Recro Pharma, Inc. Form 10-Q August 11, 2017

#### **UNITED STATES**

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 For the Quarterly Period Ended: June 30, 2017

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

Recro Pharma, Inc.

(Exact name of registrant as specified in its charter)

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

incorporation or organization) Identification No.)

490 Lapp Road, Malvern, Pennsylvania 19355 (Address of principal executive offices) (Zip Code)

(484) 395-2470

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth 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

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section13(a) of the Exchange Act.

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 August 9, 2017, there were 19,059,604 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)

(amounts in thousands, except share and per share data)	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$8,728	\$ 64,483
Short-term investments	41,517	<u> </u>
Accounts receivable	10,102	10,411
Inventory	6,888	8,746
Prepaid expenses and other current assets	2,572	1,118
Total current assets	69,807	84,758
Property, plant and equipment, net	37,638	37,300
Deferred income taxes	19,777	17,060
Intangible assets, net	36,141	37,433
Goodwill	6,446	6,446
Total assets	\$169,809	\$ 182,997
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$3,421	\$ 4,132
Accrued expenses and other current liabilities	6,551	9,893
Current portion of long-term debt, net	2,057	2,236
Total current liabilities	12,029	16,261
Long-term debt, net	22,657	22,152
Warrants and other long-term liabilities	2,788	3,397
Contingent consideration	75,347	69,574
Total liabilities	112,821	111,384
Commitments and contingencies (Note 13)		
Shareholders' equity:		
Preferred stock, \$0.01 par value. Authorized, 10,000,000 shares; none issued and		
outstanding		_
Common stock, \$0.01 par value. Authorized, 50,000,000 shares; issued and		
outstanding, 19,054,566 shares at June 30, 2017 and 19,043,216 shares at		
December 31, 2016	191	190
Additional paid-in capital	135,083	132,691
Accumulated deficit	(78,210)	

Accumulated other comprehensive loss	(76 ) —
Total shareholders' equity	56,988 71,613
Total liabilities and shareholders' equity	\$169,809 \$ 182,997
See accompanying notes to consolidated financial statements.	
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Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

	For the Three Months Ended June 30,		For the Six June 30,	Months Ended
(amounts in thousands, except share and per share data)	2017	2016	2017	2016
Revenue:				
Manufacturing, royalty and profit sharing revenue	\$16,750	\$16,933	\$34,878	\$34,072
Research and development revenue	184	346	798	949
Total revenues	16,934	17,279	35,676	35,021
Operating expenses:				
Cost of sales (excluding amortization of intangible assets)	10,448	9,547	20,946	19,818
Research and development	7,073	8,320	14,836	16,129
General and administrative	6,322	2,763	10,354	5,421
Amortization of intangible assets	646	646	1,292	1,291
Change in warrant valuation	(1,084	) 1,240	(793	) (354 )
Change in contingent consideration valuation	2,959	1,534	5,773	4,512
Total operating expenses	26,364	24,050	52,408	46,817
Operating loss	(9,430	) (6,771	) (16,732	) (11,796 )
Other income (expense):				
Interest income	117	8	222	17
Interest expense	(1,207	) (1,317	) (2,390	) (2,829 )
Net loss before income taxes	(10,520	) (8,080	) (18,900	) (14,608 )
Income tax benefit	1,665	195	1,958	184
Net loss	\$(8,855	) \$(7,885	) \$(16,942	) \$(14,424 )
Per share information:	¢ (O. 46	) ¢(0.02	) ¢(0,00	) \$ (1.52
Net loss per share of common stock, basic	\$(0.46	) \$(0.83	) \$(0.89	) \$(1.53)
Net loss per share of common stock, diluted	\$(0.48	) \$(0.83	) \$(0.89	) \$(1.53)
Weighted average common shares outstanding, basic	19,052,43			
Weighted average common shares outstanding, diluted	19,220,70	00 9,544,629	9 19,220,17	75 9,398,288
Other comprehensive loss:				
Unrealized loss on available-for-sale securities	(19	) —	(76	) —
Comprehensive loss	\$(8,874	) \$(7,885	) \$(17,018	) \$(14,424 )
See accompanying notes to consolidated financial statement	s.			
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Consolidated Statements of Shareholders' Equity

For the Six Months Ended June 30, 2017

(Unaudited)

(amounts in thousands, except share	Common Sto	ock	Additional paid-in	Accumulated	Accumulated other d comprehensiv	e
data)	Shares	Amount	capital	Deficit	loss	Total
Balance, December 31, 2016	19,043,216	190	132,691	(61,268	) —	71,613
Stock-based compensation expense			2,370	<del></del>	<u> </u>	2,370
Stock option exercise	3,600	1	22	_	_	23
Issuance of restricted stock units	7,750		_	_	_	_
Other comprehensive loss	_		_	_	(76	) (76 )
Net loss				(16,942	) —	(16,942)
Balance, June 30, 2017	19,054,566	\$ 191	\$135,083	\$ (78,210	) \$ (76	) \$56,988

See accompanying notes to consolidated financial statements.

Consolidated Statements of Cash Flows

(Unaudited)

	For the Six Ended June	
(amounts in thousands)	2017	2016
Cash flows from operating activities:		
Net loss	\$(16,942)	\$(14,424)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,370	1,430
Non-cash interest expense	326	449
Depreciation expense	2,424	2,511
Amortization	1,292	1,291
Acquired in-process research & development charges	766	_
Change in warrant valuation	(793)	(354)
Change in contingent consideration valuation	5,773	4,512
Deferred income taxes	(2,717)	(1,007)
Changes in operating assets and liabilities, net of effect of acquisition:		
Inventory	1,858	2,254
Prepaid expenses and other current assets	(1,454)	(1,098)
Accounts receivable	309	(2,887)
Accounts payable, accrued expenses and other liabilities	(4,194)	1,928
Net cash used in operating activities	(10,982)	
Cash flows from investing activities:		
Purchase of property and equipment	(3,185)	(1,081)
Purchase of short-term investments	(53,593)	
Proceeds from maturity/redemption of investments	12,000	_
Acquisition of license agreement	(18)	
Net cash used in investing activities	(44,796)	(1,081)
Cash flows from financing activities:		, , ,
Proceeds from Aspire facility	_	4,175
Payments on long-term debt	_	(2,633)
Proceeds from option exercise	23	_
Net cash provided by financing activities	23	1,542
Net decrease in cash and cash equivalents	(55,755)	(4,934)
Cash and cash equivalents, beginning of period	64,483	19,779
Cash and cash equivalents, end of period	\$8,728	\$14,845
Supplemental disclosure of cash flow information:	+ 0,1 = 0	7 - 1,0 10
Cash paid for interest	\$2,064	\$2,373
Cash paid for taxes	\$467	\$166
Unrealized loss on available-for-sale securities	\$76	\$-
Purchase of property, plant and equipment included in accrued expenses and accounts	Ψ, σ	7
payable	\$385	\$129

Amortization of deferred equity costs

\$—

\$224

See accompanying notes to consolidated financial statements.

Notes to the Consolidated Financial Statements

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

(Unaudited)

#### (1)Background

Recro Pharma, Inc., or the Company, was incorporated in Pennsylvania on November 15, 2007. The Company is a specialty pharmaceutical company that operates through two business divisions: an Acute Care division and a revenue-generating contract development and manufacturing, or CDMO division. Each of these divisions are deemed to be reportable segments (see Note 3(m) and Note 17). The Acute Care division is primarily focused on developing innovative products for hospital and other acute care settings, and the CDMO division leverages the Company's formulation expertise to develop and manufacture pharmaceutical products using the Company's proprietary delivery technologies for commercial partners who commercialize or plan to commercialize these products. 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 being developed for the management of moderate to severe pain, as well as a contract manufacturing facility, royalty and formulation business in Gainesville, Georgia. The acquisition is referred to herein as the Gainesville Transaction. In July 2017, the Company submitted a New Drug Application, or NDA, to the U.S. Food and Drug Administration for our lead investigational product candidate intravenous, or IV meloxicam 30 mg for the management of moderate to severe pain.

# (2) Development-Stage Risks and Liquidity

The Company has incurred losses from operations since inception and has an accumulated deficit of \$78,210 as of June 30, 2017. Though its CDMO segment has been profitable, 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, including the payment of the Gainesville Transaction contingent payments, which may become due upon achievement of certain development and commercialization milestones for meloxicam (see Note 4). The Company's future operations are highly dependent on a combination of factors, including (i) the continued profitability of the CDMO segment; (ii) the timely and successful completion of additional financing and/or alternative sources of capital, debt or partnering transactions; (iii) the success of its research and development, including the results and timing of its clinical trials; (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. Management believes that the Company's existing cash, cash equivalents and short-term investments as of June 30, 2017 will be sufficient to fund its operations through mid-year 2018.

#### (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 and with the instructions of Form 10-Q and Article 10 of Regulation S-X and, therefore, do not include all of the information and notes required by the U.S. GAAP for complete annual financial statements. 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 results for the interim periods. Operating results for the three and six months ended June 30, 2017 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2017.

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, 2016 included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016.

#### (b) Use of Estimates

The preparation of financial statements and the notes to the 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.

#### RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

(Unaudited)

#### (c) Cash, Cash Equivalents

Cash and cash equivalents represents cash in banks and highly liquid short-term investments that have maturities of three months or less when acquired to be cash equivalents. These highly liquid short-term investments are both readily convertible to known amounts of cash and so near their maturity that they present insignificant risk of changes in value because of the changes in interest rates.

#### (d)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: three to ten years for furniture and office equipment; six to ten or more 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.

# (e) Business Combinations

In accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 805, "Business Combinations," or ASC 805, the Company allocates the purchase price of acquired companies to the tangible and intangible assets acquired and liabilities assumed based on their estimated fair values. Valuations are performed to assist in determining the fair values of assets acquired and liabilities assumed, which requires management to make significant estimates and assumptions, in particular with respect to intangible assets. Management makes estimates of fair value based upon assumptions believed to be reasonable. These estimates are based in part on historical experience and information obtained from management of the acquired companies and expectations of future cash flows. Transaction costs and restructuring costs associated with the transaction are expensed as incurred. In-process research and development, or IPR&D, is the value assigned to those projects for which the related products have not received regulatory approval and have no alternative future use. Determining the portion of the purchase price allocated to IPR&D requires the Company to make significant estimates. In a business combination, the Company capitalizes IPR&D as an intangible asset, and for an asset acquisition the Company expenses IPR&D in the Consolidated Statements of Operations on the acquisition date.

#### (f) 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 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

#### RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

(Unaudited)

unless a triggering event occurs between annual assessments, which would then require an assessment in the period which a triggering event occurred. The most recent tests as of November 30, 2016, indicated that goodwill and indefinite-lived intangible assets were not impaired. There were no indicators of impairment as of June 30, 2017.

#### (g) Revenue Recognition

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

Manufacturing and other related services 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.

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 commercial partner. Royalty and profit sharing revenues are generally recognized under the terms of the applicable license, development and/or supply agreement in the period the products are sold and when 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. In agreements which specify milestones, the related revenues are recognized upon the achievement of a substantive milestone.

#### (h) Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash, cash equivalents, short-term investments and accounts receivable. The Company manages its cash, cash equivalents and short-term investments based on established guidelines relative to diversification and maturities to maintain safety and liquidity.

The Company's accounts receivable balances are concentrated amongst approximately five customers and if any of these customers' receivable balances should be deemed uncollectible, it could have a material adverse effect on the Company's results of operations and financial condition.

#### (i) 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 pre-commercialization and manufacturing scale-up activities, drug development, clinical trials, statistical analysis and report writing and regulatory filing fees and 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 expenses 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 product technology licenses are charged to research and development expense as acquired IPR&D if the technology licensed has not reached technological feasibility and has no alternative future use.

## (j) 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

#### RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

(Unaudited)

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/or 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.

Non-employee 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, which is known as 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.

## (k) 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.

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

Basic 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 unvested restricted stock units have been excluded from the calculation of diluted net loss per share

because their effect would be anti-dilutive.

For purposes of calculating diluted loss per common share, the denominator includes both the weighted average common shares outstanding and the number of common stock equivalents if the inclusion of such common stock equivalents would be dilutive. Dilutive common stock equivalents for the three and six months ended June 30, 2017 include warrants using the treasury stock method. The diluted loss per common share calculation is further affected by an add-back of change in fair value of warrant liability to the numerator, net of tax, under the assumption that the change in fair value of warrant liability would not have been incurred if the warrants had been converted into common stock.

The following table sets forth the computation of basic earnings per share and diluted earnings per share:

Notes to the Consolidated Financial Statements

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

(Unaudited)

	Three Months June 30,	s Ended	Six Months E June 30,	Ended
	2017	2016	2017	2016
Basic Earnings Per Share				
Net loss	\$(8,855)	\$(7,885)	\$(16,942	\$(14,424)
Weighted average common shares outstanding, basic	19,052,430	9,544,629	19,050,931	9,398,288
Net loss per share of common stock, basic	\$(0.46	\$ (0.83	\$(0.89	\$(1.53)
Diluted Earnings Per Share				
Net loss	\$(8,855	\$(7,885)	\$(16,942	\$(14,424)
Add change in warrant valuation	(341	) —	(234	) —
Diluted net loss	\$(9,196	\$(7,885)	\$(17,176	\$(14,424)
Weighted average common shares outstanding, basic	19,052,430	9,544,629	19,050,931	9,398,288
Add shares from outstanding warrants	168,270		169,244	
Weighted average common shares outstanding, diluted	19,220,700	9,544,629	19,220,175	9,398,288
Net loss per share of common stock, diluted	\$(0.48	\$(0.83)	\$(0.89	\$(1.53)

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as of June 30, 2017 and 2016, as they would be anti-dilutive:

	June 30,	
	2017	2016
Options and restricted stock units outstanding	3,680,799	2,229,343
Warrants	490,000	784,928

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

#### (m) Segment Information

The Company determined its reportable segments based on its strategic business units, the commonalities among the products and services within each segment and the manner in which the Company reviews and evaluates operating performance. The Company has identified CDMO and Acute Care as reportable segments. Segment disclosures are included in Note 17. Segment operating profit (loss) is defined as segment revenue less segment operating expenses (segment operating expenses consist of general and administrative expenses, research and development expenses, and the change in valuation of contingent consideration and warrants). The following items are excluded from segment operating profit (loss): interest income and expense, and income tax benefit (expense). Segment assets are those assets and liabilities that are recorded and reported by segment operations. Segment operating capital employed represents segment assets less segment liabilities.

# (n) Recent Accounting Pronouncements

In July 2017, the FASB issued Accounting Standards Update, or ASU, No. 2017-11 "Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): Accounting for Certain Financial Instruments with Down Round Features," or ASU 2017-11. ASU 2017-11 simplifies the accounting for certain financial instruments with down round features, as equity-linked instruments or embedded equity-linked features will not be accounted for as a liability solely because there is a down-round feature. The amendments are effective for public companies for annual and interim periods beginning after December 15, 2018. The Company is currently evaluating the effect that this guidance may have on its consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, Stock Compensation - Scope of Modification Accounting. ASU 2017-09 provides guidance on which changes to the terms or conditions of a share-based payment award require an entity to

#### RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

(Unaudited)

apply modification accounting. The new standard is effective for fiscal years beginning after December 15, 2017. The Company is currently evaluating the effect that this guidance may have on its consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-04 "Intangibles - Goodwill and Other (Topic 350): Simplifying the Accounting for Goodwill Impairment," or ASU 2017-04. ASU 2017-04 allows companies to apply a one-step quantitative test and record the amount of goodwill impairment as the excess of a reporting unit's carrying amount over its fair value, not to exceed the total amount of goodwill allocated to the reporting unit. The amendments of the ASU are effective for annual or interim goodwill impairment tests in fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company is currently evaluating the effect that this guidance may have on its consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15 "Classification of Certain Cash Receipts and Cash Payments," or ASU 2016-15. ASU 2016-15 provides guidance in the classification of certain cash receipts and payments in the statement of cash flows where diversity in practice exists. This new guidance is effective for annual periods beginning after December 15, 2017, with early adoption permitted. The Company is currently evaluating the effect that the updated standard will have on its consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)," or ASU 2016-02. ASU 2016-02 establishes a wholesale change to lease accounting and introduces a lease model that brings most leases on the balance sheet. It also eliminates the required use of bright-line tests in current U.S. GAAP for determining lease classification. The new guidance is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating the effect that this guidance may have on its consolidated financial statements.

In September 2015, the FASB issued ASU No. 2015-16, "Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments," or ASU 2015-16. ASU 2015-16 addresses 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 updated guidance is effective for annual and interim periods beginning after December 15, 2016. The Company adopted the guidance effective January 1, 2017. The guidance did not have a material impact to the consolidated financial statements upon adoption.

In July 2015, the FASB issued ASU No. 2015-11, "Simplifying the Measurement of Inventory," or ASU 2015-11. ASU 2015-11 addresses changes in 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, or 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 methods. 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. The Company adopted the guidance effective January 1, 2017. The guidance did not have a material impact to the consolidated financial statements upon adoption.

In May 2014, the FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers," or ASU 2014-09. ASU 2014-09 represents 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 new standard permits two methods of adoption: the full retrospective method, which requires the standard to be applied to each prior period presented, or the modified retrospective method, which requires the cumulative effect of adoption to be recognized as an adjustment to opening retained earnings in the period of adoption. The Company currently anticipates adopting the standard using the modified retrospective method. The Company plans to complete an analysis of existing contracts with its customers and to assess the differences in accounting for such contracts under ASU 2014-09 compared with current revenue accounting standards by the end of the third quarter. The new standard will result in additional revenue-related disclosures in the

#### RECRO PHARMA, INC. AND SUBSIDIARIES

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footnotes to the consolidated financial statements. The Company will continue to assess new customer contracts during 2017. Adoption of this standard will require changes to business processes, systems and controls to support the additional required disclosures. The Company is in the process of identifying such changes.

## (4) Acquisition of Gainesville Facility and Meloxicam

On April 10, 2015, the Company completed the Gainesville Transaction. The consideration paid in connection with the Gainesville Transaction consisted of \$50.0 million cash 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 \$125.0 million in milestone payments (including, at the Company's election, either (i) \$10 million upon a new drug application, or NDA, filing and \$30 million upon regulatory approval or (ii) an aggregate of \$45 million upon regulatory approval, as well as net sales milestones related to injectable meloxicam) and a percentage of future product net sales related to injectable meloxicam between 10% and 12% (subject to a 30% reduction when no longer covered by patent). 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 contingent consideration consists of three separate components. The first component consists of two potential payments, which will be payable upon the submission of the NDA for meloxicam and the related regulatory approval or one payment upon regulatory approval. 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.

#### (5) NMB Related License Agreement

In June 2017, the Company acquired the exclusive global rights to two novel neuromuscular blocking agents, or NMBs, and a proprietary chemical reversal agent from Cornell University, or Cornell. The NMBs and reversal agent are referred to herein as the NMB Related Compounds. The NMB Related Compounds include one novel intermediate-acting NMB that has initiated Phase I clinical trials and two other agents, a novel short-acting NMB, and

a rapid-acting reversal agent proprietary to these NMB Related Compounds.

The transaction was accounted for as an asset acquisition, with the total cost of the acquisition of \$766 allocated to acquired IPR&D. The Company recorded an upfront payment obligation of \$350 that is included within Accounts payable, as well as operational liabilities and acquisition-related costs of \$416, primarily consisting of reimbursement to Cornell for specified past patent, legal and pre-clinical costs, each of which is reported as a component of Accrued expenses and other current liabilities and Other non-current liabilities on the Consolidated Balance Sheet as of June 30, 2017.

In addition, the Company is obligated to make: (i) an annual license maintenance fee payment until the first commercial sale of the NMB Related Compounds; and (ii) milestone payments upon the achievement of certain milestones, up to a maximum, for each NMB, of \$5 million for U.S. regulatory approval and commercialization milestones and \$3 million for European regulatory approval and commercialization milestones. The Company is also obligated to pay Cornell royalties on net sales of the NMB Related Compounds at a rate ranging from low to mid-single digits, depending on the applicable NMB Related Compounds and whether there is a valid patent claim in the applicable country, subject to an annual minimum royalty amount. Further, the Company will reimburse Cornell ongoing patent costs related to prosecution and maintenance of the patents related to the Cornell patents for the NMB Related Compounds.

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The Company accounted for the transaction as an asset acquisition based on an evaluation of the accounting guidance (ASC Topic 805) and considering the early clinical stage of the novel and unproven NMB Related Compounds. The Company concluded that the acquired IPR&D of Cornell did not constitute a business as defined under ASC 805 due to the incomplete nature of the inputs and the absence of processes from a market participant perspective. Substantial additional research and development will be required to develop any NMB Related Compounds into a commercially viable drug candidate, including completion of pre-clinical testing and clinical trials, and, if such clinical trials are successful, application for regulatory approvals and manufacturing repeatability and scale-up. There is risk that a marketable compound may not be well tolerated and may never be approved.

Acquired IPR&D in the asset acquisition was accounted for in accordance with FASB ASC Topic 730, "Research and Development." At the date of acquisition, the Company determined that the development of the projects underway at Cornell had not yet reached technological feasibility and that the research in process had no alternative future uses. Accordingly, the acquired IPR&D was charged to expense in the Consolidated Statements of Operations on the acquisition date. The acquired IPR&D charge is expected to be deductible over a 15-year period for income tax purposes.

#### (6) Fair Value of Financial Instruments

The Company follows the provisions of FASB ASC Topic 820, "Fair Value Measurements and Disclosures," for fair value measurement recognition and disclosure purposes for its financial assets and financial liabilities that are remeasured and reported at fair value each reporting period. The Company measures certain financial assets and liabilities at fair value on a recurring basis, including cash equivalents, short-term investments, warrants and the contingent consideration. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of financial assets and financial liabilities and their placement within the fair value hierarchy. Categorization is based on a three-tier valuation hierarchy, which prioritizes the inputs used in measuring fair value, as follows:

- Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities;
- Level 2: Inputs that are other than quoted prices in active markets for identical assets and liabilities, inputs that are quoted prices for identical or similar assets or liabilities in inactive markets, or other inputs that are either directly or indirectly observable; and
- Level 3: Unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

# RECRO PHARMA, INC. AND SUBSIDIARIES

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

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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 Significant			
	markets f	outher		Significant
	identical	observ	able	unobservable
	assets	inputs		inputs
	(Level 1)	(Level	2)	(Level 3)
At December 31, 2016:	,			
Assets:				
Money market mutual funds (See Note 7)	\$37,079	\$		\$ —
U.S. Treasury obligations (See Note 7)	20,517			
Cash equivalents	\$57,596	\$	—	\$ —
Liabilities:				
Warrants (See Note 14(d))	_		—	\$ 3,397
Contingent consideration (See Note 4)	_		_	69,574
	\$—	\$	—	\$ 72,971
At June 30, 2017:				
Assets:				
Cash equivalents				
Money market mutual funds (See Note 7)	\$6,043	\$	—	\$ —
Total cash equivalents	\$6,043	\$	_	\$ —
Short-term investments				
U.S. Treasury obligations (See Note 7)	\$41,517	\$	_	\$ —
Total financial assets	\$47,560	\$	—	\$ —
Liabilities:				
Warrants (See Note 14(d))	—		—	\$ 2,604
Contingent consideration (See Note 4)	.—		_	75,347
	<b>\$</b> —	\$	—	\$ 77,951

The Company developed its own assumptions to determine the value of the warrants that do not have observable inputs or available market data to support the fair value. This method of valuation involves using inputs such as the fair value of the Company's common stock, stock price volatility, the contractual term of the warrants, risk free interest rates and dividend yield. Due to the nature of these inputs, the valuation of the warrants is considered a Level 3 measurement.

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

	Warrants	Cor	ntingent Consideration
Balance at December 31, 2016	\$ 3,397	\$	69,574
Additions	_		_
Remeasurement	(793)		5,773
Balance at June 30, 2017	\$ 2,604	\$	75,347

The Company follows the disclosure provisions of FASB ASC Topic 825, "Financial Instruments" (ASC 825), for disclosure purposes for financial assets and financial liabilities that are not measured at fair value. As of June 30, 2017, the financial assets and liabilities recorded on the Consolidated Balance Sheets that are not measured at fair value on a recurring basis include accounts receivable, accounts payable, accrued expenses and current debt obligations approximate fair value due to the short-term nature of these instruments. The fair value of long-term debt, where a quoted market price is not available, is evaluated based on, among other factors, interest rates currently available to the Company for debt with similar terms, remaining payments and considerations of the Company's creditworthiness. The Company determined that the recorded book value of long-term debt approximated fair value at June 30, 2017 due to the estimated amount of the Excess Cash Flow payments and terms of the debt.

#### RECRO PHARMA, INC. AND SUBSIDIARIES

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#### (7) Short-term Investments

Short-term investments as of June 30, 2017 consist of government money market funds and U.S. Treasury obligations. In accordance with FASB ASC Topic 320, "Investments – Debt and Equity Securities," or ASC 320, the Company has classified its entire investment portfolio as available-for-sale securities with secondary or resale markets, and, as such, its portfolio is reported at fair value with unrealized gains and losses included in Comprehensive Income in stockholders' equity and realized gains and losses included in other income/expense. The following is a summary of available-for-sale securities as of June 30, 2017.

	June 30,	2017		
	Gross			
	Amortize	Estimated		
			Fair	
Description	Cost	GainLoss	Value	
Money market mutual funds	\$6,043	\$ <b>—</b> \$ <b>—</b>	\$ 6,043	
U.S. Treasury obligations	41,593	<b>—</b> (76 )	41,517	
Total Investments	\$47,636	\$ —\$ (76)	\$ 47,560	

As of June 30, 2017, the Company's investments had maturities ranging from one to six months. As of December 31, 2016, all of the Company's investments in US. Treasury obligations had original maturities of less than three months. The fair value of the Company's U.S. Treasury obligations is determined by taking into consideration valuations obtained from third-party pricing services. The third-party pricing services utilize industry standard valuation models, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities, and other observable inputs.

Certain investment securities as of June 30, 2017 had fair values less than their amortized costs and, therefore, contained unrealized losses. The Company has evaluated these investments and has determined that the decline in value was not related to any Company or industry specific event. As of June 30, 2017, there were 23 U.S. Treasury investments with unrealized losses. The gross unrealized losses related to these investments were due to changes in interest rates. Given that the Company has no intent to sell any of these investments until a recovery of its fair value, which may be at maturity, and there are no current requirements to sell any of these investments, the Company did not consider these investments to be other-than-temporarily impaired as of June 30, 2017. The Company anticipates full recovery of amortized costs with respect to these investments at maturity or sooner in the event of a more favorable market interest rate environment. The duration of time the investments had been in a continuous unrealized loss position as of June 30, 2017 was less than 12 months.

# (8) Inventory

Inventory is stated at the lower of cost and net realizable value. Included in inventory are raw materials and work-in-process used in the production of commercial products. Cost is determined using the first-in, first-out method. Inventory was as follows as of June 30, 2017 and December 31, 2016:

	June 30, 2017	December 31, 2016
Raw materials	\$2,371	\$ 2,618
Work in process	3,151	5,219
Finished goods	1,777	1,793
	7,299	9,630
Provision for inventory obsolescence	(411)	(884)
	\$6,888	\$ 8,746

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The provision for inventory obsolescence decreased approximately \$473 during the six months ended June 30, 2017, primarily due to the disposal of the fully reserved inventory at December 31, 2016. Adjustments to inventory are determined at the raw materials, work-in-process, and finished good levels to reflect obsolescence or impaired balances. Inventory is ordered to meet specific customer orders and largely reflects demand. Factors influencing inventory obsolescence include changes in demand, product life cycle, product pricing, physical deterioration and quality concerns.

#### (9) Property, Plant and Equipment

Property, plant and equipment consists of the following:

	June 30,	December 31,
	2017	2016
Land	\$3,263	\$ 3,263
Building and improvements	15,757	15,613
Furniture, office and computer equipment	4,031	3,811
Vehicles	30	30
Manufacturing equipment	23,454	21,508
Construction in progress	2,650	2,198
	49,185	46,423
Less: accumulated depreciation and amortization	11,547	9,123
Property, plant and equipment, net	\$37,638	\$ 37,300

Depreciation expense for the three and six months ended June 30, 2017 was \$1,228 and \$2,424, respectively. Depreciation expense for the three and six months ended June 30, 2016 was \$1,240 and \$2,511, respectively.

## (10) Intangible Assets

The following represents the balance of the intangible assets at June 30, 2017:

		Accumulated		
	Cost	Amortization	Nε	et Intangible Assets
Royalties and contract manufacturing relationships:	\$15,500	\$ 5,759	\$	9,741
In-process research and development	26,400	_		26,400
Total	\$41,900	\$ 5,759	\$	36,141

The following represents the balance of intangible assets at December 31, 2016:

		Accumulated	
	Cost	Amortization	Net Intangible Assets
Royalties and contract manufacturing relationships:	\$15,500	\$ 4,467	\$ 11,033
In-process research and development	26,400		26,400
Total	\$41,900	\$ 4,467	\$ 37,433

#### RECRO PHARMA, INC. AND SUBSIDIARIES

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Amortization expense for each of the six months ended June 30, 2017 and 2016 was \$1,292 and \$1,291, respectively, and for the three months ended June 30, 2017 and 2016 was \$646. As of June 30, 2017, future amortization expense is as follows:

	Amortization		
July - December 2017	\$	1,291	
2018		2,583	
2019		2,583	
2020		2,583	
2021		701	
Total	\$	9,741	

# (11) Accrued Expenses and Other Current Liabilities Accrued expenses and other current liabilities consist of the following:

	June 30, 2017	December 31, 2016
Clinical trial and related costs	\$ 340	\$ 2,564
Professional and consulting fees	643	360
Payroll and related costs	3,218	4,547
Property plant and equipment	383	720
Deferred revenue	518	418
Income tax payable	603	311
Other	846	973
	\$6,551	\$ 9,893

# (12)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. The unpaid principal amount under the credit agreement is due and payable on April 10, 2020, 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. The Company 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 equal to (A) for full prepayments of the unpaid principal amount, \$75,000 less all previously prepaid principal amounts and all previously paid interest or (B)

for partial prepayments of the unpaid principal amount, 0.5 times the partial prepayment amount less interest payments previously paid in respect to the partial prepayment amount and (ii) after the 36-month anniversary of the closing of the credit agreement, payment of an exit fee amount equal to 10% of the amount of any prepayments. As defined by the agreement, based upon the CDMO segment financial results, OrbiMed has the option to require the Company to prepay a portion of the loan balance based upon an Excess Cash Flow calculation. No payments under this option shall be subject to the buy-out premium. As of June 30, 2017, the Company has paid \$22,653 of principal payments on the senior secured loan from the Excess Cash Flow calculation. The credit agreement carries interest at three month LIBOR plus 14.0% with a 1.0% floor. The Company's 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 June 30, 2017, 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.

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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 \$2,633 as of June 30, 2017. As of June 30, 2017, the long-term debt balance is comprised of the following:

Principal balance outstanding	\$27,347
Unamortized deferred issuance costs	(2,633)
	\$24,714
Current portion	(2,057)
	\$22,657

The Company has estimated the amount of the Excess Cash Flow payments that could be payable within one year of June 30, 2017 upon request of OrbiMed and has classified that amount as a current debt in the accompanying consolidated balance sheet.

#### (13) Commitments and Contingencies

#### (a) Licenses

The Company is party to an exclusive license with Orion for the development and commercialization of Dexmedetomidine, or Dex, for use in the treatment of pain in humans in any dosage form for transdermal, transmucosal (including sublingual and intranasal), topical, enteral or pulmonary (inhalational) delivery, but specifically excluding delivery vehicles for administration by injection or infusion, worldwide, except for Europe, Turkey and the CIS (currently includes Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine and Uzbekistan), referred to herein as the Territory. The Company is required to pay Orion lump sum payments of up to €20,500 (\$23,393 as of June 30, 2017) on the achievement of certain developmental and commercial milestones, as well as a royalty on net sales during the term, which varies from 10% to 20% depending on annual sales levels. Through June 30, 2017, no such milestones have been achieved.

The Company is also party to an exclusive license agreement with Orion for the development and commercialization of Fadolmidine, or Fado, for use as a human therapeutic, in any dosage form in the Territory. The Company is required to pay Orion lump sum payments of up to €12,200 (\$13,921 as of June 30, 2017) on achievement of certain developmental and commercial milestones, as well as a royalty on net sales during the term, which varies from 10% to 15% depending on annual sales levels. Through June 30, 2017, No such milestones have been achieved.

The Company is party to a license agreement with Cornell University for the exclusive license of the NMB Related Compounds. Under the terms of the agreement, the Company will pay Cornell an initial upfront fee and Cornell is also entitle to receive additional milestone payments, and annual license maintenance fees as well as royalties. See Note 5 for further information regarding these payment obligations.

#### (b) Contingent Consideration for the Gainesville Transaction

Pursuant to the purchase and sale agreement governing the Gainesville Transaction, the Company agreed to pay to Alkermes up to an additional \$125.0 million in milestone payments (including, at the Company's election, either (i) \$10 million upon NDA filing and \$30 million upon regulatory approval or (ii) an aggregate of \$45 million upon regulatory approval, as well as net sales milestones related to injectable meloxicam and royalties on future product sales of injectable meloxicam between 10% and 12% (subject to a 30% reduction when no longer covered by patent). At the end of July 2017, the Company has filed the NDA and has not made the election as to which milestone payment it will make as of the 10-Q filing date.

The Company is party to 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 commercial bulk supplies of injectable meloxicam formulation and (ii) provide development services with respect to the Chemistry, Manufacturing and Controls section of an NDA for injectable meloxicam. Pursuant to the Supply Agreement, Alkermes will supply the Company with such quantities of bulk injectable meloxicam formulation as shall be reasonably required for the completion of clinical trials of injectable meloxicam. During the term of the Supply Agreement, the Company will purchase its clinical and commercial supplies of bulk injectable meloxicam formulation exclusively from Alkermes, subject to certain exceptions, for a period of time.

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#### (c) Product Manufacturing

The Company is party to a Development, Manufacturing and Supply Agreement, or Supply Agreement, with Alkermes (through a subsidiary of Alkermes), for the clinical and, if approved by the U.S. Food and Drug Administration, or FDA, commercial supply of injectable meloxicam. Pursuant to the Supply Agreement, the Company will purchase its clinical and commercial supplies of bulk injectable meloxicam formulation exclusively from Alkermes, subject to certain exceptions, for a period of time.

The Company is also party to an active pharmaceutical ingredient, or API, supply agreement with Orion, whereby Orion provides the Company with API for the development and commercialization of its Dex product candidates. Prior to obtaining regulatory approval, subject to advance notice to Orion, Orion will provide API without charge for agreed-upon amounts. Any amounts ordered by the Company that are greater than the planned supply will be charged at 50% of the supply price for commercial product.

## (d)Litigation

The Company is involved, from time to time, in various claims and legal proceedings arising in the ordinary course of its business. Except as disclosed below, the Company is not currently a party to any such claims or proceedings that, if decided adversely to it, would either individually or in the aggregate have a material adverse effect on its business, financial condition or results of operations.

As part of the Gainesville Transaction, the Company acquired the rights to Zohydro ER®, which the Company licenses to its 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 six 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®, one of which was filed in April 2015 by Actavis regarding the filing of a supplemental ANDA, or sANDA, and another three of which were filed in November 2015 and October 2016 by Actavis, and in December 2015 by Alvogen regarding one of our recently issued patents relating to a formulation of Zohydro ER®. These certification notices allege that three U.S. patents listed in the FDA's Orange Book for Zohydro ER®, with an expiration date of November 2019 and September 2034, 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 the Company's 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, the Company 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, or the USPTO, declared an interference between one of the Company's patent applications relating to a dosage form of Zohydro ER® and two Purdue Pharma, LP, or Purdue, applications. On April 29, 2016, the USPTO found the Company's claims and the Purdue claims involved in the interference to be invalid. Purdue appealed this decision to the U.S. Court of Appeals for the Federal Circuit on June 28, 2016, and on June 13, 2017 the U.S. Court of Appeals for the Federal Circuit affirmed the decision of the USPTO.

Under the Company's license agreement with Pernix, the Company has the right to control the enforcement of the Company's patents and related proceedings involving Zohydro ER® and any prospective generic entrant, and Pernix has the obligation to reimburse the Company for all reasonable costs of paragraph IV certification actions. On September 29, 2016, the Company entered into a settlement agreement with Alvogen pursuant to which the case against Alvogen was dismissed. In February 2017, the District Court in the Actavis case ruled in the Company's favor and enjoined Actavis from selling the proposed generic version of Zohydro ER®. Actavis has appealed this decision to the U.S. Court of Appeals for the Federal Circuit.

#### (e)Leases

On January 1, 2017, the Company entered into a six-year lease for its Malvern, Pennsylvania facility that expires on December 31, 2022. In February 2017, the Company also entered into a three-year lease for office space in Dublin, Ireland that expires April 2020. The Company is also a party to operating leases for office equipment and storage. Rent expense includes rent as well as additional operating and tenant improvement expenses.

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As of June 30, 2017, future minimum lease payments excluding operating expenses and tenant improvements for the leases, are as follows:

Lease				
payments				
2017\$	281			
2018	568			
2019	497			
2020	403			
2021	362			
2022	373			
Total\$	2,484			

#### (f) Purchase Commitments

As of June 30, 2017, the Company had outstanding non-cancelable and cancelable purchase commitments in the amount of \$13,612 related to inventory, capital expenditures and other goods and services.

## (g) Certain Compensation and Employment Agreements

The Company has entered into employment agreements with certain of its named executive officers. As of June 30, 2017, these employment agreements provided for, among other things, annual base salaries in an aggregate amount of not less than \$1,420, from that date through calendar year 2018.

#### (14) 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 initial public offering, or 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, 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 of \$11.60 per share, 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.

On August 19, 2016, the Company closed an underwritten public offering in which the company sold 1,986,666 shares of common stock at a price per share of \$7.50, for net proceeds of \$13,367 after deducting underwriting

commissions and offering expenses.

On December 16, 2016, the Company closed an underwritten public offering in which the company sold 6,670,000 shares of common stock at a price per share of \$6.00, for net proceeds of \$36,888 after deducting underwriting commissions and offering expenses.

## (b) 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 was committed to purchase, at the Company's election, up to an aggregate of \$10,000 of shares of the Company's common stock over the 24-month term of the Purchase Agreement. On the execution of the Purchase Agreement, the Company issued 96,463 shares of common stock to Aspire Capital with a fair value of \$285, as consideration for entering in the Purchase Agreement. In addition, the Company incurred \$253 of costs in connection with the Purchase Agreement, which, along with the fair value of the

## RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

(Unaudited)

common stock, has been recorded as deferred equity costs. During 2016, the Company sold 1,143,940 shares of common stock under the Purchase Agreement for \$7,796. The agreement expired in February 2017.

#### (c)Preferred Stock

The Company is authorized to issue 10,000,000 shares of preferred stock, with a par value of \$0.01 per share. As of June 30, 2017, no preferred stock was issued or outstanding.

#### (d) Warrants

As of June 30, 2017, the Company had the following warrants outstanding to purchase shares of the Company's common stock:

	Exercise	
	Price	
	per	
Number of Shares	Share	<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.

The following table summarizes the fair value and the assumptions used for the Black-Scholes option-pricing model for these liability classified warrants.

	Date of		June 30	,	December	r 31,
	issuance	ð	2017		2016	
Fair value	\$5,331		\$2,604		\$ 3,397	
Expected dividend yield		%	_	%		%
Expected volatility	80	%	80	%	85	%
Risk-free interest rates	1.73	%	1.89	%	1.93	%
Remaining contractual term	7 years					

4.75	5.25	
years	years	

#### (15) Comprehensive Loss

The Company's comprehensive loss is shown on the Consolidated Statements of Operations as of June 30, 2017, and is comprised of net unrealized gains and losses on the Company's available-for-sale securities. The total of comprehensive loss for the three and six months ended June 30, 2017 was \$8,874 and \$17,018, respectively. The tax effect for the six months ended June 30, 2017 of other comprehensive loss was \$26.

#### (16) 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, non-employee directors, and consultants and advisors. As of June 30, 2017, 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, or the A&R Plan, which amended and restated the 2013 Plan and increased the aggregate amount of shares available for issuance to 2,000,000. On December 1st of each year, pursuant to the "Evergreen" provision of the A&R Plan, the number of shares available under the plan may be increased by the board of directors by an amount equal to 5% of the outstanding common stock on December 1st of that year. In December 2016 and 2015, the number of shares available for

## RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

(Unaudited)

issuance under the A&R Plan was increased by 619,181 and 461,215, respectively. The total number of shares authorized for issuance under the A&R plan as of June 30, 2017 is 3,080,396.

Stock options are exercisable generally for a period of 10 years from the date of grant and generally vest over four years. As of June 30, 2017, 279,905 shares and 174 shares are available for future grants under the A&R Plan and 2008 Plan, respectively.

The weighted average grant-date fair value of the options awarded to employees during the six months ended June 30, 2017 and 2016 was \$5.36 and \$4.18, respectively. The fair value of the options was estimated on the date of grant using a Black-Scholes option pricing model with the following assumptions:

	June 30,	
	2017	2016
Range of expected option life	6 years	6 years
Expected volatility	84.71%	74.82%
Risk-free interest rate	1.87-2.17	<b>%</b> .13-1.91%
Expected dividend yield	_	<del></del>

The following table summarizes stock option activity during the six months ended June 30, 2017:

		Weighted	Weighted
		average	average
	Number of	exercise	remaining
	shares	price	contractual life
Balance, December 31, 2016	2,611,929	\$ 7.01	
Granted	753,570	7.46	
Exercised	(3,600)	6.00	
Expired/forfeited/cancelled	(19,393)	8.65	
Balance, June 30, 2017	3,342,506	\$ 7.10	7.4 years
Vested	1,740,772	\$ 6.59	6.0 years
Vested and expected to vest	3,226,304	\$ 7.08	7.4 years

Included in the table above are 501,000 options granted outside the plan. The grants were made pursuant to the NASDAQ inducement grant exception in accordance with NASDAQ Listing Rule 5635(c)(4).

The following table summarizes restricted stock units activity during the six months ended June 30, 2017.

	Number of shares
Balance, December 31, 2016	7,750
Granted	339,043
Vested	(7,750)
Expired/forfeited/cancelled	(750)
Balance, June 30, 2017	338,293
Expected to vest	338,293

During 2017, the Company granted 91,150 performance-based restricted stock units, or RSUs, which vest based on attaining clinical and operational goals during 2017, as well as 247,893 time-based RSUs, which vest over four years.

Stock-based compensation expense for the six months ended June 30, 2017 and 2016 was \$2,370 and \$1,430, respectively.

As of June 30, 2017, there was \$11,588 of unrecognized compensation expense related to unvested options and RSUs that are expected to vest and will be expensed over a weighted average period of 2.7 years.

The aggregate intrinsic value represents the total amount by which the fair value of the common stock subject to options exceeds the exercise price of the related options. As of June 30, 2017, the aggregate intrinsic value of the vested and unvested options was \$2,266 and \$603, respectively.

## RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

(Unaudited)

#### (17) Segment Reporting

The Company operates through two business segments: an Acute Care segment and a revenue-generating CDMO segment. The Acute Care segment is primarily focused on developing innovative products for hospital and related settings, and the CDMO segment leverages the Company's formulation expertise to develop and manufacture pharmaceutical products using the Company's proprietary delivery technologies for commercial partners who commercialize or plan to commercialize these products. Acute Care has no revenue, and its costs consist primarily of expenses incurred in conducting the Company's clinical and preclinical studies, acquiring clinical trial materials, regulatory activities, personnel costs and pre-commercialization of meloxicam. CDMO revenue streams are derived from manufacturing, royalty and profit-sharing revenues, as well as CDMO's research and development services performed for commercial partners.

The accounting policies of the segments are the same as those described in the summary of significant accounting policies (see Note 3). The Company evaluates performance of its reportable segments based on revenue and operating income (loss). The Company does not allocate interest income, interest expense or income taxes to its operating segments.

The following table summarizes segment information as of and for the six months ended June 30, 2017 and 2016:

For the Three			
Months Ended		For the Six Months	
June 30,		Ended June 30,	
2017	2016	2017	2016
\$16,934	\$17,279	\$35,676	\$35,021
_	_	_	_
\$16,934	\$17,279	\$35,676	\$35,021
\$4,060	\$5,634	\$10,258	\$11,277
(13,490)	(12,405)	(26,990)	(23,073)
\$(9,430)	\$(6,771)	\$(16,732)	\$(11,796)
\$1,865	\$1,917	\$3,702	\$3,802
9	_	14	_
\$1,874	\$1,917	\$3,716	\$3,802
\$1,366	\$737	\$2,896	\$1,081
	Months Er June 30, 2017 \$16,934 — \$16,934 \$4,060 (13,490) \$(9,430) \$1,865 9 \$1,874	Months Ended June 30, 2017 2016  \$16,934 \$17,279	Months Ended June 30, Ended June 2017 2016 2017  \$16,934 \$17,279 \$35,676

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Acute Care		75	_	289	
Total		\$1,441	\$737	\$3,185	\$1,081
		June 30,	December	31,	
		2017	2016		
7	Γotal assets:				
(	CDMO	\$78,986	\$ 77,828		
A	Acute Care	90,823	105,169		
7	Γotal	\$169,809	\$ 182,997		

## (18) Related Party Transactions

The Company's President and Chief Executive Officer, or CEO, owns a majority of the stock of Malvern Consulting Group, or MCG, a pharmaceutical incubator and consulting firm. The CEO's husband, who is also a shareholder of the Company, is a consultant and a shareholder of MCG. In addition, the CEO's son is the President and a shareholder of MCG. During 2016, certain immediate family members of the CEO were employees of MCG, including the CEO's brother and sister-in-law. Since formation, the Company entered into various transactions with MCG, as detailed below. However, since becoming a public

## RECRO PHARMA, INC. AND SUBSIDIARIES

Notes to the Consolidated Financial Statements

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

(Unaudited)

company, the Company sought to decrease its involvement with MCG, and, as of December 31, 2016, the Company no longer has any involvement or transactions with MCG.

During 2016, certain of the Company's executive officers, its CEO, its Senior Vice President, Development and its Senior Vice President, Regulatory Affairs and Quality Assurance, who is also the CEO's sister, provided minimal consulting services from time to time to MCG. Until December 31, 2016, the Company was a party to a Master Consulting Services Agreement with MCG. Pursuant to the agreement, MCG provided the Company with certain consulting services for a fee based upon hourly rates previously approved by the Company's Board of Directors. In consideration for such services, the Company recorded \$89 and \$190 for the three and six months ended June 30, 2016, respectively. A portion of these amounts were used during 2016 to pay a portion of the respective salaries of MCG employees that, as described above, included immediate family members of the Company's CEO.

Until December 31, 2016, the Company was party to an Office Services Agreement with MCG for the lease of an aggregate of 8,458 square feet of office and lab space located at its Malvern, Pennsylvania facility and the provision of IT services and general office support. Pursuant to the Office Services Agreement, the Company paid MCG \$57 in the three and six months ended June 30, 2016. The Company terminated this agreement on December 31, 2016 and is now a party to a six-year lease directly with the landlord of the Company's Malvern, Pennsylvania facility (see Note 13).

As of December 31, 2016, the Company terminated the Master Consulting Agreement and the Office Services Agreement and MCG no longer provides any services or has any contracts with the Company.

The Company's Senior Vice President, Regulatory and Quality, who is the CEO's sister, has held that position since 2014. Effective January 1, 2017, the CEO's sister-in-law and brother, respectively, terminated their employment with MCG and were hired as the Company's Director of Human Resources and the Company's Vice President, Manufacturing. The Company's board of directors approved these hires consistent with the Company's related person transaction policy.

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, 2016 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 9, 2017. 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," "est "potential" or "continue" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements.

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

- our estimates regarding expenses, future revenue, capital requirements and timing and availability of and the need for additional financing;
- our ability to obtain and maintain regulatory approval of injectable meloxicam and our product candidates, and the labeling under any approval that we may obtain;
- the results, timing and outcome of our clinical trials of injectable meloxicam or our other product candidates, and any future clinical and preclinical studies;
- our ability to successfully commercialize injectable meloxicam or our other product candidates, upon regulatory approval;
- our ability to comply with the legal and regulatory frameworks applicable to our business and other regulatory developments in the United States and foreign countries;
- our ability to raise future financing and attain profitability for continued development of our business and our product candidates and to meet required debt payments, and any milestone payments owing to Alkermes, or our other licensing and collaboration partners;
- our ability to operate under increased leverage and associated lending covenants;
- the performance of third-parties upon which we depend, including third-party contract research organizations, or CRO's, and third-party suppliers and manufacturers;
- our ability to obtain patent protection and defend our intellectual property rights against third parties;
- our ability to maintain our relationships and contracts with our key commercial partners;
- our ability to recruit or retain key scientific, technical, commercial, and management personnel or to retain our executive officers;
- 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; and
- the effects of changes in our effective tax rate due to changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities and changes in the tax laws. 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" included in Part II, Item 1A of this Quarterly Report and Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 filed with the SEC on March 9, 2017 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 specialty pharmaceutical company that operates through two business divisions: an Acute Care division and a revenue-generating CDMO division. Each of these divisions are deemed to be reportable segments for financial reporting purposes.

Our Acute Care segment is primarily focused on developing innovative products for commercialization in hospital and other acute care settings. Our lead product candidate, IV meloxicam, has successfully completed two pivotal Phase III clinical trials, a large Phase III safety trial and other safety studies for the management of moderate to severe pain. Overall, we enrolled a total of approximately 1,100 patients in our Phase III program. At the end of July 2017, we submitted an NDA to the FDA for IV meloxicam 30mg for the management of moderate to severe pain. The FDA has a 60-day filing review period to determine whether the NDA is complete and acceptable for filing. Our Acute Care segment has no revenue and our costs consist primarily of expenses incurred in conducting our clinical trials and preclinical studies, manufacturing scale-up, regulatory activities, initial pre-commercialization of meloxicam and personnel costs.

Our CDMO segment leverages our formulation expertise to develop and manufacture pharmaceutical products using our proprietary delivery technologies for commercial partners who commercialize or plan to commercialize these products. These collaborations result in revenue streams including royalties, profit sharing, research and development and manufacturing, which support continued operations for our CDMO segment and have contributed funds to be used in our research and development and pre-commercialization activities in our Acute Care segment. We operate a 97,000 square-foot, DEA-licensed manufacturing facility in Gainesville, Georgia, and we currently develop and/or manufacture the following key products with our commercial partners: Ritalin LA®, Focalin XR®, Verelan PM®, generic Verapamil sustained release and Zohydro ER®, as well as development stage products. Our CDMO segment's revenue streams are derived from manufacturing, royalty and profit sharing revenues, as well as our research and development of services performed for commercial partners.

We have incurred losses and generated negative cash flows from operations since inception, and expect to continue to incur significant and increasing operating losses for the foreseeable future. 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, clinical trials and pre-commercialization activities. We have used revenue generated by our CDMO segment primarily to fund operations at our Gainesville, Georgia manufacturing facility, to make payments under our credit facility and to partially fund our development and pre-commercialization activities of our Acute Care segment. We believe our CDMO's revenue will continue to contribute cash for general corporate purposes that may, to some extent, reduce the amount of external capital needed to fund development operations. We expect to incur increasing expenses over the next several years to develop and commercialize injectable meloxicam, including continued pre-commercial activities for IV meloxicam. Based upon the availability of additional financial resources, we may also develop and commercialize our other product candidates in our pipeline, as well as other products we may in-license.

On April 10, 2015, we completed the Gainesville Transaction. The Gainesville Transaction transformed our business through the addition of a revenue-generating business and the increase in our workforce as a result of the addition of the employees at our Gainesville, Georgia manufacturing facility. The consideration paid consisted of \$50.0 million cash, a \$4.0 million working capital adjustment and a seven-year warrant to purchase 350,000 shares of our common stock at an exercise price of \$19.46 per share. In addition, we may be required to pay up to an additional \$125.0 million in milestone payments (including, at our election, either (i) \$10 million upon NDA filing and \$30 million upon regulatory approval or (ii) an aggregate of \$45 million upon regulatory approval, as well as net sales

milestones) and a royalty percentage of future product net sales related to injectable meloxicam.

The up-front payment was funded with \$50.0 million in borrowings under a credit agreement that we entered into with OrbiMed and cash on hand. The interest rate under the credit agreement is equal to LIBOR plus 14.0%, with a 1.0% LIBOR floor. Pursuant to the credit agreement, we issued OrbiMed a warrant to purchase an aggregate of 294,928 shares of our common stock at an exercise price of \$3.28 per share, subject to certain adjustments.

#### Financial Overview

#### Revenues

During the three and six months ended June 30, 2017 and June 30, 2016, we recognized revenues in four categories: manufacturing revenue, royalty, profit sharing and research and development revenue. All revenue is generated from our CDMO segment.

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, development and/or 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, development and/or 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, and preparation of pre-clinical and clinical testing drug product materials prepared by our CDMO segment 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 hourly rate, plus direct external costs, if any. In an agreement which specifies milestones, we recognize revenue upon achievement of manufacturing and regulatory events.

#### Research and Development Expenses

Research and development expenses currently consist primarily of costs incurred in connection with the development of injectable meloxicam and other pipeline activities. 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;
- acquired in process research and development;
- costs associated with non-clinical and regulatory activities;
- salaries and related costs for personnel in research and development and regulatory functions.
- costs associated with pre-commercialization activities; and
- costs related to scale up and validation for injectable meloxicam.

The majority of our external research and development costs relate to clinical trials, manufacturing of drug supply for pre-commercial products analysis and testing of product candidates and patent costs. Costs related to facilities, depreciation and support are not charged to specific programs.

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

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

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Risk involved with development of manufacturing processes and successful completion of manufacturing batches for clinical development and other regulatory purposes;

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 other risks disclosed in the section titled "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2016.

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 to primarily relate to injectable meloxicam for the foreseeable future as we advance this product candidate through the pre-commercialization scale-up, clinical and other pre-approval activities. We also expect to have expenses as we initiate clinical trials and related work for our other product candidates. 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. We expect our research and development costs to continue to increase as we continue clinical and pre-commercialization manufacturing activities for IV meloxicam, and engage in pipeline development activities.

In addition, research and development expenses consist of costs incurred by our CDMO segment in connection with research and development services performed for our commercial partners, as well as other product development activities. 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.

## General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, pre-commercial 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.

We expect our general and administrative expenses to continue to increase as we build our Acute Care commercialization team, and engage in pre-commercialization IV meloxicam marketing, sales, market access and medical affairs activities. In addition, we will continue to incur costs relating to our operations as a public company, including increased headcount and increased salary, consulting, legal, patent and compliance, accounting, insurance and investor relations costs.

## 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 injectable meloxicam represents 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 injectable meloxicam in the Gainesville Transaction, we are required to pay up to an additional \$125.0 million in milestone payments (including, at our election, either (i) \$10 million upon NDA filing and \$30 million upon regulatory approval or (ii) an aggregate of \$45 million upon regulatory approval, as well as net sales milestones) and royalties on future net product sales of between 10% and 12% (subject to a 30% reduction when no longer covered by patent). 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.

## Change in Fair Value of Warrants

We have classified as liabilities certain warrants outstanding which contain a contingent net cash settlement feature, or an anti-dilution provision. The fair value of these warrants are remeasured through settlement or expiration with changes in fair value recognized as a period charge within the statement of operations.

#### Interest Expense

Interest expense for the three and six months ended June 30, 2017 and June 30, 2016 was a result of interest expense incurred on our OrbiMed senior secured term loan and the amortization of the related financing costs.

#### **Results of Operations**

Comparison of the Three Months Ended June 30, 2017 and 2016

	Three Mor	
	Ended Jun	,
	2017	2016
	(amounts i	n
	thousands)	)
Revenue:		
Manufacturing, royalty and profit sharing revenue	\$16,750	\$16,933
Research and development revenue	184	346
Total revenues	16,934	17,279
Operating expenses:		
Cost of sales (excluding amortization of intangible assets)	10,448	9,547
Research and development	7,073	8,320
General and administrative	6,322	2,763
Amortization of intangible assets	646	646
Change in warrant valuation	(1,084)	1,240
Change in contingent consideration valuation	2,959	1,534
Total operating expenses	26,364	24,050
Operating loss	(9,430)	(6,771)
Other income (expense):		
Interest expense, net	(1,090)	(1,309)
Loss before income taxes	(10,520)	(8,080)
Income tax benefit	1,665	195
Net loss	\$(8,855)	\$(7,885)

Revenue and costs of sales. Our revenues were \$16.9 million and \$17.3 million and cost of sales were \$10.4 million and \$9.5 million for the three months ended June 30, 2017 and 2016, respectively. The decrease of \$0.3 million in revenue, or 2%, for this quarter year-over-year, was primarily the result of a decrease in royalty revenue due to the change in the mix of generic and brand sales by our partners offset by an increase in profit sharing revenue due to increased sales volume and pricing by our partner. Cost of sales increased \$0.9 million, or 9%, due to changes in the product mix of manufacturing revenue.

Research and Development. Our research and development expenses were \$7.1 million and \$8.3 million for the three months ended June 30, 2017 and 2016, respectively. Lower IV meloxicam clinical trial expenses of \$4.3 million were offset by increases of \$1.6 million of pre-commercialization manufacturing costs and other development costs for IV meloxicam, \$0.8 million in IPR&D costs for the NMB Related Compounds and \$0.5 million of salaries and benefits expense due to increased Acute Care clinical headcount.

General and Administrative. Our general and administrative expenses were \$6.3 million and \$2.8 million for the three months ended June 30, 2017 and 2016, respectively. The increase of \$3.5 million was primarily due to increased headcount in our Acute Care division, and pre-commercialization and medical affairs expenses.

Amortization of Intangible Assets. Amortization expense was \$0.6 million for each of the quarters ended June 30, 2017 and 2016, which was exclusively related to the amortization of our royalties and contract manufacturing relationships intangible asset over its six-year estimated useful life.

Interest Expense, net. Interest expense, net was \$1.1 million and \$1.3 million during the three months ended June 30, 2017 and 2016, respectively. The decrease in interest expense, net, was due to a lower principal balance on our OrbiMed senior secured term loan and amortization of the related financing costs.

Income Tax Benefit. Income tax benefit was \$1.7 million and \$0.2 million for the three months ended June 30, 2017 and 2016, respectively, due to income tax benefit related to our a loss in our U.S. operations. We believe that it is more likely than not that the deferred income tax assets associated with our foreign operations will not be realized, and as such, there is a full valuation allowance against our foreign deferred tax assets.

Operating Income (Loss) per Segment.

#### CDMO Segment-

Our CDMO's gross margin percentage was 38% and 45% in the three months ended June 30, 2017 and 2016, respectively. Our revenues decreased by \$0.3 million, or 2%, and was primarily the result of a decrease in royalty revenue due to a change in the mix of generic and brand sales by our partners offset by an increase in profit sharing revenue due to increased sales volume and pricing by our partner. One of our commercial partners, Pernix, is out of stock for the 20mg dosage strength of Zohydro ER®. The 20mg dosage strength is one of six strengths we manufacture for Pernix. For fiscal year 2016, revenues across all Zohydro ER® strengths represented less than 10% of our total revenues. Cost of sales increased \$0.9 million, or 9% as a result of our product mix of manufacturing revenue.

CDMO's operating expenses (excluding cost of sales) increased by \$0.3 million, from \$2.1 million in the three months ended June 30, 2016, to \$2.4 million in the three months ended June 30, 2017. Research and development expenses increased by \$0.2 million due to increased overhead costs in 2017. General and administration expenses increased by \$0.1 million due to an increase in marketing expenses. All of the above contributed to CDMO's operating income of \$4.1 million for the three months ended June 30, 2017, which included non-cash charges of \$1.9 million for depreciation and amortization and \$0.2 million for stock-based compensation.

## Acute Care Segment-

Acute Care's operating expenses increased \$1.1 million from \$12.4 million in the three months ended June 30, 2016 to \$13.5 million in the three months ended June 30, 2017. Research and development expenses decreased \$1.5 million as a result of a decrease in our IV meloxicam clinical trial expenses, which was partially offset by increased costs in IV meloxicam pre-commercialization manufacturing costs, IPR&D costs for the acquisition of the NMB Related Compounds and increased headcount. General and administrative costs increased by \$3.5 million as a result of increased headcount and increased pre-commercialization marketing expenses. Non-cash charges of the warrant valuation decreased \$2.3 million and contingent consideration increased by \$1.4 million. All of the above contributed to Acute Care's operating loss of \$13.5 million for the three months ended June 30, 2017, which included non-cash charges of \$1.2 million for stock-based compensation, depreciation and amortization.

Comparison of the Six Months Ended June 30, 2017 and 2016

	Six Month June 30, 2017 (amounts : thousands	2016 in
Revenue:		
Manufacturing, royalty and profit sharing revenue	\$34,878	\$34,072
Research and development revenue	798	949
Total revenues	35,676	35,021
Operating expenses:		
Cost of sales (excluding amortization of intangible assets)	20,946	19,818
Research and development	14,836	16,129
General and administrative	10,354	5,421
Amortization of intangible assets	1,292	1,291
Change in warrant valuation	(793)	(354)
Change in contingent consideration valuation	5,773	4,512
Total operating expenses	52,408	46,817
Operating loss	(16,732)	(11,796)
Other income (expense):		
Interest expense, net	(2,168)	(2,812)
Loss before income taxes	(18,900)	(14,608)
Income tax benefit	1,958	184
Net loss	\$(16,942)	\$(14,424)

Revenue and costs of sales. Our revenues were \$35.7 million and \$35.0 million and cost of sales were \$20.9 million and \$19.8 million for the six months ended June 30, 2017 and 2016, respectively. The increase of \$0.7 million in revenue, or 2%, was primarily the result of increased profit share revenue due to increased sales volumes and pricing by our partner and was partially offset by a decrease in manufacturing revenue due to a change in the timing of product shipments compared to prior year and decreased royalty revenue due to a change in the mix of generic and brand sales by our partners. Cost of sales increased \$1.1 million, or 6%, due to changes in the product mix of manufacturing revenue.

Research and Development. Our research and development expenses were \$14.8 million and \$16.1 million for the six months ended June 30, 2017 and 2016, respectively. Lower IV meloxicam clinical trial expenses of \$5.5 million were offset by increases of \$2.5 million of pre-commercialization manufacturing costs and other development costs for IV meloxicam, \$0.8 million in IPR&D costs for the acquisition of the NMB Related Compounds and \$0.9 million of salaries and benefits expense due to increased Acute Care clinical headcount.

General and Administrative. Our general and administrative expenses were \$10.4 million and \$5.4 million for the six months ended June 30, 2017 and 2016, respectively. The increase of \$5.0 million was primarily due to increased headcount in our Acute Care division and pre-commercialization and medical affairs expenses.

Amortization of Intangible Assets. Amortization expense was \$1.3 million for the six months ended June 30, 2017 and 2016 which was exclusively related to the amortization of our royalties and contract manufacturing relationships

intangible asset over its six-year estimated useful life.

Interest Expense, net. Interest expense, net was \$2.2 million and \$2.8 million during the six months ended June 30, 2017 and 2016, respectively. The decrease in interest expense, net, was due to a lower principal balance on our OrbiMed senior secured term loan and amortization of the related financing costs.

Income Tax Benefit. Income tax benefit was \$2.0 million and \$0.2 million for the six months ended June 30, 2017 and 2016, respectively, due to income tax benefit related to our loss in our U.S. operations. We believe that it is more likely than not that the deferred income tax assets associated with our foreign operations will not be realized, and as such, there is a full valuation allowance against our foreign deferred tax assets.

Operating Income (Loss) per Segment.

## CDMO Segment-

Our CDMO's gross margin percentage was 41% and 43% in the six months ended June 30, 2017 and 2016, respectively. Our revenues increased by \$0.7 million, or 2%, and was primarily the result of increased profit share revenue due to increased sales volumes and pricing by our partner and was partially offset by a decrease in manufacturing revenue due to a change in the timing of product shipments compared to prior year and decreased royalty revenue due to a change in the mix of generic and brand sales by our partners. One of our commercial partners, Pernix, is out of stock for the 20mg dosage strength of Zohydro ER®. The 20mg dosage strength is one of six strengths we manufacture for Pernix. For fiscal year 2016, revenues across all Zohydro ER® strengths represented less than 10% of our total revenues. Cost of sales increased \$1.1 million, or 6%, as a result of our product mix of manufacturing revenue.

CDMO's operating expenses (excluding cost of sales) increased by \$0.6 million, from \$3.9 million in the six months ended June 30, 2016 to \$4.5 million in the six months ended June 30, 2017. Research and development expenses increased by \$0.5 million due to expanded investment in our future capabilities in 2017. General and administration expenses remained constant in the six months ended June 30, 2017 and 2016. All of the above contributed to CDMO's operating income of \$10.3 million for the six months ended June 30, 2017, which included non-cash charges of \$3.7 million for depreciation and amortization and \$0.5 million for stock-based compensation.

## Acute Care Segment-

Acute Care's operating expenses increased \$3.9 million from \$23.1 million in the six months ended June 30, 2016 to \$27.0 million in the six months ended June 30, 2017. Research and development expenses decreased \$1.9 million as a result of a decrease in our IV meloxicam clinical trial expenses, which was partially offset by increased costs in IV meloxicam pre-commercialization manufacturing costs and increased headcount. General and administrative costs increased by \$5.0 million as a result of increased headcount and increased pre-commercialization marketing expenses. Non-cash charges of the warrant valuation decreased \$0.4 million and contingent consideration increased by \$1.3 million. All of the above contributed to Acute Care's operating loss of \$27.0 million for the six months ended June 30, 2017, which included non-cash charges of \$1.9 million for stock-based compensation, depreciation and amortization.

## Liquidity and Capital Resources

As of June 30, 2017, we had \$50.2 million in cash and cash equivalents and short-term investments.

Since inception through June 30, 2017, we have financed our product development, operations and capital expenditures primarily from sales of equity and debt securities, including sales of our common stock of \$116.4 million, which includes \$57.6 million raised in 2016. Revenues from our CDMO segment are used primarily to fund operations at our Gainesville, Georgia manufacturing facility, to make payments under our credit facility and to partially fund the development and pre-commercialization activities of our Acute Care segment. During the six months ended June 30, 2017, our capital expenditures were \$3.2 million.

We will need to raise substantial additional funds in order to fund the payments which may become due, including milestone payments owed to Alkermes or other licensing partners, to continue our clinical trials of our approved or development state product candidates, to commercialize any approved 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, and the costs of commercialization activities, as well as the continued profitability of our CDMO segment. If additional funds are required, we may raise such funds through debt refinancing, bank or other loans, through strategic research and development, licensing and/or marketing arrangements or through public or private sales of equity or debt securities 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 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 equal to (A) for full prepayments, \$75 million less all previously prepaid principal amount and all previously paid interest or (B) for partial prepayments of the unpaid principal amount, 0.5 times the partial prepayment amount less interest payments previously paid in respect to the partial prepayment amount and; and (ii) after the 36-month anniversary of the closing of the credit agreement, payment of an exit fee amount equal to 10% of the amount of any prepayments. As defined by the agreement, based upon our CDMO segment financial results, OrbiMed has the option to require us to prepay a portion of the Loan balance based upon an Excess Cash Flow calculation. No payments under this option shall be subject to the buy-out premium. The credit agreement carries interest at three-month LIBOR plus 14.0% with 1.0% floor. This obligation is secured by substantially all of our assets. As of June 30, 2017, we have paid \$22.7 million of the outstanding principal on our senior secured term loan from free cash flow.

#### Sources and Uses of Cash

Cash used in operations was \$11.0 million and \$5.4 million for the six months ended June 30, 2017 and 2016, 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 and amortization of intangibles, as well as changes in operating assets and liabilities.

Cash used in investing activities was \$44.8 million and \$1.1 million for the six months ended June 30, 2017 and 2016, respectively, and reflected cash used for the purchase of short-term investments offset by maturities/redemption of investments in 2017 and property and equipment in 2017 and 2016. Our short-term investments are classified as available for sales securities maturities of less than one year.

There was \$0.02 million cash provided by financing activities in six months ended June 30, 2017 from proceeds from exercise of options. Cash provided by financing activities was \$1.5 million for the six months ended June 30, 2016, primarily as a result of \$4.2 million in proceeds from the sale of shares of common stock through our common stock purchase agreement with Aspire Capital offset by excess cash flow payments of \$2.6 million made related to the OrbiMed credit agreement.

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

- the timing and outcome of the FDA's review of an NDA for IV meloxicam;
- the timing and outcome of our Phase IIIB clinical studies for IV meloxicam;
- the extent to which the FDA may require us to perform additional preclinical studies, clinical trials or pre-commercial manufacturing of injectable meloxicam;
- the timing to fund the Gainesville Transaction regulatory milestone payments and other contingent consideration;
- the costs of our commercialization activities, if our product candidates are approved by the FDA;
- the cost of purchasing manufacturing and other capital equipment for our product candidates;
- 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 in-license, acquire or invest in products, businesses and technologies;
- the timing and extent of our manufacturing and capital expenditures related to our CDMO division;
- 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 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;

the costs of preparing, submitting and prosecuting patent applications and maintaining, enforcing and defending intellectual property claims; and

the effect of any changes in our effective tax rate due to changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities and changes in tax laws.

We might use existing cash and cash equivalents on hand, additional debt or equity financing or a combination of the three 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 June 30, 2017.

#### Licenses

We have in-licensed product candidates that generally trigger or require payments to the partner from whom we have licensed the product. Such payments frequently take the form of:

- an up-front payment, the size of which varies depending on the phase of the product candidate and how many other companies would like to obtain the product, which is paid very soon after signing a license agreement; royalties as a percentage of net sales of the product; and
- •milestone payments, which are paid when certain parts of the overall development program and regulatory milestones (such as filing an IND or an NDA) are successfully accomplished, as well meeting certain sales thresholds.

We are party to exclusive licenses with Orion for the development and commercialization of Dex and Fado, under which we may be required to make certain milestone and royalty payments to Orion. We also license the NMB Related Compounds from Cornell pursuant to a license agreement pursuant to which we are obligated to make annual license maintenance fee payments, milestone payments and patent cost payments and to pay royalties on net sales of the NMB Related Compounds. See Note 5 and Note 13(a) to the Consolidated Financials Statements included in the Form 10-Q. We are unable to reliably estimate the timing of these payments because they are dependent on the type and complexity of the clinical studies and intended uses of the products, which have not been established. In accordance with U.S. GAAP, these obligations are not recorded on our Consolidated Balance Sheets.

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 and would seek appropriate compensation.

#### **Contingent Consideration**

Pursuant to the purchase and sale agreement governing the Gainesville Transaction, we agreed to pay to Alkermes up to an additional \$125.0 million in milestone payments (including, at our election, either (i) \$10 million upon NDA filing and \$30 million upon regulatory approval or (ii) an aggregate of \$45 million upon regulatory approval, as well as net sales milestones) and royalties on future product sales of injectable meloxicam between 10% and 12% (subject to a 30% reduction when no longer covered by patent). Through June 30, 2017, no milestones have been achieved. At the end of July 2017, we filed the NDA and have not made the election as to which milestone payment we will make as of the 10-Q filing date.

#### **Product Manufacturing**

We are party to a supply agreement with Alkermes for the clinical and, if approved by the FDA, commercial supply of injectable meloxicam. Pursuant to our agreement with Alkermes, we will purchase our clinical and commercial

supplies of bulk injectable meloxicam formulation exclusively from Alkermes, subject to certain exceptions. We are also party to an API supply agreement with Orion, whereby Orion provides us with API for the development and commercialization of our Dex product candidates. Prior to obtaining regulatory approval, subject to advance notice to Orion, Orion will provide API without charge for agreed-upon amounts. Any amounts ordered by us that are greater than the planned supply will be charged at 50% of the supply price for commercial product.

#### Leases

On January 1, 2017, we entered into a six-year lease of our Malvern, Pennsylvania facility that expires on December 31, 2022. In February 2017, we also entered into a three-year lease for office space in Dublin, Ireland that expires in April 2020. We are also party to operating leases for office equipment and storage.

#### Debt

Pursuant to our credit agreement with OrbiMed, OrbiMed provided us with a term loan in the original principal amount of \$50.0 million on April 10, 2015. The unpaid principal amount under the credit agreement is due and payable in April 2020. The credit agreement also provides for certain mandatory prepayment events, including a quarterly excess cash flow prepayment requirement at OrbiMed's request. As defined by the agreement, based upon our CDMO segment financial results, OrbiMed has the option to require the Company to prepay a portion of the loan balance based upon an Excess Cash Flow calculation. As of June 30, 2017, we have paid \$22.7 million of the outstanding principal on our senior secured term loan from free cash flow.

#### 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

Our critical accounting policies and estimates are disclosed in the Management's Discussion and Analysis of Financial Condition and Results of Operations section of our Annual Report on Form 10-K December 31, 2016 filed with the SEC on March 9, 2017. There have not been any significant changes to such critical accounting policies since.

#### Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business. These market risks are principally limited to interest rate fluctuations. At June 30, 2017, we had approximately \$47.6 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 June 30, 2017, all less than one year, 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.

We have license agreements with Orion for Dex and Fado which require the payment of milestones upon the achievement of certain regulatory and commercialization events and royalties on product sales, which are required to be made in Euros. As of June 30, 2017, no milestones or royalties were due under these agreements, and we do not anticipate incurring milestone or royalty costs under these agreements until we advance our development of Dex or Fado. We do not believe foreign currency exchange rate risk is a material risk at this time; however, these agreements could, in the future, give rise to foreign currency transaction gains or losses. As a result, our results of operations and financial position could be exposed to changing currency exchange rates. In the future, we may periodically use forward contracts to hedge certain transactions or to neutralize exposures.

# Item 4. Controls and Procedures Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of June 30, 2017. 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 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.

A control system, no matter how well conceived and operated, can provide only reasonable, and not absolute, assurance that the objectives of the control system will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. However, our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives. Based on the evaluation of our disclosure controls and procedures as of June 30, 2017, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

## Changes in Internal Control over Financial Reporting

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

#### 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® has been subject to six 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®, one of which was filed in April 2015 by Actavis regarding the filing of a supplemental ANDA, or sANDA, and another three of which were filed in November 2015 and October 2016 by Actavis and in December 2015 by Alvogen regarding one of our recently issued patents relating to a formulation of Zohydro ER®. These certification notices allege that the three U.S. patents listed in the FDA's Orange Book for Zohydro ER®, with an expiration date in November 2019 or September 2034, 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 one of our patent applications relating to a dosage form of Zohydro ER® and two Purdue Pharma, LP, or Purdue, applications. On April 29, 2016, the USPTO found our claims and the Purdue claims involved in the interference to be invalid. Purdue appealed this decision to the U.S. Court of Appeals for the Federal Circuit on June 28, 2016, and on June 13, 2017 the U.S. Court of Appeals for the Federal Circuit affirmed the decision of the USPTO.

Under our license agreement with Pernix, we have the right to control the enforcement of our patents and related proceedings involving Zohydro ER® and any prospective generic entrant, and Pernix has the obligation to reimburse us for all reasonable costs of such actions. On September 29, 2016, we entered into a settlement agreement with Alvogen pursuant to which the case against Alvogen was dismissed. In February 2017, the District Court in the Actavis case ruled in our favor and enjoined Actavis from selling the proposed generic version of Zohydro ER®. Actavis has appealed this decision to the U.S. Court of Appeals for the Federal Circuit.

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, 2016.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds. None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

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

# EXHIBIT INDEX

# Exhibit

No.	Description	Method of Filing
10.1†	Third Amendment to the Development, Manufacturing and Supply Agreement, dated June 15, 2017, by and between Alkermes Pharma Ireland Limited and Recro Pharma, Inc.	Filed herewith.
10.2†	Licensing Agreement, dated June 30, 2017, by and between Cornell University and Recro Pharma, Inc.	Filed herewith.
10.3†	Master Manufacturing Services Agreement, dated July 14, 2017, by and between Patheon UK Limited and Recro Ireland Limited	Filed herewith.
10.4†	Product Agreement, dated July 14, 2017, by and between Patheon UK Limited and Recro Ireland Limited	Filed herewith.
10.5	Employment Agreement, dated June 5, 2017, between Recro Pharma, Inc. and Ryan D. Lake	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 9, 2017 (File No. 001-36329).
31.1	Rule 13a-14(a)/15d-14(a) certification of Principal Executive Officer.	Filed herewith.
31.2	Rule 13a-14(a)/15d-14(a) certification of Principal Financial Officer.	Filed herewith.
31.3	Rule 13a-14(a)/15d-14(a) certification of Principal Accounting Officer.	Filed herewith.
32.1	Section 1350 certification, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
101 INS	XBRL Instance Document	Filed herewith.
101 SCH	XBRL Taxonomy Extension Schema	Filed herewith.
101 CAL	XBRL Taxonomy Extension Calculation Linkbase	Filed herewith.
101 DEF	XBRL Taxonomy Extension Definition Linkbase	Filed herewith.
101 LAB	XBRL Taxonomy Extension Label Linkbase	Filed herewith.

101 PRE XBRL Taxonomy Extension Presentation Linkbase
Document Filed herewith.

Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 406 under the Securities Act of 1933.

## **SIGNATURES**

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

#### RECRO PHARMA, INC.

Date: August 11, 2017 By:/s/ Gerri A. Henwood
Gerri A. Henwood
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 11, 2017 By:/s/ Michael Celano
Michael Celano
Chief Financial Officer
(Principal Financial Officer)

Date: August 11, 2017 By:/s/ Ryan D. Lake
Ryan D. Lake
Chief Accounting Officer
(Principal Accounting Officer)

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