

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
Assets		
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	
Total current assets	48,445	20,374
Property, plant and equipment, net	38,659	
Intangible assets, net	40,662	
Goodwill	6,744	
Total assets	\$ 134,510	\$ 20,374
Liabilities and Shareholders Equity		
Current liabilities:		
Accounts payable	\$ 781	\$ 871
Accrued expenses	4,695	575
Current portion of long-term debt	13,662	
Total current liabilities	19,138	1,446
Long-term debt	24,360	
Warrants	5,450	
Contingent consideration	57,186	
Total liabilities	106,134	1,446
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)
Total shareholders' equity	28,376	18,928
 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)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue:				
Manufacturing, royalty and profit sharing revenue	\$ 16,120	\$	\$ 32,824	\$
Research and development revenue	419		2,375	
Total revenue	16,539		35,199	
Operating expenses:				
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	
Total operating expenses	16,703	4,718	38,923	8,387
Operating loss	(164)	(4,718)	(3,724)	(8,387)
Other income (expense):				
Interest income	2	5	10	7
Interest expense	(1,990)		(3,888)	(4,273)
Net loss	(2,152)	(4,713)	(7,602)	(12,653)
Accretion of redeemable convertible preferred stock and deemed dividend				(1,270)
Net loss applicable to common shareholders	\$ (2,152)	\$ (4,713)	\$ (7,602)	\$ (13,923)
Basic and diluted net loss per common share	\$ (0.24)	\$ (0.61)	\$ (0.92)	\$ (2.42)
Weighted average basic and diluted common shares outstanding	9,118,664	7,707,600	8,243,909	5,743,527

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)	Common stock		Additional paid-in capital	Accumulated deficit	Total
	Shares	Amount			
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)	Nine Months Ended September 30,	
	2015	2014
Cash flows from operating activities:		
Net loss	\$ (7,602)	\$ (12,653)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
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	
Changes in operating assets and liabilities, net of effect of acquisition:		
Inventory	1,384	
Prepaid expenses	(475)	(118)
Accounts receivable and other receivables	3,007	(48)
Accounts payable and accrued expenses	2,688	1,569
Net cash provided by (used in) operating activities	7,839	(6,648)
Cash flows from investing activities:		
Acquisition of Gainesville, net of cash acquired	(52,690)	
Purchase of property and equipment	(1,787)	
Net cash used in investing activities	(54,477)	
Cash flows from financing activities:		
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	
Net cash provided by financing activities	55,231	30,539
Net increase in cash and cash equivalents	8,593	23,891
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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(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:

	September 30, 2015	December 31, 2014
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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(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:

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

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

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

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

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

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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:

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

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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:

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

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

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

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

The in-process research and development asset and customer relationships were valued using the multi-period excess earnings method, which is an income approach in which excess earnings are the earnings remaining after deducting the market rates of return on the estimated values of contributory assets, including debt-free net working capital, tangible and intangible assets. The excess earnings are thereby calculated for each quarter of a multi-quarter projection period discounted to a present value utilizing an appropriate discount rate for the subject asset. Amortization expense was \$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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(amounts in thousands, except share and per share data)

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

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

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

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

	Warrants	Contingent Consideration
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:

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

(8) Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2015	December 31, 2014
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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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:

Number of Shares	Exercise Price per Share	Expiration Date
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

Notes to Unaudited Consolidated Financial Statements

(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[®], Focalin XR[®], Verelan PM[®], generic Verapamil and Zohydro ER[®]; 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:***

Three months ended	
September 30,	
2015	2014