Recro Pharma, Inc. Form 10-Q May 12, 2016 Table of Contents

### **UNITED STATES**

### SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### **FORM 10-Q**

- x Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 For the Quarterly Period Ended: March 31, 2016
- 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 x No "

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

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

Large accelerated filer "

Accelerated filer

Non-accelerated filer " (Do not check if a smaller reporting company) Smaller reporting company x Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes "No x

As of May 12, 2016, there were 9,468,255 shares of common stock, par value \$0.01 per share, outstanding.

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## PART I. FINANCIAL INFORMATION

#### Item 1. **Financial Statements**

# RECRO PHARMA, INC. AND SUBSIDIARIES

### **Consolidated Balance Sheets**

(unaudited)

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١	amounts	111	uiousanus,

except share and per share data)	March 31, 2016	December 31, 2015	
Assets	2010	2013	
Current assets:			
Cash and cash equivalents	\$ 14,917	\$ 19,779	
Accounts receivable	12,182	8,580	
Other receivables	23	36	
Inventory	7,638	8,982	
Prepaid expenses	934	757	
Deferred equity costs	512	542	
Total current assets	36,206	38,676	
Property, plant and equipment, net	36,995	37,922	
Deferred income taxes	16,043	15,637	
Intangible assets, net	39,370	40,016	
Goodwill	6,446	6,446	
Total assets	\$ 135,060	\$ 138,697	
Liabilities and Shareholders Equity			
Current liabilities:			
Accounts payable	\$ 1,990	\$ 1,553	
Accrued expenses	5,606	3,418	
Current portion of long-term debt	4,859	4,516	
Total current liabilities	12,455	9,487	
Long-term debt	22,563	25,244	
Warrants	2,176	3,770	
Contingent consideration	62,824	59,846	
Total liabilities	100,018	98,347	
Commitments and contingencies (Note 12) Shareholders, equity			

Shareholders equity

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Preferred stock, \$0.01 par value. Authorized, 10,000,000 shares; none issued and outstanding		
Common stock, \$0.01 par value. Authorized, 50,000,000 shares; issued and outstanding, 9,318,255 shares at March 31, 2016 and 9,224,315 shares at		
December 31, 2015	93	92
Additional paid-in capital	72,551	71,321
Accumulated deficit	(37,602)	(31,063)
Total shareholders equity	35,042	40,350
Total liabilities and shareholders equity	\$ 135,060	\$ 138,697

See accompanying notes to unaudited consolidated financial statements.

# RECRO PHARMA, INC. AND SUBSIDIARIES

# **Consolidated Statements of Operations**

(unaudited)

(amounts in the coord a great shore and manches data)	Thr	March 31, 2015		
(amounts in thousands, except share and per share data) Revenue:		2016		2015
Manufacturing, royalty and profit sharing revenue	\$	17,138	\$	
Research and development revenue	Ψ	604	Ψ	
Total revenues		17,742		
Operating expenses:				
Cost of sales (excluding amortization of intangible assets)		10,271		
Research and development		7,808		1,754
General and administrative		2,658		2,386
Amortization of intangible assets		646		
Change in warrant valuation		(1,594)		
Change in contingent consideration valuation		2,978		
Total operating expenses		22,767		4,140
Operating loss		(5,025)		(4,140)
Other income (expense):				
Interest income		9		4
Interest expense		(1,512)		
Net loss before income taxes		(6,528)		(4,136)
				(4,130)
Income tax expense		(11)		
Net loss applicable to common shareholders	\$	(6,539)	\$	(4,136)
Basic and diluted net loss per common share	\$	(0.71)	\$	(0.53)
Weighted average basic common shares outstanding		9,251,948		7,768,693

See accompanying notes to unaudited consolidated financial statements.

# RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statement of Shareholders Equity

Three Months Ended March 31, 2016

(unaudited)

(amounts in thousands,	Common stock		Additional paid-in		Accumulated			
except share and per share data)	Shares	Am	ount	(	capital		deficit	Total
Balance, December 31, 2015	9,224,315	\$	92	\$	71,321	\$	(31,063)	\$40,350
Shares issued in Aspire equity facility, net of								
transaction costs	93,940		1		529			530
Stock-based compensation expense					701			701
Net loss							(6,539)	(6,539)
Balance, March 31, 2016	9,318,255	\$	93	\$	72,551	\$	(37,602)	\$35,042

See accompanying notes to unaudited consolidated financial statements.

# RECRO PHARMA, INC. AND SUBSIDIARIES

### Consolidated Statements of Cash Flows

(unaudited)

(amounts in thousands,	Three Mon Marc	
except share and per share data)	2016	2015
Cash flows from operating activities:		
Net loss	\$ (6,539)	\$ (4,136)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Stock-based compensation	701	233
Depreciation expense	1,271	
Noncash interest expense	296	
Amortization	646	
Change in warrant valuation	(1,594)	
Change in contingent consideration valuation	2,978	
Deferred income taxes	(406)	
Changes in operating assets and liabilities:		
Inventory	1,344	
Prepaid expenses	(177)	394
Accounts receivable and other receivables	(3,589)	9
Accounts payable and accrued expenses	2,624	533
Net cash used in operating activities	(2,445)	(2,967)
Cash flows from investing activities:		
Purchase of property and equipment	(344)	
Net cash used in investing activities	(344)	
Cash flows from financing activities:		
Proceeds from private placement, net of offering costs	560	
Payment on long-term debt	(2,633)	
Payment of deferred financing costs		(125)
Net cash used in financing activities	(2,073)	(125)
Net decrease in cash and cash equivalents	(4,862)	(3,092)
Cash and cash equivalents, beginning of period	19,779	19,682
	¢ 14.017	·
Cash and cash equivalents, end of period	\$ 14,917	\$ 16,590
Supplemental disclosure of cash flow information:		
Common stock issued in connection with equity facility		\$ 285

Cash paid for interest \$ 1,215

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. The Company is a revenue-generating, specialty pharmaceutical company focused on products for hospital and ambulatory care settings that is currently developing non-opioid products for treatment of serious acute pain. On April 10, 2015, the Company acquired from Alkermes plc, or Alkermes, worldwide rights to intravenous and intramuscular or injectable meloxicam, a proprietary, 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, now operating through the Company 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 from operations since its incorporation and has an accumulated deficit of \$37,602 as of March 31, 2016. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its products currently in development. Substantial additional financing will be needed by the Company to fund its operations and to commercially develop its product candidates.

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

### (3) Summary of Significant Accounting Principles

### (a) Basis of Presentation and Principles of Consolidation

The accompanying unaudited 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 March 31, 2016 and its results of operations and cash flows for the three months ended March 31, 2016 and 2015. Operating results for the three months ended March 31,

2016 are not necessarily indicative of the results that may be expected for the year ending December 31, 2016. 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, 2015 included in the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2015.

#### (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) Cash and Cash Equivalents

The Company considers all highly liquid investments that have maturities of three months or less when acquired to be cash equivalents. Cash equivalents as of March 31, 2016 and 2015 consisted of money market mutual funds and government and agency bonds.

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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) Fair Value of Financial Instruments

Management believes that the carrying amounts of the Company's financial instruments, including cash equivalents, accounts receivable, accounts payable, and accrued expenses, approximate fair value due to the short-term nature of those instruments. Management believes the carrying value of debt approximates fair value as the interest rates are reflective of the rate the Company could obtain on debt with similar terms and conditions.

#### (e) 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 expense when consumed.

### (f) Property and Equipment

Property and equipment are recorded at cost less accumulated depreciation and amortization. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the assets, which are as follows: four to ten years for furniture, office and computer equipment; six to ten years for manufacturing equipment; two to five years for vehicles; 35 to 40 years for buildings; and the shorter of the lease term or useful life for leasehold improvements. Repairs and maintenance cost are expensed as incurred.

### (g) 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 the Company s 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 is amortized on a straight-line basis over a useful

life 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.

### (h) 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 the 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.

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### RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements

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

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 the 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.

#### (i) Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash, cash equivalents and accounts receivable. The Company s policy is to limit the amount of credit exposure to any one financial institution and place its cash and cash equivalents with financial institutions evaluated as being creditworthy. To date, the Company has not experienced any losses on its cash equivalents.

#### (j) Research and Development

Research and development costs for the Company's proprietary products/product candidates are charged to expense as incurred. Research and development expenses consist primarily of funds paid to third parties for the provision of services for manufacturing of clinical supplies, drug development, clinical trials, statistical analysis and report writing, and regulatory compliance costs. At the end of the reporting period, the Company compares payments made to third-party service providers to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that the Company estimates has been made as a result of the service provided, the Company may record net prepaid or accrued expense relating to these costs.

Upfront and milestone payments made to third parties who perform research and development services on the Company s behalf are expensed as services are rendered. Costs incurred in obtaining technology licenses are charged to research and development expense as acquired in-process research and development if the technology licensed has not reached technological feasibility and has no alternative future use.

### (k) Stock-Based Awards

The Company measures employee stock-based awards at grant-date fair value and recognizes employee compensation expense on a straight-line basis over the vesting period of the award.

Determining the appropriate fair value of stock options requires the input of subjective assumptions, including the expected life of the option and expected stock price volatility. The Company uses the Black-Scholes option pricing model to value its stock option awards. The assumptions used in calculating the fair value of stock-based awards represent management s best estimates and involve inherent uncertainties and the application of management s judgment. As a result, if factors change and management uses different assumptions, stock-based compensation expense could be materially different for future awards.

The expected life of stock options was estimated using the simplified method, as the Company has limited historical information to develop reasonable expectations about future exercise patterns and post vesting employment termination behavior for its stock options grants. The simplified method is based on the average of the vesting tranches and the contractual life of each grant. For stock price volatility, the Company uses comparable public companies as a basis for its expected volatility to calculate the fair value of options grants. The risk-free interest rate is based on U.S. Treasury notes with a term approximating the expected life of the option.

Nonemployee stock-based awards are revalued until an award vests and the Company recognizes compensation expense on a straight-line basis over the vesting period of each separated vesting tranche of the award, or the accelerated attribution method. The estimation of the number of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from the Company s current estimates, such amounts are recognized as an adjustment in the period in which estimates are revised.

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### RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to Unaudited Consolidated Financial Statements

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

#### (l) Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. A valuation allowance is recorded to the extent it is more likely than not that some portion or all of the deferred tax assets will not be realized.

Unrecognized income tax benefits represent income tax positions taken on income tax returns that have not been recognized in the consolidated financial statements. The Company recognizes the benefit of an income tax position only if it is more likely than not (greater than 50%) that the tax position will be sustained upon tax examination, based solely on the technical merits of the tax position. Otherwise, no benefit is recognized. The tax benefits recognized are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. The Company accrues interest and related penalties are classified as income tax expense in the Consolidated Statements of Operations. The Company does not anticipate significant changes in the amount of unrecognized income tax benefits over the next year.

#### (m) Net Loss Per Common Share

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

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as of March 31, 2016 and December 31, 2015, as they would be anti-dilutive:

March 31, 2016 March 31, 2015
Options and restricted stock units outstanding 2,22