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

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the Quarterly Period Ended: September 30, 2018

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

Recro Pharma, Inc.

(Exact name of registrant as specified in its charter)

Pennsylvania	26-1523233
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
490 Lapp Road, Malvern, Pennsylvania	19355
(Address of principal executive offices)	(Zip Code)

(484) 395-2470

(Registrant’s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically 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	Accelerated filer
Non-accelerated filer	Smaller reporting company
	Emerging growth company

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of November 5, 2018, there were 21,477,498 shares of common stock, par value $0.01 per share, outstanding.

TABLE OF CONTENTS

Index

		Page
PART I. FINANCIAL INFORMATION		3
Item 1.	Consolidated Financial Statements (Unaudited)	3
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	26
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	37
Item 4.	Controls and Procedures	37
PART II. OTHER INFORMATION		38
Item 1.	Legal Proceedings	38
Item 1A.	Risk Factors	38
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	39
Item 3.	Defaults Upon Senior Securities	39
Item 4.	Mine Safety Disclosures	39
Item 5.	Other Information	39
Item 6.	Exhibits	39
SIGNATURES		41

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)	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 35,788	$ 60,984
Short-term investments	1,243	3,498
Accounts receivable	11,745	9,686
Contract asset	7,465	—
Inventory	10,182	9,839
Prepaid expenses and other current assets	3,274	3,276
Total current assets	69,697	87,283
Property, plant and equipment, net	41,528	39,074
Deferred income taxes	25,066	18,573
Intangible assets, net	32,912	34,850
Goodwill	6,446	6,446
Total assets	$ 175,649	$ 186,226
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 4,888	$ 7,954
Accrued expenses and other current liabilities	12,295	9,897
Current portion of contingent consideration	33,957	32,053
Total current liabilities	51,140	49,904
Long-term debt, net	54,675	53,598
Warrants and other long-term liabilities	801	3,516
Long-term portion of contingent consideration	55,486	50,360
Total liabilities	162,102	157,378
Commitments and contingencies (Note 13)		
Shareholders' equity:		
Preferred stock, $0.01 par value. Authorized, 10,000,000 shares; none issued and outstanding	—	—
Common stock, $0.01 par value. Authorized, 50,000,000 shares; issued and outstanding, 20,727,498 shares at September 30, 2018 and 19,127,435 shares at December 31, 2017	207	191
Additional paid-in capital	160,296	140,006

Accumulated deficit	(146,956)	(111,348)
Accumulated other comprehensive loss	—	(1)
Total shareholders' equity	13,547	28,848
Total liabilities and shareholders' equity	$ 175,649	$ 186,226

See accompanying notes to consolidated financial statements.

RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(amounts in thousands, except share and per share data)	For the Three Months Ended September 30, 2018	2017	For the Nine Months Ended September 30, 2018	2017
Revenue	$18,283	$17,114	$59,564	$52,790
Operating expenses:				
Cost of sales (excluding amortization of intangible assets)	8,472	6,882	31,033	27,829
Research and development	11,348	9,296	29,947	24,132
General and administrative	6,969	6,635	29,442	16,990
Amortization of intangible assets	646	646	1,938	1,937
Change in warrant valuation	287	808	(78)	15
Change in contingent consideration valuation	4,115	3,550	7,030	9,323
Total operating expenses	31,837	27,817	99,312	80,226
Operating loss	(13,554)	(10,703)	(39,748)	(27,436)
Other income (expense):				
Interest income	126	62	382	284
Interest expense	(2,198)	(1,235)	(6,490)	(3,625)
Net loss before income taxes	(15,626)	(11,876)	(45,856)	(30,777)
Income tax benefit	2,370	2,821	7,430	4,780
Net loss	$(13,256)	$(9,055)	$(38,426)	$(25,997)
Per share information:				
Net loss per share of common stock, basic and diluted	$(0.64)	$(0.48)	$(1.91)	$(1.36)
Weighted average common shares outstanding, basic and diluted	20,721,330	19,058,956	20,122,569	19,053,636
Net loss	$(13,256)	$(9,055)	$(38,426)	$(25,997)
Other comprehensive loss:				
Unrealized gain/(loss) on available-for-sale securities	—	68	1	(8)
Comprehensive loss	$(13,256)	$(8,987)	$(38,425)	$(26,005)

See accompanying notes to consolidated financial statements.

RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Shareholders' Equity

For the Nine Months Ended September 30, 2018

(Unaudited)

(amounts in thousands, except share data)	Common Stock Shares	Amount	Additional paid-in capital	Accumulated Deficit	Accumulated other comprehensive loss	Total
Balance, December 31, 2017	19,127,435	$ 191	$ 140,006	$ (111,348)	$ (1)	$ 28,848
Stock-based compensation expense	—	—	5,250	—	—	5,250
Stock option exercise	179,562	2	1,056	—	—	1,058
Issuance of restricted stock units, net of shares withheld for income taxes	122,746	1	(92)	—	—	(91)
Sale of common stock under equity facility, net of transaction costs	1,083,040	11	11,489	—	—	11,500
Cashless exercise of warrants	214,715	2	2,587	—	—	2,589
Change in other comprehensive loss	—	—	—	—	1	1
Net loss	—	—	—	(38,426)	—	(38,426)
Cumulative effect of adoption of new accounting standards, net of tax	—	—	—	2,818	—	2,818
Balance, September 30, 2018	20,727,498	$ 207	$ 160,296	$ (146,956)	$ —	$ 13,547

See accompanying notes to consolidated financial statements.

RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

(Unaudited)

	For the Nine Months Ended September 30,	
(amounts in thousands)	2018	2017
Cash flows from operating activities:		
Net loss	$ (38,426)	$ (25,997)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	5,250	4,265
Non-cash interest expense	968	612
Depreciation expense	3,819	3,655
Amortization	1,938	1,937
Acquired in-process research and development charges	—	766
Change in warrant valuation	(78)	15
Change in contingent consideration valuation	7,030	9,323
Deferred income taxes	(7,430)	(4,698)
Changes in operating assets and liabilities:		
Inventory	(343)	(1,146)
Contract asset	(3,710)	—
Prepaid expenses and other current assets	170	(1,667)
Accounts receivable	(2,059)	(2,715)
Accounts payable, accrued expenses and other liabilities	(2,192)	(2,391)
Net cash used in operating activities	(35,063)	(18,041)
Cash flows from investing activities:		
	(4,363)	(4,586)

Purchase of property and equipment				
Purchase of short-term investments		(6,225)		(55,626)
Proceeds from maturity of investments		8,500		26,000
Acquisition of license agreement		(82)		(437)
Net cash used in investing activities		(2,170)		(34,649)
Cash flows from financing activities:				
Payment of deferred financing costs		(261)		—
Proceeds from sale of common stock, net of transaction costs		11,331		—
Payments of withholdings on shares withheld for income taxes		(91)		(17)
Proceeds from option exercise		1,058		27
Net cash provided by financing activities		12,037		10
Net decrease in cash and cash equivalents		(25,196)		(52,680)
Cash and cash equivalents, beginning of period		60,984		64,483
Cash and cash equivalents, end of period	$	35,788	$	11,803
Supplemental disclosure of cash flow information:				
Cash paid for interest	$	6,214	$	3,122
Cash paid for taxes	$	—	$	467
Purchase of property, plant and equipment included in accrued expenses and accounts payable	$	3,185	$	774
Withholdings on shares withheld for income taxes included in accrued expenses	$	—	$	233

Retirement of fully depreciated property, plant and equipment	$	30	$	152
Common stock issued in connection with equity facility	$	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 specialty pharmaceutical company that operates through two business divisions: an Acute Care division and a revenue-generating contract development and manufacturing, or CDMO division. Each of these divisions are deemed to be reportable segments (see Note 3(m) and Note 17). The Acute Care division is primarily focused on developing innovative products for hospital and other acute care settings, and the CDMO division leverages the Company's formulation expertise to develop and manufacture pharmaceutical products using the Company's proprietary delivery technologies for commercial partners who commercialize or plan to commercialize these products. On April 10, 2015, the Company acquired from Alkermes plc, or Alkermes, worldwide rights to intravenous and intramuscular, or injectable, meloxicam, a proprietary long-acting preferential COX-2 inhibitor being developed for the management of moderate to severe pain, as well as a contract manufacturing facility, royalty and formulation business in Gainesville, Georgia. The acquisition is referred to herein as the Gainesville Transaction. In July 2017, the Company submitted a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or the FDA, for its lead investigational product candidate intravenous, or IV, meloxicam 30 mg for the management of moderate to severe pain. In May 2018, the Company received a Complete Response Letter, or CRL, from the FDA regarding its NDA for IV meloxicam. In July 2018, the Company participated in a Type A End-of-Review meeting with the FDA to discuss the topics covered in the CRL. Upon receipt and review of the meeting minutes, the Company resubmitted the NDA for IV meloxicam in September 2018. The FDA has set a date for decision on the NDA under the Prescription Drug User Fee Act, or PDUFA, of March 24, 2019.

(2) Development-Stage Risks and Liquidity

The Company has incurred losses from operations since inception and has an accumulated deficit of $146,956 as of September 30, 2018. Though its CDMO segment has been profitable, the Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its products currently in development. Additional financing will be needed by the Company to fund its operations and to commercially develop its product candidates, including the payment of the Gainesville Transaction contingent payments, which may become due upon achievement of certain development and commercialization milestones for meloxicam (see Note 4). Insufficient funds may cause the Company to delay, reduce the scope of or eliminate one or more of its development, commercialization or expansion activities. The Company may raise such funds through debt refinancing, bank or other loans, sale of assets, through strategic research and development, licensing (including out-licensing) and/or marketing arrangements or through public or private sales of equity or debt securities from time to time. Financing may not be available on acceptable terms, or at all, and failure to raise capital when needed could materially adversely impact the Company's growth plans and its financial condition or results of operations. Additional debt or equity financing, if available, may be dilutive to the holders of its common stock and may involve significant cash payment obligations and covenants that restrict the Company's ability to operate its business. The Company's future operations are highly dependent on a combination of factors, including (i) the continued profitability of the CDMO segment; (ii) the timely and successful completion of additional financing and/or alternative sources of capital, debt, partnering or out-licensing transactions; (iii) the success of its research and development, including the results and timing of its clinical trials; (iv) the development of competitive therapies by other biotechnology and pharmaceutical companies; and, ultimately,

(v) regulatory approval and market acceptance of the Company's proposed future products, including IV meloxicam. Management believes that it is probable that the Company will be able to meet its obligations as they become due within one year after the date of the financial statements are issued.

(3) Summary of Significant Accounting Principles

(a) Basis of Presentation and Principles of Consolidation

The accompanying unaudited consolidated financial statements of the Company and its subsidiaries have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP, for interim financial information and with the instructions of Form 10-Q and Article 10 of Regulation S-X and, therefore, do not include all of the information and notes required by U.S. GAAP for complete annual financial statements. The Company's consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated. In the opinion of management, the accompanying consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company's results for the interim periods. Operating results for the three and nine months ended September 30, 2018 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2018.

The accompanying unaudited interim consolidated financial statements should be read in conjunction with the annual audited financial statements and related notes as of and for the year ended December 31, 2017 included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2017.

(b) Use of Estimates

The preparation of financial statements and the notes to the financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from such estimates.

(c) Cash and Cash Equivalents

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

(d) Property and Equipment

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

(e) Business Combinations

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

(f) Goodwill and Intangible Assets

Goodwill represents the excess of purchase price over the fair value of net assets acquired by the Company. Goodwill is not amortized but assessed for impairment on an annual basis or more frequently if impairment indicators exist. The impairment model prescribes a two-step method for determining impairment.

The first step compares a reporting unit's fair value to its carrying amount to identify potential goodwill impairment. If the carrying amount of a reporting unit exceeds the reporting unit's fair value, the second step of the impairment test must be completed to measure the amount of the reporting unit's goodwill impairment loss, if any. Step two requires an assignment of the reporting unit's fair value to the reporting unit's assets and liabilities to determine the implied fair value of the reporting unit's goodwill. The implied fair value of the reporting unit's goodwill is then compared with the carrying amount of the reporting unit's goodwill to determine the goodwill impairment loss to be recognized, if any.

Intangible assets include the Company’s royalties and contract manufacturing relationships intangible asset as well as an IPR&D asset. The royalties and contract manufacturing relationships intangible asset is considered a definite-lived intangible asset and is amortized on a straight-line basis over a useful life of six years.

Intangible assets related to IPR&D are considered indefinite-lived intangible assets and are assessed for impairment annually or more frequently if impairment indicators exist. If the associated research and development effort is abandoned, the related assets will be written-off, and the Company will record a noncash impairment loss on its Consolidated Statements of Operations and Comprehensive Loss. For those compounds that reach commercialization, the IPR&D assets will be amortized over their estimated useful lives.

The impairment test for indefinite-lived intangible assets is a one-step test, which compares the fair value of the intangible asset to its carrying value. If the carrying value exceeds its fair value, an impairment loss is recognized in an amount equal to the excess. Based on accounting standards, it is required that these assets be assessed at least annually for impairment unless a triggering event occurs between annual assessments, which would then require an assessment in the period which a triggering event occurred. The Company performs its annual goodwill and indefinite-lived intangible asset impairment test as of November 30th, or whenever an event or change in circumstances occurs that would require reassessment of the recoverability of those assets. In performing the evaluation, the Company 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 May 2018, an indicator of potential impairment, the Company performed an impairment test as of June 30, 2018, which indicated that there was no impairment to goodwill or indefinite-lived intangible assets. There have been no further triggering factors of impairment as of September 30, 2018. The Company will perform its annual test as of November 30, 2018.

(g) Revenue Recognition

The Company generates revenues from manufacturing, packaging, research and development, and related services for multiple pharmaceutical companies through its CDMO segment. The agreements that the Company has with its commercial partners provide for manufacturing revenues, sales-based royalties and/or profit sharing components. The Company's revenue policies listed below are reflective of Accounting Standards Update, or ASU, No. 2014-09, "Revenue from Contracts with Customers," or ASU 2014-09, which the company adopted effective January 1, 2018. See Note 18 for additional information regarding the Company's adoption of ASU 2014-09 and its impact on the Company's financial statements.

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

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

and ordering patterns, as well as unforeseen price adjustments made by the Company's commercial partners.

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

(h) Concentration of Credit Risk

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

The Company's accounts receivable balances are 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 99% of its revenues for three and nine months ended September 30, 2018. A portion of the Company's revenues are dependent on U.S. based customers selling to end-users outside the United States.

(i) Research and Development

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

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

(j) Stock-Based Awards

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

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

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

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

(k) Income Taxes

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

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

(l) Net Loss Per Common Share

Basic net loss per common share is determined by dividing net loss applicable to common shareholders by the weighted average common shares outstanding during the period.

For purposes of calculating diluted loss per common share, the denominator includes both the weighted average common shares outstanding and the number of common stock equivalents if the inclusion of such common stock equivalents would be dilutive.

For the three and nine months ended September 30, 2018 and 2017, 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Basic and Diluted Loss Per Share				
Net loss	$(13,256)	$(9,055)	$(38,426)	$(25,997)
Weighted average common shares outstanding, basic and diluted	20,721,330	19,058,956	20,122,569	19,053,636
Net loss per share of common stock, basic and diluted	$(0.64)	$(0.48)	$(1.91)	$(1.36)

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

	September 30,	
	2018	2017
Options and restricted stock units outstanding	5,057,765	3,928,013
Warrants	838,664	784,928

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

(m) Segment Information

The Company determined its reportable segments based on its strategic business units, the commonalities among the products and services within each segment and the manner in which the Company reviews and evaluates operating performance. The Company has identified its CDMO and Acute Care divisions as reportable segments. Segment disclosures are included in Note 17. Segment operating profit (loss) is defined as segment revenue less segment operating expenses (segment operating expenses consist of cost of sales, general and administrative expenses, research and development expenses, and the change in valuation of contingent consideration and warrants). The following

items are excluded from segment operating profit (loss): interest income and expense, and income tax benefit. Segment assets are those assets and liabilities that are recorded and reported by segment operations. Segment operating capital employed represents segment assets less segment liabilities.

(n) Recent Accounting Pronouncements

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

In May 2017, the FASB issued ASU No. 2017-09, “Stock Compensation – Scope of Modification Accounting” or ASU 2017-09. ASU 2017-09 provides guidance on which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The new standard 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 will early adopt this guidance in the fourth quarter of 2018 and does not expect it to have a material 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. The new guidance is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted. The Company plans to adopt this ASU in the first quarter of 2019. The Company will elect an optional transition method to account for the impact of the adoption with a cumulative-effect adjustment in the period of adoption and will not restate prior periods. The Company expects to elect certain practical expedients permitted under the transition guidance. The Company currently expects that most of its operating lease commitments will be subject to the update and recognized as operating lease liabilities and right-of-use assets upon adoption. The Company expects total assets and total liabilities will materially increase in the period of adoption. The Company is currently evaluating the impact the adoption of this accounting standard will have on its results of operations, cash flows and related disclosures. The Company continues to assess any potential impacts on its internal controls, business processes, and accounting policies related to both the implementation and ongoing compliance of the new guidance.

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

(4) Acquisition of Gainesville Facility and Meloxicam

On April 10, 2015, the Company completed the Gainesville Transaction. The consideration paid in connection with the Gainesville Transaction consisted of $50,000 cash at closing, a $4,000 working capital adjustment and a seven-year warrant to purchase 350,000 shares of the Company’s common stock at an exercise price of $19.46 per share. In addition, the Company may be required to pay up to an additional $125,000 in milestone payments including $45,000 upon regulatory approval 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).

The contingent consideration consists of three separate components. The first component will be payable upon regulatory approval. The second component consists of three potential payments, based on the achievement of specified annual revenue targets, the last of which represents over 60% of these milestone payments and currently does not have a fair value assigned to its achievement. The third component consists of a royalty payment between 10% and 12% (subject to a 30% reduction when no longer covered by patent) for a defined term on future injectable meloxicam net sales.

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

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

(5) NMB Related License Agreement

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

The transaction was accounted for as an asset acquisition, with the total cost of the acquisition of $766 allocated to acquired IPR&D. The Company recorded an upfront payment obligation of $350, as well as operational liabilities and acquisition-related costs of $416, primarily consisting of reimbursement to Cornell for specified past patent, legal and pre-clinical costs.

In addition, the Company is obligated to make: (i) an annual license maintenance fee payment until the first commercial sale of the NMB Related Compounds; and (ii) milestone payments upon the achievement of certain milestones, up to a maximum, for each NMB, of $5,000 for U.S. regulatory approval and commercialization milestones and $3,000 for European regulatory approval and commercialization milestones. The Company is also obligated to pay Cornell royalties on net sales of the NMB Related Compounds at a rate ranging from low to mid-single digits, depending on the applicable NMB Related Compounds and whether there is a valid patent claim in the applicable country, subject to an annual minimum royalty amount. Further, the Company will reimburse Cornell ongoing patent costs related to prosecution and maintenance of the patents related to the Cornell patents for the NMB Related Compounds.

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

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

(6) Fair Value of Financial Instruments

The Company follows the provisions of FASB ASC Topic 820, “Fair Value Measurements and Disclosures,” for fair value measurement recognition and disclosure purposes for its financial assets and financial liabilities that are remeasured and reported at fair value each reporting period. The Company measures certain financial assets and liabilities at fair value on a recurring basis, including cash equivalents, short-term investments, warrants and the contingent consideration. The Company’s assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of financial assets and financial liabilities and their

placement within the fair value hierarchy. Categorization is based on a three-tier valuation hierarchy, which prioritizes the inputs used in measuring fair value, as follows:

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

13

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

	Fair value measurements at reporting date using Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
At December 31, 2017:			
Assets:			
Cash equivalents			
Money market mutual funds (See Note 7)	$38,959	$ —	$ —
Total cash equivalents	$38,959	$ —	$ —
Short-term investments			
U.S. Treasury obligations (See Note 7)	$3,498	$ —	$ —
Total financial assets	$42,457	$ —	$ —
Liabilities:			
Warrants (See Note 14(d))	$—	$ —	$ 3,406
Contingent consideration (See Note 4)	—	—	82,413
	$—	$ —	$ 85,819
At September 30, 2018:			
Assets:			
Cash equivalents			
Money market mutual funds (See Note 7)	$25,701	$ —	$ —
U.S. Treasury obligations (See Note 7)	1,498	—	—
Commercial Paper (See Note 7)	—	1,245	—
Total cash equivalents	$27,199	$ 1,245	$ —
Short-term investments			
Commercial Paper (See Note 7)	$—	$ 1,243	$ —
Total financial assets	$27,199	$ 2,488	$ —
Liabilities:			
Warrants (See Note 14(d))	$—	$ —	$ 739
Contingent consideration (See Note 4)	—	—	89,443
	$—		