Recro Pharma, Inc.
Form 10-Q
August 07, 2018

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, 2018

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 incorporation or organization)	(I.R.S. Employer 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 5, 2018, there were 20,718,063 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, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$48,911	$ 60,984
Short-term investments	—	3,498
Accounts receivable	11,671	9,686
Contract asset	6,866	—
Inventory	8,113	9,839
Prepaid expenses and other current assets	3,468	3,276
Total current assets	79,029	87,283
Property, plant and equipment, net	38,740	39,074
Deferred income taxes	22,696	18,573
Intangible assets, net	33,558	34,850
Goodwill	6,446	6,446
Total assets	$180,469	$ 186,226
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$6,357	$ 7,954
Accrued expenses and other current liabilities	9,500	9,897
Current portion of contingent consideration	33,957	32,053
Total current liabilities	49,814	49,904
Long-term debt, net	54,316	53,598
Warrants and other long-term liabilities	481	3,516
Long-term portion of contingent consideration	51,372	50,360
Total liabilities	155,983	157,378
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, 20,716,269 shares at June 30, 2018 and 19,127,435 shares at December 31, 2017	207	191
Additional paid-in capital	157,981	140,006

Accumulated deficit	(133,702)	(111,348)
Accumulated other comprehensive loss	—	(1)
Total shareholders' equity	24,486	28,848
Total liabilities and shareholders' equity	$180,469	$ 186,226

See accompanying notes to consolidated financial statements.

RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(amounts in thousands, except share and per share data)	For the Three Months Ended June 30, 2018	2017	For the Six Months Ended June 30, 2018	2017
Revenue	$21,739	$16,934	$41,281	$35,676
Operating expenses:				
Cost of sales (excluding amortization of intangible assets)	12,071	10,448	22,561	20,946
Research and development	10,157	7,073	18,599	14,836
General and administrative	12,955	6,322	22,473	10,354
Amortization of intangible assets	646	646	1,292	1,292
Change in warrant valuation	(1,139)	(1,084)	(365)	(793)
Change in contingent consideration valuation	396	2,959	2,916	5,773
Total operating expenses	35,086	26,364	67,476	52,408
Operating loss	(13,347)	(9,430)	(26,195)	(16,732)
Other income (expense):				
Interest income	114	117	255	222
Interest expense	(2,189)	(1,207)	(4,292)	(2,390)
Net loss before income taxes	(15,422)	(10,520)	(30,232)	(18,900)
Income tax benefit	2,707	1,665	5,060	1,958
Net loss	$(12,715)	$(8,855)	$(25,172)	$(16,942)
Per share information:				
Net loss per share of common stock, basic	$(0.62)	$(0.46)	$(1.27)	$(0.89)
Net loss per share of common stock, diluted	$(0.62)	$(0.48)	$(1.27)	$(0.89)
Weighted average common shares outstanding, basic	20,410,615	19,052,430	19,818,227	19,050,931
Weighted average common shares outstanding, diluted	20,410,615	19,220,700	19,818,227	19,220,175
Net loss	$(12,715)	$(8,855)	$(25,172)	$(16,942)
Other comprehensive loss:				
Unrealized gain/(loss) on available-for-sale securities	1	(19)	1	(76)
Comprehensive loss	$(12,714)	$(8,874)	$(25,171)	$(17,018)

See accompanying notes to consolidated financial statements.

RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Shareholders' Equity

For the Six Months Ended June 30, 2018

(Unaudited)

(amounts in thousands, except share data)	Common Stock Shares	Amount	Additional paid-in capital	Accumulated Deficit	Accumulated other comprehensive loss	Total
Balance, December 31, 2017	19,127,435	$ 191	$ 140,006	$ (111,348)	$ (1)	$ 28,848
Stock-based compensation expense	—	—	3,303	—	—	3,303
Stock option exercise	174,361	2	1,025	—	—	1,027
Issuance of restricted stock units, net of shares withheld for income taxes	116,718	1	(88)	—	—	(87)
Sale of common stock under equity facility, net of transaction costs	1,083,040	11	11,148	—	—	11,159
Cashless exercise of warrants	214,715	2	2,587	—	—	2,589
Other comprehensive income	—	—	—	—	1	1
Net loss	—	—	—	(25,172)	—	(25,172)
Cumulative effect of adoption of new accounting standards, net of tax	—	—	—	2,818	—	2,818
Balance, June 30, 2018	20,716,269	$ 207	$ 157,981	$ (133,702)	$ —	$ 24,486

See accompanying notes to consolidated financial statements.

RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

(Unaudited)

	For the Six Months Ended June 30,	
(amounts in thousands)	2018	2017
Cash flows from operating activities:		
Net loss	$ (25,172)	$ (16,942)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	3,303	2,370
Non-cash interest expense	639	326
Depreciation expense	2,498	2,424
Amortization	1,292	1,292
Acquired in-process research and development charges	—	766
Change in warrant valuation	(365)	(793)
Change in contingent consideration valuation	2,916	5,773
Deferred income taxes	(5,060)	(2,717)
Changes in operating assets and liabilities:		
Inventory	1,726	1,858
Contract asset	(3,111)	—
Prepaid expenses and other current assets	(17)	(1,454)
Accounts receivable	(1,985)	309
Accounts payable, accrued expenses and other liabilities	(905)	(4,194)
Net cash used in operating activities	(24,241)	(10,982)
Cash flows from investing activities:		
	(2,931)	(3,185)

Purchase of property and equipment				
Purchase of short-term investments		(4,982)		(53,593)
Proceeds from maturity of investments		8,500		12,000
Acquisition of license agreement		(82)		(18)
Net cash provided by/(used in) investing activities		505		(44,796)
Cash flows from financing activities:				
Payment of deferred financing costs		(261)		—
Proceeds from sale of common stock, net of transaction costs		10,984		—
Payments of withholdings on shares withheld for income taxes		(87)		—
Proceeds from option exercise		1,027		23
Net cash provided by financing activities		11,663		23
Net decrease in cash and cash equivalents		(12,073)		(55,755)
Cash and cash equivalents, beginning of period		60,984		64,483
Cash and cash equivalents, end of period	$	48,911	$	8,728
Supplemental disclosure of cash flow information:				
Cash paid for interest	$	4,375	$	2,064
Cash paid for taxes	$	—	$	467
Purchase of property, plant and equipment included in accrued expenses and accounts payable	$	508	$	385
Retirement of fully depreciated property, plant and equipment	$	30	$	—
	$	357	$	—

Common stock issued in connection with equity facility	

See accompanying notes to consolidated financial statements.

RECRO PHARMA, INC. AND SUBSIDIARIES

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, or the FDA, for its lead investigational product candidate intravenous, or IV, meloxicam 30 mg for the management of moderate to severe pain. In May 2018, the Company received a Complete Response Letter, or CRL, from the FDA regarding its NDA for IV meloxicam. In July 2018, the Company participated in a Type A End-of-Review meeting with the FDA to discuss the topics covered in the CRL. The Company plans to provide an update on its path forward following receipt of the written meeting minutes.

(2) Development-Stage Risks and Liquidity

The Company has incurred losses from operations since inception and has an accumulated deficit of $133,702 as of June 30, 2018. 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. 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). Insufficient funds may cause the Company to delay, reduce the scope of or eliminate one or more of its development, commercialization or expansion activities. The Company may raise such funds through debt refinancing, bank or other loans, sale of assets, through strategic research and development, licensing (including out-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 failure to raise capital when needed could materially adversely impact the Company's growth plans and its financial condition or results of operations. Additional debt or equity financing, if available, may be dilutive to the holders of its common stock and may involve significant cash payment obligations and covenants that restrict the Company's ability to operate its business. 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, partnering or out-licensing 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, including IV meloxicam.

Management believes that it is probable that the Company will be able to meet its obligations as they become due within one year after the date of the financial statements are issued.

(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 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, 2018 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2018.

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, 2017 included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017.

(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.

(c) Cash and Cash Equivalents

Cash and cash equivalents represent cash in banks and highly liquid short-term investments that have maturities of three months or less when acquired. These highly liquid short-term investments are both readily convertible to known amounts of cash and so near to 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 costs 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 and Comprehensive Loss 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 and Comprehensive Loss. For those compounds that reach commercialization, the IPR&D assets will be amortized over their estimated useful lives.

The impairment test for indefinite-lived intangible assets is a one-step test, which compares the fair value of the intangible asset to its carrying value. If the carrying value exceeds its fair value, an impairment loss is recognized in an amount equal to the excess. Based on accounting standards, it is required that these assets be assessed at least annually for impairment unless a triggering event occurs between annual assessments, which would then require an assessment in the period which a triggering event occurred. The Company performs its annual goodwill and indefinite-lived intangible asset impairment test as of November 30th, or whenever an event or change in circumstances occurs that would require reassessment of the recoverability of those assets. In performing the evaluation, the Company assessed qualitative factors such as overall financial performance of its reporting units, anticipated changes in industry and market conditions, including recent tax reform, intellectual property protection, and competitive environments. Due to the receipt of the CRL in May 2018, an indicator of potential impairment, the Company performed an impairment test, which indicated that there was no impairment to goodwill or indefinite-lived intangible assets as of June 30, 2018.

(g) Revenue Recognition

The Company generates revenues from manufacturing, packaging, research and development, 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, sales-based royalties and/or profit sharing components. The Company's revenue policies listed below are reflective of Accounting Standards Update, or ASU, No. 2014-09, "Revenue from Contracts with Customers," or ASU 2014-09, which the company adopted effective January 1, 2018. See footnote 18 for additional information regarding the Company's adoption of ASU 2014-09 and its impact on the Company's financial statements.

Manufacturing and other related services revenue is recognized upon transfer of control of a product to a customer, generally upon shipment, based on a transaction price that reflects the consideration the Company expects to be entitled to as specified in the agreement with the commercial partner, which could include pricing and volume-based adjustments.

In addition to manufacturing and packaging revenue, certain customer agreements may have intellectual property sales-based royalties and/or profit sharing consideration, collectively referred to as royalties, computed on the net product sales of the commercial partner. Royalty revenues are generally recognized under the terms of the applicable license, development and/or supply agreement. For arrangements that include sales-based royalties where the license for intellectual property is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue when the related sales occur by the commercial partner. For arrangements that include sales-based royalties where the license for intellectual property is not deemed to be the predominant item to which the royalties relate, the Company recognizes revenue upon transfer of control of the manufactured product. In these cases, significant judgement is required to calculate this estimated variable consideration using the most-likely amount method based on historical customer pricing and deductions and is partially constrained due to items that are outside of the Company's control including the uncertainty of the timing of future commercial partner sales, mix of volume, customer stocking and ordering patterns, as well as unforeseen price adjustments made by the Company's commercial partners.

Revenues related to research and development are generally recognized over-time as the related services or activities are performed using the output method and in accordance with the contract terms. In agreements which specify milestones, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. Milestone payments related to arrangements under which the Company has continuing performance obligations would be deferred and recognized over the period of performance. Milestone payments that are not within the control of the Company, such as submission for approval to regulators by a commercial partner or approvals from regulators, are not considered probable of being achieved until those submissions are submitted by the customer or approvals are received.

(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.

The Company's CDMO segment is dependent on its relationships with a small number of commercial partners, with its four largest customers having generated 99% of its revenues for three and six months ended June 30, 2018. A portion of the Company's revenues are dependent on U.S. based customers selling to end-users outside the United States.

(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 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 the historical volatility of its publicly traded stock in order to estimate future stock price trends. 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 does not anticipate significant changes in the amount of unrecognized income tax benefits over the next year.

(l) 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 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.

For the three and six months ended June 30, 2018, the outstanding common stock options, warrants and unvested restricted stock units have been excluded from the calculation of diluted net loss per share because their effect would be anti-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 and diluted loss per share:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Basic and Diluted Loss Per Share				
Net loss	$(12,715)	$(8,855)	$(25,172)	$(16,942)
Weighted average common shares outstanding, basic	20,410,615	19,052,430	19,818,227	19,050,931
Net loss per share of common stock, basic	$(0.62)	$(0.46)	$(1.27)	$(0.89)
Diluted Earnings Per Share				
Net income (loss)	$(12,715)	$(8,855)	$(25,172)	$(16,942)
Add change in warrant valuation	—	(341)	—	(234)
Diluted net income (loss)	$(12,715)	$(9,196)	$(25,172)	$(17,176)
Weighted average common shares outstanding, diluted	20,410,615	19,052,430	19,818,227	19,050,931
Add shares from outstanding warrants	—	168,270	—	169,244
Weighted average common shares outstanding, diluted	20,410,615	19,220,700	19,818,227	19,220,175
Net income (loss) per share of common stock, diluted	$(0.62)	$(0.48)	$(1.27)	$(0.89)

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as of June 30, 2018 and 2017, as they would be anti-dilutive:

	June 30,	
	2018	2017
Options and restricted stock units outstanding	5,121,104	3,680,799
Warrants	838,664	490,000

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 its CDMO and Acute Care divisions 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. 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 June 2018, the FASB issued ASU No. 2018-07, "Compensation – Stock Compensation (Topic 718)" or ASU 2018-07. ASU 2018-07 simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The new guidance expands the scope of ASC 718 "Compensation—Stock Compensation" to include share-based payments granted to nonemployees in exchange for goods or services used or consumed in an entity's own operations and supersedes the guidance in ASC 505-50 "Equity-Based Payments to Non-Employees". The guidance is effective for public business entities in annual periods beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted, including in an interim period for which financial statements have not been issued, but not before an entity adopts ASU 2014-09 "Revenue from Contracts with Customers (Topic 606)". The Company adopted this guidance effective June 30, 2018. There was no impact upon adoption.

In May 2017, the FASB issued ASU No. 2017-09, "Stock Compensation – Scope of Modification Accounting" or ASU 2017-09. ASU 2017-09 provides guidance on which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The new standard is effective for fiscal years beginning after December 15, 2017. The Company adopted the guidance effective January 1, 2018. There was no impact upon adoption.

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 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 plans to adopt this ASU in the first quarter of 2019. The Company currently expects that most of its operating lease commitments will be subject to the update and recognized as operating lease liabilities and right-of-use assets upon adoption. The Company expects total assets and total liabilities will materially increase in the period of adoption. The Company is currently evaluating the impact the adoption of this accounting standard will have on its results of operations, cash flows and related disclosures. The Company is in the process of assessing any potential impacts on our internal controls, business processes, and accounting policies related to both the implementation and ongoing compliance of the new guidance.

In May 2014, the FASB issued ASU 2014-09. ASU 2014-09 represents a comprehensive new revenue recognition model that requires a company to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which a company expects to be entitled to receive in exchange for those goods or services. This ASU sets forth a new five-step revenue recognition model which replaces the prior revenue recognition guidance in its entirety and is intended to eliminate numerous industry-specific pieces of revenue recognition guidance that have historically existed. In January 2018, the Company adopted the standard using the modified retrospective method. See Footnote 18 for additional information on the impact of the transition on the Company's financial statements.

(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 $50,000 cash at closing, a $4,000 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 $125,000 in milestone payments including $45,000 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 were 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 will be payable upon regulatory approval. The second component consists of three potential payments, based on the achievement of specified annual revenue targets, the last of which represents over 60% of these milestone payments and currently does not have a fair value assigned to its achievement. The third component consists of a royalty payment between 10% and 12% (subject to a 30% reduction when no longer covered by patent) for a defined term on future meloxicam net sales.

The fair value of the first contingent consideration component is 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 is estimated using the Monte Carlo simulation method and applying a risk-adjusted discount rate to the potential payments resulting from probability-weighted revenue projections based upon the intellectual property protection and expected revenue target attainment dates. The fair value of the third contingent consideration component recognized was estimated by applying a risk-adjusted discount rate to the potential payments resulting from revenue projections, expected intellectual property protection 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 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 specific to these NMBs.

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, 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.

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 $5,000 for U.S. regulatory approval and commercialization milestones and $3,000 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.

The Company accounted for the transaction as an asset acquisition based on an evaluation of the accounting guidance (ASC Topic 805) and considered 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 and Comprehensive Loss 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.

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

	Fair value measurements at reporting date using Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
At December 31, 2017:			
Assets:			
Cash equivalents			
Money market mutual funds (See Note 7)	$38,959	$ —	$ —
Total cash equivalents	$38,959	$ —	$ —
Short-term investments			
U.S. Treasury obligations (See Note 7)	$3,498	$ —	$ —
Total financial assets	$42,457	$ —	$ —
Liabilities:			
Warrants (See Note 14(d))	—	—	$ 3,406
Contingent consideration (See Note 4)	—	—	82,413
	$—	$ —	$ 85,819
At June 30, 2018:			
Assets:			
Cash equivalents			
Money market mutual funds (See Note 7)	$41,329	$ —	$ —
Total cash equivalents	$41,329	$ —	$ —
Liabilities:			
Warrants (See Note 14(d))	—	—	$ 452
Contingent consideration (See Note 4)	—	—	85,329
	$—	$ —	$ 85,781

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	Contingent Consideration
Balance at December 31, 2017	$ 3,406	$ 82,413
Additions	—	—
Exercise of warrants	(2,589)	—
Remeasurement	(365)	2,916
Total at June 30, 2018	$ 452	$ 85,329
Current portion as of June 30, 2018	—	33,957
Long-term portion as of June 30, 2018	452	51,372

The current portion of the contingent consideration represents the amount the Company currently expects to become payable within one year as of June 30, 2018 (see Note 4 for additional information). The Company plans to reevaluate this classification following receipt of the FDA minutes from its recent Type A End-of-Review meeting regarding its NDA for IV meloxicam.

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, 2018, 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 and accrued expenses 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, 2018 due to the comparison of the terms of the debt, including borrowing rates available to the Company through its debt refinancing process in the fourth quarter of 2017, availability of additional term loan tranches, and maturity.

(7) Short-term Investments

Short-term investments as of June 30, 2018 consist of government money market funds. As of June 30, 2018, all of the Company’s short-term investments are included in Cash and cash equivalents due to their original maturity of three months or less when acquired. In accordance with FASB ASC Topic 320, “Investments – Debt and Equity Securities,” 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 Loss in stockholders’ equity and realized gains and losses included in other income/expense. The following is a summary of available-for-sale securities:

	December 31, 2017			
	Amortized	Gross Unrealized		Estimated Fair
Description	Cost	Gain	Loss	Value
Money market mutual funds	$38,959	$ —	$ —	$ 38,959
U.S. Treasury obligations	3,499	—	(1)	3,498
Total investments	$42,458	$ —	$ (1)	$ 42,457

	June 30, 2018			
	Amortized	Gross Unrealized		Estimated Fair
Description	Cost	Gain	Loss	Value
Money market mutual funds	$41,329	$ —	$ —	$ 41,329
Total investments	$41,329	$ —	$ —	$ 41,329

As of December 31, 2017, all of the Company’s investments in U.S. Treasury obligations had original maturities of less than two 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. To derive the fair value of its commercial paper, the

Company uses benchmark inputs and industry standard analytical models.

As of June 30, 2018, there were no investments with unrealized losses.

(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. The Company expenses costs related to inventory until such time as it receives approval from the FDA to market a product, at which time the Company commences capitalization of costs relating to that product.

Inventory was as follows as of June 30, 2018 and December 31, 2017:

	June 30, 2018	December 31, 2017
Raw materials	$ 2,295	$ 2,130
Work in process	3,089	3,931
Finished goods	3,170	4,488
	8,554	10,549
Provision for inventory obsolescence	(441)	(710)
	$ 8,113	$ 9,839

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, 2018	December 31, 2017
Land	$3,263	$ 3,263
Building and improvements	15,771	15,751
Furniture, office and computer equipment	5,035	4,406
Manufacturing equipment	28,976	24,153
Construction in progress	1,988	5,326
	55,033	52,899
Less: accumulated depreciation and amortization	16,293	13,825
Property, plant and equipment, net	$38,740	$ 39,074

Depreciation expense for the three and six months ended June 30, 2018 was $1,282 and $2,498, respectively. Depreciation expense for the three and six months ended June 30, 2017 was $1,228 and $2,424, respectively.

(10) Intangible Assets

The following represents the balance of the intangible assets at June 30, 2018:

	Cost	Accumulated Amortization	Net Intangible Assets
Royalties and contract manufacturing relationships	$15,500	$ 8,342	$ 7,158
In-process research and development	26,400	—	26,400
Total	$41,900	$ 8,342	$ 33,558

The following represents the balance of intangible assets at December 31, 2017:

	Cost	Accumulated Amortization	Net Intangible Assets
Royalties and contract manufacturing relationships	$15,500	$ 7,050	$ 8,450
In-process research and development	26,400	—	26,400
Total	$41,900	$ 7,050	$ 34,850

Amortization expense for each of the three months ended June 30, 2018 and 2017 was $646, respectively. Amortization expense for each of the six months ended June 30, 2018 and 2017 was $1,292, respectively.

As of June 30, 2018, future amortization expense is as follows:

	Amortization
2018	1,292
2019	2,583
2020	2,583
2021	700
Total	$ 7,158

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(11) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	June 30, 2018	December 31, 2017
Clinical trial and related costs	$ 1,277	$ 383
Professional and consulting fees	1,293	1,010
Payroll and related costs	4,840	6,387
Property plant and equipment	100	216
Deferred revenue	225	546
Interest payable	—	802
Production Costs	980	—
Other	785	553
	$ 9,500	$ 9,897

(12) Long-Term Debt

On November 17, 2017, the Company entered into a $100,000 Credit Agreement, or the Credit Agreement, with Athyrium Opportunities III Acquisition LP, or Athyrium. The Credit Agreement provides for an initial term loan in the original principal amount of $60,000 funded at closing. Pursuant to the terms of the Credit Agreement, there are two additional tranches of term loans, each in an aggregate original principal amount of $20,000. The second tranche term loan may be drawn upon on or before December 31, 2018 provided that the Company receives regulatory approval of the Company's IV meloxicam product candidate and will have at least $20,000 in unrestricted cash after payment of the milestone payment due to Alkermes. The third tranche term loan may be drawn upon at any time on or prior to March 31, 2020 provided that the second term loan has been drawn upon and net sales of IV meloxicam achieve $20,000 for the most recent trailing twelve-month period. The maturity date of the Credit Agreement is November 17, 2022, the five-year anniversary of the closing.

The Term Loans will bear interest at a rate equal to the three-month LIBOR rate, with a 1% floor plus 9.75% per annum, with quarterly, interest-only payments until the maturity date. The unpaid principal amount of the Term Loans is due and payable on the maturity date. In addition, in accordance with the Credit Agreement the Company will have to pay a 1% exit fee of $600, which will be accreted to the carrying amount of the debt using the effective interest method over the term of the loan. In addition, if there is an early repayment, there is a sliding scale of prepayment penalties.

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, 2018, the Company was in compliance with the covenants.

As of June 30, 2018, the remaining payments due under the Credit Agreement include a principal payment of $60,000 and an exit fee of $600 due at the maturity date.

In connection with the Credit Agreement, the Company issued warrants to each of Athyrium and its affiliate, Athyrium Opportunities II Acquisition LP, or Athyrium II, to purchase an aggregate of 348,664 shares of the Company's common stock with an exercise price of $8.6043 per share. See Note 14(d) for additional information. The warrants are exercisable through November 17, 2024. The initial fair value of the warrant of $2,143 was recorded as a debt issuance cost.

In addition, the Company recorded debt issuance costs for the Credit Agreement of $4,439, which, along with the fair value of warrants, are being amortized using the effective interest method over the term of the Credit Agreement. Debt issuance cost amortization is included in interest expense within the Consolidated Statements of Operations and Comprehensive Loss. As of June 30, 2018, the effective interest rate was 15.74%, which takes into consideration the non-cash accretion of the exit fee and the amortization of the debt issuance cost.

The components of the carrying value of the debt as of June 30, 2018, are detailed below:

Principal balance outstanding	$60,000
Unamortized deferred issuance costs	(5,759)
Exit fee accretion	75
Total	$54,316

The Company used proceeds from the $60,000 initial term loan to (i) repay in full all outstanding indebtedness under its previous credit facility governed by the Credit Agreement, dated April 10, 2015, between the Company's subsidiary, Recro Gainesville LLC and OrbiMed Royalty Opportunities II, LP, or the OrbiMed Credit Agreement of $31,767, which included the remaining debt principal balance of $27,347 and early termination charges of $4,420 and (ii) pay transaction fees associated with the Athyrium Credit Agreement of $4,178.

Associated with the refinancing of the OrbiMed Credit Agreement and in accordance with ASC 405-20 "Extinguishments of Liabilities", the Company booked one-time loss on extinguishment of $6,772 as of December 31, 2017, which was reflected in the interest expense line within the Consolidated Statement of Operations and Comprehensive Loss.

The Company recorded debt issuance cost amortization for both credit agreements of $329 and $168 for the three months ended June 30, 2018 and 2017, respectively, and $658 and $326 for the six months ended June 30, 2018 and 2017, respectively.

(13) Commitments and Contingencies

(a) Licenses

The Company is party to an exclusive license with Orion for the development and commercialization of Dexmedetomidine 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 ($23,945 as of June 30, 2018) 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, 2018, 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 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 ($14,250 as of June 30, 2018) 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, 2018, 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 entitled to receive additional milestone payments, 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 $125,000 in milestone payments including $45,000 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).

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.

(c) 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.

On May 31, 2018, a securities class action lawsuit was filed against the Company and certain of its officers and directors in the U.S. District Court for the Eastern District of Pennsylvania (Case No. 2:18-cv-02279-MMB) that purported to state a claim for alleged violations of Section 10(b) and 20(a) of the Exchange Act and Rule 10(b)(5) promulgated thereunder, based on statements made by the Company concerning the NDA for IV meloxicam. The complaint seeks unspecified damages, interest, attorneys' fees and other costs. The Company believes that the lawsuit is without merit and intends to vigorously defend against it. The lawsuit is in the early stages and, at this time, no assessment can be made as to its likely outcome or whether the outcome will be material to the Company.

(d) Leases

The Company is a party to various operating leases in Malvern, Pennsylvania, Gainesville, Georgia and Dublin, Ireland for office, manufacturing, and chemistry, manufacturing and controls development space. 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.

As of June 30, 2018, future minimum lease payments excluding operating expenses and tenant improvements for the leases, are as follows:

	Lease payments
2018	358
2019	713
2020	561
2021	518
2022	529
2023 and thereafter	404
Total	$ 3,083

(e) Purchase Commitments

As of June 30, 2018, the Company had outstanding non-cancelable and cancelable purchase commitments in the aggregate amount of $21,516 related to inventory, capital expenditures and other goods and services, including pre-commercial/manufacturing scale-up and clinical activities. In addition, in July 2018, the Company committed to reimburse Alkermes for the costs related to the fit out of the Alkermes facility for commercial inventory production of IV meloxicam, which the Company estimates will be approximately $6,300.

(f) Certain Compensation and Employment Agreements

The Company has entered into employment agreements with certain of its named executive officers. As of June 30, 2018, these employment agreements provided for, among other things, annual base salaries in an aggregate amount of not less than $714, from that date through calendar year 2018.

(14) Capital Structure

(a) Common Stock

The Company is authorized to issue up to 50,000,000 shares of common stock, with a par value of $0.01 per share.

Reflected below are the Company's capital raises since its initial public offering, or IPO:

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 expenses, 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 discounts, 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 discounts, commissions and offering expenses.

On December 29, 2017, the Company entered into a sales agreement, or the Sales Agreement, with Cowen and Company, LLC, or Cowen, pursuant to which the Company may sell from time to time, at its option, shares of its common stock, $0.01 par value per share, having an aggregate offering price of up to $40,000 through Cowen, as the placement agent. As of June 30, 2018, the Company did not have any sales of common stock under the Sales Agreement.

(b) Common Stock Purchase Agreement

On February 2, 2015, the Company entered into a Common Stock Purchase Agreement, or the 2015 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 2015 Purchase Agreement. On the execution of the 2015 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 2015 Purchase Agreement. In addition, the Company incurred $253 of costs in connection with the 2015 Purchase Agreement, which, along with the fair value of the common stock, has been recorded as deferred equity costs. During 2016, the Company sold 1,143,940 shares of common stock under the 2015 Purchase Agreement for $7,796. The agreement expired in February 2017.

On March 2, 2018, the Company entered into a Common Stock Purchase Agreement, or the Purchase Agreement, with Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth in the Purchase Agreement, Aspire Capital is committed to purchase, at the Company's sole election, up to an aggregate of $20,000 of shares of the Company's common stock over the approximately 30-month term of the Purchase Agreement. On the execution of the Purchase Agreement, the Company agreed to issue 33,040 shares of common stock to Aspire Capital as consideration for entering into the Purchase Agreement. As of June 30, 2018, the Company sold 1,050,000 shares of common stock under the Purchase Agreement for proceeds of $11,018.

(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, 2018, no preferred stock was issued or outstanding.

(d) Warrants

As of June 30, 2018, the Company had the following warrants outstanding to purchase shares of the Company's common stock:

Number of Shares	Exercise Price per Share	Expiration Date
140,000	$ 12.00	March 2019
350,000	$ 19.46	April 2022
348,664	$ 8.60	November 2024

The warrants to purchase 140,000 and 348,664 shares related to Aegis Capital Corporation and Athyrium, respectively, are equity classified.

The warrants to purchase 350,000 shares related to Alkermes are liability classified since they contain a contingent net cash settlement feature. The fair value of the 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 the liability classified warrants.

	June 30, 2018	December 31, 2017
Fair value	$452	$ 3,406
Expected dividend yield	— %	— %
Expected volatility	77 %	75 %
Risk-free interest rates	2.68 %	2.09 %
Remaining contractual term	3.75 years	4.25 years

In April 2015, the Company issued a warrant to purchase 294,928 shares of common stock at an exercise price of $3.28 per share to OrbiMed in connection with the Company's prior credit agreement, which was liability classified. In April 2018, the warrant was exercised on a cashless basis, with OrbiMed surrendering 80,213 shares, to cover the aggregate exercise price, resulting in the issuance of 214,715 shares of common stock based on the closing bid price of the Company's Common Stock on April 27, 2018 of $12.06.

(15) Comprehensive Loss

The Company's comprehensive loss is shown on the Consolidated Statements of Operations and Comprehensive Loss as of June 30, 2018, 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 months ended June 30, 2018 and 2017 was $12,714 and $8,874, respectively. The total of comprehensive loss for the six months ended June 30, 2018 and 2017 was $25,171 and $17,018, respectively. There was no tax effect of other comprehensive loss for the six months ended June 30, 2018. The tax effect of other comprehensive loss for the six months ended June 30, 2017 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, 2018, 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 2017 and 2016, the number of shares available for issuance under the A&R Plan was increased by 956,341 and 619,181, respectively. In May 2018, the Company's shareholders approved the 2018 Amended and Restated Equity Incentive Plan, which amended and restated the A&R Plan to increase the aggregate amount of shares available for issuance to 7,036,737.

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, 2018, 2,723,462 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, 2018 and 2017 was $6.18 and $5.36, 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,	
	2018	2017
Range of expected option life	5.5 - 6 years	6 years
Expected volatility	73.26% - 82.00%	84.71%
Risk-free interest rate	2.32 - 2.96%	1.87 - 2.17%
Expected dividend yield	—	—

The following table summarizes stock option activity during the six months ended June 30, 2018:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life
Balance, December 31, 2017	3,594,875	$ 7.17	7.1 years
Granted	816,991	9.33	
Exercised	(174,361)	5.89	
Expired/forfeited/cancelled	(233,529)	9.33	
Balance, June 30, 2018	4,003,976	$ 7.54	7.3 years
Vested	2,230,438	$ 6.94	6.0 years
Vested and expected to vest	4,003,976	$ 7.54	7.3 years

Included in the table above are 980,000 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).

During the year ending December 31, 2016, the Company adopted ASU 2016-09 “Compensation – Stock Compensation (Topic 718) Improvements to Employee Share-Based Payment Accounting” and elected to account for forfeitures as they occur.

The following table summarizes restricted stock units, or RSUs, activity during the six months ended June 30, 2018.

	Number of shares
Balance, December 31, 2017	270,593
Granted	993,319
Vested and settled	(126,518)
Expired/forfeited/cancelled	(20,266)
Balance, June 30, 2018	1,117,128
Expected to vest	1,117,128

Included in the table above are 47,000 time-based RSUs granted outside the plan. The grants were made pursuant to the NASDAQ inducement grant exception in accordance with NASDAQ Listing Rule 5635(c)(4).

In January 2018, the Company granted 242,396 time-based RSUs, which vest over four years. In March 2018, the Company granted 240,224 performance-based RSUs, which may vest based on attaining 2018 financial, clinical and operational goals. In June 2018, the Company granted 444,418 time-based RSUs, which vest in two installments at nine and 18 months from the grant date.

Stock-based compensation expense for the six months ended June 30, 2018 and 2017 was $3,303 and $2,370, respectively.

As of June 30, 2018, there was $15,631 of unrecognized compensation expense related to unvested options and time-based RSUs that are expected to vest and will be expensed over a weighted average period of 2.2 years. As of June 30, 2018, there was $2,611 of unrecognized compensation expense related to unvested performance-based RSUs and will be expensed when the performance criteria are met.

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, 2018, the aggregate intrinsic value of the vested and unvested options was $1,248 and $59, respectively.

(17) Segment Reporting

The Company operates through two business divisions that are treated as separate financial 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 revenues, as well as CDMO segment’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 three and six months ended June 30, 2018:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2018	2017	2018	2017
Revenues:				
CDMO	$21,739	$16,934	$41,281	$35,676
Acute Care	—	—	—	—
Total	$21,739	$16,934	$41,281	$35,676
Operating income (loss):				
CDMO	$7,288	$4,060	$13,854	$10,258
Acute Care	(20,635)	(13,490)	(40,049)	(26,990)
Total	$(13,347)	$(9,430)	$(26,195)	$(16,732)
Depreciation and amortization:				
CDMO	$1,858	$1,865	$3,678	$3,702
Acute Care	69	9	112	14
Total	$1,927	$1,874	$3,790	$3,716
Capital expenditures:				
CDMO	$824	$1,366	$1,153	$2,896
Acute Care	453	75	1,778	289
Total	$1,277	$1,441	$2,931	$3,185

	June 30, 2018	December 31, 2017
Total assets:		
CDMO	$80,157	$ 78,136
Acute Care	100,312	108,090
Total	$180,469	$ 186,226

(18) Revenue Recognition

Effective January 1, 2018, the Company adopted ASU 2014-09 using the modified retrospective method applied to contracts existing as of January 1, 2018. Results for reporting periods beginning after January 1, 2018 are presented under the new guidance while prior period amounts are not adjusted and continue to be reported in accordance with previous guidance. See Note 3 for additional information on the Company’s revenue recognition policies.

The Company uses the practical expedient to not account for significant financing components because the period between recognition and collection does not exceed one year in any contract.

Upon adoption, the Company recorded a decrease of $2,818 to the opening balance of accumulated deficit as of January 1, 2018. This adjustment resulted from a change in revenue recognition associated with a variable portion of certain of its royalty revenue. Under the new accounting standard, estimated royalty revenue to be received in the future that is deemed predominantly related to product sales rather than the license for intellectual property, is included as a component of the product sale transaction consideration to the extent such consideration is not probable to significant reversal. Prior to adoption of the new guidance, the Company recognized this royalty revenue in the period the products were sold by the commercial partner.

The cumulative effect of the changes made to the Company's consolidated January 1, 2018 balance sheet for the adoption of ASU 2014-09 were as follows:

	Balance at December 31, 2017	Adoption of ASU 2014-09	Balance at January 1, 2018
Contract asset	$ —	$ 3,755	$3,755
Deferred income taxes	18,573	(937)	17,636
Total shareholders' equity	28,848	(2,818)	26,030

The impact of the adoption of ASU 2014-09 on the Company's condensed consolidated statement of operations and condensed consolidated balance sheet was as follows:

	Previous Revenue Standard	Adoption of ASU 2014-09	As Reported
	Three Months Ended June 30, 2018		
Revenue	$20,381	$ 1,358	$21,739
Income tax benefit	3,110	(403)	2,707
Net loss	(13,670)	955	(12,715)
	Six Months Ended June 30, 2018		
Revenue	$38,170	$ 3,111	$41,281
Income tax benefit	5,900	(840)	5,060
Net loss	(27,443)	2,271	(25,172)

	June 30, 2018		
	Previous Revenue Standard	Adoption of ASU 2014-09	As Reported
Contract assets	$—	$ 6,866	$6,866
Deferred income taxes	24,473	(1,777)	22,696
Total assets	175,380	5,089	180,469
Accumulated deficit	(138,791)	5,089	(133,702)
Total shareholders' equity	19,397	5,089	24,486
Total liabilities and shareholders' equity	175,380	5,089	180,469

Contract assets represent revenue recognized for performance obligations completed before an unconditional right to payment exists, and therefore invoicing or associated reporting from the customer regarding the computation of the net product sales has not yet occurred. Contract assets were $6,866 and $3,755 at June 30, 2018 and January 1, 2018, respectively. Generally, the contract assets balance is impacted by the recognition of additional contract assets, offset by amounts invoiced to customers or actual net product sale amounts reported by the commercial partner for the period. For the six months ended June 30, 2018, actual net product sale amounts reported by the Company's commercial partner exceeded estimates of royalty amounts attributed to manufactured product shipped as of January 1, 2018 for the related arrangements by approximately $1,279.

The following table presents changes in the Company's contract assets for the six months ended June 30, 2018:

Contract asset, beginning of year	$3,755
Change in estimate arising from changes in transaction price	1,279
Reclassification of contract asset to receivables, as the result of rights to consideration becoming unconditional	(10,542)
Contract assets recognized	12,374
Contract asset, end of period	$6,866

The following table disaggregates revenue by business segment and timing of revenue recognition:

	Three Months Ended June 30, 2018		
	Point in time	Over time	Total
CDMO	$21,377	$362	$21,739
Acute Care	—	—	—
Revenue	21,377	362	21,739

	Six Months Ended June 30, 2018		
	Point in time	Over time	Total
CDMO	$40,790	$491	$41,281
Acute Care	—	—	—
Revenue	40,790	491	41,281

Adoption of ASU 2014-09 did not require capitalization of any costs to obtain or fulfill contracts. In general, the Company's payment terms for manufacturing revenue and research and development services is 30 days. Royalty revenue is recorded to accounts receivable in the quarter that the product is sold by the commercial partner upon reporting from the commercial partner and payment terms are generally 45 days after quarter end. Based on the adoption of ASU 2014-09, the timing difference between recognition of certain royalty revenues as a contract asset and cash receipt is increased by an estimated 90 days.

(19) Related Party Transactions

A Non-Executive Director of the Company's Irish subsidiary is a Managing Director and a majority shareholder of HiTech Health Ltd, or HiTech Health, a consultancy firm for the biotech, pharmaceutical and medical device industry. Since 2016, HiTech Health has provided the Company with certain consulting services and in November 2017 both parties entered into a Service Agreement to engage in regulatory project support and consultancy. In consideration for such services, the Company recorded $144 and $253 for the three and six months ended June 30, 2018, respectively. A portion of the amount relates to consultancy services provided by the Non-Executive Director.

(20) Retirement Plan

The Company has a voluntary 401(k) Savings Plan (the 401(k) Plan) in which all employees are eligible to participate. The Company's policy is to match 100% of the employee contributions up to a maximum of 5% of employee compensation. Total Company contributions to the 401(k) plan for the three months ended June 30, 2018 and 2017 were $311 and $208, respectively. The Company contributions for the six months ended June 30, 2018 and 2017 were $701 and $551, respectively.

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the 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, 2017 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 2, 2018. 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," "believes," "esti "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 resolve the complete response letter, or CRL, issued by the United States Food and Drug Administration, or FDA, for our new drug application, or NDA, for intravenous, or IV, meloxicam and obtain and maintain regulatory approval of IV meloxicam, and the labeling under any approval that we may obtain;
    - our ability to successfully commercialize IV meloxicam upon regulatory approval;
- our ability to generate sales and other revenues from IV meloxicam or any of our other product candidates, once approved, including setting an acceptable price for and obtaining adequate coverage and reimbursement of such products;
- the results, timing and outcome of our clinical trials of IV meloxicam or our other product candidates, and any future clinical and preclinical studies;
- 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 plc, or Alkermes, or our other licensing and collaboration partners;
    - our ability to obtain and maintain regulatory approval for, and commercialize, our other product candidates;
- our ability to comply with the regulatory schemes applicable to our business and other regulatory developments in the United States and foreign countries;
- 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, and third-party suppliers, manufacturers, distributers and logistics providers;
- our ability to obtain and maintain 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, 2017 filed with the SEC on March 2, 2018 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 and commercializing innovative products for hospital and related acute care settings. Our lead product candidate is a proprietary injectable form of meloxicam, a long-acting preferential COX-2 inhibitor. IV meloxicam has successfully completed three Phase III clinical trials for the management of moderate to severe pain, consisting of two pivotal efficacy trials and a large double-blind Phase III safety trial, as well as other safety studies. Overall, the total new drug application, or NDA, program included over 1,400 patients. In late July 2017, we submitted a NDA to the U.S. Food and Drug Administration, or FDA, for IV meloxicam 30mg for the management of moderate to severe pain. In May 2018, we received a CRL from the FDA regarding our NDA for IV meloxicam. In July 2018, we participated in a Type A End-of-Review meeting with the FDA to discuss the topics covered in the CRL. We plan to provide an update on our path forward following receipt of the written meeting minutes. Our Acute Care segment has no revenue and our costs consist primarily of expenses incurred in conducting our manufacturing scale-up, clinical trials and preclinical studies, regulatory activities, pre-commercialization of meloxicam and personnel costs.

Our CDMO segment leverages formulation expertise to develop and manufacture pharmaceutical products using proprietary delivery technologies for commercial partners who commercialize or plan to commercialize these products. These collaborations result in revenue streams including manufacturing, royalties, and research and development, which support continued operations for our CDMO segment and have contributed excess cash flow to be used for our research and development 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®, Verelan SR®, Verapamil PM, Verapamil SR and Zohydro ER®, as well as supporting development stage products. Our CDMO segment’s revenue streams are derived from manufacturing, and royalty revenues, as well as research and development 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 previous credit facility and to partially fund our development and pre-commercialization activities of our Acute Care segment. We believe our CDMO segment’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 and commercial operations. We expect to incur increasing expenses over the next several years as we seek to resolve the CRL issued by the FDA with regard to the NDA for IV meloxicam, obtain regulatory approval for IV meloxicam, successfully commercialize IV meloxicam, if approved, and continue to develop our other current and future product candidates.

On April 10, 2015, we completed the acquisition from Alkermes of certain assets, including the worldwide rights to injectable meloxicam and the development, formulation and manufacturing business that comprised our CDMO segment, which we refer to as the Gainesville Transaction, which 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 $45.0 million upon regulatory approval of IV meloxicam, as well as net sales milestones and a royalty percentage of future product net sales related to IV meloxicam.

We funded the up-front payment of the Gainesville Transaction with borrowings under our previous credit facility with OrbiMed Royalties, II, LP, or OrbiMed, and cash on hand. Pursuant to the credit facility with OrbiMed, 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. In April 2018, OrbiMed fully exercised the warrant on a cashless basis, surrendering 80,213 shares to cover the aggregate exercise price, and resulting in the issuance of 214,715 shares of common stock.

In November 2017, we entered into our Credit Agreement with Athyrium Opportunities III Acquisition LP, or Athyrium, pursuant to which we drew $60.0 million in an initial term loan. We also have the ability to draw upon two additional tranches of the terms loans, each in the aggregate original principal amount of $20.0 million. Pursuant to the terms of the credit agreement, we may draw upon the second $20.0 million tranche on or before December 31, 2018, provided that we receive regulatory approval for IV meloxicam and retain at least $20.0 million in unrestricted cash following payment of the $45.0 million milestone payment to Alkermes. We may draw upon the final $20.0 million tranche on or prior to March 31, 2020, provided that we have drawn on the second tranche and have achieved net sales for IV meloxicam of $20.0 million in the most recent trailing twelve-month period. We used the proceeds from the initial term loan to repay in full all outstanding indebtedness and transaction fees under the previous credit facility with OrbiMed. The interest rate under the credit agreement with Athyrium is equal to three-month LIBOR plus 9.75%, with a 1.0% LIBOR floor. Pursuant to the credit agreement with Athyrium, we issued to each of Athyrium and its affiliate, Athyrium Opportunities II Acquisition LP, warrants to purchase an aggregate of 348,664 shares of our common stock at an exercise price of $8.6043 per share, subject to certain adjustments.

Financial Overview

Revenues

During the six months ended June 30, 2018 and 2017 we recognized revenues from three revenue streams: manufacturing revenue, royalty and research and development revenue. All revenue is generated from our CDMO segment.

Manufacturing revenue

We recognize manufacturing revenue from the sale of products we manufacture for our commercial partners. Manufacturing revenues are recognized upon transfer of control of a product to a customer, generally upon shipment, based on a transaction price that reflects the consideration we expect to be entitled to as specified in the agreement with the commercial partner, which could include pricing and volume-based adjustments.

Royalty revenue

We recognize royalty or profit sharing revenue, collectively referred to as royalty revenue, related to the sale of products by our commercial partners that incorporate our technologies. Royalty revenues are generally recognized under the terms of the applicable license, development and/or supply agreement. For arrangements that include sales-based royalties and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue when the related sales occur by the commercial partner. For arrangements that include sales-based royalties and the license is not deemed to be the predominant item to which the royalties relate, we recognize revenue when the performance obligation to which the royalty has been allocated has been satisfied, which is upon transfer of control of a product to a customer. In this case, significant judgement is used in the estimation of these royalties based on historical customer pricing and deductions and is partially constrained due to items that are outside of our control including the uncertainty of the timing of future commercial partner sales, mix of volume, customer stocking and ordering patterns, as well as unforeseen price adjustments made by our commercial partners.

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. Revenues related to research and development are generally recognized as the related services or activities are performed using the output method and 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, we evaluate whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone is recognized at a point in time. Non-refundable milestone payments related to arrangements under which we have continuing performance obligations would be deferred and recognized over the period of performance. Milestone payments that are not within our control, such as submission for approval to regulators by a commercial partner or approvals from regulators, are not considered probable of being achieved until those submissions are submitted by the customer or approvals are received.

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 and pre-commercial product inventory manufacturing expenses;
- costs related to facilities, depreciation and other allocated expenses;
- acquired in process research and development;
- costs associated with non-clinical and regulatory activities; and
- salaries and related costs for personnel in research and development and regulatory functions.

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 IV meloxicam and our other product candidates is highly uncertain and subject to a number of risks, including, but not limited to:

- the nature and scope of any activities required to resolve the CRL issued by the FDA in response to our NDA for IV meloxicam, which may include the completion of additional studies;
- the costs, timing and outcome of regulatory review of a product candidate;
- the duration of clinical trials, which varies substantially according to the type, complexity and novelty of the product candidate;
- substantial requirements on the introduction of pharmaceutical products imposed by the FDA and comparable agencies in foreign countries, which require lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures;
- the possibility that data obtained from pre-clinical 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;
- risk involved with development of manufacturing processes, FDA pre-approval inspection practices and successful completion of manufacturing batches for clinical development and other regulatory purposes;
- 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, 2017.

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, additional information as we progress through our discussions with the FDA around the CRL regarding our NDA for IV meloxicam, as well as ongoing assessments of such product candidate’s commercial potential and available capital resources. 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 product candidates will generate revenues and cash flows.

We expect our research and development costs to relate to IV meloxicam for the foreseeable future as we seek to resolve the CRL issued by the FDA with regard to our NDA for IV meloxicam and obtain regulatory approval for IV meloxicam, and if successful in obtaining regulatory approval, advance IV meloxicam through the commercialization scale-up, clinical and other 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 for its product and formulation development activities, including regulatory support. 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 and information technology functions. General and administrative expenses also include professional fees for legal, including patent-related expenses, consulting, auditing and tax services.

We currently expect our general and administrative expenses to be lower for the second half of 2018 as we progress through our discussions with the FDA regarding the CRL. These expenses could increase depending on the timing of regulatory approval and subsequent commercialization of IV meloxicam. In addition, we will continue to incur costs relating to our operations as a public company, including 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 in process research and development, or IPR&D, which is considered an indefinite-lived intangible asset that is assessed for impairment annually or more frequently if impairment indicators exist.

Change in Fair Value of Contingent Consideration

In connection with the acquisition of injectable meloxicam in the Gainesville Transaction, we are required to pay up to an additional $125.0 million in milestone payments, including $45.0 million upon regulatory approval of IV meloxicam, as well as net sales milestones and a royalty percentage of future product net sales related to IV meloxicam 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. We have since reevaluated our fair value determination and as of June 30, 2018 recorded a $85.3 million payment obligation, representing the estimated probability adjusted fair value. 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, upon a change in control. The fair value of these warrants is remeasured through settlement or expiration with changes in fair value recognized as a period charge within the Consolidated Statements of Operations and Comprehensive Loss.

Interest Expense, net

Interest expense, net for the six months ended June 30, 2018 was a result of interest expense incurred on our Athyrium senior secured term loans and the amortization of the related financing costs, net of interest income on cash equivalents and short-term investments. Interest expense for the six months ended June 30, 2017 was a result of interest expense incurred on our OrbiMed senior secured term loan and the amortization of the related financing costs,

net of interest income on cash equivalents and short-term investments.

Net Operating Losses and Tax Carryforwards

As of December 31, 2017, we had approximately $9.0 million of federal net operating loss carryforwards. We also had federal and state research and development tax credit carryforwards of $3.4 million available to offset future taxable income. U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. These federal and state net operating loss and federal and state tax credit carryforwards will begin to expire at various dates beginning in 2028, if not utilized. Based on our projected future taxable income we expect to be able to utilize all federal and state net operating losses. We have also generated foreign net operating loss carryforwards in Ireland. We currently do not believe it is more likely than not we will use any of these net operating losses and as a result have recorded a full valuation allowance against the deferred tax asset related to the losses.

Under the Tax Reform Act of 1986, or the Act, the utilization of a corporation's net operating loss and research and development tax credit carryforwards is limited following a greater than 50% change in ownership during a three-year period. Any unused annual limitation may be carried forward to future years for the balance of the carryforward period. We determined that we have experienced ownership changes, as defined by the Act, during the 2008, 2014 and 2016 tax years as a result of past financings; accordingly, our ability to utilize the aforementioned carryforwards will be limited. Although the carryforwards will be limited, we have determined that none of the net operating losses will expire prior to being utilized as a result of the changes. In addition, state net operating loss carryforwards may be further limited, including in Pennsylvania, which has a limitation of 30%, 35% or 40% of taxable income after modifications and apportionment on state net operating losses utilized in any one year during tax years beginning during 2017, 2018 or 2019 going forward respectively. In addition, since we will need to raise substantial additional funding to finance our operations, we may undergo further ownership changes in the future, including changes to our organizational structure relating to foreign operations, purchases, sales and licenses, which could further limit our ability to use net operating loss carryforwards. As a result, if we generate taxable income, our ability to use some of our net operating loss carryforwards to offset U.S. federal and state taxable income may be subject to limitations, which could result in increased future tax liabilities to us or a determination that it is more likely than not that we will be able to use any of the net operating losses resulting in the need to record a full valuation allowance against the deferred tax asset related to the loses.

In December 2017, the federal government enacted numerous amendments to the Internal Revenue Code of 1986 pursuant to the Tax Cuts and Jobs Act, or the Tax Act. The Tax Act will impact our income tax expense/(benefit) from operations in future periods. The Tax Act resulted in the following impacts to us:

- Our federal statutory income tax rate was reduced from 34% to 21% for 2018 and tax years following.

- Our results for the fourth quarter of 2017 included a one-time net expense of $7.9 million, as a result of remeasuring our deferred tax balances to the new statutory rate.

- We will be able to claim an immediate deduction for investments in qualified fixed assets acquired and placed in service beginning September 27, 2017 through 2022. This provision phases out through 2026.

Results of Operations

Comparison of the Three Months Ended June 30, 2018 and 2017

	Three Months Ended June 30,	
	2018	2017
	(amounts in thousands)	
Revenue	$21,739	$16,934
Operating expenses:		
Cost of sales (excluding amortization of intangible assets)	12,071	10,448
Research and development	10,157	7,073
General and administrative	12,955	6,322

Amortization of intangible assets	646	646
Change in warrant valuation	(1,139)	(1,084)
Change in contingent consideration valuation	396	2,959
Total operating expenses	35,086	26,364
Operating loss	(13,347)	(9,430)
Other income (expense):		
Interest expense, net	(2,075)	(1,090)
Loss before income taxes	(15,422)	(10,520)
Income tax benefit	2,707	1,665
Net loss	$(12,715)	$(8,855)

Revenue and costs of sales. Our revenues were $21.7 million and $16.9 million and cost of sales were $12.1 million and $10.4 million for the three months ended June 30, 2018 and 2017, respectively. The increase of $4.8 million in revenue includes the impact from the new Accounting Standards Update, or ASU, No. 2014-09 “Revenue from Contracts with Customers,” or ASU 2014-09, and was primarily due to increased royalties recognized from one of our commercial partners and an increase in product sales to one of our commercial partners. Cost of sales increased primarily due to increased product sales.

Research and Development. Our research and development expenses were $10.2 million and $7.1 million for the three months ended June 30, 2018 and 2017, respectively. The increase of $3.1 million was primarily due to an increase in pre-commercialization manufacturing costs for IV meloxicam, an increase in salaries and benefits expense, an increase in Phase IIIb clinical trials and related costs and a modest increase in development costs for other pipeline products. These increases were partially offset by a decrease in Phase III clinical trial costs.

General and Administrative. Our general and administrative expenses were $13.0 million and $6.3 million for the three months ended June 30, 2018 and 2017, respectively. The increase of $6.7 million was primarily due to commercial team personnel and related costs as well as increased legal and consulting fees associated with addressing the CRL issued by the FDA regarding our NDA for IV meloxicam.

Amortization of Intangible Assets. Amortization expense was $0.6 million for each of the quarters ended June 30, 2018 and 2017, respectively, which was exclusively related to the amortization of our CDMO royalties and contract manufacturing relationships intangible asset over its estimated useful life.

Interest Expense, net. Interest expense, net was $2.1 million and $1.1 million during the three months ended June 30, 2018 and 2017, respectively. The increase of $1.0 million was primarily due to the higher principal balance on our Athyrium senior secured term loan and amortization of the related financing costs, which was partially offset by a lower interest rate on our Athyrium senior secured term loan versus our previous loan with OrbiMed.

Income Tax Benefit. Income tax benefit was $2.7 million and $1.7 million for the three months ended June 30, 2018 and 2017, respectively, related exclusively to our U.S. operations. The increase of $1.0 million was primarily due to increased losses in the United States. 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 segment’s revenues were $21.7 million and $16.9 million in the three months ended June 30, 2018 and 2017, respectively. The increase of $4.8 million in revenue includes the impact from the new standard ASU 2014-09, and was primarily due to increased royalties recognized from one of our commercial partners and an increase in product sales to one of our commercial partners.

Our CDMO segment’s operating expenses increased by $1.6 million, from $12.9 million in the three months ended June 30, 2017 to $14.5 million in the three months ended June 30, 2018. Cost of sales were $12.1 million and $10.4 million in the three months ended June 30, 2018 and 2017, respectively. Cost of sales increased primarily due to increased product sales. Research and development expenses and general and administration expenses remained constant for the three months ended June 30, 2018 compared to the three months ended June 30, 2017. All of the above contributed to CDMO segment’s operating income of $7.3 million for the three months ended June 30, 2018, which included non-cash charges of $1.9 million for depreciation and amortization and $0.3 million for stock-based compensation.

Acute Care Segment-

Our Acute Care segment's operating expenses increased $9.8 million from $11.6 million in the three months ended June 30, 2017 to $21.4 million in the three months ended June 30, 2018. Research and development expenses increased $3.1 million as a result of increased IV meloxicam pre-commercialization manufacturing costs, salaries and benefits and Phase IIIb clinical trial costs. The increase was partially offset by a decrease in Phase III clinical trial costs. General and administrative costs increased by $6.7 million as a result of increased salaries and benefits, increased pre-commercialization marketing expenses and severance and increased legal and consulting fees associated with addressing the CRL issued by the FDA regarding our NDA for IV meloxicam. Non-cash charges related to the warrant valuation remained constant and contingent consideration expense decreased by $2.6 million year over year primarily as a result of the reevaluation conducted following receipt of the CRL from the FDA. All of the above contributed to our Acute Care segment's operating loss of $20.7 million for the three months ended June 30, 2018, which also included non-cash charges of $1.5 million for stock-based compensation, depreciation and amortization.

Comparison of the Six Months Ended June 30, 2018 and 2017

	Six Months Ended June 30,	
	2018	2017
	(amounts in thousands)	
Revenue	$41,281	$35,676
Operating expenses:		
Cost of sales (excluding amortization of intangible assets)	22,561	20,946
Research and development	18,599	14,836
General and administrative	22,473	10,354
Amortization of intangible assets	1,292	1,292
Change in warrant valuation	(365)	(793)
Change in contingent consideration valuation	2,916	5,773
Total operating expenses	67,476	52,408
Operating loss	(26,195)	(16,732)
Other income (expense):		
Interest expense, net	(4,037)	(2,168)
Loss before income taxes	(30,232)	(18,900)
Income tax benefit	5,060	1,958
Net loss	$(25,172)	$(16,942)

Revenue and costs of sales. Our revenues were $41.3 million and $35.7 million and cost of sales were $22.6 million and $20.9 million for the six months ended June 30, 2018 and 2017, respectively. The increase of $5.6 million in revenue includes the impact from the new standard ASU 2014-09, and was primarily due to increased royalties recognized from one of our commercial partners and an increase in product sales to one of our commercial partners. Cost of sales increased primarily due to increased product sales.

Research and Development. Our research and development expenses were $18.6 million and $14.8 million for the six months ended June 30, 2018 and 2017, respectively. The increase of $3.8 million was primarily due to an increase in pre-commercialization manufacturing costs for IV meloxicam, an increase in salaries and benefits expense, an increase in Phase IIIb clinical trials and related costs and a modest increase in development costs for other pipeline products. These increases were partially offset by a decrease in Phase III clinical trial costs.

General and Administrative. Our general and administrative expenses were $22.5 million and $10.4 million for the six months ended June 30, 2018 and 2017, respectively. The increase of $12.1 million was primarily due to commercial team personnel and related costs as well as increased legal and consulting fees associated with addressing the CRL issued by the FDA regarding our NDA for IV meloxicam.

Amortization of Intangible Assets. Amortization expense was $1.3 million for the six months ended June 30, 2018 and 2017 which was exclusively related to the amortization of our royalties and contract manufacturing relationships intangible asset over its estimated useful life.

Interest Expense, net. Interest expense, net was $4.0 million and $2.2 million during the six months ended June 30, 2018 and 2017, respectively. The increase of $1.8 million was primarily due to the higher principal balance on our

Athyrium senior secured term loan and amortization of the related financing costs, which was partially offset by a lower interest rate on our Athyrium senior secured term loan versus our previous loan with OrbiMed.

Income Tax Benefit. Income tax benefit was $5.1 million and $2.0 million for the six months ended June 30, 2018 and 2017, respectively. The increase of $3.1 million was primarily due to increased losses in the United States. 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 segment's revenues were $41.3 million and $35.7 million for the six months ended June 30, 2018 and 2017, respectively. The increase of $5.6 million in revenue was primarily due to increased royalties recognized from one of our commercial partners including the impact from the new standard ASU 2014-09 and an increase in product sales to one of our commercial partners.

Our CDMO segment's operating expenses (including cost of sales) increased by $2.0 million, from $25.4 million in the six months ended June 30, 2017 to $27.4 million in the six months ended June 30, 2018. Cost of sales were $22.6 million and $20.9 million in the six months ended June 30, 2018 and 2017, respectively. Cost of sales increased primarily due to increased product sales. Research and development expenses increased by $0.2 million due to expanded investment in our formulation and development capabilities and general and administration expenses increased by $0.3 million. All of the above contributed to our CDMO segment's operating income of $13.9 million for the six months ended June 30, 2018, which included non-cash charges of $3.7 million for depreciation and amortization and $0.6 million for stock-based compensation.

Acute Care Segment-

Our Acute Care segment's operating expenses increased $15.5 million from $22.0 million in the six months ended June 30, 2017 to $37.5 million in the six months ended June 30, 2018. Research and development expenses increased $3.6 million as a result of increased IV meloxicam pre-commercialization manufacturing costs, salaries and benefits and Phase IIIb clinical trial costs. The increase was partially offset by a decrease in Phase III clinical trial costs. General and administrative costs increased by $11.9 million as a result of increased salaries and benefits and increased pre-commercialization marketing expenses as well as costs due to the CRL including severance and increased legal and consulting fees associated with addressing the CRL issued by the FDA regarding our NDA for IV meloxicam. The non-cash charge for contingent consideration decreased by $2.9 million and the non-cash benefit from the reduction in value of warrants decreased by $0.4 million primarily as a result of the receipt of a CRL from the FDA and the resulting decrease in our stock price. All of the above contributed to our Acute Care segment's operating loss of $40.1 million for the six months ended June 30, 2018, which also included non-cash charges of $2.9 million for stock-based compensation, depreciation and amortization.

Liquidity and Capital Resources

As of June 30, 2018, we had $48.9 million in cash and cash equivalents.

Since inception through June 30, 2018, we have financed our product development, operations and capital expenditures primarily from sales of equity and debt securities, including sales of our common stock with net proceeds of $127.5 million, and term loans made under our previous and existing credit facilities, including our credit facility with Athyrium with an outstanding balance of $60.0 million. 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, 2018, our capital expenditures were $2.9 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 or commence our clinical trials of our 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 our ability to timely and adequately resolve the CRL issued by the FDA regarding our NDA for IV meloxicam, the cost of studies and other actions that may be needed to obtain regulatory approval for IV meloxicam or our other product candidates in development, the timing of approval of IV meloxicam, the level of market acceptance of IV meloxicam and the costs of commercialization activities for IV meloxicam, if approved, the continued profitability of our CDMO segment, and our ability to access additional tranches under our Credit Agreement with Athyrium, which depends in part on our ability to obtain regulatory approval of IV meloxicam by December 31, 2018. We may raise such additional funds through debt refinancing, bank or other loans, through strategic research and development, licensing, including

out-licensing activities, 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 debt or 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 or access to capital.

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. On November 17, 2017, we entered into our credit agreement with Athyrium, pursuant to which we drew $60.0 million in an initial term loan and have the ability to draw upon two additional tranches of terms loans, each in the aggregate original principal amount of $20.0 million. Pursuant to the terms of the credit agreement, we may draw upon the second $20.0 million tranche on or before December 31, 2018, provided that we receive regulatory approval for IV meloxicam and retain at least $20.0 million in unrestricted cash following payment of the $45.0 million milestone payment to Alkermes. We may draw upon the final $20.0 million tranche on or prior to March 31, 2020, provided that we have drawn on the second tranche and have achieved net sales for IV meloxicam of $20.0 million in the most recent trailing twelve-month period. We used the proceeds from the $60.0 million initial term loan to (i) repay in full all outstanding indebtedness under our credit facility with OrbiMed of approximately $31.7 million, which included the remaining debt principal balance of $27.3 million and early termination charges of $4.4 million and (ii) pay transaction fees associated with the credit facility with Athyrium of approximately $4.2 million. As of June 30, 2018, we had $60.0 million outstanding principal under our Credit Agreement with Athyrium.

Sources and Uses of Cash

Cash used in operations was $24.2 million and $11.0 million for the six months ended June 30, 2018 and 2017, 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 provided by/(used in) investing activities was $0.5 million and ($44.8) million for the six months ended June 30, 2018 and 2017, respectively, and reflected cash maturities/redemption of investments offset by cash used for the purchase of short-term investments and for the purchase of property and equipment.

There was $11.7 million of cash provided by financing activities in the six months ended June 30, 2018 from net proceeds of $11.0 million from the sale of shares of common stock through our Common Stock Purchase Agreement with Aspire Capital and proceeds of $1.0 million from exercise of options, which was partially offset by deferred financing costs of $0.3 million from the Athyrium transaction. Our future use of operating cash and capital requirements will depend on many forward-looking factors, including the following:

- our ability to resolve the CRL issued by the FDA regarding our NDA for IV meloxicam and obtain and maintain regulatory approval of IV meloxicam, and the labeling under any approval that we may obtain;
- the timing and outcome of our Phase IIIb clinical trials for IV meloxicam;
- the extent to which the FDA may require us to perform additional studies or other actions in order to obtain regulatory approval for IV meloxicam;
- the timing of 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 manufacturing scale-up, acquiring drug product and other capital equipment for our product candidates;
- the level of market acceptance of IV meloxicam, if approved;
- 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 segment;
- 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;
- our ability to access additional tranches of term loans under our credit agreement with Athyrium;
- our ability to raise additional funds through equity or debt financings;
- 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, equity financing, sale of assets or out-licensing revenue or a combination thereof 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 or debt securities. This dilution may be significant depending upon the amount of equity or debt securities that we issue and the prices at which we issue any securities.

Contractual Commitments

The table below reflects our contractual commitments as of June 30, 2018:

	Payments Due by Period (in 000s)				
Contractual Obligations	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Long-Term Debt Obligations (1):					
Athyrium Debt	$60,600	$—	$—	$60,600	$—
Interest on Debt	$32,354	7,356	14,813	10,185	—
Purchase Obligations (2):	$21,516	16,025	2,453	11	—
Operating Leases (3)	$3,083	747	1,144	866	325
Other Long-Term Liabilities:					
Other License Commitments and Milestone payments (4), (5)	$54,890	25	100	150	315
Alkermes Payments (6)	$125,000	—	—	—	—
Employment Agreements (7)	$714	714	—	—	—
Other Non-Current Liabilities (8)	$29	—	29	—	—
Total Contractual Obligations	$298,186	$24,867	$18,539	$71,812	$640

(1) The long-term debt obligations consist of principal, an exit fee of 1% of the principal, and interest on the initial $60.0 million of our $100 million credit facility with Athyrium as of June 30, 2018. The debt bears interest at a rate of LIBOR plus 9.75% per annum. Due to fluctuations of the future LIBOR interest rate, it has been set at the rate as at June 28, 2018 to calculate the obligation. In accordance with U.S. GAAP, the future interest obligations are not recorded on our Consolidated Balance Sheet. See Note 12 to the Consolidated Financial Statements included in this Form 10-Q.

(2) These obligations consist of cancelable and non-cancelable purchase commitments related to inventory, capital expenditures and other goods or services. In addition, in July 2018, we committed to reimburse Alkermes for the costs related to the fit out of the Alkermes facility for commercial inventory production of IV meloxicam, which we estimate will be approximately $6.3 million. In accordance with U.S. GAAP, these obligations are not recorded on our Consolidated Balance Sheets. See Note 13 to the Consolidated Financial Statements included in this Form 10-Q.

(3) We have become party to certain operating leases, for the leased space in Malvern, Pennsylvania, Gainesville, Georgia and Dublin, Ireland, as well as for office equipment, for which the minimum lease payments are presented.

(4) We are party to exclusive licenses with Orion for the development and commercialization of certain pipeline product candidates, under which we may be required to make certain milestone and royalty payments to

Orion. See Note 5 and Note 13(a) to the Consolidated Financial Statements included in the Form 10-Q. The amount reflects only payment obligations that are fixed and determinable. 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.

(5) We license the NMBs from Cornell University pursuant to a license agreement under 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 NMBs. The amount reflects only payment obligations that are fixed and determinable. We are unable to reliably estimate the timing of certain 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, certain of these obligations are not recorded on our Consolidated Balance Sheets. See Note 5 and 13(a) to the Consolidated Financial Statements included in this Form 10-Q.

(6) Pursuant to the purchase and sale agreement governing the Gainesville Transaction, we agreed to pay to Alkermes milestone and royalty payments. The amount reflects only payment obligations that are fixed and determinable. We are unable to reliably estimate the timing of these payments because they are in some instances, events that are not in our control and dependent on the commercial success of the product. In accordance with U.S. GAAP, the fair value of these obligations is recorded as contingent consideration on our Consolidated Balance Sheets. See Note 4 and Note 13(b) to the Consolidated Financial Statements included in this Form 10-Q.

(7) We have entered into employment agreements with certain of our named executive officers. As of June 30, 2018, these employment agreements provided for, among other things, annual base salaries in an aggregate amount of not less than this amount, from that date through June 30, 2019. In accordance with U.S. GAAP, these obligations are not recorded on our Consolidated Balance Sheets. See Note 13 (f) to the Consolidated Financial Statements included in this Form 10-Q.

(8) This value represents the deferred rent and non-current portion of payments due to Cornell University for past patent costs associated with the license agreement for the NMBs. In accordance with U.S. GAAP, these liabilities are recorded on our Consolidated Balance Sheets. See Note 5 and 13(a) to the Consolidated Financial Statements included in this Form 10-Q.

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, 2017 filed with the SEC on March 2, 2018. In the three months ended March 31, 2018, there were changes to the application of critical accounting policies previously disclosed in our most recent Annual Report on Form 10-K related to the adoption of ASU 2014-09 on January 1, 2018, as described below.

Revenue Recognition

Revenue Recognition

We generate revenues from manufacturing, packaging, research and development, and related services for multiple pharmaceutical companies through its CDMO segment. Our agreements with our commercial partners provide for manufacturing revenues, sales-based royalties and/or profit sharing components. Our revenue policies listed below are reflective of ASU 2014-09, which the company adopted effective January 1, 2018. See Note 18 to the Consolidated Financial Statements included in this Form 10-Q for additional information regarding our adoption of ASU 2014-09 and its impact on our financial statements.

Manufacturing and other related services revenue is recognized upon transfer of control of a product to a customer, generally upon shipment, based on a transaction price that reflects the consideration we expect to be entitled to as specified in the agreement with the commercial partner.

In addition to manufacturing and packaging revenue, certain customer agreements may have intellectual property sales-based royalties and/or profit sharing consideration, collectively referred to as royalties, computed on the net product sales of the commercial partner. Royalty revenues are generally recognized under the terms of the applicable license, development and/or supply agreement. For arrangements that include sales-based royalties where the license for intellectual property is deemed to be the predominant item to which the royalties relate, we recognize revenue when the related sales occur by the commercial partner. For arrangements that include sales-based royalties where the license for intellectual property is not deemed to be the predominant item to which the royalties relate, we recognize revenue upon transfer of control of the manufactured product. In these cases, significant judgement is required to calculate this estimated variable consideration using the most-likely amount method based on historical customer pricing and deductions and is partially constrained due to items that are outside of our control including the uncertainty of the timing of future commercial partner sales, mix of volume, customer stocking and ordering patterns,

as well as unforeseen price adjustments made by our commercial partners.

Revenues related to research and development are generally recognized over-time as the related services or activities are performed using the output method and in accordance with the contract terms. In agreements which specify milestones, we evaluate whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. Milestone payments related to arrangements under which we have continuing performance obligations would be deferred and recognized over the period of performance. Milestone payments that are not within our control, such as submission for approval to regulators by a commercial partner or approvals from regulators, are not considered probable of being achieved until those submissions are submitted by the customer or approvals are received.

Item 3.Quantitative and Qualitative Disclosures About Market Risk

There has been no material change in our assessment of its sensitivity to market risk described in the “Quantitative and Qualitative Disclosures About Market Risk” section of our Annual Report on Form 10-K December 31, 2017 filed with the SEC on March 2, 2018.

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, 2018. 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, 2018, 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.

On May 31, 2018, a securities class action lawsuit was filed against us and certain of our officers and directors in the U.S. District Court for the Eastern District of Pennsylvania (Case No. 2:18-cv-02279-MMB) that purported to state a claim for alleged violations of Section 10(b) and 20(a) of the Exchange Act and Rule 10(b)(5) promulgated thereunder, based on statements made by us concerning the NDA for IV meloxicam. The complaint seeks unspecified damages, interest, attorneys' fees and other costs. We believe that the lawsuit is without merit and intend to vigorously defend against it. The lawsuit is in the early stages and, at this time, no assessment can be made as to its likely outcome or whether the outcome will be material to us.

Item 1A. Risk Factors.

Except as set forth below, there have been no material changes from our risk factors as previously reported in our Annual Report on Form 10-K for the year ended December 31, 2017.

Considering our receipt of a CRL from the FDA regarding our NDA for IV meloxicam, the U.S. regulatory pathway for IV meloxicam is uncertain, and we will need to successfully address deficiencies raised by the FDA in order to obtain regulatory approval.

In July 2017 we submitted an NDA for IV meloxicam for the management of moderate to severe pain to the FDA. On May 23, 2018, we received a CRL from the FDA regarding the NDA, which stated that the FDA determined it could not approve the NDA in its present form. The CRL stated that data from ad hoc analyses and selective secondary endpoints suggest that the analgesic effect did not meet the expectations of the FDA. In addition, the CRL identified certain CMC related questions on extractable and leachable data provided in the NDA. The CRL did not identify any issues relating to the safety of IV meloxicam. In July 2018, we participated in a Type A End-of-Review meeting with the FDA to discuss the topics covered in the CRL. We plan to provide an update on our path forward following receipt of the written meeting minutes.

Our anticipated commercialization of IV meloxicam has been delayed by the CRL and we will incur additional costs and be required to devote some resources to address the FDA's concerns raised in the CRL. Our receipt of the CRL and delay in the commercialization of IV meloxicam has adversely affected our business and caused our stock price to decline. We will need to raise additional funds if the FDA requires us to conduct additional studies and cannot guarantee that we will be able to do so on favorable terms or at all. In addition, if we do not obtain FDA approval of IV meloxicam by December 31, 2018, we will need to seek to renegotiate the conditions relating to our ability to draw the two additional $20 million tranches available under our credit agreement with Athyrium, or we will not be able to draw on these additional tranches.

Even if the outstanding items identified in the CRL are resolved to the satisfaction of the FDA with regard to our NDA for IV meloxicam, the FDA retains the right not to approve the NDA or to require additional information, or to raise additional issues with regard to regulatory approval of IV meloxicam, which could further delay or prevent its approval or limit the product labelling claims for IV meloxicam. In addition, either the substance of the items

identified by the FDA in the CRL, or the CRL itself, could have an adverse impact on future efforts to obtain marketing authorization for IV meloxicam from the EMA and other foreign regulatory authorities, or on our future efforts to commercialize IV meloxicam and gain acceptance of IV meloxicam from third party payors.

Should we fail to address the concerns raised in the CRL in a timely manner and obtain regulatory approval of IV meloxicam, we may be forced to rely on our other product candidates, which are at an earlier development stage and will require additional time and resources to obtain regulatory approval and proceed with commercialization.

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) The following exhibits are filed herewith or incorporated by reference herein:
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EXHIBIT INDEX

Exhibit No.	Description	Method of Filing
10.1	Recro Pharma, Inc. 2018 Amended and Restated Equity Incentive Plan.	Incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on May 9, 2018 (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 and 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.

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 7, 2018 By: /s/ Gerri A. Henwood
Gerri A. Henwood
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 7, 2018 By: /s/ Ryan D. Lake
Ryan D. Lake
Chief Financial Officer
(Principal Financial and Accounting Officer)