

**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, 2019**

Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Commission File Number: **001-36329**

Recro Pharma, Inc.

(Exact name of registrant as specified in its charter)

Pennsylvania
(State or other jurisdiction of
incorporation or organization)

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

26-1523233
(I.R.S. Employer
Identification No.)

19355
(Zip Code)

(484) 395-2470
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of Each Class</u>	<u>Trading Symbol</u>	<u>Name of Exchange on Which Registered</u>
Common Stock, par value \$0.01	REPH	Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act:

None

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 every Interactive Data File required to be submitted 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 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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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 Section 13(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 6, 2019, there were 22,427,645 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, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 30,400	\$ 38,514
Short-term investments	1,998	—
Accounts receivable	17,796	12,866
Contract asset	8,154	5,201
Inventory	9,639	10,699
Prepaid expenses and other current assets	5,503	3,861
Total current assets	73,490	71,141
Property, plant and equipment, net	49,394	45,640
Right-of-use asset	1,527	—
Intangible assets, net	30,974	32,266
Goodwill	6,446	6,446
Total assets	\$ 161,831	\$ 155,493
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 706	\$ 4,510
Accrued expenses and other current liabilities	7,189	14,165
Current operating lease liability	592	—
Current portion of contingent consideration	—	10,354
Total current liabilities	8,487	29,029
Long-term debt, net	107,399	64,243
Warrants and other long-term liabilities	1,880	1,163
Long-term operating lease liability	1,012	—
Long-term portion of contingent consideration	61,762	80,558
Total liabilities	180,540	174,993
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, 22,414,607 shares at June 30, 2019 and 21,799,961 shares at December 31, 2018	224	218
Additional paid-in capital	174,134	168,535
Accumulated deficit	(193,067)	(188,253)
Accumulated other comprehensive loss	—	—
Total shareholders' equity	(18,709)	(19,500)
Total liabilities and shareholders' equity	\$ 161,831	\$ 155,493

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,		For the Six Months Ended June 30,	
	2019	2018	2019	2018
Revenue	\$ 31,256	\$ 21,739	\$ 56,322	\$ 41,281
Operating expenses:				
Cost of sales (excluding amortization of intangible assets)	14,100	12,071	28,491	22,561
Research and development	7,180	10,157	16,734	18,599
General and administrative	9,997	12,955	24,175	22,473
Amortization of intangible assets	646	646	1,292	1,292
Change in warrant valuation	1,041	(1,139)	779	(365)
Change in contingent consideration valuation	(4,059)	396	(19,150)	2,916
Total operating expenses	28,905	35,086	52,321	67,476
Operating income (loss)	2,351	(13,347)	4,001	(26,195)
Other income (expense):				
Interest income	182	114	320	255
Interest expense	(5,370)	(2,189)	(9,135)	(4,292)
Net loss before income taxes	(2,837)	(15,422)	(4,814)	(30,232)
Income tax benefit	—	2,707	—	5,060
Net loss	\$ (2,837)	\$ (12,715)	\$ (4,814)	\$ (25,172)
Per share information:				
Net loss per share of common stock, basic and diluted	\$ (0.13)	\$ (0.62)	\$ (0.22)	\$ (1.27)
Weighted average common shares outstanding, basic and diluted	22,265,612	20,410,615	22,092,853	19,818,227
Net loss	\$ (2,837)	\$ (12,715)	\$ (4,814)	\$ (25,172)
Other comprehensive loss:				
Unrealized gain on available-for-sale securities	1	1	—	1
Comprehensive loss	\$ (2,836)	\$ (12,714)	\$ (4,814)	\$ (25,171)

See accompanying notes to consolidated financial statements.

RECRO PHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Shareholders' Equity
(Unaudited)

For the Six Months Ended June 30, 2019

(amounts in thousands, except share data)	Common Stock		Additional paid-in capital	Accumulated Deficit	Accumulated other comprehensive loss	Total
	Shares	Amount				
Balance, December 31, 2018	21,799,961	\$ 218	\$ 168,535	\$ (188,253)	\$ —	\$ (19,500)
Stock-based compensation expense	—	—	2,826	—	—	2,826
Stock option exercise	29,750	—	185	—	—	185
Issuance of restricted stock units, net of shares withheld for income taxes	268,915	3	(865)	—	—	(862)
Issuance of common stock for equity facility	34,762	—	301	—	—	301
Change in other comprehensive loss	—	—	—	—	(1)	(1)
Net loss	—	—	—	(1,977)	—	(1,977)
Balance, March 31, 2019	22,133,388	\$ 221	\$ 170,982	\$ (190,230)	\$ (1)	\$ (19,028)
Stock-based compensation expense	—	—	2,359	—	—	2,359
Stock option exercise	206,625	2	907	—	—	909
Issuance of restricted stock units, net of shares withheld for income taxes	74,594	1	(114)	—	—	(113)
Change in other comprehensive loss	—	—	—	—	1	1
Net loss	—	—	—	(2,837)	—	(2,837)
Balance, June 30, 2019	22,414,607	\$ 224	\$ 174,134	\$ (193,067)	\$ —	\$ (18,709)

For the Six Months Ended June 30, 2018

(amounts in thousands, except share data)	Common Stock		Additional paid-in capital	Accumulated Deficit	Accumulated other comprehensive loss	Total
	Shares	Amount				
Balance, December 31, 2017	19,127,435	\$ 191	\$ 140,006	\$ (111,348)	\$ (1)	\$ 28,848
Stock-based compensation expense	—	—	1,584	—	—	1,584
Stock option exercise	14,575	—	65	—	—	65
Issuance of restricted stock units, net of shares withheld for income taxes	25,364	—	(86)	—	—	(86)
Sale of common stock under equity facility, net of transaction costs	383,040	4	3,798	—	—	3,802
Net loss	—	—	—	(12,457)	—	(12,457)
Cumulative effect of adoption of new accounting standards, net of tax	—	—	—	2,818	—	2,818
Balance, March 31, 2018	19,550,414	\$ 195	\$ 145,367	\$ (120,987)	\$ (1)	\$ 24,574
Stock-based compensation expense	—	—	1,719	—	—	1,719
Stock option exercise	159,786	2	960	—	—	962
Issuance of restricted stock units, net of shares withheld for income taxes	91,354	1	(2)	—	—	(1)
Sale of common stock under equity facility, net of transaction costs	700,000	7	7,350	—	—	7,357
Cashless exercise of warrants	214,715	2	2,587	—	—	2,589
Other comprehensive loss	—	—	—	—	1	1
Net loss	—	—	—	(12,715)	—	(12,715)
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)

(amounts in thousands)	For the Six Months Ended June 30,	
	2019	2018
Cash flows from operating activities:		
Net loss	\$ (4,814)	\$ (25,172)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	5,185	3,303
Non-cash interest expense	2,414	639
Depreciation expense	3,030	2,498
Amortization	1,292	1,292
Change in warrant valuation	779	(365)
Change in contingent consideration valuation	(19,150)	2,916
Deferred income taxes	—	(5,060)
Changes in operating assets and liabilities:		
Inventory	1,060	1,726
Contract asset	(2,953)	(3,111)
Prepaid expenses and other current assets	(1,340)	(17)
Right-of-use asset	339	—
Accounts receivable	(4,930)	(1,985)
Accounts payable, accrued expenses and other liabilities	(8,356)	(905)
Operating lease liability	(343)	—
Net cash used in operating activities	(27,787)	(24,241)
Cash flows from investing activities:		
Purchase of property and equipment	(9,108)	(2,931)
Purchase of short-term investments	(12,021)	(4,982)
Proceeds from maturity of investments	10,100	8,500
Acquisition of license agreement	(82)	(82)
Net cash (used in)/provided by investing activities	(11,111)	505
Cash flows from financing activities:		
Proceeds from issuance of long-term debt, net of original issue discount of \$11,400	43,600	—
Payment of deferred financing costs	(2,936)	(261)
Proceeds from sale of common stock, net of transaction costs	—	10,984
Payments of withholdings on shares withheld for income taxes	(974)	(87)
Payment of contingent consideration	(10,000)	—
Proceeds from option exercise	1,094	1,027
Net cash provided by financing activities	30,784	11,663
Net decrease in cash and cash equivalents	(8,114)	(12,073)
Cash and cash equivalents, beginning of period	38,514	60,984
Cash and cash equivalents, end of period	\$ 30,400	\$ 48,911
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 6,644	\$ 4,375
Purchase of property, plant and equipment included in accrued expenses and accounts payable	\$ 257	\$ 508
Common stock issued in connection with equity facility	\$ 301	\$ 357

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 pharma services and pharmaceutical company that operates through two business segments: a revenue-generating contract development and manufacturing, or CDMO, segment and an Acute Care segment. Each of these segments are deemed to be reportable segments (see Note 3(m) and Note 17). 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 and the Acute Care segment develops proprietary product candidates including intravenous, or IV, Meloxicam, for which the Company is pursuing resolution of a Complete Response Letter, or CRL, received from the U.S. Food and Drug Administration, or FDA, regarding the New Drug Application, or NDA, for IV meloxicam.

In April 2019, after receipt of the second CRL for IV meloxicam, the Company announced it had implemented a strategic restructuring initiative, and corresponding reduction in the Acute Care segment workforce, aimed at reducing operating expenses, while maintaining key personnel needed to partner and obtain FDA approval of IV meloxicam.

(2) Development-Stage Risks and Liquidity

The Company has incurred losses from operations since inception and has an accumulated deficit of \$193,067 as of June 30, 2019. Although its CDMO segment has been profitable, the Company anticipates incurring additional losses until such time when its development costs are reduced and/or partners have been obtained or alternative structures have been put in place for its Acute Care product candidates. Additional financing may be needed by the Company to fund its operations and to repay the principal on its debt. The Company may raise such capital through debt refinancing, bank or other loans, sale of assets, spin-off transactions, strategic research and development, licensing and/or other partnering transactions, 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 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, spin-off transactions, partnering or out-licensing transactions; (iii) the development of competitive therapies by other biotechnology and pharmaceutical companies; and, ultimately, (iv) 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 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, 2019 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2019.

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, 2018 included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018.

(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 one-step method for determining impairment.

The one-step quantitative test calculates 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.

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 30^h, 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 assesses 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 March 2019, an indicator of potential impairment, the Company performed an impairment test as of March 31, 2019, which indicated that there was no impairment to goodwill or indefinite-lived intangible assets. There have been no additional triggering events as of June 30, 2019. The Company will perform its annual test as of November 30, 2019.

(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.

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 judgment 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 for our CDMO segment 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 primarily concentrated amongst four 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 97% of its revenues for three and six months ended June 30, 2019. A portion of the Company's revenues is 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, pre-clinical activities, 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. The Company accounts for forfeitures as they occur.

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 our 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.

For non-employee stock-based awards, 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 basis, operating losses 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 all periods presented, 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.

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. There are no dilutive common stock equivalents for the three and six months ended June 30, 2019 and 2018.

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Basic and Diluted Loss Per Share				
Net loss	\$ (2,837)	\$ (12,715)	\$ (4,814)	\$ (25,172)
Weighted average common shares outstanding, basic and diluted	<u>22,265,612</u>	<u>20,410,615</u>	<u>22,092,853</u>	<u>19,818,227</u>
Net loss per share of common stock, basic and diluted	<u>\$ (0.13)</u>	<u>\$ (0.62)</u>	<u>\$ (0.22)</u>	<u>\$ (1.27)</u>

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as of June 30, 2019 and 2018, as they would be anti-dilutive:

	<u>June 30,</u>	
	<u>2019</u>	<u>2018</u>
Options and restricted stock units outstanding	5,284,206	5,121,104
Warrants	698,664	838,664

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

(m) **Segment Information**

The Company determined its reportable segments based on its strategic business units, the commonalities among the products and services within each segment and the manner in which the Company reviews and evaluates operating performance. The Company has identified CDMO and Acute Care as reportable segments. Segment disclosures are included in Note 17. Segment operating income (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 income (loss): interest income and expense, and income tax benefit (expense). Segment assets are those assets and liabilities that are recorded and reported by segment operations.

(n) **Recent Accounting Pronouncements**

Recently Adopted 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 was 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 adopted this guidance as of October 1, 2018 and there was no impact 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. In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842), Targeted Improvements*, which provides an alternative transition method permitting the recognition of a cumulative-effect adjustment on the date of adoption rather than restating comparative periods in transition as originally prescribed by Topic 842. The new guidance is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted. The Company adopted this guidance as of January 1, 2019. The Company elected the optional transition method to account for the impact of the adoption with a cumulative-effect adjustment in the period of adoption and did not restate prior periods. The Company opted to elect the package of practical expedients to not reassess prior conclusions related to contracts containing leases, lease classification and initial direct costs, and certain other practical expedients, including the use of hindsight to determine the lease term for existing leases and in assessing impairment of the right-of-use asset, and the exception for short-term leases. For its current classes of underlying assets, the Company did not elect the practical expedient under which the lease components would not be separated from the nonlease components. At January 1, 2019, the Company recorded a right-of-use asset of \$1,866 and an operating lease liability of \$1,947. For additional information regarding how the Company is accounting for leases under the new guidance, refer to Note 13 (d).

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 that 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 Note 18 for additional information on the impact of the transition on the Company’s financial statements.

Accounting Pronouncements Not Yet Adopted

In August 2018, the FASB issued ASU 2018-13, “*Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*,” or ASU 2018-13. ASU 2018-13 removes, modifies and adds certain disclosure requirements in Topic 820 “*Fair Value Measurement*”. ASU 2018-13 eliminates certain disclosures related to transfers and the valuations process, clarifies the measurement uncertainty disclosure, and requires additional disclosures for Level 3 fair value measurements, including the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. ASU 2018-13 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. The Company is currently evaluating the potential impact on its disclosures.

In June 2016, the FASB issued ASU No. 2016-13, “*Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*,” or ASU 2016-13. ASU 2016-13 requires companies to measure credit losses utilizing a methodology that reflects expected credit losses and requires consideration of a range of reasonable information to estimate credit losses on certain types of financial instruments, including trade receivables and available-for-sale debt securities. ASU 2016-13 is effective for fiscal years beginning after December 15, 2019, including those interim periods within those fiscal years. The Company is currently assessing the impact of adopting this standard, but based on a preliminary assessment, does not expect the adoption of this guidance to have a material impact on its consolidated 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 of injectable meloxicam, 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).

In December 2018, the Company entered into an Amendment to the Purchase and Sale Agreement that restructured the \$45,000 milestone to \$60,000 therefore increasing the amount the Company may be required to pay Alkermes to \$140,000, however, the amendment spread the payments of the development milestone over a seven-year period. In addition, the Company amended the warrant agreement with Alkermes, which decreased the exercise price of the warrant to \$8.26 per share.

Based on the amended terms of the Alkermes agreement, the contingent consideration consists of four separate components. The first component is (i) a \$5,000 payment made in the first quarter of 2019 and (ii) a \$5,000 payment made in the second quarter of 2019. The second components will be payable upon certain regulatory approval and include (i) a \$5,000 payment due within 180 days following regulatory approval for IV meloxicam and (ii) \$45,000 payable in seven equal annual payments of approximately \$6,400 beginning on the first anniversary of such approval. The third 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 fourth 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. During the six months ended June 30, 2019, the Company paid the first component consisting of two payments of \$5,000 each to Alkermes.

The fair value of the second contingent consideration components 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 third 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 expected revenue target attainment dates. The fair value of the fourth contingent consideration component is estimated by applying a risk-adjusted discount rate to the potential payments resulting from probability-weighted revenue projections and the defined royalty percentage.

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

(5) NMBA Related License Agreement

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

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 NMBA Related Compounds; and (ii) milestone payments upon the achievement of certain milestones, up to a maximum, for each NMBA, 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 NMBA Related Compounds at a rate ranging from low to mid-single digits, depending on the applicable NMBA 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 NMBA 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 NMBA 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 NMBA 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, 2018:			
Assets:			
Cash equivalents (See Note 7)			
Money market mutual funds	\$ 24,720	\$ —	\$ —
Commercial paper	—	2,247	—
U.S. Treasury obligations	2,748	—	—
Total cash equivalents	\$ 27,468	\$ 2,247	\$ —
Liabilities:			
Warrants (See Note 14(d))	\$ —	\$ —	\$ 1,101
Contingent consideration (See Note 4)	—	—	90,912
	\$ —	\$ —	\$ 92,013
At June 30, 2019:			
Assets:			
Cash equivalents (See Note 7)			
Money market mutual funds	\$ 17,379	\$ —	\$ —
Total cash equivalents	\$ 17,379	\$ —	\$ —
Short-term investments (See Note 7)			
Commercial Paper	\$ —	\$ 1,998	\$ —
Total financial assets	\$ 17,379	\$ 1,998	\$ —
Liabilities:			
Warrants (See Note 14(d))	\$ —	\$ —	\$ 1,880
Contingent consideration (See Note 4)	—	—	61,762
	\$ —	\$ —	\$ 63,642

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, 2018	\$ 1,101	\$ 90,912
Payment of contingent consideration	—	(10,000)
Remeasurement	779	(19,150)
Total at June 30, 2019	\$ 1,880	\$ 61,762
Current portion as of June 30, 2019	—	—
Long-term portion as of June 30, 2019	1,880	61,762

The Company does not currently expect a portion of the contingent consideration to become payable within one year as of June 30, 2019 (see Note 4 for additional information). The Company plans to continue to reevaluate this classification and measurement as it progresses through discussions with the FDA regarding 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, 2019, 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 and 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, 2019 due to the comparison of the terms of the debt, including borrowing rates available to the Company through its recent debt refinancing process in the first quarter of 2019.

(7) Cash Equivalents and Short-term Investments

Cash equivalents and short-term investments as of June 30, 2019 consist of government money market mutual funds and commercial paper. A portion of short-term investments is 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:

Description	June 30, 2019			
	Amortized	Gross Unrealized		Estimated
	Cost	Gain	Loss	Fair Value
Money market mutual funds	\$ 17,379	\$ —	\$ —	\$ 17,379
Commercial Paper	1,998	—	—	1,998
Total investments	\$ 19,377	\$ —	\$ —	\$ 19,377

Description	December 31, 2018			
	Amortized	Gross Unrealized		Estimated
	Cost	Gain	Loss	Fair Value
Money market mutual funds	\$ 24,720	\$ —	\$ —	\$ 24,720
Commercial paper	2,247	—	—	2,247
U.S. Treasury obligations	2,747	1	—	2,748
Total investments	\$ 29,714	\$ 1	\$ —	\$ 29,715

As of June 30, 2019, the Company had one investment with an original maturity of four months. As of December 31, 2018, all of the Company's investments 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.

(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 within the Research and development line in the Consolidated Statements of Operations and Comprehensive Loss until 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, 2019 and December 31, 2018:

	June 30, 2019	December 31, 2018
Raw materials	\$ 2,710	\$ 2,611
Work in process	3,373	4,935
Finished goods	3,938	3,440
	<u>10,021</u>	<u>10,986</u>
Provision for inventory obsolescence	(382)	(287)
	<u>\$ 9,639</u>	<u>\$ 10,699</u>

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, 2019	December 31, 2018
Land	\$ 3,263	\$ 3,263
Building and improvements	21,052	17,880
Furniture, office and computer equipment	7,373	7,226
Manufacturing equipment	33,776	30,197
Construction in progress	5,938	6,078
	<u>71,402</u>	<u>64,644</u>
Less: accumulated depreciation and amortization	22,008	19,004
Property, plant and equipment, net	<u>\$ 49,394</u>	<u>\$ 45,640</u>

Depreciation expense for the three and six months ended June 30, 2019 was \$1,590 and \$3,030, respectively. Depreciation expense for three and six months ended June 30, 2018 was \$1,282 and \$2,498, respectively.

(10) Intangible Assets

The following represents the balance of the intangible assets at June 30, 2019:

	Cost	Accumulated Amortization	Net Intangible Assets
Royalties and contract manufacturing relationships	\$ 15,500	\$ 10,926	\$ 4,574
In-process research and development	26,400	—	26,400
Total	<u>\$ 41,900</u>	<u>\$ 10,926</u>	<u>\$ 30,974</u>

The following represents the balance of intangible assets at December 31, 2018:

	Cost	Accumulated Amortization	Net Intangible Assets
Royalties and contract manufacturing relationships	\$ 15,500	\$ 9,634	\$ 5,866
In-process research and development	26,400	—	26,400
Total	\$ 41,900	\$ 9,634	\$ 32,266

Amortization expense for each of the three months ended June 30, 2019 and 2018 was \$646. Amortization expense for each of the six months ended June 30, 2019 and 2018 was \$1,292.

As of June 30, 2019, future amortization expense is as follows:

	Amortization
2019	\$ 1,292
2020	2,583
2021	699
Total	\$ 4,574

(11) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	June 30, 2019	December 31, 2018
Clinical trial and related costs	\$ 124	\$ 683
Professional and consulting fees	813	672
Payroll and related costs	2,876	4,782
Accrued restructuring costs	1,836	—
Property, plant and equipment	97	1,737
Deferred revenue	637	66
Pre-commercialization scale-up costs	—	4,445
Other research and development costs	205	678
Other	601	1,102
	\$ 7,189	\$ 14,165

After the receipt of the second CRL, the Company incurred approximately \$7,200 in restructuring costs (\$6,000 incurred in the three months ended June 30, 2019), of which \$1,836 remains accrued and unpaid as of June 30, 2019.

(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 provided for a term loan in the original principal amount of \$60,000 funded at closing. In December 2018, the Company amended the Credit Agreement, (as amended, the "Amended Credit Agreement"). Pursuant to the Amended Credit Agreement, the \$20,000 term B loan and \$20,000 term C loan provided for under the Credit Agreement, which were contingent on the Company receiving approval of IV meloxicam by December 31, 2018, were restructured into (i) a \$10,000 term B-1 loan, funded on December 28, 2018; (ii) a \$15,000 term B-2 loan; and (iii) a \$15,000 term C loan.

On February 28, 2019, the Company entered into a Second Amendment to Credit Agreement (the "Second Amendment") with Athyrium. Pursuant to the Second Amendment, (i) the total commitments of the term loan credit facility governed by the Amended Credit Agreement was increased from \$100,000 to \$125,000, (ii) the \$15,000 term B-2 loan and \$15,000 term C loan provided for under the Amended Credit Agreement were restructured into a \$55,000 term B-2 loan, which was funded on the date of execution of the Second Amendment and (iii) the maturity date was extended to March 31, 2023 (the "Maturity Date"). Beginning on March 31, 2021, the Company must repay the outstanding principal amount in quarterly installments of \$3,000 with the outstanding principal balance due on the Maturity Date.

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. In addition, in accordance with the Credit Agreement the Company will have to pay a 1% exit fee, which is \$1,250 at the current outstanding loan balance and is being 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 beginning with a 10% penalty and including a make-whole interest payment. No prepayment penalties are assessed for payments made after March 31, 2022.

The Amended 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, 2019, the Company was in compliance with the covenants.

As of June 30, 2019, the remaining payments due under the Amended Credit Agreement include a principal payment of \$125,000 and an exit fee of \$1,250 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. In connection with the Amended Credit Agreement, the warrants were amended to decrease the exercise price to \$6.84 per share. See Note 14(d) for additional information. The warrants are exercisable through November 17, 2024. The initial fair value of the warrant and revaluation adjustment from the repricing of the warrants of \$2,232 was recorded as a debt issuance cost.

In addition, the Company recorded debt issuance costs for the Amended Credit Agreement of \$4,439 at original signing, an amendment fee of \$500 as well as certain other fees and expenses in December 2018, and recorded debt issuance costs for the Second Amendment consisting of a \$2,500 amendment fee, \$436 closing fee and \$11,400 original issue discount which, along with the fair value of warrants, are being amortized using the effective interest method over the term of the Second Amendment. Debt issuance cost amortization is included in interest expense within the Consolidated Statements of Operations and Comprehensive Loss. As of June 30, 2019, the effective interest rate was 16.71%, which takes into consideration the non-cash accretion of the exit fee, the amortization of the debt issuance cost and the original issue discount.

The components of the carrying value of the debt as of June 30, 2019, are detailed below:

Principal balance outstanding	\$	125,000
Unamortized deferred issuance costs		(17,867)
Exit fee accretion		266
Total	\$	<u>107,399</u>

The Company recorded debt issuance cost amortization related to the credit agreements of \$1,384 and \$329 for the three months ended June 30, 2019 and 2018, respectively. The Company recorded debt issuance cost amortization related to the credit agreements of \$2,362 and \$658 for the six months ended June 30, 2019 and 2018, 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 (\$23,301 as of June 30, 2019) 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, 2019, 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 (\$13,867 as of June 30, 2019) 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, 2019, no such milestones have been achieved.

The Company is party to a license agreement with Cornell for the exclusive license of the NMBA 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 and subsequent amendment governing the Gainesville Transaction, the Company agreed to pay to Alkermes up to an additional \$140,000 in milestone payments including \$50,000 upon regulatory approval payable over a seven-year period 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). As of June 30, 2019, the Company has paid \$10,000 in milestone payments to Alkermes.

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. On December 10, 2018, lead plaintiff filed an amended complaint that asserted the same claims and sought the same relief but included new allegations and named additional officers and directors as defendants. On February 8, 2019, the Company filed a motion to dismiss the amended complaint in its entirety, which the lead plaintiff opposed on April 9, 2019. On May 9, 2019, the Company filed its response and briefing was completed on the motion to dismiss. On June 26, 2019, the judge heard oral arguments on the motion to dismiss. The judge asked the plaintiffs to file a supplemental brief by August 30, 2019, and the Company will have 30 days to submit a reply brief. 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 leases for office equipment and storage.

The Company determines if an arrangement is a lease at inception. The arrangement is a lease if it conveys the right to the Company to control the use of identified property, plant, or equipment for a period of time in exchange for consideration. Lease terms vary based on the nature of operations, however, all leased facilities are classified as operating leases with remaining lease terms between 1 and 6 years. Most leases contain specific renewal options where notice to renew must be provided in advance of lease expiration or automatic renewals where no advance notice is required. Periods covered by an option to extend the lease were included in the non-cancellable lease term when exercise of the option was determined to be reasonably certain. Costs determined to be variable and not based on an index or rate were not included in the measurement of operating lease liabilities. As most leases do not provide an implicit rate, the Company's effective interest rate was used to discount its lease liabilities.

The Company's leases with an initial term of 12 months or less that do not have a purchase option or extension that is reasonably certain to be exercised are not included in the right of use asset or lease liability on the Consolidated Balance Sheets. Lease expense is recognized on a straight-line basis over the lease term.

As of June 30, 2019, undiscounted future lease payments for non-cancellable operating leases are as follows:

	Lease payments
2019	\$ 368
2020	606
2021	527
2022	529
2023	156
2024 and thereafter	247
Total lease payments	2,433
Less imputed interest	(829)
Total operating liabilities	<u>\$ 1,604</u>

As of December 31, 2018 under legacy ASC 840 “Leases”, undiscounted future lease payments for non-cancellable operating leases were as follows:

	Lease payments
2019	\$ 781
2020	613
2021	523
2022	529
2023	156
2024 and thereafter	247
Total	<u>\$ 2,849</u>

For the six months ended June 30, 2019, the weighted average remaining lease term was 4 years and the weighted average discount rate was 16%.

The components of the Company’s lease cost were as follows for the three and six months ended June 30, 2019:

	Three Months Ended June 30, 2019	Six Months Ended June 30, 2019
Operating lease cost	\$ 171	\$ 355
Short-term lease cost	27	42
Variable lease cost	1	9
Total lease cost	<u>\$ 199</u>	<u>\$ 406</u>

(e) Purchase Commitments

As of June 30, 2019, the Company had outstanding non-cancelable and cancelable purchase commitments in the aggregate amount of \$11,125 related to inventory, capital expenditures and other goods and services, including pre-commercial/manufacturing scale-up and clinical activities. The timing of certain purchase commitments cannot be estimated as it is dependent on timing of FDA approval or the outcome of other strategic evaluations.

(f) Certain Compensation and Employment Agreements

The Company has entered into employment agreements with certain of its named executive officers. As of June 30, 2019, these employment agreements provided for, among other things, annual base salaries in an aggregate amount of not less than \$947, from that date through June 2020.

(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 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 certain 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, 2019, 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 2018 Purchase Agreement, with Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth in the 2018 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 2018 Purchase Agreement. On the execution of the 2018 Purchase Agreement, the Company agreed to issue 33,040 shares of common stock to Aspire Capital as consideration for entering into the 2018 Purchase Agreement. As of June 30, 2019, the Company sold 1,950,000 shares of common stock under the 2018 Purchase Agreement for proceeds of \$16,999, at an average per share price of \$8.72 none of which transactions occurred during 2019.

On February 19, 2019, the Company entered into a common stock purchase agreement, or the 2019 Purchase Agreement, with Aspire Capital Fund, LLC, or Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth in the 2019 Purchase Agreement, Aspire Capital is committed to purchase, at the Company's sole election, up to an aggregate of \$20,000 of its shares of common stock over the approximately 30-month term of the 2019 Purchase Agreement. On the execution of the 2019 Purchase Agreement, the Company agreed to issue 34,762 shares of common stock to Aspire Capital as consideration for entering into the 2019 Purchase Agreement. As of June 30, 2019, the Company did not have any sales of common stock under the 2019 Purchase Agreement.

(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, 2019, no preferred stock was issued or outstanding.

(d) Warrants

As of June 30, 2019, 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
350,000	\$ 8.26	April 2022
348,664	\$ 6.84	November 2024

The warrant to purchase 348,664 shares related to Athyrium is equity classified. During March 2019, the warrant to purchase 140,000 shares originally issued to Aegis Capital Corporation, which was equity classified, was forfeited upon expiration.

The warrant to purchase 350,000 shares related to Alkermes is 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, 2019	December 31, 2018
Fair value	\$ 1,880	\$ 1,101
Expected dividend yield	— %	— %
Expected volatility	76 %	69 %
Risk-free interest rates	1.73 %	2.49 %
Remaining contractual term	2.75 years	3.25 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 OrbiMed 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 for the three and six months ended June 30, 2019 and 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, 2019 and 2018 was \$2,836 and \$12,714, respectively. The total of comprehensive loss for the six months ended June 30, 2019 and 2018 was \$4,814 and \$25,171, respectively. There was no tax effect of other comprehensive loss for the six months ended June 30, 2019 and 2018.

(16) Stock-Based Compensation

The Company established the 2008 Stock Option Plan, or the 2008 Plan, which allowed 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, 2019, 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. This plan expired in 2018. 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 2018 and 2017, the number of shares available for issuance under the A&R Plan was increased by 1,082,972 and 956,341, 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 8,119,709.

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, 2019, 2,666,387 shares are available for future grants under the A&R Plan.

The weighted average grant-date fair value of the options awarded to employees during the six months ended June 30, 2019 and 2018 was \$5.60 and \$6.18, respectively. The fair value of the options was estimated on the date of grant using a Black-Scholes option pricing model with the following assumptions:

	June 30,	
	2019	2018
Range of expected option life	5.5 - 6 years	5.5 - 6 years
Expected volatility	79.11% - 81.54%	73.26% - 82.00%
Risk-free interest rate	1.82 - 2.66%	2.32 - 2.96%
Expected dividend yield	—	—

The following table summarizes stock option activity during the six months ended June 30, 2019:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life
Balance, December 31, 2018	3,775,065	\$ 7.62	7.4 years
Granted	1,463,519	8.05	
Exercised	(239,469)	4.68	
Expired/forfeited/cancelled	(663,375)	7.85	
Balance, June 30, 2019	<u>4,335,740</u>	<u>\$ 7.74</u>	7.2 years
Vested	2,505,931	\$ 7.89	5.9 years
Vested and expected to vest	4,335,740	\$ 7.74	7.2 years

Included in the table above are 624,820 options outstanding as of June 30, 2019 that were 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 June 2019, 3,094 stock options were exercised, however, the issuance of common shares was not settled until July 2019. Due to the timing of settlement, these options are reflected as exercised in the table above, but not reflected in the common stock shares in the Company's Consolidated Statements of Shareholders' Equity as they were not shares outstanding as of June 30, 2019.

As a result of the Company's reduction in workforce announced in April 2019, the Company cancelled approximately 600,000 unvested stock options upon termination, which are reflected in the table above. The Company expects an additional approximately 300,000 shares related to stock options to be affected in which the shares will be cancelled if not exercised within the exercisable period in the termination agreements.

The following table summarizes restricted stock units, or RSUs, activity during the six months ended June 30, 2019.

	Number of shares
Balance, December 31, 2018	1,103,396
Granted	757,641
Vested and settled	(456,239)
Expired/forfeited/cancelled	(456,332)
Balance, June 30, 2019	<u>948,466</u>
Expected to vest	682,266

Included in the table above are 25,500 time-based RSUs outstanding as of June 30, 2019 that were granted outside the plan. The grants were made pursuant to the NASDAQ inducement grant exception in accordance with NASDAQ Listing Rule 5635(c)(4).

As a result of the Company's reduction in workforce announced in April 2019, the Company cancelled approximately 300,000 shares related to RSUs upon termination, which is reflected in the table above.

In January 2019, the Company granted 1,184,655 stock options at a price of \$7.99 per share, as well as 328,985 time-based RSUs, which vest over four years, and 299,950 performance-based RSUs, which may vest based on attaining 2019 financial, clinical and operational goals.

Stock-based compensation expense for the six months ended June 30, 2019 and 2018 was \$5,185 and \$3,303, respectively.

As of June 30, 2019, there was \$14,331 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 2.4 years. As of June 30, 2019, there was \$2,127 of unrecognized compensation expense related to unvested performance-based RSUs and will be expensed if 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, 2019, the aggregate intrinsic value of the vested and unvested options was \$6,705 and \$3,839, respectively.

(17) Segment Reporting

The Company operates through two business segments that are treated as separate financial segments—a revenue-generating CDMO segment and an Acute Care segment. 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. The Acute Care segment develops the Company’s proprietary product candidates and is currently focused on achieving FDA approval for IV meloxicam following the receipt of a second CRL. Acute Care has no revenue, and its costs historically have consisted 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. Following the receipt of the second CRL for IV meloxicam, the Company announced a strategic restructuring initiative that reduced the Acute Care operating expenses, including the reduction of staff of approximately 50 employees. CDMO revenue streams are derived from manufacturing, royalty and profit-sharing revenues, as well as CDMO’s research and development services performed for commercial partners.

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

The following table summarizes segment information as of and for the three and six months ended June 30, 2019:

	For the Three Months Ended		For the Six Months Ended	
	June 30,		June 30,	
	2019	2018	2019	2018
Revenues:				
CDMO	\$ 31,256	\$ 21,739	\$ 56,322	\$ 41,281
Acute Care	—	—	—	—
Total	<u>\$ 31,256</u>	<u>\$ 21,739</u>	<u>\$ 56,322</u>	<u>\$ 41,281</u>
Operating income (loss):				
CDMO	\$ 15,533	\$ 7,288	\$ 24,599	\$ 13,854
Acute Care	(13,182)	(20,635)	(20,598)	(40,049)
Total	<u>\$ 2,351</u>	<u>\$ (13,347)</u>	<u>\$ 4,001</u>	<u>\$ (26,195)</u>
Depreciation and amortization:				
CDMO	\$ 2,113	\$ 1,858	\$ 4,076	\$ 3,678
Acute Care	123	69	246	112
Total	<u>\$ 2,236</u>	<u>\$ 1,927</u>	<u>\$ 4,322</u>	<u>\$ 3,790</u>
Capital expenditures:				
CDMO	\$ 4,818	\$ 824	\$ 7,473	\$ 1,153
Acute Care	1,358	453	1,635	1,778
Total	<u>\$ 6,176</u>	<u>\$ 1,277</u>	<u>\$ 9,108</u>	<u>\$ 2,931</u>

	June 30, 2019	December 31, 2018
Total goodwill:		
CDMO	\$ 4,319	\$ 4,319
Acute Care	2,127	2,127
Total	<u>\$ 6,446</u>	<u>\$ 6,446</u>
Total assets:		
CDMO	\$ 99,931	\$ 87,879
Acute Care	61,900	67,614
Total	<u>\$ 161,831</u>	<u>\$ 155,493</u>

(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. 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.

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 \$8,154 and \$5,201 at June 30, 2019 and December 31, 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, 2019, actual net product sale amounts reported by the Company's commercial partner exceeded estimates of royalty amounts attributed to manufactured product shipped as of December 31, 2018 for the related arrangements by approximately \$2,084.

The following table presents changes in the Company's contract assets for the six months ended June 30, 2019:

Contract asset, beginning of year	\$ 5,201
Change in estimate arising from changes in transaction price	2,084
Reclassification of contract asset to receivables, as the result of rights to consideration becoming unconditional	(7,285)
Contract assets recognized	8,154
Contract asset, end of period	<u>\$ 8,154</u>

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

	Three Months Ended June 30, 2019		
	Point in time	Over time	Total
CDMO	\$ 30,432	\$ 824	\$ 31,256
Acute Care	—	—	—
Revenue	<u>30,432</u>	<u>824</u>	<u>31,256</u>

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

	Six Months Ended June 30, 2019		
	Point in time	Over time	Total
CDMO	\$ 55,382	\$ 940	\$ 56,322
Acute Care	—	—	—
Revenue	<u>55,382</u>	<u>940</u>	<u>56,322</u>

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

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 both regulatory and supply chain project support and consultancy. In consideration for such services, the Company recorded \$29 and \$144 for the three months ended June 30, 2019 and 2018, respectively. For the six months ended June 30, 2019 and 2018 the Company recorded \$104 and \$253, in consideration for such services, 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, 2019 and 2018 were \$322 and \$311, respectively. Total Company contributions to the 401(k) plan for the six months ended June 30, 2019 and 2018 were \$718 and \$701, respectively.

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, 2018 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 February 19, 2019. 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," "estimates," "predicts," "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 deficiencies identified by the U.S. Food and Drug Administration, or FDA, in the second complete response letter, or CRL, for intravenous, or IV, meloxicam;
- the time frame otherwise associated with resolving the deficiencies identified by the FDA in the CRL and whether the FDA will require additional clinical studies to support the approval of IV meloxicam and the time and cost of such studies;
- whether the FDA will accept an amended new drug application, or NDA, for IV meloxicam and, if approved, the labeling under any such approval that we may obtain;
- our ability to successfully partner IV meloxicam before approval or 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 successfully evaluate and execute on other possible organization structures, including but not limited to, the possibility of a separation of the Acute Care segment from the entity containing the CDMO segment;
- our ability to obtain and maintain regulatory approval for, and commercialize or partner, 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, distributors 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 defend the securities class action lawsuit filed against us, or any future material litigation filed against us;
- 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, 2018 filed with the SEC on February 19, 2019 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 pharma services and pharmaceutical company that operates through two business segments: a revenue-generating CDMO segment and an Acute Care segment. Each of these segments are deemed to be reportable segments for financial reporting purposes.

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 or profit sharing, and research and development, which support continued operations for our CDMO segment and have contributed excess cash flow to be used for activities in our Acute Care segment. We operate a 97,000 square foot, DEA-licensed manufacturing facility in Gainesville, Georgia, as well as a 24,000 square foot development and high potency product facility in Gainesville, Georgia that we opened in October 2018. 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 primarily derived from manufacturing, and royalty revenues, as well as research and development services performed for partners.

Our Acute Care segment is primarily focused on innovative products for hospital and other 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 July 2017, we submitted an NDA to the FDA, for our lead investigational product candidate IV meloxicam 30 mg for the management of moderate to severe pain. In May 2018, we received a CRL from the FDA regarding our NDA for IV meloxicam. We resubmitted the NDA for IV meloxicam in September 2018 and in March 2019, we received a second CRL from the FDA regarding our NDA for IV meloxicam. In April 2019, we announced we had implemented a strategic restructuring initiative, and corresponding reduction in the Acute Care segment workforce, aimed at reducing operating expenses, while maintaining key personnel needed to partner the product and obtain FDA approval of IV meloxicam. We plan to pursue resolution of the IV meloxicam CRL, including appeal to one or more levels, if required. Our Acute Care segment has no revenue and historically 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. In light of the strategic restructuring, the operating expenses for Acute Care will be greatly reduced following the restructuring and associated costs incurred in the first half of 2019. The Company and the Board of Directors continue to explore partnering opportunities for IV meloxicam and to evaluate other possible structures, including the plan to spin out the Acute Care segment and have the CDMO business and the Acute Care business as two separately traded companies.

We have incurred losses and generated negative cash flows from operations since inception and expect to continue to incur operating losses for 2019. Due to cost reductions from the strategic restructuring following the receipt of the second CRL, we expect to be cash flow positive in the second half of 2019 (excluding the impact from any potential partnering or strategic transactions). 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 cash flow generated by our CDMO segment primarily to fund operations at our Gainesville, Georgia manufacturing facilities, to make payments under our credit facility and to partially fund our development and pre-commercialization activities of our Acute Care segment. We believe our CDMO segment will continue to contribute cash for general corporate purposes and support the IV meloxicam appeal process, maintenance of our other product candidates, explore partnering opportunities and plan for other possible structures.

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. 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, according to the agreement, as amended, we were required to pay up to an additional \$140.0 million in milestone payments, including regulatory and net sales milestones, and a royalty percentage of future product net sales related to IV meloxicam. In December 2018, we entered into an Amendment to the Purchase and Sale Agreement with Alkermes, which restructured the \$45.0 million milestone originally due upon FDA approval of IV meloxicam to (i) a \$5.0 million payment made within 30 days of the amendment; (ii) a \$5.0 million payment made by April 23, 2019; (iii) a \$5.0 million payment due within 180 days following approval of an NDA for IV meloxicam; and (iv) an additional \$45.0 million following approval of an NDA for injectable meloxicam, payable over a seven year period. In addition, we amended our warrant held by Alkermes to decrease the exercise price to \$8.26 per share. As of June 30, 2019, we have paid \$10.0 million in milestone payments to Alkermes.

Following the receipt of the second CRL, we implemented a strategic restructuring initiative, and corresponding reduction in the Acute Care segment workforce, aimed at reducing operating expenses, while maintaining key personnel needed to select a partner and obtain FDA approval of IV meloxicam. The restructuring initiative included a reduction of a majority of our Acute Care segment workforce of approximately 50 positions. We have incurred approximately \$7.2 million of costs in connection with the strategic restructuring plan (\$6.0 million of which was incurred during the three months ended June 30, 2019), which includes severance and related termination benefits and canceled marketing and production costs.

Financial Overview

Revenues

During the six months ended June 30, 2019 and 2018 we recognized revenues from three revenue streams—manufacturing revenue, royalty revenue and research and development revenue. This 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 judgment 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 revenue that compensates us for services performed at our CDMO, such as formulation, process development, and preparation of pre-clinical and clinical drug product materials prepared by our CDMO segment under research and development arrangements with partners. 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 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 by our Acute Care segment 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 drug supply and related manufacturing services and pre-commercial product validation and 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 have related 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 costs, timing and outcome of regulatory review of a product candidate, including, with respect to IV meloxicam, 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 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, 2018.

Development timelines, probability of success and development costs vary widely. As a result of the uncertainties discussed above, we will assess our IV meloxicam development program based on additional available information as we progress through our discussions with the FDA around the CRL regarding our NDA for IV meloxicam and assess IV meloxicam’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 expend in the future on IV meloxicam prior to regulatory approval, if such approval is ever granted. As a result of these uncertainties surrounding the timing and outcome of any approval, 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 as we seek to obtain regulatory approval for IV meloxicam, and if successful in obtaining regulatory approval, advance IV meloxicam through the commercialization scale-up and other activities. We also expect to have expenses related to development of our other product candidates. We may elect to seek collaborative relationships in order to provide us with diversified revenue stream and to help facilitate the development and commercialization of our product candidate pipeline. We expect our research and development costs to decrease as we restructure and reduce clinical and pre-commercialization manufacturing activities for IV meloxicam and our other pipeline associated activities.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, pre-commercial, finance and information technology functions. General and administrative expenses also include professional fees for legal, including patent-related expenses, consulting, auditing and tax services and CDMO business development activities. In light of the restructuring and our decision to seek a partner for IV meloxicam, our future expected general and administrative expenses related to pre-commercial costs has been substantially reduced.

We currently expect our general and administrative expenses to be lower for the second half of 2019 as we progress through our discussions with the FDA regarding the CRL and operating under our new structure. 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. If the associated research and development effort is abandoned, the related assets will be written-off, and we will record a noncash impairment loss on our 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.

Change in Fair Value of Contingent Consideration

Pursuant to the Purchase and Sale Agreement for the Gainesville Transaction, as amended in December 2018, we are required to pay up to an additional \$140.0 million in milestone payments, including \$10.0 million during the first half of 2019, another \$5.0 million due within 180 days of approval of IV meloxicam and \$45.0 million over seven years beginning one year after approval, 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 continued to reevaluate the fair value each subsequent period and as of June 30, 2019 recorded a \$61.8 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 gain. As of June 30, 2019, we have paid \$10.0 million in milestone payments to Alkermes.

Change in Fair Value of Warrants

We have classified as liabilities certain warrants outstanding that 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 three months ended June 30, 2019 and 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.

Net Operating Losses and Tax Carryforwards

As of December 31, 2018, we had approximately \$21.3 million of federal net operating loss carryforwards. We also had federal and state research and development tax credit carryforwards of \$4.3 million available to offset future taxable income. U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. With the exception of the 2018 federal net operating loss which has an indefinite carry forward period, these federal and state net operating loss and federal and state tax credit carryforwards will begin to expire at various dates beginning in 2028, if not utilized. As of December 31, 2018, we had also generated foreign net operating loss carryforwards in Ireland of approximately \$92.8 million. We currently anticipate that we would continue to book a full valuation allowance against the deferred tax asset until there is sufficient evidence to support the reversal of all or a portion of the valuation allowance.

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. 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, we may undergo further ownership changes in the future, including changes to our organizational structure relating to foreign operations, purchases, sales and licenses, spin-offs, bad debt write-offs, 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.

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 the current and 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.
- Given our taxable losses in the U.S., we will be limited in our ability to deduct interest expense, and any disallowed interest expense for 2018 and tax years following will result in an indefinite carry forward until such time as we meet the taxable income thresholds required to deduct interest expense.

Results of Operations

Comparison of the Three Months Ended June 30, 2019 and 2018

	Three Months Ended June 30,	
	2019	2018
	(amounts in thousands)	
Revenue	\$ 31,256	\$ 21,739
Operating expenses:		
Cost of sales (excluding amortization of intangible assets)	14,100	12,071
Research and development	7,180	10,157
General and administrative	9,997	12,955
Amortization of intangible assets	646	646
Change in warrant valuation	1,041	(1,139)
Change in contingent consideration valuation	(4,059)	396
Total operating expenses	28,905	35,086
Operating loss	2,351	(13,347)
Other income (expense):		
Interest expense, net	(5,188)	(2,075)
Loss before income taxes	(2,837)	(15,422)
Income tax benefit	—	2,707
Net loss	<u>\$ (2,837)</u>	<u>\$ (12,715)</u>

Revenue and costs of sales. Our revenues were \$31.3 million and \$21.7 million and cost of sales were \$14.1 million and \$12.1 million for the three months ended June 30, 2019 and 2018, respectively. The increase of \$9.6 million in revenue was primarily due to increased royalties recognized from two of our commercial partners and an increase in product sales to one of our commercial partners. Cost of sales increased \$2.0 million primarily due to expansion of our service and development capabilities as well as growth in manufacturing demand which was partially offset by operating efficiencies gained as a result of higher production volumes.

Research and Development. Our research and development expenses were \$7.2 million and \$10.2 million for the three months ended June 30, 2019 and 2018, respectively. Excluding \$2.6 of costs associated with the strategic restructuring initiative recorded in the three months ended June 30, 2019, the decrease of \$5.6 million was primarily due to a decrease in pre-commercialization manufacturing costs for IV meloxicam, the shift in focus of our CDMO formulation and development capabilities to cost of sales activities, a decrease in development costs for other pipeline products and a decrease in personnel costs.

General and Administrative. Our general and administrative expenses were \$10.0 million and \$13.0 million for the three months ended June 30, 2019 and 2018, respectively. Excluding \$3.4 million of costs associated with the strategic restructuring initiative recorded in the three months ended June 30, 2019, the decrease of \$6.4 million was due to a reduction in commercial team personnel and related costs following the receipt of the second CRL, which suspended our preparation of the anticipated launch of IV meloxicam.

Amortization of Intangible Assets. Amortization expense was \$0.6 million for each of the three months ended June 30, 2019 and 2018, 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 \$5.2 million and \$2.1 million during the three months ended June 30, 2019 and 2018, respectively. The increase of \$3.1 million was primarily due to the higher principal balance on our Athyrium senior secured term loan and amortization of the related financing costs.

Income Tax Benefit. We believe that it is more likely than not that the deferred income tax assets associated with our federal, state and foreign operations will not be realized, and as such, there is a full valuation allowance against our deferred tax assets related to the losses. As a result of the recording of a full valuation allowance, there was no income tax benefit for the three months ended June 30, 2019. For the three months ended June 30, 2018, the income tax benefit was \$2.7 million, which was recorded prior to the recording of the full valuation allowance for United States operations in the fourth quarter of 2018.

Operating Income (Loss) per Segment.

CDMO Segment-

Our CDMO segment's revenues were \$31.3 million and \$21.7 million in the three months ended June 30, 2019 and 2018, respectively. The increase of \$9.6 million in revenue was primarily due to increased royalties recognized from two of our commercial partners and an increase in product sales to one of our commercial partners.

Our CDMO segment's operating expenses (including cost of sales) increased by \$1.2 million, from \$14.5 million in the three months ended June 30, 2018 to \$15.7 million in the three months ended June 30, 2019. Cost of sales were \$14.1 million and \$12.1 million in the three months ended June 30, 2019 and 2018, respectively. Cost of sales increased by \$2.0 million due to expansion of our service and development capabilities as well as growth in manufacturing demand which was offset by operating efficiencies gained as a result of higher production volumes. Research and development expenses decreased by \$1.4 million due to the shift in focus of our formulation and development capabilities to cost of sales activities and general and administration expenses increased by \$0.6 million due to increased business development activities. All of the above contributed to CDMO segment's operating income of \$15.5 million for the three months ended June 30, 2019, which included non-cash charges of \$2.1 million for depreciation and amortization and \$0.4 million for stock-based compensation.

Acute Care Segment-

Our Acute Care segment's operating expenses (excluding non-cash charges for contingent consideration and warrants) decreased \$5.2 million from \$21.4 million in the three months ended June 30, 2018 to \$16.2 million in the three months ended June 30, 2019. Excluding the \$6.0 million of costs associated with the strategic restructuring initiative recorded in the three months ended June 30, 2019, Acute Care segment's operating expenses (excluding non-cash charges for contingent consideration and warrants) decreased \$11.2 million in three months ended June 30, 2019 compared to the prior year period. Research and development expenses, excluding the strategic restructuring costs, decreased \$4.2 million as a result of a decrease in pre-commercialization manufacturing costs for IV meloxicam, a decrease in development costs for other pipeline products and a decrease in personnel costs. General and administrative costs, excluding the strategic restructuring costs, decreased by \$7.0 million as a result of decreased salaries and benefits and decreased pre-commercialization marketing expenses following the receipt of the second CRL, which halted our preparation of the anticipated launch of IV meloxicam. The non-cash charge for contingent consideration decreased by \$4.5 million due to the adjusted timing of estimated milestone and royalty payments and the non-cash change in value of warrants increased by \$2.2 million primarily as a result of the increase in our stock price. All of the above contributed to our Acute Care segment's operating loss of \$13.2 million for the three months ended June 30, 2019, which also included non-cash charges of \$2.1 million for stock-based compensation, depreciation and amortization.

Comparison of the Six Months Ended June 30, 2019 and 2018

	Six Months Ended June 30,	
	2019	2018
	(amounts in thousands)	
Revenue	\$ 56,322	\$ 41,281
Operating expenses:		
Cost of sales (excluding amortization of intangible assets)	28,491	22,561
Research and development	16,734	18,599
General and administrative	24,175	22,473
Amortization of intangible assets	1,292	1,292
Change in warrant valuation	779	(365)
Change in contingent consideration valuation	(19,150)	2,916
Total operating expenses	52,321	67,476
Operating income (loss)	4,001	(26,195)
Other income (expense):		
Interest expense, net	(8,815)	(4,037)
Loss before income taxes	(4,814)	(30,232)
Income tax benefit	—	5,060
Net loss	\$ (4,814)	\$ (25,172)

Revenue and costs of sales. Our revenues were \$56.3 million and \$41.3 million and cost of sales were \$28.5 million and \$22.6 million for the six months ended June 30, 2019 and 2018, respectively. The increase of \$15.0 million in revenue was due to increased royalties recognized from one of our commercial partners and an increase in product sales to various commercial partners. Cost of sales increased \$5.9 million due to expansion of our service and development capabilities as well as growth in manufacturing demand which was partially offset by operating efficiencies gained as a result of higher production volumes.

Research and Development. Our research and development expenses were \$16.7 million and \$18.6 million for the six months ended June 30, 2019 and 2018, respectively. Excluding \$2.8 of costs associated with the strategic restructuring initiative recorded in the six months ended June 30, 2019, the decrease of \$4.7 million was primarily due to the shift in focus of our CDMO formulation and development capabilities to cost of sales activities, a decrease in pre-commercialization manufacturing costs for IV meloxicam and a decrease in personnel costs. These decreases were partially offset by an increase in development costs for other pipeline products prior to the second CRL.

General and Administrative. Our general and administrative expenses were \$24.2 million and \$22.5 million for the six months ended June 30, 2019 and 2018, respectively. Excluding \$4.4 million of costs associated with the strategic restructuring initiative recorded in the six months ended June 30, 2019, the decrease of \$2.7 million was due to a reduction in commercial team personnel and pre-commercial consulting costs in preparation of the anticipated launch of IV meloxicam following the receipt of the second CRL. These decreases in costs were offset by increases in costs associated with the debt financing, public company costs including legal fees, business development costs in our CDMO segment as well as increased professional fees associated with addressing the first and second CRLs 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, 2019 and 2018, 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 \$8.8 million and \$4.0 million during the six months ended June 30, 2019 and 2018, respectively. The increase of \$4.8 million was primarily due to the higher principal balance on our Athyrium senior secured term loan and amortization of the related financing costs.

Income Tax Benefit. We believe that it is more likely than not that the deferred income tax assets associated with our federal, state and foreign operations will not be realized, and as such, there is a full valuation allowance against our deferred tax assets related to the losses. As a result of the recording of a full valuation allowance, there was no income tax benefit for the six months ended June 30, 2019. For the six months ended June 30, 2018, the income tax benefit was \$5.1 million, which was recorded prior to the recording of the full valuation allowance for United States operations in the fourth quarter of 2018.

Operating Income (Loss) per Segment.

CDMO Segment-

Our CDMO segment's revenues were \$56.3 million and \$41.3 million for the six months ended June 30, 2019 and 2018, respectively. The increase of \$15.0 million in revenue was primarily due to increased royalties recognized from one of our commercial partners and an increase in product sales to various commercial partners.

Our CDMO segment's operating expenses (including cost of sales) increased by \$4.1 million, from \$27.5 million in the six months ended June 30, 2018 to \$31.6 million in the six months ended June 30, 2019. Cost of sales were \$28.5 million and \$22.6 million in the six months ended June 30, 2019 and 2018, respectively. Cost of sales increased \$5.9 million due to expansion of our service and development capabilities as well as growth in manufacturing demand which was offset by operating efficiencies gained as a result of higher production volumes. Research and development expenses decreased by \$2.8 million due to the shift in focus of our formulation and development capabilities to cost of sales activities and general and administration expenses increased by \$1.0 million due to increased business development activities. All of the above contributed to our CDMO segment's operating income of \$24.6 million for the six months ended June 30, 2019, which included non-cash charges of \$4.1 million for depreciation and amortization and \$0.9 million for stock-based compensation.

Acute Care Segment-

Our Acute Care segment's operating expenses (excluding non-cash charges for contingent consideration and warrants) increased \$1.4 million from \$37.5 million in the six months ended June 30, 2018 to \$38.9 million in the six months ended June 30, 2019. Excluding the \$7.2 million of costs associated with the strategic restructuring initiative recorded in the six months ended June 30, 2019, Acute Care segment's operating expenses (excluding non-cash charges for contingent consideration and warrants) decreased \$5.8 million in the six months ended June 30, 2019 compared to the prior year period. Research and development expenses, excluding the strategic restructuring costs, decreased \$1.9 million as a result of a decrease in pre-commercialization manufacturing costs for IV meloxicam and a decrease in personnel costs. These decreases were partially offset by an increase in development costs for other pipeline products prior to the second CRL. General and administrative costs, excluding the strategic restructuring costs, decreased by \$3.9 million as a result of decreased commercial team personnel and pre-commercial consulting costs in preparation of the anticipated launch of IV meloxicam following the receipt of the second CRL. These decreases in costs were offset by an increase in costs associated with the debt financing, public company costs including legal fees, as well as increased professional fees associated with addressing the first and second CRLs issued by the FDA regarding our NDA for IV meloxicam. The non-cash charge for contingent consideration decreased by \$22.1 million due to the adjusted timing of estimated milestone and royalty payments and the non-cash change in value of warrants increased by \$1.1 million primarily as a result of the increase in our stock price. All of the above contributed to our Acute Care segment's operating loss of \$20.6 million for the six months ended June 30, 2019, which also included non-cash charges of \$4.5 million for stock-based compensation, depreciation and amortization.

Liquidity and Capital Resources

As of June 30, 2019, we had \$32.4 million in cash, cash equivalents and short-term investments.

Since inception through June 30, 2019, 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 \$133.5 million, and term loans made under our previous and existing credit facilities, including our credit facility with Athyrium with an outstanding balance of \$125.0 million and contributions of excess cash flow from our CDMO segment.

We continue to explore partnering discussions regarding IV meloxicam and other possible corporate structures, including the plan to spin out the Acute Care segment and have the CDMO business and the Acute Care business as two separately traded companies. In order to proceed with the development of our product candidates, make the payments which may become due, including milestone payments owed to Alkermes or other licensing partners, to commercialize IV meloxicam, if approved, to commence our clinical trial programs of our other product candidates, to commercialize any of our other product candidates or technologies that receive regulatory approval and to enhance our sales and marketing efforts for additional products we may acquire, we would need to raise substantial additional funding. 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 any corporate reorganization regarding the Acute Care segment, our ability to timely and adequately resolve the second 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, the timing of approval of IV meloxicam, our ability to partner IV meloxicam for commercialization, the level of market acceptance of IV meloxicam and the costs of commercialization activities for IV meloxicam, if approved, as well as, the continued profitability of our CDMO segment, and our ability to raise additional funds through debt refinancing, bank or other loans, licensing, including out-licensing activities, sale of assets 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 upon an initial \$60.0 million term loan. We used the proceeds from the 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. In December 2018 we amended the credit agreement with Athyrium and drew upon a \$10.0 million term B-1 loan. In February 2019, we entered into a second amendment to the credit agreement with Athyrium pursuant to which the credit facility was (i) expanded from \$100.0 million to \$125.0 million and (ii) the two additional \$15.0 million tranches were restructured into a \$55.0 million term B-2 loan, which was funded on the date of execution of the Second Amendment, net of the original issue discount of \$11.4 million. Beginning on March 31, 2021, we must repay the outstanding principal amount in quarterly installments of \$3.0 million with the outstanding principal balance due on March 31, 2023. As of June 30, 2019, we had \$125.0 million outstanding principal under our credit agreement with Athyrium.

Sources and Uses of Cash

Cash used in operations was \$27.8 million and \$24.2 million for the six months ended June 30, 2019 and 2018, respectively, which represents our operating losses less our stock-based compensation, depreciation, non-cash interest expense, changes in fair value of warrants and contingent consideration and amortization of intangibles, as well as changes in operating assets and liabilities.

Cash used in investing activities was \$11.1 million for the six months ended June 30, 2019. Cash provided by investing activities was \$0.5 million for the six months ended June 30, 2018. This reflected cash used for the purchases of short-term investments and for the purchases of property and equipment partially offset by the related maturities of short-term investments. During the six months ended June 30, 2019, our capital expenditures were \$9.1 million, which primarily related to the investment in our CDMO capabilities to scale and support our anticipated growth.

There was \$30.8 million of cash provided by financing activities in the six months ended June 30, 2019 from net proceeds of issuance of long-term debt of \$43.6 million and \$1.1 million of cash from proceeds related to stock option exercises, which was partially offset by \$10.0 million of contingent consideration payments, deferred financing costs of \$2.9 million from the Athyrium transaction, and \$1.0 million of payments of withholdings on shares withheld for income taxes. 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 \$1.0 million of cash provided by financing activities from proceeds related to stock option exercises, 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:

- 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 continue profitability in our CDMO segment;
- 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 resolve the deficiencies identified by the FDA in the second CRL, for IV meloxicam;
- whether the FDA will approve an amended NDA for IV meloxicam and, if approved, the labeling under any such approval that we may obtain;
- the time frame associated with resolving the deficiencies identified by the FDA in the second CRL and whether the FDA will require additional clinical studies to support the approval of IV meloxicam and the time and cost of such studies;
- the timing of the Gainesville Transaction regulatory milestone payments and other contingent consideration;
- the costs of manufacturing scale-up and commercialization activities, for IV meloxicam, if approved;
- the level of market acceptance of IV meloxicam, if approved;
- the extent to which we in-license, acquire or invest in products, businesses and technologies;

- our ability to raise additional funds through equity or debt financings or sale of certain assets;
- our ability to successfully evaluate and execute on other possible organization structures, including but not limited to, the possibility of a separation of the Acute Care segment from the entity containing the CDMO segment;
- 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, 2019:

Contractual Obligations	Payments Due by Period (in 000s)				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Long-Term Debt Obligations (1):					
Athyrium Debt	\$ 126,250	\$ —	\$ 18,000	\$ 108,250	\$ —
Interest on Debt	49,808	15,493	29,353	4,962	—
Purchase Obligations (2):	11,125	6,370	1,075	—	—
Operating Leases (3)	2,433	712	1,053	499	169
Other Long-Term Liabilities:					
Other License Commitments and Milestone payments (4), (5)	53,765	40	130	170	225
Alkermes Payments (6)	130,000	—	—	—	—
Employment Agreements (7)	947	947	—	—	—
Total Contractual Obligations	\$ 374,328	\$ 23,562	\$ 49,611	\$ 113,881	\$ 394

- (1) The long-term debt obligations consist of principal, an exit fee of 1% of the principal, and interest on the \$125.0 million outstanding principal under our \$125.0 million credit facility with Athyrium as of June 30, 2019. 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 of June 27, 2019 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. The timing of certain purchase commitments cannot be estimated as it is dependent on timing of FDA approval or the outcome of other strategic evaluations. 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 neuromuscular blocking agents, or NMBAs, 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 NMBAs. 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, 2019, 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 2020. 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.

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 for the fiscal year ended December 31, 2018 filed with the SEC on February 19, 2019. In the six months ended June 30, 2019, there were no significant changes to the application of critical accounting policies previously disclosed in our most recent Annual Report on Form 10-K.

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 for the fiscal year ended December 31, 2018 filed with the SEC on February 19, 2019.

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, 2019. 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, 2019, 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.

None.

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 fiscal year ended December 31, 2018 and our Quarterly Report of Form 10-Q for the quarterly period ended March 31, 2019.

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:

EXHIBIT INDEX

Exhibit No.	Description	Method of Filing
10.1	<u>Supplemental Agreement No. 3 to the Amended and Restated License and Supply Agreement, dated as of April 15, 2019, by and between Recro Gainesville LLC and Teva Pharmaceutical Industries Ltd.</u>	Incorporated herein by reference to Exhibit 10.1 to the Company's current report on Form 8-K filed on April 18, 2019 (File No. 001-36329).
10.2	<u>Separation and Mutual Release Agreement, dated as of May 14, 2019, by and between Recro Pharma, Inc. and Michael Celano.</u>	Incorporated herein by reference to Exhibit 10.1 to the Company's current report on Form 8-K filed on May 9, 2019 (File No. 001-36329).
31.1	<u>Rule 13a-14(a)/15d-14(a) certification of Principal Executive Officer.</u>	Filed herewith.
31.2	<u>Rule 13a-14(a)/15d-14(a) certification of Principal Financial and Accounting Officer.</u>	Filed herewith.
32.1	<u>Section 1350 certification, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>	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 8, 2019

By: /s/ Gerri A. Henwood

Gerri A. Henwood
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 8, 2019

By: /s/ Ryan D. Lake

Ryan D. Lake
Chief Financial Officer
(Principal Financial and Accounting Officer)

CERTIFICATION

I, Gerri A. Henwood, certify that:

1. I have reviewed this Quarterly Report of Recro Pharma, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2019

/s/ Gerri A. Henwood

Gerri A. Henwood
President and Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION

I, Ryan D. Lake, certify that:

1. I have reviewed this Quarterly Report of Recro Pharma, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2019

/s/ Ryan D. Lake

Ryan D. Lake
Chief Financial Officer
(Principal Financial and Accounting Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Recro Pharma, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to such officer's knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 8, 2019

/s/ Gerri A. Henwood

Gerri A. Henwood
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Ryan D. Lake

Ryan D. Lake
Chief Financial Officer
(Principal Financial and Accounting Officer)