

Recro Pharma, Inc.  
Form 10-Q  
November 13, 2015  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**

**FORM 10-Q**

- x **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
For the Quarterly Period Ended: September 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**  
**(State or other jurisdiction of**

**26-1523233**  
**(I.R.S. Employer**

**incorporation or organization)**

**Identification No.)**

**490 Lapp Road, Malvern, Pennsylvania**  
**(Address of principal executive offices)**

**19355**  
**(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  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  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

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

As of November 13, 2015, there were 9,224,315 shares of common stock, par value \$0.01 per share, outstanding.

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## Consolidated Balance Sheets

(unaudited)

(amounts in thousands,

except share and per share data)	September 30, 2015	December 31, 2014
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 28,275	\$ 19,682
Accounts receivable	9,572	
Other receivables	29	90
Inventory	8,571	
Prepaid expenses	1,456	602
Deferred equity costs	542	
<b>Total current assets</b>	<b>48,445</b>	<b>20,374</b>
Property, plant and equipment, net	38,659	
Intangible assets, net	40,662	
Goodwill	6,744	
<b>Total assets</b>	<b>\$ 134,510</b>	<b>\$ 20,374</b>
<b>Liabilities and Shareholders Equity</b>		
Current liabilities:		
Accounts payable	\$ 781	\$ 871
Accrued expenses	4,695	575
Current portion of long-term debt	13,662	
<b>Total current liabilities</b>	<b>19,138</b>	<b>1,446</b>
Long-term debt	24,360	
Warrants	5,450	
Contingent consideration	57,186	
<b>Total liabilities</b>	<b>106,134</b>	<b>1,446</b>
Shareholders equity		
Preferred stock, \$0.01 par value. Authorized, 10,000,000 shares; none issued and outstanding		

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Common stock, \$0.01 par value. Authorized, 50,000,000 shares; issued and outstanding, 9,224,315 shares at September 30, 2015 and 7,707,600 shares at December 31, 2014

	92	77
Additional paid-in capital	69,982	52,947
Accumulated deficit	(41,698)	(34,096)
<b>Total shareholders' equity</b>	<b>28,376</b>	<b>18,928</b>
 Total liabilities and shareholders' equity	 \$ 134,510	 \$ 20,374

See accompanying notes to unaudited consolidated financial statements.

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## Consolidated Statements of Operations

(unaudited)

(amounts in thousands, except share and per share data)	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
<b>Revenue:</b>				
Manufacturing, royalty and profit sharing revenue	\$ 16,120	\$	\$ 32,824	\$
Research and development revenue	419		2,375	
<b>Total revenue</b>	<b>16,539</b>		<b>35,199</b>	
<b>Operating expenses:</b>				
Cost of sales (excluding amortization of intangible assets)	10,039		19,228	
Research and development	2,716	3,634	7,260	5,619
General and administrative	3,478	1,084	8,492	2,768
Amortization of intangible assets	646		1,238	
Change in warrant valuation	(762)		119	
Change in contingent consideration valuation	586		2,586	
<b>Total operating expenses</b>	<b>16,703</b>	<b>4,718</b>	<b>38,923</b>	<b>8,387</b>
<b>Operating loss</b>	<b>(164)</b>	<b>(4,718)</b>	<b>(3,724)</b>	<b>(8,387)</b>
<b>Other income (expense):</b>				
Interest income	2	5	10	7
Interest expense	(1,990)		(3,888)	(4,273)
<b>Net loss</b>	<b>(2,152)</b>	<b>(4,713)</b>	<b>(7,602)</b>	<b>(12,653)</b>
Accretion of redeemable convertible preferred stock and deemed dividend				(1,270)
<b>Net loss applicable to common shareholders</b>	<b>\$ (2,152)</b>	<b>\$ (4,713)</b>	<b>\$ (7,602)</b>	<b>\$ (13,923)</b>
<b>Basic and diluted net loss per common share</b>	<b>\$ (0.24)</b>	<b>\$ (0.61)</b>	<b>\$ (0.92)</b>	<b>\$ (2.42)</b>
<b>Weighted average basic and diluted common shares outstanding</b>	<b>9,118,664</b>	<b>7,707,600</b>	<b>8,243,909</b>	<b>5,743,527</b>

See accompanying notes to unaudited consolidated financial statements.

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## Consolidated Statement of Shareholders' Equity

Nine Months Ended September 30, 2015

(unaudited)

(amounts in thousands, except share and per share data)	<b>Common stock</b>		<b>Additional paid-in capital</b>	<b>Accumulated deficit</b>	<b>Total</b>
	<b>Shares</b>	<b>Amount</b>			
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			1,725		1,725
Sale of common stock, net of offering costs	1,379,311	14	14,798		14,812
Cashless warrant exercises	2,941				
Net loss				(7,602)	(7,602)
Balance, September 30, 2015	9,224,315	\$ 92	\$ 69,982	\$ (41,698)	\$ 28,376

See accompanying notes to unaudited consolidated financial statements.

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## Consolidated Statements of Cash Flows

(unaudited)

(amounts in thousands, except share and per share data)	<b>Nine Months Ended September 30,</b>	
	<b>2015</b>	<b>2014</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (7,602)	\$ (12,653)
<b>Adjustments to reconcile net loss to net cash provided by (used in) operating activities:</b>		
Stock-based compensation	1,725	329
Depreciation expense	2,730	
Noncash interest expense	439	4,273
Amortization	1,238	
Change in warrant valuation	119	
Change in contingent consideration valuation	2,586	
<b>Changes in operating assets and liabilities, net of effect of acquisition:</b>		
Inventory	1,384	
Prepaid expenses	(475)	(118)
Accounts receivable and other receivables	3,007	(48)
Accounts payable and accrued expenses	2,688	1,569
<b>Net cash provided by (used in) operating activities</b>	<b>7,839</b>	<b>(6,648)</b>
<b>Cash flows from investing activities:</b>		
Acquisition of Gainesville, net of cash acquired	(52,690)	
Purchase of property and equipment	(1,787)	
<b>Net cash used in investing activities</b>	<b>(54,477)</b>	
<b>Cash flows from financing activities:</b>		
Proceeds from initial public offering		30,364
Proceeds from private placement, net of offering costs	14,812	
Proceeds from long-term debt	50,000	175
Payment on long-term debt	(7,838)	
Payment of debt issuance costs	(1,718)	
Payment of deferred equity costs	(253)	
Proceeds from option exercise	228	
<b>Net cash provided by financing activities</b>	<b>55,231</b>	<b>30,539</b>
<b>Net increase in cash and cash equivalents</b>	<b>8,593</b>	<b>23,891</b>
Cash and cash equivalents, beginning of period	19,682	13



Cash and cash equivalents, end of period	\$ 28,275	\$ 23,904
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
Cash paid for interest	\$ 3,449	
Purchases of property, plant and equipment included in accrued expenses	\$ 179	
See accompanying notes to unaudited consolidated financial statements.		

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**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 both acute post-operative and peri-procedural pain. On April 10, 2015, the Company acquired from Alkermes plc, or Alkermes, worldwide rights to intravenous and intramuscular or 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 for pharmaceutical companies who commercialize or plan to commercialize these products.

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

The Company has incurred losses since inception and has an accumulated deficit of \$41,698 as of September 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 commercialize, or partner with pharmaceutical companies to commercialize its product candidates; (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 consolidated 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 September 30, 2015 and its results of operations and cash flows for the nine months ended September 30, 2015 and 2014. Operating results for the three and nine months ended September 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 will be charged to research and development expenses when consumed.

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**RECRO PHARMA, INC. AND SUBSIDIARIES**

Notes to Unaudited Consolidated Financial Statements

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

***(d) Revenue Recognition***

The Company generates revenues from manufacturing, packaging and related 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.

Manufacturing and packaging service revenue is 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.

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 under the terms of a license and supply agreement in the period the products are sold and expenses are incurred by our commercial partner and collectability is reasonably assured.

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) Goodwill and Intangible Assets***

Goodwill represents the excess of purchase price over the fair value of net assets acquired by the

Company. Goodwill is not amortized, but assessed for impairment on an annual basis or more frequently if impairment indicators exist. The impairment model prescribes a two-step method for determining impairment.

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.

Intangible assets include our royalties and contract manufacturing relationships intangible asset as well as an in-process research and development (IPR&D) asset. The royalties and contract manufacturing relationships intangible asset is considered a definite-lived intangible asset and are amortized on a straight-line basis over a useful lives of six years.

Intangible assets related to IPR&D are considered indefinite-lived intangible assets and are assessed for impairment annually or more frequently if impairment indicators exist. If the associated research and development effort is

abandoned, the related assets will be written-off and the Company will record a noncash impairment loss on its consolidated statements of operations. For those compounds that reach commercialization, the IPR&D assets will be amortized over their estimated useful lives.

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.

*(f) 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.

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## Notes to Unaudited Consolidated Financial Statements

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

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

	<b>September 30, 2015</b>	<b>December 31, 2014</b>
Options outstanding	1,570,982	1,033,300
Warrants	784,928	150,000

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

**(g) 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 nine month period ended September 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.

In July 2015, the FASB issued ASU No. 2015-11, *Simplifying the Measurement of Inventory*, which changes the measurement principle for inventory from the lower of cost or market to the lower of cost and net realizable value. The amendments in this guidance do not apply to inventory that is measured using last-in, first-out (LIFO) or the retail inventory method. The amendments apply to all other inventory, which includes inventory that is measured using first-in, first-out or average cost. Within the scope of this new guidance, an entity should measure inventory at the lower of cost and net realizable value; where, net realizable value is defined as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The new guidance is effective for annual periods beginning after December 15, 2016, with early adoption permitted. The new

guidance must be applied on a prospective basis. We are evaluating the effect that the new guidance will have on our consolidated financial statements and related disclosures.

In September 2015, the FASB issued updated guidance regarding the accounting for and disclosure of measurement-period adjustments that occur in periods after a business combination is consummated. This update requires that the acquirer recognize measurement-period adjustments in the reporting period in which they are determined. Prior period information should not be revised. This update also requires an entity to present separately on the face of the income statement or disclose in the notes the amount recorded in the current-period income statement that would have been recorded in previous reporting periods if the adjustments had been recognized as of the acquisition date. The effective date for annual and interim periods begins after December 15, 2016. 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 million 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

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## Notes to Unaudited Consolidated Financial Statements

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

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).

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

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

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.



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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:

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

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## 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:

	<b>Estimated Fair Value</b>	<b>Estimated Useful Life</b>
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
	<b>\$ 39,424</b>	

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:

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

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 \$646 and \$1,238 for the three and nine months ended September 30, 2015, respectively. The amortization expense for the next five years will be \$2,583 per year.

**(5) Unaudited Pro Forma Results of Operations**

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

	Nine Months Ended September 30, 2015	
Net revenue	\$	56,244
Net loss		(4,271)

**(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

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## 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:

	<b>Fair value measurements at reporting date using</b>		
	<b>Quoted prices in active markets for identical assets (Level 1)</b>	<b>Significant other observable inputs (Level 2)</b>	<b>Significant unobservable inputs (Level 3)</b>
<b>At December 31, 2014:</b>			
<b>Assets:</b>			
Money market mutual funds (included in cash and cash equivalents)	\$ 10,922		
Government and agency bonds	8,663		
<b>Cash equivalents</b>	<b>\$ 19,585</b>		
<b>At September 30, 2015:</b>			
<b>Assets:</b>			
Money market accounts (included in cash and cash equivalents)	\$ 12,858		
Government and agency bonds	9,508		
<b>Cash equivalents</b>	<b>\$ 22,366</b>		
<b>Liabilities:</b>			
Warrants			\$ 5,450

Contingent consideration	57,186
	\$ 62,636

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:

	<b>Warrants</b>	<b>Contingent Consideration</b>
Balance at December 31, 2014	\$	\$
Additions	5,331	54,600
Remeasurement	119	2,586
Balance at September 30, 2015	\$ 5,450	\$ 57,186

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## Notes to Unaudited Consolidated Financial Statements

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

**(7) Inventory**

Inventory consists of the following:

	<b>September 30, 2015</b>
Raw materials	\$ 2,852
Work in process	3,490
Finished goods	2,229
	\$ 8,571

**(8) Accrued Expenses**

Accrued expenses consist of the following:

	<b>September 30, 2015</b>	<b>December 31, 2014</b>
Clinical trial and related costs	\$ 823	\$ 112
Professional and consulting fees	394	394
Payroll and related costs	2,119	25
Other	1,359	44
	\$ 4,695	\$ 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 contingent 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 with cash on hand and a \$50,000 five-year senior secured term loan, pursuant to a credit agreement, 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.

The credit agreement contains certain usual and customary affirmative and negative covenants, as well as financial covenants that the Company will need to satisfy on a monthly and quarterly basis. As of September 30, 2015, the Company was in compliance with the covenants.

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

Debt issuance costs related to the term loan of \$4,579, 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 \$4,140 as of September 30, 2015. As of September 30, 2015, the long-term debt balance is comprised of the following:

Principal balance outstanding	\$ 42,162
Unamortized deferred issuance costs	(4,140)
	38,022
Current portion	(13,662)
	\$ 24,360

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**RECRO PHARMA, INC. AND SUBSIDIARIES**

Notes to Unaudited Consolidated Financial Statements

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

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 September 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.

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.

On July 7, 2015, the Company closed a Private Placement with certain accredited investors in which the Company sold 1,379,311 shares of common stock at a price per share of \$11.60, for net proceeds of \$14,812. The Company paid the placement agents a fee equal to 6.0% of the aggregate gross proceeds from the Private Placement, plus reimbursement of certain expenses.

***(b) Preferred Stock***

The Company is authorized to issue 10,000,000 shares of preferred stock, with a par value of \$0.01 per share. As of September 30, 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 September 30, 2015, the Company had the following warrants outstanding to purchase shares of the Company's common stock:

<b>Number of Shares</b>	<b>Exercise Price per Share</b>	<b>Expiration Date</b>
140,000	\$ 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

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## Notes to Unaudited Consolidated Financial Statements

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

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 September 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.

Stock options are exercisable generally for a period of 10 years from the date of grant and generally vest over four years. As of September 30, 2015, 902,844 shares and 174 shares are available for future grants under the 2013 Plan and 2008 Plan, respectively.

Stock-based compensation expense for the nine months ended September 30, 2015 and 2014 was \$1,725 and \$329, respectively, and for the three months ended September 30, 2015 and 2014 was \$988 and \$155, respectively.

The following table summarizes stock option activity during the nine months ended September 30, 2015:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life
Balance, December 31, 2014	1,033,300	\$ 5.77	
Granted	588,150	8.07	
Exercised	(38,000)	6.00	
Canceled	(12,468)	11.17	
Balance, September 30, 2015	1,570,982	\$ 7.26	8.0 years
Options exercisable, September 30, 2015	578,704	\$ 6.72	6.1 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. The remaining portion of the performance-based options vest monthly over a three-year period beginning on July 24, 2015.

As of September 30, 2015, there was \$6,548 of unrecognized compensation expense related to unvested options that are expected to vest and will be expensed over a weighted average period of 3.6 years.

Included in the table above are 30,000 of options granted outside the plan. The grant was made pursuant to the NASDAQ inducement grant exception in accordance with NASDAQ Listing Rule 5635(c)(4).

### **(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 \$135 and \$123 for the three months ended September 30, 2015 and 2014, respectively, and \$372 and \$330 for the nine months ended September 30, 2015 and 2014, respectively. As of September 30, 2015, \$19 and \$45 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 \$85 in rental fees to MCG for a month to month lease for facilities space for the nine months ended September 30, 2015 and \$72 for facilities space for the nine months ended September 30, 2014.

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**RECRO PHARMA, INC. AND SUBSIDIARIES**

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

**(14) Subsequent Event**

On October 12, 2015, Charles Garner's employment as Chief Financial Officer of the Company terminated. Effective October 12, 2015, Donna Nichols, Vice President and Corporate Controller of the Company, assumed the duties of the principal financial officer on an interim basis until such time as the Company appoints a new Chief Financial Officer.

On October 26, 2015, the Company provided a clinical and regulatory update on its pipeline candidates, announcing that, based on feedback from the U.S. Food and Drug Administration, the Company intends to (i) initiate a pivotal Phase III clinical development program for IV/IM meloxicam in the first quarter of 2016 and (ii) pursue Dex-IN for the treatment of peri-procedural pain rather than post-operative pain.

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**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, potential or continue or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. believ

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 intravenous and intramuscular, or IV/IM, meloxicam, Dex-IN 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 maintain our relationships and contracts with our commercial partners;

our ability to comply with stringent U.S. and foreign government regulation in the manufacture of pharmaceutical products, including Good Manufacturing Practice, or cGMP, compliance and U.S. Drug Enforcement Agency, or DEA, compliance;

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, in our Quarterly Reports for the periods ended March 31, 2015 and June 30, 2015, filed with the SEC on May 12, 2015 and August 14, 2015, respectively, 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. Our lead product candidate IV/IM meloxicam is ready to begin pivotal Phase III clinical trials for the management of acute post-operative pain. IV/IM meloxicam, a proprietary, long-acting preferential COX-2 inhibitor for moderate to severe acute pain has

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successfully completed multiple Phase II clinical trials. We believe IV/IM meloxicam compares favorably to competitive therapies in onset of pain relief duration of pain relief and time to peak analgesic effect. Based on feedback from the U.S. Food and Drug Administration, or FDA, we intend to initiate a Phase III program that will include two pivotal clinical trials, as well as other trials. We expect to enroll a total of approximately 1,300 patients in these trials. One pivotal clinical trial will be designed to demonstrate pain relief over a 48-hour period in a hard tissue, post-operative pain model, and the other pivotal trial will be designed to demonstrate pain relief over a 24-hour period in a soft tissue, post-operative pain model. Our pipeline also includes Dex-IN, a proprietary intranasal formulation of dexmedetomidine, or Dex, which successfully completed a Phase II clinical trial in post-operative pain. We recently met with the FDA to obtain feedback on the Phase II efficacy and safety data, and for our proposed DEX-IN clinical development program. Based on feedback from the FDA, regarding DEX-IN's benefit-risk profile, specifically its efficacy and blood pressure effects, which was demonstrated in post-operative pain, and the subsequent requirements for a post-operative pain clinical program, we believe that such a program is not advisable due to time, cost and associated risk. We plan to reevaluate DEX-IN as discussed with the FDA and intend to pursue a Phase II dose-ranging program in peri-procedural pain. 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 peri-procedural 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<sup>®</sup>, Focalin XR<sup>®</sup>, Verelan PM<sup>®</sup>, generic Verapamil and Zohydro ER<sup>®</sup>; as well as development stage products.

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. On July 7, 2015, we closed a Private Placement with certain accredited investors in which we sold 1,379,311 shares of common stock at a price per share of \$11.60, for net proceeds of approximately \$14.8 million. The Company paid the placement agents a fee equal to 6.0% of the aggregate gross proceeds from the Private Placement, plus reimbursement of certain expenses.

We have incurred losses and generated negative cash flows from operations since inception. As of September 30, 2015, we had an accumulated deficit of \$41.7 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, including a planned Phase III pivotal and safety trials for IV/IM meloxicam and Phase II dose-ranging trials for Dex. Based upon additional financial resources, we may develop and commercialize our proprietary formulations of IV/IM 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 \$52.7 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 \$52.7 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.



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### **Financial Overview**

#### ***Revenues***

During the three and nine months ended September 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 and supply 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 and supply agreement in the period the products are sold and expenses are incurred by our commercial partner and collectability is reasonably assured.

***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 IV/IM meloxicam and Dex in different delivery forms. These expenses consist primarily of:

expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and a substantial portion of our preclinical studies;

the cost of acquiring and manufacturing clinical trial materials and manufacturing services;

costs related to facilities, depreciation and other allocated expenses;

costs associated with non-clinical activities and regulatory approvals; and

salaries and related costs for personnel in research and development functions.

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

Since inception, we have developed and evaluated a series of Dex product candidates through Phase I pharmacokinetic and efficacy trials and placebo controlled Phase II efficacy trials. IV/IM meloxicam has been successfully evaluated in multiple Phase II clinical trials and based on feedback from the FDA at the end of Phase II meeting, we intend to initiate a Phase III program that will include two pivotal clinical trials, as well as other trials. Dex-IN recently completed a Phase II bunionectomy study and we met with the FDA to obtain feedback on Dex-IN for post-operative pain management. Based on this meeting, we intend to pursue a Phase II dose-ranging program in peri-procedural pain. In addition to the development of 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 procedural or peri-operative in pain as well as 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.

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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, our quarterly reports for the periods ended March 31, 2015 and June 30, 2015 and our Annual Report on Form 10-K for the fiscal year ended December 31, 2014.

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 to be substantial for the foreseeable future as we advance this product candidates through clinical trials, manufacturing scale-up and other pre-approval activities. We also expect to have significant expenses with Dex-IN Phase II clinical trials and related work. 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 and our acquisition of Gainesville, 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.

**Table of Contents*****Interest Expense***

Interest expense for the three and nine months ended September 30, 2015 was a result of interest expense incurred on our senior secured term loan with OrbiMed. Interest expense for the three and nine months ended September 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 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 September 30, 2015 and 2014:***

	<b>Three months ended September 30, 2015      2014</b>	
	(amounts in thousands)	
<b>Revenue:</b>		
Manufacturing, royalty and profit sharing revenue	\$ 16,120	\$
Research and development revenue	419	
 Total revenues	 16,539	
<b>Operating expenses:</b>		
Costs of sales (excluding amortization of intangible assets)	10,039	
Research and development	2,716	3,634
General and administrative	3,478	1,084
Amortization of intangible assets	646	

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Change in warrant valuation	(762)	
Change in contingent consideration valuation	586	
Total operating expenses	16,703	4,718
Other income (expense):		
Interest income (expense)	(1,988)	5
Net loss	\$ (2,152)	\$ (4,713)

**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 September 30, 2015 increased to \$16.5 million and cost of sales increased to \$10.0 million.

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**Research and Development.** Our research and development expenses were \$2.7 million and \$3.6 million for the three months ended September 30, 2015 and 2014, respectively, a decrease of \$0.9 million and 25% from September 30, 2014, primarily due to reduction of \$3.1 million in Dex study expenses, partially offset by an increase of \$1.1 million in our IV/IM Meloxicam clinical expenses and \$1.0 million in research and development costs incurred at our Gainesville facility, which are primarily related to process development, regulatory affairs and research and development analytical work.

**General and Administrative.** Our general and administrative expenses were \$3.5 million and \$1.1 million for the three months ended September 30, 2015 and 2014, respectively, an increase of \$2.4 million and 218% from September 30, 2014, due to management's salaries, benefits and stock-based compensation, and increased consulting and legal fees associated with being a public company and acquisition of the Gainesville facility.

**Amortization of Intangible Assets.** Amortization expense was \$0.6 million for the three months ended September 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 \$2.0 million during the three months ended September 30, 2015 as a result 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.

**Comparison of the Nine Months Ended September 30, 2015 and 2014:**

	<b>Nine months ended September 30, 2015      2014</b>	
	(amounts in thousands)	
<b>Revenue:</b>		
Manufacturing, royalty and profit sharing revenue	\$ 32,824	\$
Research and development revenue	2,375	
<b>Total revenues</b>	<b>35,199</b>	
<b>Operating expenses:</b>		
Costs of sales (excluding amortization of intangible assets)	19,228	
Research and development	7,260	5,619
General and administrative	8,492	2,768
Amortization of intangible assets	1,238	
Change in warrant valuation	119	
Change in contingent consideration valuation	2,586	
<b>Total operating expenses</b>	<b>38,923</b>	<b>8,387</b>
<b>Other income (expense):</b>		
Interest income (expense)	(3,878)	(4,266)
<b>Net loss</b>	<b>\$ (7,602)</b>	<b>\$ (12,653)</b>

**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 nine months ended September 30, 2015 increased to \$35.2 million and cost of sales increased to \$19.2 million.

**Research and Development.** Our research and development expenses were \$7.3 million and \$5.6 million for the nine months ended September 30, 2015 and 2014, respectively, an increase of \$1.7 million or 30% from September 30, 2014, primarily due to an increase of \$1.8 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, and an increase of \$1.4 million in costs associated with a work plan for our IV/IM meloxicam manufacturing and clinical trial offset by a \$ 1.7 million reduction of clinical trial, manufacturing and supply costs for Dex Phase II clinical trial.

**General and Administrative.** Our general and administrative expenses were \$8.5 million and \$2.8 million for the nine months ended September 30, 2015 and 2014, respectively, an increase of \$5.7 million and 204% from September 30, 2014, due to \$1.7 million in costs associated with the Gainesville Transaction, an increase of \$1.7 million in management s salaries, benefits and stock-based compensation, and \$1.9 million in increased consulting and legal fees associated with being a public company and acquisition of our Gainesville facility.



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***Amortization of Intangible Assets.*** Amortization expense was \$1.2 million for the nine months ended September 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 \$3.9 million during the nine months ended September 30, 2015, as a result 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 nine months ended September 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 September 30, 2015 and December 31, 2014, we had \$28.3 million and \$19.7 million, respectively, in cash and cash equivalents. On July 7, 2015, we closed a private placement of shares of our common stock in which we received net proceeds of \$14.8 million. Since inception through September 30, 2015, we have financed our product development, operations and capital expenditures primarily from private sales of \$4.0 million of our Series A Stock, \$9.6 million of our Bridge Notes and \$15 million of our common stock, as well as \$30.3 million from our IPO. Revenues from the Gainesville manufacturing business are used to 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 lesser 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. On August 20, 2015, we paid \$7.8 million of the outstanding principal on our senior secured term loan from free cash flow generated during the second quarter of 2015 by Gainesville.

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**Sources and Uses of Cash**

Cash provided by (used in) operations was \$7.8 million and (\$6.6) million for the nine months ended September 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 \$54.5 million for the nine months ended September 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 \$55.2 million for the nine months ended September 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, closing on \$14.8 million of net proceeds from a private placement of our common stock and a principal payment of \$7.8 million made on the OrbiMed credit agreement. Cash provided by financing activities for the nine months ended September 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.

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 IV/IM meloxicam and Dex-IN;

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

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

the costs of our commercialization activities if approved by the FDA;

the cost of purchasing manufacturing and other capital equipment for our potential products;

the scope, progress, results and costs of development for our other product candidates;

the cost, timing and outcome of regulatory review of our other product candidates;

the extent to which we acquire or invest in products, businesses and technologies;

our ability to maintain our relationships and contracts with our commercial partners;

our ability to comply with stringent U.S. & foreign government regulation in the manufacture of pharmaceutical products, including current Good Manufacturing Practice, or cGMP and U.S. DEA requirements;

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 third 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

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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%.

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 NDA 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. We have elected 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 commercial supplies of bulk IV/IM meloxicam formulation 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/Farnos 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 (\$22.9 million as of September 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 September 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 (\$13.6 million as of September 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 September 30, 2015, no milestones have been achieved.

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### ***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 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 September 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.



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**Table of Contents****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 September 30, 2015, we had approximately \$22.4 million invested in money market instruments, and government and agency bonds. We believe our policy of investing in highly rated securities, whose liquidities are, at September 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 \$0.1 million 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 accounting officer (performing the functions of a 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 September 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 September 30, 2015, our principal executive officer and principal accounting 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.**

As part of the Gainesville Transaction, we acquired the rights to Zohydro ER, which we license to our commercial partner, Pernix Therapeutics Holdings, Inc., or Pernix, in the United States, and which is subject to ongoing intellectual property litigation and proceedings.

Zohydro ER is subject to three paragraph IV certifications, two of which were filed in 2014 by Actavis plc, or Actavis, and Alvogen Pine Brook, Inc., or Alvogen, regarding the filing of Abbreviated NDAs, or ANDAs, with the FDA for a generic version of Zohydro ER, and one of which was filed in April 2015 by Actavis regarding the filing of a supplemental ANDA, or sANDA. These certification notices allege that the two U.S. patents listed in the FDA's Orange Book for Zohydro ER, each with an expiration date in November 2019, will not be infringed by Actavis' or Alvogen's proposed products, are invalid and/or are unenforceable. In 2014, Daravita Limited (a subsidiary of Alkermes and our predecessor in interest) filed suit against each of Actavis and Alvogen in the U.S. District Court for the District of Delaware based on the ANDAs, and in 2015 we filed suit against Actavis in the U.S. District Court for the District of Delaware based on the sANDA. In addition, in April 2015, the U.S. Patent and Trademark Office declared an interference between our U.S. Patent Application No. 11/372,857 relating to Zohydro ER, or the 857 application, and two Purdue Pharma, LP, or Purdue, applications.

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Under our license agreement with Pernix, we have the right to control the enforcement of patents and related proceedings involving Zohydro ER and any prospective generic entrant. We intend to vigorously enforce the intellectual property rights relating to Zohydro ER and prosecute the 857 patent, but we cannot predict the outcome of these matters or guarantee the outcome of any litigation or interference.

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**Item 1A. Risk Factors**

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 and our Quarterly Reports on Form 10-Q for the quarters ended on March 31, 2015 and June 30, 2015.

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

***Unregistered Sales of Equity Securities***

On July 22, 2015, we issued 2,941 shares of our common stock pursuant to a cashless exercise of 10,000 outstanding warrants with a per share exercise price of \$12.00 per share. We relied on the exemption from registration contained in Section 4(2) of the Securities Act for the issuance of the shares.

Other than as disclosed above and the shares of our common stock sold in the Private Placement, as disclosed on our Form 8-K filed with the SEC on July 8, 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 September 30, 2015, we have used approximately \$22.8 million of the net proceeds from the IPO for our Dex 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.**

On November 12, 2015, we entered into a fifth amendment to our credit agreement with Orbimed (the Fifth Amendment ). The Fifth Amendment, among other things, revised the definition of excess cash flow in the credit agreement to clarify that excess cash flow prepayment amounts paid to Orbimed during a quarter based on the excess cash flow calculation for the prior quarter are not deducted from the calculation of excess cash flow for the current quarter. The foregoing description of the Fifth Amendment is qualified in its entirety by reference to the full text of the Fifth Amendment, which is filed herewith as Exhibit 10.3 to this Quarterly Report on Form 10-Q and is incorporated herein by reference.

**Item 6. Exhibits.**

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

**Exhibit**

<b>No.</b>	<b>Description</b>	<b>Method of Filing</b>
10.1	Form of Securities Purchase Agreement, dated July 1, 2015, by and among Recro Pharma, Inc. and the Purchasers party thereto.	Incorporated herein by reference to Exhibit 10.1 to The Company's Current Report on Form 8-K filed on July 8, 2015
10.2	Development, Manufacturing and Supply Agreement, dated July 10, 2015, by and between Alkermes Pharma Ireland Limited and Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2015.
10.3	Fifth Amendment to Credit Agreement, dated November 12, 2015, by and between Recro Gainesville LLC and Orbimed Royalty Opportunities, LP	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 Accounting Officer (performing the functions of a 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.

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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.

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**SIGNATURES**

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

**RECRO PHARMA, INC.**

Date: November 13, 2015

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

Date: November 13, 2015

By: /s/ Donna M. Nichols  
Donna M. Nichols  
Corporate Controller and Chief Accounting Officer  
(Principal Accounting Officer)

**Table of Contents****EXHIBIT INDEX**

<b>Exhibit</b>		
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32.1	Section 1350 certification, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
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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.