primarily due to an increase of $1.5 million of higher Phase 2 clinical trial costs as a result of a full quarter of trial costs compared to a trial starting in May 2014, an increase in costs in association with a work plan for the start of our IV/IM meloxicam Phase III clinical trial and an additional $0.9 million of research and development costs incurred at our Gainesville facility, which primarily related to process development, regulatory affairs and research and development analytical work at Gainesville.

General and Administrative. Our general and administrative expenses were $5.0 million and $1.6 million for the six months ended June 30, 2015 and 2014, respectively, an increase of $3.4 million and 211% from June 30, 2014, due to $1.1 million in costs associated with the Gainesville Transaction, an increase of $1.0 million in management s salaries, benefits and stock-based compensation, and $0.8 million in increased consulting and legal fees associated with being a public company.

Amortization of Intangible Assets. Amortization expense was $0.6 million for the six months ended June 30, 2015 exclusively related to the amortization of our royalties and contract manufacturing relationships intangible asset over its six year estimated useful life.

Interest Expense. Interest expense was $1.7 million during the six months ended June 30, 2015, which consists of our interest expense incurred on our OrbiMed senior secured term loan. The interest rate under the credit agreement with OrbiMed is equal to LIBOR plus 14.0%, with a 1.0% LIBOR floor. For the six months ended June 30, 2014, interest expense of $0.2 million was recorded on our Bridge Notes. Since the conversion price of our Bridge Notes allowed the note holders to convert at 75% of the initial offering price per share in the IPO, we recorded a non-cash interest charge of approximately $4.1 million upon the closing of the IPO.

Liquidity and Capital Resources

As of June 30, 2015 and December 31, 2014, we had $15.7 million and $19.7 million, respectively, in cash and cash equivalents. On July 1, 2015, we entered into a securities purchase agreement related to a private placement of shares of our common stock in which we received net proceeds of approximately $15.0 million. Since inception through June 30, 2015, we have financed

Table of Contents

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 our IPO. We also expect that revenues from the Gainesville manufacturing business will fund operations and capital expenditures at the Gainesville facility.

We will need to raise additional funds in order to continue our clinical trials of our product candidates, to commercialize any product candidates or technologies and to enhance our sales and marketing efforts for additional products we may acquire. Insufficient funds may cause us to delay, reduce the scope of, or eliminate one or more of our development, commercialization or expansion activities. Our future capital needs and the adequacy of our available funds will depend on many factors, including the cost of clinical studies and other actions needed to obtain regulatory approval of our products in development. If additional funds are required, we may raise such funds through public or private sales of equity or debt securities or from bank or other loans or through strategic research and development, licensing and/or marketing arrangements from time to time. Financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could materially adversely impact our growth plans and our financial condition or results of operations. Additional equity financing, if available, may be dilutive to the holders of our common stock and may involve significant cash payment obligations and covenants that restrict our ability to operate our business.

On February 2, 2015, we entered into a common stock purchase agreement, or the Purchase Agreement, with Aspire Capital Fund, LLC, or Aspire Capital, pursuant to which Aspire Capital is committed to purchase, at our election, up to an aggregate of $10.0 million of shares of our common stock over the 24-month term of the Purchase Agreement. The shares may be sold by us to Aspire Capital on any business day we select in two ways: (1) through a regular purchase of up to 50,000 shares at a known price based on the market price of our common stock prior to the time of each sale, and (2) through a purchase at a volume weighted average price, or VWAP, of a number of shares up to 30% of the volume traded on the purchase date at a price equal to the lessor of the closing sale price or 95% of the VWAP for such purchase date. To date, we have not sold any shares to Aspire Capital under the Purchase Agreement.

On March 7, 2015, in connection with the Gainesville Transaction, we, through a wholly owned subsidiary, entered into a credit agreement with OrbiMed. Pursuant to the credit agreement, OrbiMed provided us with a term loan in the original principal amount of $50.0 million on April 10, 2015, which amount was used to fund the Gainesville Transaction. The unpaid principal amount under the credit agreement is due and payable on the five year anniversary of the loan provided thereunder by OrbiMed. The credit agreement also provides for certain mandatory prepayment events, including a quarterly excess cash flow prepayment requirement at OrbiMed s request. We may make voluntary prepayments in whole or in part, subject to: (i) on or prior to the 36 month anniversary of the closing of the credit agreement, payment of a Buy-Out Premium Amount (as defined in the credit agreement); and (ii) after the 36 month anniversary of the closing of the credit agreement, payment of an Exit Fee Amount (as defined in the credit agreement). In the event that there shall be Excess Cash Flow (as defined in the credit agreement) for any fiscal quarter, OrbiMed has the option to require us to prepay the unpaid principal amount of the Loan in an aggregate principal amount equal to the Excess Cash Flow, or any lesser amount requested by OrbiMed, provided that no payments under this option shall be subject to the premiums or exit fees due. The interest rate under the credit agreement is a rate per annum equal to 14.0% plus the greater of: (i) the LIBO Rate (as defined in the credit agreement) and (ii) 1.0%. In addition, the credit agreement contains certain financial and other covenants, including a minimum liquidity requirement and minimum revenue targets, maximum leverage ratios and includes limitations on, among other things, additional indebtedness, paying dividends in certain circumstances, acquisitions and certain investments. OrbiMed has indicated an interest in retiring an estimated $7.8 million, on or before August 20, 2015, of the outstanding principal on our senior secured term loan from free cash flow generated during the second quarter of 2015 by the Gainesville contract manufacturing facility.

Sources and Uses of Cash

Cash provided by (used in) operations was $1.7 million and ($2.7) million for the six months ended June 30, 2015 and 2014, respectively, which represents our operating losses less our stock-based compensation, depreciation, non-cash interest expense, changes in fair value of warrants and contingent consideration, amortization of intangibles and beneficial conversion charge taken on our Bridge Notes upon the conversion of such Bridge Notes, including accrued interest, into common stock.

Cash used in investing activities was $53.9 million for the six months ended June 30, 2015 as a result of the Gainesville Transaction and purchase of property and equipment at the plant in Gainesville.

Cash provided by financing activities was $48.2 million for the six months ended June 30, 2015 primarily as a result of the credit agreement with OrbiMed for $50.0 million, net of the payment of $1.7 million of issuance costs incurred in conjunction with the agreement. Cash provided by financing activities for the six months ended June 30, 2014 was as a result of successfully raising net proceeds of $30.4 million from the IPO and the issuance of $0.2 million of Bridge Notes to SCP Vitalife.

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

- the timing and expenses of trials prior to a New Drug Application, or NDA, for Dex-IN and IV/IM meloxicam;

- the timing and outcome of the FDA s review of an NDA for Dex-IN and IV/IM meloxicam if our trials are successful;

Table of Contents

- the extent to which the FDA may require us to perform additional preclinical studies, clinical trials or pre-commercial manufacturing of Dex-IN and IV/IM meloxicam;
- 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

The following is a discussion of our contractual commitments as of the end of the second quarter of 2015. We are involved with in-licensing of product candidates that are generally associated with payments to the partner from whom we have licensed the product. Such payments frequently take the form of:

- an up-front payment, the size of which varies depending on the phase of the product candidate and how many other companies would like to obtain the product, which is paid very soon after signing a license agreement;
- royalties as a percentage of net sales of the product; and

milestone payments which are paid when certain parts of the overall development program and regulatory milestones (such as filing an investigational new drug application, or IND, or an NDA) are successfully accomplished, as well meeting certain sales thresholds.

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

an up-front payment made at or shortly after signing a partnering agreement;

royalties as a percentage of net sales of the product;

milestone payments that may be made on completion of a phase of a clinical program, or regulatory approval in a given territory; and

a payment or payments made upon achievement of a certain level of sales in a given year.

Alkermes

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

Table of Contents

In July 2015, we also entered into a Development, Manufacturing and Supply Agreement, or Supply Agreement, with Alkermes (through a subsidiary of Alkermes), pursuant to which Alkermes will (i) provide clinical and, if elected by us, commercial bulk supplies of IV/IM meloxicam formulation and (ii) provide development services with respect to the Chemistry, Manufacturing and Controls section of a New Drug Application for IV/IM meloxicam. Pursuant to the Supply Agreement, Alkermes will supply us with such quantities of bulk IV/IM meloxicam formulation as shall be reasonably required for the completion of clinical trials of IV/IM meloxicam, subject to a maximum of eight clinical batches in any twelve-month period unless otherwise agreed by the parties. Prior to the initiation of Phase III clinical trials for IV/IM meloxicam, we may also elect to have Alkermes supply our initial commercial requirements of bulk IV/IM meloxicam formulation. During the term of the Supply Agreement, we will purchase our clinical and, if elected, commercial supplies of bulk IV/IM meloxicam formlulation exclusively from Alkermes for a period of time.

Orion

In August 2008, we entered into a License Agreement with Orion for non-injectable Dex. Under the Dex 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 make 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 API 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 ($22.7 million as of June 30, 2015) after regulatory approval of Dex dosage forms and upon achieving certain sales milestones. We will also pay Orion royalty payments on net sales of our products, which royalty payments will be paid at varying percentages. Through June 30, 2015, no milestones have been achieved.

We also have an active pharmaceutical ingredient, or API, agreement with Orion for the supply of Dex, which we believe provides fair pricing for the purchase of the Dex API that is produced in compliance with current good manufacturing practices, 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 make products worldwide solely for purposes of commercialization.

We will pay milestone payments to Orion of up to 12.2 million Euros ($13.5 million as of June 30, 2015) based on regulatory filings and approval and on commercialized net sales levels. We will also pay Orion royalty payments on net sales of our products, which royalty payments will be paid at varying percentages. Through June 30, 2015, no milestones have been achieved.

Leases

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

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

This management s discussion and analysis of our financial condition and results of operations is based on our interim unaudited consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, revenue recognition, and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Other than as disclosed below, we believe there have been no significant changes in our critical accounting policies as discussed in our annual report on Form 10-K filed with the SEC on March 25, 2015.

Impairment of Goodwill and Indefinite-lived Intangible Assets As a result of the Gainesville Transaction, we will be required to review the carrying value of goodwill and indefinite-lived intangible assets, to determine whether impairment may exist. The first

Table of Contents

step in the impairment analysis is to assess qualitative factors to determine whether it is necessary to perform the current two-step test. If an entity believes, as a result of its qualitative assessment, that it is more-likely-than-not (a likelihood of more than 50%) that the fair value of a reporting unit is less than its carrying amount, the quantitative impairment test is required. Otherwise, no further testing is required. The two-step goodwill impairment test consists of the following steps. The first step compares a reporting unit s fair value to its carrying amount to identify potential goodwill impairment. If the carrying amount of a reporting unit exceeds the reporting unit s fair value, the second step of the impairment test must be completed to measure the amount of the reporting unit s goodwill impairment loss, if any. Step two requires an assignment of the reporting unit s fair value to the reporting unit s assets and liabilities to determine the implied fair value of the reporting unit s goodwill. The implied fair value of the reporting unit s goodwill is then compared with the carrying amount of the reporting unit s goodwill to determine the goodwill impairment loss to be recognized, if any. The impairment test for indefinite-lived intangible assets is a one-step test, which compares the fair value of the intangible asset to its carrying value. If the carrying value exceeds its fair value, an impairment loss is recognized in an amount equal to the excess. Based on accounting standards, it is required that these assets be assessed at least annually for impairment unless a triggering event occurs between annual assessments which would then require an assessment in the period which a triggering event occurred.

Impairment of Long-lived Assets As a result of the Gainesville Transaction, we will be required to review the carrying value of long-lived fixed and intangible assets for recoverability whenever events occur or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable.

ASC 360-10-35 provides guidance with respect to the measurement of impairment. The impairment test is a two-step test. Under step one we assess the recoverability of an asset (or asset group). The carrying amount of an asset (or asset group) is not recoverable if it exceeds the sum of the undiscounted cash flows expected from the use and eventual disposition of the asset (or asset group). The impairment loss is measured in step two as the difference between the carrying value of the asset (or asset group) and its fair value. Assumptions and estimates used in the evaluation of impairment are subjective and changes in these assumptions may negatively impact projected undiscounted cash flows, which could result in impairment charges in future periods. On an ongoing periodic basis, we evaluate the useful life of our long-lived assets and determine if any economic, governmental or regulatory even has modified their estimated useful lives.

Classification of debt Under the Company s credit agreement with OrbiMed, Orbimed, at its option, has the right to require the Company to prepay the principal balance outstanding under the loan based on quarterly Excess Cash Flows of Gainesville, as defined in the credit agreement. Accounting policies require that the Company estimate the amount of the Excess Cash Flow payments that could be payable within one year of June 30, 2015 upon request of OrbiMed and classify this amount as current debt in the consolidated balance sheet. Changes in estimates of future cash flows caused by items such as customer and product demand, changing operating cost structure or other unforeseen events or changes in market conditions, could cause actual future cash flows to vary from our estimates.

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 June 30, 2015, we had approximately $8.7 million invested in money market instruments and government agency bonds. We believe our policy of investing in highly rated securities, whose liquidities are, at June 30, 2015, all less than 90 days, minimizes such risks. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10.0% change in interest rates would not have a material effect on the fair market value of our portfolio. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our investment

portfolio. We do not enter into investments for trading or speculative purposes. Our OrbiMed senior secured term loan interest expense is based on the current committed rate of LIBOR plus 14% with a 1.0% LIBOR floor. A fluctuation in LIBOR of 0.25% would result in a charge of $62,500 of interest expense.

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 the Exchange Act) as of June 30, 2015. We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s, or the SEC s, rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure. 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 June 30, 2015, 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.

Our Annual Report on Form 10-K for the year ended December 31, 2014, which was our first Annual Report on Form 10-K, was not required to include a report of management s assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm under a transition period established by SEC rules applicable to new public registrants. Management will be required to provide an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2015. We are not required to comply with the independent registered public accounting firm attestation requirement of Section 404 of the Sarbanes-Oxley Act while we qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

None.

Table of Contents

Item 1A. Risk Factors

Except as set forth below, there have been no material changes from our risk factors as previously reported in our Annual Report on Form 10-K for the year ended December 31, 2014.

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

Prior to the Gainesville Transaction in April 2015, we had no outstanding indebtedness. Contemporaneously with the closing of the Gainesville Transaction, we entered into a $50.0 million credit agreement with OrbiMed. Accordingly, we have substantially increased indebtedness following the acquisition in comparison to a recent historical basis. Our indebtedness could have important consequences to you. For example, it:

- requires us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, reducing the availability of our cash flow to fund working capital, capital expenditures, development activity, acquisitions and other general corporate purposes.;
- increases our vulnerability to adverse general economic or industry conditions;
- limits our flexibility in planning for, or reacting to, changes in our business or the industries in which we operate;
- makes us more vulnerable to increases in interest rates, as borrowings under our senior secured credit facility are at variable rates;
- limits our ability to obtain additional financing in the future for working capital or other purposes; and
- places us at a competitive disadvantage compared to our competitors that have less indebtedness.

Any of the above listed factors could materially adversely affect our business, financial condition, results of operations and cash flows. Our credit agreement with OrbiMed also contains certain financial and other covenants, including a minimum liquidity requirement and minimum revenue targets, maximum leverage ratios and includes limitations on, among other things, additional indebtedness, paying dividends in certain circumstances, acquisitions and certain investments. Any failure to comply with the terms, covenants and conditions of the term loan may result in an event of default under such agreements, and could have a material adverse effect on our business, financial condition and results of operation.

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

The FDA or other regulatory agencies may not approve IV/IM meloxicam or may impose limitations upon any product approval.

We must obtain government approvals before marketing or selling our IV/IM meloxicam or any other product candidates in the United States and in jurisdictions outside the United States. The FDA, and comparable regulatory agencies in other countries, impose substantial and rigorous requirements for the development, production and commercial introduction of drug products. These may include pre-clinical, laboratory and clinical testing procedures, sampling activities, clinical trials GMP manufacturing of products tested and following these products for stability, and other costly and time-consuming procedures. In addition, regulation is not static, and regulatory agencies, including the FDA, evolve in their staff, interpretations and practices and may impose more stringent requirements than currently in effect, which may adversely affect our planned drug development and/or our commercialization efforts. Satisfaction of the requirements of the FDA and of other regulatory agencies typically takes a significant number of years and can vary substantially based upon the type, complexity and novelty of the product candidate. The approval procedure and the time required to obtain approval also varies among countries. Regulatory agencies may have varying interpretations of the same data, and approval by one regulatory agency does not ensure approval by regulatory agencies in other jurisdictions. In addition, the FDA or regulatory agencies outside the United States may choose not to communicate with or update us during clinical testing and regulatory review periods. The ultimate decision by the FDA or other regulatory agencies regarding drug approval may not be consistent with prior communications.

This product development process can last many years, be very costly and still be unsuccessful. Regulatory approval by the FDA or regulatory agencies outside the United States can be delayed, limited or not granted at all for many reasons, including:

- a product candidate may not demonstrate safety and efficacy for each target indication in accordance with FDA standards or standards of other regulatory agencies;

- poor rate of patient enrollment, including limited availability of patients who meet the criteria for certain clinical trials;

Table of Contents

data from pre-clinical testing and clinical trials may be interpreted by the FDA or other regulatory agencies in different ways than we or our partners interpret it;

the FDA or other regulatory agencies might not approve our or our partners manufacturing and analytical processes or facilities;

the FDA or other regulatory agencies may not approve accelerated development timelines for our product candidates;

third-party CROs and other third-party service providers and independent clinical investigators we hire to manage and conduct the trials, may fail to perform their oversight of the trials or to meet expected deadlines;

that our clinical investigational sites and the records kept at such sites, including the clinical trial data, may fail to be to be in compliance with the FDA s GCP, or EU legislation governing GCP, including the failure to pass FDA, EMA or EU Member State inspections of clinical trials as interpreted by the regulators;

the FDA or other regulatory agencies may change their approval policies or adopt new regulations or requirements;

adverse medical events during the trials could lead to requirements that trials be repeated or extended, or that a program be terminated or placed on clinical hold, even if other studies or trials relating to the program are successful, or that other specialized studies may be required as follow up; and

the FDA or other regulatory agencies may not agree with our or our partners regulatory approval strategies or components of our or our partners filings, such as clinical trial designs.

In addition, our product development timelines may be impacted by third-party patent litigation. In summary, we cannot be sure that regulatory approval will be granted for IV/IM meloxicam or any other product candidates that we submit for regulatory review. Our ability to generate revenues from the commercialization and sale of IV/IM meloxicam or additional products will be limited by any failure to obtain these approvals. In addition, share prices have declined significantly in certain instances where companies have failed to obtain FDA approval of a product candidate or if the timing of FDA approval is delayed. If the FDA s or any other regulatory agency s response to any application for approval is delayed or not favorable for IV/IM meloxicam, our share price could decline.

Even if regulatory approval to market a drug product is granted, the approval may impose limitations on the indicated use for which the drug product may be marketed and/or additional post-approval requirements with which we would need to comply in order to maintain the approval of such products. Our business could be seriously harmed if we do not complete these studies and the FDA, as a result, requires us to change related sections of the marketing label for our products, or rescinds regulatory approval as a result. In addition, adverse medical events that occur during clinical trials or during commercial marketing of our products could result in the temporary or permanent withdrawal by the FDA or other regulatory agencies of our products from commercial marketing, which could seriously harm our business and cause our share price to decline.

We cannot predict the outcome for the remaining clinical trials for IV/IM meloxicam.

Conducting clinical trials is a lengthy, time-consuming and expensive process. Before obtaining regulatory approvals for the commercial sale of any products, we or our partners must demonstrate, that our product candidates are safe and effective for use in humans. In April 2015, we acquired IV/IM meloxicam from Alkermes Plc, who has completed multiple Phase II trials. We currently expect after our meeting with the FDA and our receipt of new supplies of IV/IM meloxicam drug product which have met release specifications, we will prepare to initiate our Phase III program. There can be no assurance that the pre-clinical and clinical development efforts performed to date have been successfully completed. Completion of clinical trials may take several years or more. The length of time can vary substantially with the type, complexity, novelty and intended use of the product candidate. The commencement and rate of completion of clinical trials may be delayed by many factors, including:

the potential delay by a collaborative partner or investigators in beginning a clinical trial;

the inability to recruit clinical trial participants at the expected rate;

the failure of clinical trials to demonstrate a product candidate s safety or efficacy;

the inability to follow patients adequately after treatment;

unforeseen safety issues;

the inability to manufacture sufficient quantities of materials that meet release specifications and have adequate shelf life stability for use in clinical trials; and

unforeseen governmental or regulatory issues, including those by the FDA and other regulatory agencies.

Table of Contents

If IV/IM meloxicam fails to demonstrate safety and efficacy in clinical trials, or if third parties fail to conduct clinical trials in accordance with their obligations, the development, approval and commercialization of IV/IM meloxicam may be delayed or prevented, and such events could adversely affect our business, financial condition, cash flows and results of operations.

We rely on Alkermes and a contract manufacturer to supply us with clinical and commercial supplies of IV/IM meloxicam, and any disruption in the chain of supply may cause delay in developing and commercializing IV/IM meloxicam.

Alkermes is currently our sole supplier of bulk IV/IM meloxicam formulation. Additionally, we intend to enter into an agreement with a contract manufacturer for the provision of sterile fill and finish services. Although the supply agreement that we have with Alkermes allows us to qualify and purchase from an alternative supplier in certain circumstances, it would be time-consuming and expensive for us to do so, and there can be no assurance that an alternative supplier could be found. Currently, Alkermes is the only established supplier of bulk IV/IM meloxicam formulation.

If supply from our suppliers is interrupted, there could be a significant disruption in commercial or clinical supply of IV/IM meloxicam. The FDA, state regulatory authorities or other regulatory authorities outside of the United States may also require additional studies if any new suppliers are relied upon for commercial production.

Any interruption in the supply of IV/IM meloxicam 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 IV/IM meloxicam on a timely basis and at all, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

Integrating the assets acquired in the Gainesville Transaction in April 2015 may be more difficult, costly or time consuming than expected and the anticipated benefits of the acquisition may not be realized.

The success of the Gainesville Transaction, including anticipated benefits, will depend, in part, on our ability to successfully combine and integrate such assets and the associated employees with our business. It is possible that the integration process could result in the loss of key employees, higher than expected costs, diversion of management attention, the disruption of ongoing businesses or inconsistencies in standards, controls, procedures and policies that adversely affect our ability to maintain relationships with customers, vendors and employees or to achieve the anticipated benefits and cost savings of the acquisition. If we experience difficulties with the integration process, the anticipated benefits of the acquisition may not be realized fully or at all, or may take longer to realize than expected.

Revenues from our manufacturing business are dependent on a small number of commercial partners, and the loss of one of these partners, or a decline in their orders, may adversely affect our business.

Our manufacturing business is currently dependent on our relationships with our commercial partners. We have five key commercial partners: Novartis Pharma AG (Ritalin LA®, Focalin XR®), Kremers Urban Pharmaceuticals, Inc. (generic Verapamil), Watson Laboratories, Inc. (Verelan PM®), Paladin Labs Inc. (Zohydro ER®) and Pernix Therapeutics Holdings, Inc. (Zohydro ER®). Our contracts with our commercial partners are for a short term, generally of one year. If any one or more of these commercial partners fail to renew their contract or otherwise significantly reduce their purchasing volume our revenues could be adversely affected.

Manufacturing revenues also depend on the ability of our commercial partners to effectively market and sell their products to their customers. A commercial partner may choose to devote its efforts to its other products or may reduce or fail to devote the necessary resources to provide effective sales and marketing support of the products we manufacture and supply. Our commercial partners face competition from other pharmaceutical companies for sales of products to end users. Competition from sellers of generic drugs is a major challenge for our commercial partners, and the loss or expiration of intellectual property rights for the products we manufacture can have a significant adverse effect on their sales volume. For example, the last-to-expire patents listed in the U.S. Orange Book covering Focalin XR® all expire in December 2015. Following such date, we anticipate that orders for Focalin XR® from Novartis will decrease substantially. This and any other significant reduction, delay or cancellation of orders from our commercial partners could adversely effect our revenues.

In addition, the financial covenants in our credit agreement with OrbiMed include minimum revenue targets for Gainesville, and any significant reduction, delay or cancellation of orders from our commercial partners may cause us to fail to meet such targets, which may result in an event of default under the credit agreement with OrbiMed, which could have a material adverse effect on our business, financial condition and results of operation.

Table of Contents

We and our third-party suppliers must comply with environmental and health and safety laws and regulations, which can be expensive and restrict how we do business.

In connection with our research and development activities and our manufacturing business, we are subject to federal, state and local laws, rules, regulations and policies concerning the environment and the health and safety of our employees. Although we believe that we have complied with the applicable laws, regulations and policies in all material respects and have not been required to correct any material noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

In addition, our research and development activities and our manufacturing business involve the use, generation and disposal of hazardous materials, including chemicals, solvents, agents and biohazardous materials. As a result, we are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. Although we believe that our safety procedures for storing, handling and disposing of such materials comply with the standards prescribed by those regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. We currently contract with third parties to dispose of these substances that we generate, and we rely on these third parties to properly dispose of these substances in compliance with applicable laws and regulations. If these third parties do not properly dispose of these substances in compliance with applicable laws and regulations, we may be subject to legal action by governmental agencies or private parties for improper disposal of these substances. The costs of defending such actions and the potential liability resulting from such actions are often very large. In the event we are subject to such legal action or we otherwise fail to comply with applicable laws and regulations governing the use, generation and disposal of hazardous materials and chemicals, we could be held liable for any damages that result, and any such liability could exceed our resources.

Although we maintain workers compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, including those resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities.

Our employees, partners, independent contractors, principal investigators, consultants, vendors and contract research organizations may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, partners, independent contractors, principal investigators, consultants, vendors and contract research organizations, or CROs, may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these employees could include intentional, reckless and/or negligent conduct or unauthorized activity that violates: (1) FDA or DEA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA; (2) manufacturing standards; (3) federal and state healthcare fraud and abuse laws and regulations; or (4) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. Any incidents or any other conduct that leads to an employee receiving an FDA debarment could result in a loss of business from our partners and severe reputational harm. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or

asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business, operating results and financial condition.

Table of Contents

We are subject to risks related to large-scale commercial manufacturing.

Manufacturing pharmaceuticals, especially in large quantities, is complex. The products we manufacture for our commercial partners require several manufacturing steps, and may involve complex techniques to assure quality and sufficient quantity. Our manufactured products must be made consistently and in compliance with a clearly defined manufacturing process. Slight deviations anywhere in the manufacturing process, including obtaining materials, equipment malfunctions, filling, labeling, packaging, storage, shipping, quality control and testing, some of which all pharmaceutical manufacturing companies experience from time to time, may result in lot failures, delay in the release of lots, product recalls or spoilage. Success rates can vary dramatically at different stages of the manufacturing process, which can lower yields and increase costs.

In addition, we rely on a limited number of suppliers and pharmaceutical wholesalers to provide the raw materials needed for the manufacture of our commercial products. We may experience deviations in the manufacturing process or interruptions in our supply chain that may take significant time and resources to resolve and, if unresolved, may affect manufacturing output and/or cause us to fail to satisfy customer orders or contractual commitments or result in litigation or regulatory action.

Our manufacturing facility also requires specialized personnel and is expensive to operate and maintain. Any suspension of the sale of products of our commercial partners to be manufactured in our facility may cause operating losses as we continue to operate the facility and retain specialized personnel. In addition, any interruption in manufacturing could result in delays in meeting our contractual obligations and could damage our relationships with our commercial partners, including the loss of manufacturing and supply rights.

If we fail to meet the stringent requirements of governmental regulation in the manufacture of pharmaceutical products, we could incur substantial costs and a reduction in revenues.

We are required to maintain compliance with cGMP, and our manufacturing facility is subject to inspections by the FDA and other global regulators to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application(s) to the FDA and acceptance of the change by the FDA prior to release of our manufactured products. Because we produce multiple products at our manufacturing facility, there are increased risks associated with cGMP compliance. Our inability to demonstrate ongoing cGMP compliance could require us to engage in lengthy and expensive remediation efforts, withdraw or recall products and/or interrupt commercial supply of any products. Any delay, interruption, or other issue that arises in the manufacture, fill/finish, packaging, or storage of any drug product as a result of a failure of our facility to pass any regulatory agency inspection or maintain cGMP compliance could significantly impair our relationships with our commercial partners, which would substantially harm our business, prospects, operating results, and financial condition. Any finding of non-compliance could also increase our costs and cause us to lose revenue from manufactured products, which could be seriously detrimental to our business, prospects, operating results, and financial condition.

Additionally, our manufacturing activities are subject to the Controlled Substances Act and the regulations of the Drug Enforcement Agency, or DEA. Accordingly, we must adhere to a number of requirements with respect to controlled substances, including registration, recordkeeping and reporting requirements; labeling and packaging requirements; security controls, procurement and manufacturing quotas; and certain restrictions on refills. Failure to maintain compliance with applicable requirements can result in enforcement action that could have a material adverse effect on our business, financial condition, operating results and cash flows. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In certain circumstances, violations could result in criminal proceedings.

We may be adversely affected by natural disasters or other events that disrupt our business operations, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our manufacturing facility is located in Gainesville, Georgia, where natural disasters or similar events, like blizzards, tornadoes, fires, floods or explosions or large-scale accidents or power outages, could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a disaster, power outage or other event occurred that prevented us from using all or a significant portion of our Gainesville facility, that damaged critical infrastructure, such as manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations at that location, it may be difficult or, in certain cases, impossible for us to continue our manufacturing business for a substantial period of time.

Currently, we maintain insurance coverage against damage to our property and equipment, and to cover business interruption expenses, in an amount we believe is sufficient for our manufacturing operations. However, there can be no assurance that such insurance will continue to be available on acceptable terms or that such insurance will provide adequate protection against actual losses. Even if we maintain adequate insurance coverage, claims could have a material adverse effect on our financial condition, liquidity and results of operations and on our ability to obtain suitable, adequate or cost-effective insurance in the future.

Table of Contents

Product liability litigation may result in financial losses and harm our reputation.

Our manufacturing business exposes us to potential toxic tort and other types of product liability claims that are inherent in the manufacture of pharmaceutical products. We currently maintain product liability insurance in amounts we believe are sufficient for our manufacturing operations. However, there can be no assurance that such insurance will continue to be available on acceptable terms or that such insurance will provide adequate protection against actual losses. Even if we maintain adequate insurance coverage, claims could have a material adverse effect on our reputation, operating results, financial condition and liquidity and on our ability to obtain suitable, adequate or cost-effective insurance in the future.

Our ability to manufacture products for our commercial partners may be impaired if any of our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain, are found to infringe patents of others.

Our ability to continue to manufacture Ritalin LA, Focalin XR, Verelan PM, generic Verapamil and Zohydro ER for our commercial partners, or to utilize third parties to supply raw materials or other products, or to perform fill/finish services or other steps in our manufacture and supply chain, depends on our and their ability to operate without infringing the patents and other intellectual property rights of others. Other parties may allege that our manufacturing activities, or the activities of third parties involved in our manufacturing and supply chain, infringe patents or other intellectual property rights. A judicial decision in favor of one or more parties making such allegations could preclude the manufacture of the products to which those intellectual property rights apply, which could materially harm our business, operating results and financial condition.

We may not be able to protect the intellectual property related to Zohydro ER, which could result in new or additional generic competition to Zohydro ER or limit our ability to market Zohydro ER.

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. This type of litigation is commonly known as Paragraph IV litigation in the U.S. Within the past several years, the generic industry has aggressively pursued approvals of generic versions of innovator drugs at the earliest possible point in time.

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

We and our commercial partners are currently involved in Paragraph IV litigations in the United States involving our patents in respect to Zohyrdo ER. These litigations may be expensive, distracting to management and protracted and could result in new or additional generic competition to Zohydro ER. The introduction of a generic version of

Zohydro ER could cause a reduction in product revenue for our manufacturing business which could have a material adverse effect on our business, results of operations, financial condition and prospects.

In addition, we are currently involved in an interference in front of the United States Patent and Trademark Office with another party, which involves a patent application relating to Zohydro ER. We intend to vigorously prosecute our application that is involved in this interference. The result of the interference could result in the issuance of a patent that could limit our freedom to operate in respect to Zohydro ER, which could also cause a reduction in product revenue for our manufacturing business and have a material adverse effect on our business, results of operations, financial condition and prospects.

Failure to raise additional capital necessary to support increased capital requirements for our manufacturing facility may adversely affect our business.

Maintaining a world class cGMP pharmaceutical manufacturing facility is expensive. If the capital requirements for operating and maintaining our manufacturing facility exceed our current expectations, we may need to seek additional financing from banks or other lenders, or through public offerings or private placements of debt or equity securities. Securing additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop and maintain customer

Table of Contents

relationships. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to significantly scale back or discontinue our manufacturing business, which would have a material adverse effect on our business, operating results and prospects.

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

Unregistered Sales of Equity Securities

Other than the issuance of warrants to Alkermes and OrbiMed, as disclosed on our Form 8-K filed with the SEC on April 16, 2015, there were no unregistered sales of equity securities during the period.

Use of Proceeds

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

As of June 30, 2015, we have used approximately $19.8 million of the net proceeds from the IPO for our Dex-IN Phase II clinical trials, manufacturing costs, short term preclinical studies, working capital and other general corporate purposes, a portion of which was paid to MCG, an affiliate of the Company. 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 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 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.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

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

Exhibit No.	Description	Method of Filing
10.1	First Amendment to Credit Agreement, dated April 10, 2015, by and among Recro Pharma LLC and OrbiMed Royalty Opportunities II, LP.	Incorporated herein by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed on April 16, 2015.
10.2	Asset Transfer and License Agreement, dated as of April 10, 2015, between Alkermes Pharma Ireland Limited and DV Technology LLC.	Incorporated herein by reference to Exhibit 10.5 to the Company s Quarterly Report on Form 10-Q filed on May 12, 2015.
10.3	Transition Services Agreement, dated as of April 10, 2015, by and among Alkermes Pharma Ireland Limited, Recro Pharma, Inc., DV Technology LLC, and Alkermes Gainesville LLC.	Incorporated herein by reference to Exhibit 10.5 to the Company s Quarterly Report on Form 10-Q filed on May 12, 2015.

Table of Contents

Exhibit No.	Description	Method of Filing
10.4	Recro Pharma, Inc. Amended and Restated Equity Incentive Plan.	Incorporated herein by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed on June 26, 2015.
10.5	Development, Manufacturing and Supply Agreement, dated July 10, 2015, by and between Alkermes Pharma Ireland Limited and Recro Pharma, Inc.	Filed herewith.
10.6	Amended and Restated License and Supply Agreement, dated June 26, 2003, by and among Elan Corporation, plc (predecessor-in-interest to Recro Gainesville LLC) and Watson Laboratories, Inc.	Filed herewith.
10.7	Supplemental Agreement, dated December 8, 2004, to Amended and Restated License and Supply Agreement, dated June 26, 2003, by and among Elan Corporation, plc (predecessor-in-interest to Recro Gainesville LLC) and Watson Laboratories, Inc.	Filed herewith.
10.8	Supplemental Agreement No. 2, dated January 17, 2014, to Amended and Restated License and Supply Agreement, dated June 26, 2003, by and among Elan Corporation, plc (predecessor-in-interest to Recro Gainesville LLC) and Watson Laboratories, Inc.	Filed herewith.
21.1	Subsidiaries of the Registrant.	Filed herewith.
31.1	Rule 13a-14(a)/15d-14(a) certification of Principal Executive Officer.	Filed herewith.
31.2	Rule 13a-14(a)/15d-14(a) certification of Principal Financial Officer.	Filed herewith.
32.1	Section 1350 certification, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
101 INS	XBRL Instance Document	Filed herewith.
101 SCH	XBRL Taxonomy Extension Schema	Filed herewith.
101 CAL	XBRL Taxonomy Extension Calculation Linkbase	Filed herewith.
101 DEF	XBRL Taxonomy Extension Definition Linkbase	Filed herewith.
101 LAB	XBRL Taxonomy Extension Label Linkbase	Filed herewith.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith.

Portions of this exhibit have been omitted pursuant to a request for confidential treatment on file with the Securities and Exchange Commission.

Table of Contents

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: August 14, 2015

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

Date: August 14, 2015

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

Table of Contents

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