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, 2021**

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to

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.)
1 E. Uwchlan Ave, Suite 112, Exton, Pennsylvania	**19341**
(Address of principal executive offices)	(Zip Code)

(770) 534-8239
(Registrant's telephone number, including area code)

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

Title of each class	Trading symbol	Name of exchange on which registered
Common Stock, par value $0.01	**REPH**	**The NASDAQ Stock Market LLC**

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 ☐	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 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 November 2, 2021, there were 46,614,535 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)	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 23,490	$ 23,760
Accounts receivable	13,746	9,033
Contract asset	7,314	7,330
Inventory	9,440	11,612
Prepaid expenses and other current assets	2,101	2,334
Total current assets	56,091	54,069
Property, plant and equipment, net	50,021	43,841
Operating lease asset	5,963	486
Intangible assets, net	5,993	700
Goodwill	39,568	4,319
Other assets	146	—
Total assets	$ 157,782	$ 103,415
Liabilities and shareholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,916	$ 1,804
Current portion of debt	—	1,474
Current portion of related party debt	2,039	—
Current portion of operating lease liability	1,049	145
Accrued expenses and other current liabilities	7,856	4,380
Total current liabilities	12,860	7,803
Debt, net of current portion	91,029	108,097
Related party debt, net of current portion	3,259	—
Operating lease liability, net of current portion	4,947	366
Other liabilities	1,203	1,249
Total liabilities	113,298	117,515
Commitments and contingencies (note 8)		
Shareholders' equity (deficit):		
Preferred stock, $0.01 par value. 10,000,000 shares authorized, none issued or outstanding	—	—
Common stock, $0.01 par value. 95,000,000 shares authorized, 46,614,535 and 28,601,358 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	466	286
Additional paid-in capital	287,415	219,998
Accumulated deficit	(243,397)	(234,384)
Total shareholders' equity (deficit)	44,484	(14,100)
Total liabilities and shareholders' equity (deficit)	$ 157,782	$ 103,415

See accompanying notes to consolidated financial statements.

RECRO PHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Operations
(Unaudited)

(amounts in thousands, except share and per share data)	Three months ended September 30, 2021	Three months ended September 30, 2020	Nine months ended September 30, 2021	Nine months ended September 30, 2020
Revenue	$ 18,237	$ 19,287	$ 53,057	$ 56,586
Operating expenses:				
Cost of sales (excluding amortization of intangible assets)	13,160	11,741	39,831	41,629
Selling, general and administrative	4,606	4,418	13,076	14,123
Amortization of intangible assets	135	646	835	1,938
Total operating expenses	17,901	16,805	53,742	57,690
Operating income (loss)	336	2,482	(685)	(1,104)
Interest expense	(3,822)	(4,609)	(11,680)	(14,727)
Gain on extinguishment of debt	—	—	3,352	—
Net loss	$ (3,486)	$ (2,127)	$ (9,013)	$ (15,831)
Loss per share, basic and diluted	$ (0.07)	$ (0.09)	$ (0.22)	$ (0.67)
Weighted average shares outstanding:				
Basic	51,416,388	23,641,973	40,137,069	23,538,378
Diluted	51,416,388	23,641,973	40,137,069	23,538,378

See accompanying notes to consolidated financial statements.

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

(amounts in thousands, except share data)	Common stock Shares	Amount	Additional paid-in capital	Accumulated deficit	Total
Balance, December 31, 2020	28,601,358	$ 286	$ 219,998	$ (234,384)	$ (14,100)
Issuance of common stock, net of costs	2,202,420	22	9,318	—	9,340
Stock-based compensation expense	—	—	3,133	—	3,133
Vesting of restricted stock units, net	209,541	2	(338)	—	(336)
Net loss	—	—	—	(6,761)	(6,761)
Balance, March 31, 2021	31,013,319	310	232,111	(241,145)	(8,724)
Issuance of common stock, net of costs	15,333,332	153	31,950	—	32,103
Stock-based compensation expense	—	—	1,929	—	1,929
Vesting of restricted stock units, net	155,198	2	(128)	—	(126)
Net income	—	—	—	1,234	1,234
Balance, June 30, 2021	46,501,849	$ 465	$ 265,862	$ (239,911)	$ 26,416
Fair value of shares issuable to former equity holders of IriSys, net of costs	—	—	20,328	—	20,328
Stock-based compensation expense	—	—	1,319	—	1,319
Vesting of restricted stock units, net	112,606	1	(94)	—	(93)
Exercise of stock options	80	—	—	—	—
Net loss	—	—	—	(3,486)	(3,486)
Balance, September 30, 2021	46,614,535	$ 466	$ 287,415	$ (243,397)	$ 44,484
Balance, December 31, 2019	23,312,928	$ 233	$ 199,938	$ (206,883)	$ (6,712)
Stock-based compensation expense	—	—	3,231	—	3,231
Exercise of stock options, net	37,063	—	(105)	—	(105)
Vesting of restricted stock units, net	105,242	1	(917)	—	(916)
Net loss	—	—	—	(7,692)	(7,692)
Balance, March 31, 2020	23,455,233	234	202,147	(214,575)	(12,194)
Stock-based compensation expense	—	—	2,446	—	2,446
Exercise of stock options, net	105,606	1	378	—	379
Vesting of restricted stock units, net	78,067	1	(31)	—	(30)
Net loss	—	—	—	(6,012)	(6,012)
Balance, June 30, 2020	23,638,906	$ 236	$ 204,940	$ (220,587)	$ (15,411)
Stock-based compensation expense	—	—	2,409	—	2,409
Vesting of restricted stock units, net	5,725	—	(4)	—	(4)
Net loss	—	—	—	(2,127)	(2,127)
Balance, September 30, 2020	23,644,631	$ 236	$ 207,345	$ (222,714)	$ (15,133)

See accompanying notes to consolidated financial statements.

RECRO PHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows
(Unaudited)

(amounts in thousands)	Nine months ended September 30, 2021	2020
Cash flows from operating activities, continuing operations:		
Net loss	$ (9,013)	$ (15,831)
Adjustments to reconcile net loss to net cash provided by operating activities, continuing operations:		
Stock-based compensation expense	6,381	8,086
Non-cash interest expense	4,531	4,222
Depreciation expense	4,803	4,581
Amortization of intangible assets	835	1,938
Gain on extinguishment of debt	(3,352)	—
Changes in operating assets and liabilities:		
Accounts receivable	(3,801)	755
Contract asset	521	(877)
Inventory	2,857	3,492
Prepaid expenses and other assets	491	268
Accounts payable, accrued expenses and other liabilities	2,162	(234)
Net cash provided by operating activities, continuing operations	6,415	6,400
Cash flows from investing activities		
Acquisition of IriSys, net of cash acquired	(24,006)	—
Purchases of property and equipment	(2,765)	(5,451)
Net cash used in investing activities	(26,771)	(5,451)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of costs	32,103	—
Proceeds from issuance of debt	—	4,416
Repayments of debt	(10,100)	(1,100)
Payment of financing costs	(1,362)	(78)
Net payments related to vesting of restricted stock units	(555)	(1,185)
Net proceeds related to exercise of stock options	—	509
Net cash provided by financing activities	20,086	2,562
Net (decrease) increase in cash and cash equivalents from continuing operations	(270)	3,511
Cash flows used in discontinued operating activities	—	(1,172)
Cash and cash equivalents, beginning of period	23,760	19,148
Cash and cash equivalents, end of period	$ 23,490	$ 21,487
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 7,462	$ 10,662
Purchases of property, plant and equipment included in accrued expenses and accounts payable	158	686
Fair value of shares issuable to former equity holders of IriSys	20,931	—
Fair value of note issued to former equity holder of IriSys	5,240	—
Issuance of common stock to reduce debt principal and accrued exit fees	6,060	—
Issuance of common stock to settle interest obligations	3,211	—

See accompanying notes to consolidated financial statements.

(1) Background

Recro Pharma, Inc. (the "Company") was incorporated in the Commonwealth of Pennsylvania on November 15, 2007. The Company is a dedicated contract development and manufacturing organization dedicated to solving complex formulation and manufacturing challenges primarily in small molecule therapeutic development. The Company leverages its formulation and development expertise to develop and manufacture pharmaceutical products using proprietary delivery technologies and know-how for partners who develop and commercialize or plan to commercialize these products. The Company operates in one segment.

The Company has incurred net losses since inception and has an accumulated deficit of $243,397 as of September 30, 2021, which is primarily related to the activities of its former research and development business, which was spun-out in 2019. The Company's future operations are highly dependent on the continued profitability of its manufacturing operations. Management believes that it is probable that the Company will be able to meet its obligations as they become due within at least one year after the date financial statements included herein are issued.

(2) Summary of significant accounting principles

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 ("U.S. GAAP") for interim financial information. In accordance with Securities and Exchange Commission ("SEC") rules for interim financial statements, certain information required by U.S. GAAP may be condensed or omitted. 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 interim periods are not necessarily indicative of the results that may be expected for the full year.

The accompanying unaudited interim consolidated financial statements should be read in conjunction with the annual audited financial statements and related notes included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020.

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.

Business combinations

The Company measures the purchase price paid for acquired companies based on fair value and allocates that purchase price to the 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 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 the acquired companies and expectations of future cash flows. Costs associated with the transaction are expensed as incurred as selling, general and administrative expenses.

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 due to changes in interest rates.

Property, plant and equipment

Property, plant 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, office and computer equipment; six to ten years for manufacturing equipment; 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. The Company reviews the carrying value of property, plant and equipment for recoverability whenever events occur or changes in circumstances indicate that the carrying amount of individual assets or asset groups may not be recoverable.

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 analysis for goodwill consists of an optional qualitative assessment potentially followed by a quantitative analysis. If the Company determines that the carrying value of its reporting unit exceeds its fair value, an impairment charge is recorded for the excess.

The Company performs its annual goodwill impairment test as of November 30th, or whenever an event or change in circumstance occurs that would require reassessment of the recoverability of goodwill. In performing the evaluation, the Company assesses qualitative factors such as overall financial performance, anticipated changes in industry and market conditions, and competitive environments.

Definite-lived intangible assets are amortized on a straight-line basis over their estimated useful life. The Company is required to review the carrying value of definite-lived intangible assets for recoverability whenever events occur or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable.

Revenue recognition

The Company generates revenues from manufacturing, packaging, research and development and related services for multiple pharmaceutical companies.

Manufacturing

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.

Profit-sharing

In addition to manufacturing and packaging revenue, certain customer agreements may have intellectual property sales-based profit-sharing and/or royalties consideration, collectively referred to as profit-sharing, computed on the net product sales of the commercial partner. Profit-sharing revenues are generally recognized under the terms of the applicable license, development and/or supply agreement. For arrangements that include sales-based profit-sharing where the license for intellectual property is deemed to be the predominant item to which the profit-sharing relates, the Company recognizes revenue when the related sales occur by the commercial partner. For arrangements that include sales-based profit-sharing where the license for intellectual property is not deemed to be the predominant item to which the profit-sharing relates, the Company recognizes revenue upon transfer of control of the manufactured product. In these cases, significant judgment is required to calculate the estimated variable consideration from such profit-sharing using the expected value method based on historical commercial partner pricing and deductions. Estimated variable consideration is partially constrained due to the uncertainty of price adjustments made by the Company's commercial partners, which are outside of the Company's control. Factors causing price adjustments by the Company's commercial partners include increased competition in the products' markets, mix of volume between the commercial partners' customers, and changes in government pricing.

Research and development

Research and development revenue includes services associated with formulation, process development, clinical trials materials services, as well as custom development of manufacturing processes and analytical methods for a customer's non-clinical, clinical and commercial products. Such revenues are recognized at a point in time or over time depending on the nature and particular facts and circumstances associated with the contract terms.

In contracts that 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 are deferred and recognized over the period of performance. Milestone payments that are not within the Company's control, such as submission for approval to regulators by a commercial partner or approvals from regulators, are not considered probable of being achieved until those submissions are submitted by the customer or approvals are received.

In contracts that require revenue recognition over time, the Company utilizes input or output methods, depending on the specifics of the contract, that compare the cumulative work-in-process to date to the most current estimates for the entire performance obligation. Under these contracts, the customer typically owns the product details and process, which have no alternative use. These projects are customized to each customer to meet its specifications and typically only one performance obligation is included. Each project represents a distinct service that is sold separately and has stand-alone value to the customer. The customer also retains control of its product as the product is being created or enhanced by the Company's services and can make changes to its process or specifications upon request.

Concentration of credit risk

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

The Company's accounts receivable balances are primarily concentrated among three customers. 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 is dependent on its relationships with a small number of commercial partners. The Company's three largest customers generated 81% and 88% of its revenues for the three and nine months ended September 30, 2021, respectively.

Stock-based compensation expense

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," which 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.

Upon exercise of stock options or vesting of restricted stock units, the holder may elect to cover tax withholdings by forfeiting shares of an equivalent value. In such cases, the Company issues net new shares to the holder, pays the tax withholding on behalf of the participant and presents the payment similar to a capital distribution: a reduction to additional paid-in-capital and a financing cash outflow in the consolidated financial statements.

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.

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. A full valuation allowance was recorded as of September 30, 2021 and December 31, 2020.

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.

Income or loss per share

Basic income or loss per share is determined by dividing net income or loss (the numerator) by the weighted average common shares outstanding during the period (the denominator). Additionally, the weighted average common shares outstanding for the three- and nine-month periods ended September 30, 2021 include 9,302,718 shares issuable to the former equity holders of IriSys since the acquisition date (see note 10).

To calculate diluted income or loss per share, the numerator and denominator are adjusted to eliminate the income or loss and the dilutive effects on shares, respectively, caused by outstanding common stock options, warrants and unvested restricted stock units, using the treasury stock method, if the inclusion of such instruments would be dilutive.

For all periods presented, the Company incurred a net loss. In periods of net loss, the inclusion of dilutive securities would be antidilutive because it would reduce the amount of loss incurred per share. As a result, no additional dilutive shares were included in diluted loss per share, and there were no differences between basic and diluted loss per share.

The following table presents the potentially dilutive securities that were excluded from the computations of diluted loss per share:

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Restricted stock units	708,965	896,537	377,437	703,679
Stock options	4,965,826	3,613,173	4,496,878	3,480,572
Warrants	348,664	348,664	348,664	348,664

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

Recently adopted accounting pronouncements

On January 1, 2020, the Company adopted ASU 2018-13, "*Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*" ("ASU 2018-13"). ASU 2018-13 removes, modifies and adds certain disclosure requirements in Topic 820 "*Fair Value Measurement*". There was no impact upon adoption because the Company is not currently required to provide any of the disclosures impacted by the new standard.

On January 1, 2021, the Company adopted ASU No. 2016-13, "*Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments"* ("ASU 2016-13"), a new standard for measuring expected credit losses. That guidance impacts the measurement of doubtful accounts receivable, among other things. There was no impact upon adoption because the Company does not currently have any significant exposure to credit losses.

In March 2020, the FASB issued ASU 2020-04, *"Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting"* ("ASU 2020-04"). This ASU provides temporary optional expedients and exceptions to the guidance on contract modifications and hedge accounting to ease the financial reporting burdens of the expected market transition from the London Interbank Offered Rate and other interbank offered rates to alternative reference rates. In January 2021, the FASB issued ASU 2021-01, which refines the scope of Topic 848 and clarifies some of its guidance as part of the FASB's monitoring of global reference rate activities. The new guidance was effective upon issuance, and the Company is allowed to elect to apply the amendments prospectively through December 31, 2022. The Company is currently evaluating the impact this standard will have on its consolidated financial statements.

(3) Acquisition of IriSys

On August 13, 2021, the Company acquired all of the units of IriSys, LLC ("IriSys") pursuant to a unit purchase agreement. IriSys provides contract pharmaceutical product development and manufacturing services, specializing in formulation research and development and good manufacturing practices of clinical trial materials and specialty pharmaceutical products. The acquisition advances the Company's ongoing growth strategy and leads to key synergies within business development, clinical development and commercial scale-up, as well as a strong cultural alignment and fit between the companies.

The aggregate purchase price consideration was comprised of cash consideration, a subordinated promissory note and a contractual obligation to issue 9,302,718 shares of the Company's common stock on the six-month anniversary of the closing, subject to a working capital adjustment. The following table summarizes the estimated consideration paid:

		August 13, 2021
Cash paid, net of cash acquired	$	24,006
Fair value of shares issuable to former equity holders of IriSys		20,931
Fair value of note with former equity holder of IriSys		5,240
Total estimated consideration	$	50,177

The fair value of the shares issuable was determined by using the price of the Company's common stock on the acquisition date, less a discount for lack of marketability due to the shares being unregistered shares of the Company. The fair value of the note was determined using a discounted cash flow analysis that incorporated an estimate of the market interest rate for debt of similar terms and credit risk on the acquisition date.

The Company incurred $1,211 in transaction costs related to the acquisition that were expensed as incurred and classified as selling, general and administrative expenses.

The following table summarizes the provisional fair values of the assets acquired and liabilities assumed at the date of acquisition:

	As of August 13, 2021
Assets acquired:	
Accounts receivable	$ 912
Contract assets	505
Inventory	685
Prepaid expenses and other assets	91
Property and equipment	9,304
Right of use assets	5,559
Intangible assets	6,128
Goodwill	35,249
Other noncurrent liabilities	146
Total assets acquired	$ 58,579
Liabilities assumed:	
Accounts payable	$ 730
Accrued expenses and other liabilities	1,512
Operating lease liability	5,559
Debt from finance loan	415
Other liabilities	186
Total liabilities assumed	$ 8,402
Net assets acquired	$ 50,177

The amounts above represent the Company's current provisional fair value estimates and are subject to subsequent adjustments as additional information is obtained and valuations are finalized during the measurement period. The primary areas of estimates that are not yet finalized include the final outcome of the net working capital adjustment, certain tangible assets acquired and liabilities assumed, as well as the identifiable intangible assets. The purchase price was allocated to the tangible assets and identifiable intangible assets acquired and liabilities assumed based on their acquisition date estimated fair values. The identifiable intangible assets consisting of customer relationships, acquired backlog and trademark and tradename were assigned provisional fair values of $4,830, $957 and $341, respectively. Customer relationships, acquired backlog, and trademarks and trade names are subject to amortization on a straight-line basis and are being amortized over 12, 2.4 and 1.5 years, respectively.

The fair value of property, plant and equipment was determined using a cost approach valuation method. The customer relationships and acquired backlog were valued using the multi-period excess earnings method and trademarks and trade names were valued using the relief from royalty method. These methods require several judgments and assumptions to determine the fair value of intangible assets, including revenue growth rates, discount rates, EBITDA margins, and tax rates, among others. These nonrecurring fair value measurements are Level 3 measurements within the fair value hierarchy.

Goodwill represents the excess of the purchase price over the net identifiable tangible and intangible assets acquired. The goodwill related to the acquisition was attributable to expected synergies, the value of the assembled workforce as well as the collective experience of the management team with regards to its operations, customers, and industry. The goodwill is deductible for tax purposes.

Results for the three and nine months ended September 30, 2021 included revenue of $1,490 and net loss of $303 from IriSys. The following table presents unaudited supplemental pro forma financial information as if the IriSys acquisition had occurred on January 1, 2020:

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Revenue	$ 19,102	$ 21,977	$ 60,742	$ 62,844
Net loss	(3,821)	(2,399)	(9,625)	(18,589)

The pro forma financial information presented above has been prepared by combining the Company's historical results and the historical results of IriSys and adjusting those results to eliminate historical transaction costs and to reflect the effects of the acquisition as if they occurred on January 1, 2020. The effects of the acquisition on the historical pro forma financial information include additional depreciation and amortization expense from the increase of asset carrying values to fair value, the adoption of new accounting standards, additional interest expense from the issuance of the subordinated promissory note

and the elimination of interest expense related to indebtedness of IriSys prior to the acquisition. These results do not purport to be indicative of the results of operations which actually would have resulted had the acquisitions occurred on the date indicated above, or that may result in the future, and do not reflect potential synergies or additional costs following the acquisition.

(4) Inventory

Inventory is stated at the lower of cost or net realizable value. Included in inventory are raw materials and work-in-process used in the production of commercial products. Items are issued out of inventory using the first-in, first-out method.

Inventory was as follows:

	September 30, 2021	December 31, 2020
Raw materials	$ 3,662	$ 3,373
Work in process	2,737	5,061
Finished goods	3,475	3,544
Inventory, prior to provision	9,874	11,978
Provision for inventory obsolescence	(434)	(366)
Inventory	$ 9,440	$ 11,612

Adjustments to inventory are determined at the raw materials, work-in-process, and finished good levels to reflect obsolescence or impaired balances. Inventory is primarily 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.

(5) Property, plant and equipment

Property, plant and equipment consists of the following:

	September 30, 2021	December 31, 2020
Land	$ 3,263	$ 3,263
Building and improvements	23,891	20,924
Furniture, office and computer equipment	5,926	5,879
Manufacturing equipment	51,948	39,349
Construction in progress	885	5,568
Property, plant and equipment, gross	85,913	74,983
Less: accumulated depreciation	(35,892)	(31,142)
Property, plant and equipment, net	$ 50,021	$ 43,841

During the nine months ended September 30, 2021, $120 of interest expense was capitalized to construction in process.

(6) Goodwill and other intangible assets

The following table presents the rollforward of goodwill:

	Nine months ended September 30, 2021
Beginning balance	$ 4,319
Acquisition of IriSys	35,249
Ending balance	$ 39,568

The following table presents the components of other intangible assets:

	September 30, 2021			December 31, 2020		
	Gross value	Accumulated amortization	Carrying value	Gross value	Accumulated amortization	Carrying value
Customer relationships	$ 20,330	$ 15,553	$ 4,777	$ 15,500	$ 14,800	$ 700
Backlog	957	52	905	—	—	—
Trademarks and tradenames	341	30	311	—	—	—
Total	$ 21,628	$ 15,635	$ 5,993	$ 15,500	$ 14,800	$ 700

The following table presents estimated future amortization of other intangible assets:

Twelve months ended September 30,	
2022	$ 1,026
2023	882
2024	515
2025	403
2026	403
Thereafter	2,764
Total	$ 5,993

(7) Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consist of the following:

	September 30, 2021	December 31, 2020
Payroll and related costs	$ 3,782	$ 1,481
Current portion of contract liabilities (see note 11)	2,316	1,447
Professional and consulting fees	844	432
Property, plant and equipment	44	551
Other	870	469
Total	$ 7,856	$ 4,380

(8) Commitments and contingencies

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 (the “Securities Litigation”) was filed against the Company and certain of its officers and directors (collectively, the "Defendants") in the U.S. District Court for the Eastern District of Pennsylvania (the "Court") (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 Securities Exchange Act of 1934, as amended, and Rule 10(b)(5) promulgated thereunder, based on statements made by the Company concerning the New Drug Application (“NDA”) for IV meloxicam. The complaint seeks unspecified damages, interest, attorneys’ fees and other costs. On December 10, 2018, the lead plaintiff filed an amended complaint that asserted the same claims and sought the same relief but included new allegations and named additional officers 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. In response to questions from the Court, the parties submitted supplemental briefs regarding the motion to dismiss the amended complaint during the fall of 2019. On February 18, 2020, the motion to dismiss was granted by the Court without prejudice. On April 25, 2020, the plaintiff filed a second amended complaint. The Company filed a motion to dismiss the second amended complaint on June 18, 2020. The plaintiff filed an opposition to the Company’s motion to dismiss on August 17, 2020. On September 16, 2020, the Company filed a reply in support of its motion to dismiss. On March 1, 2021, the Court denied the Company’s second motion to dismiss. On June 21, 2021, the Defendants filed an answer and affirmative defenses to the second amended complaint. A Preliminary Pretrial Conference before the Court occurred on August 3, 2021. The parties have begun discovery and class certification briefing, which the Court has ordered to be completed by December 30, 2021. All expert and fact discovery must be completed by March 15, 2022.

In connection with the separation of the Company's former acute care research and development business into a new standalone entity named Baudax Bio, Inc. ("Baudax Bio"), Baudax Bio accepted assignment by the Company of all of its obligations in connection with the Securities Litigation and agreed to indemnify it for all liabilities related to the Securities Litigation. The Company and Baudax Bio believe that the lawsuit is without merit and intend to vigorously defend against it, unless and until a resolution satisfactory to the Company can be achieved.

Purchase commitments

As of September 30, 2021, the Company had outstanding cancelable and non-cancelable purchase commitments in the aggregate amount of $4,506 related to inventory, capital expenditures and other goods and services.

Employment agreements and certain other contingencies

The Company has entered into employment agreements with each of its named executive officers that provide for, among other things, severance commitments of up to $1,250 should the Company terminate the named executive officers for convenience or if certain events occur following a change in control. In addition, the Company is subject to other contingencies of up to $3,566 in the aggregate if certain events occur following a change in control.

(9) Debt

The following table presents the components and classification of debt:

	September 30, 2021	December 31, 2020
Debt principal:		
Terms loans under Credit Agreement	$ 100,000	$ 116,000
Note with former equity holder of IriSys	6,117	—
Other	415	3,316
Debt principal	106,532	119,316
Debt adjustments:		
Unamortized deferred issuance costs	(10,017)	(10,359)
Exit fee accretion	627	614
Unamortized original discount	(815)	—
Carrying value of debt	$ 96,327	$ 109,571
Current portion of debt	$ —	$ 1,474
Current portion of related party debt	2,039	—
Debt, net of current portion	91,029	108,097
Related party debt, net of current portion	3,259	—
Carrying value of debt	$ 96,327	$ 109,571

The following table presents the future maturity of debt principal:

Twelve months ended September 30,		
2022	$	2,039
2023		2,039
2024		102,070
2025		39
2026		45
Thereafter		300
Total debt	$	106,532

Term loans under Credit Agreement

The Company is currently party to a credit agreement (the "Credit Agreement") with Athyrium Opportunities III Acquisition LP ("Athyrium"). The Credit Agreement has been fully drawn in the form of $48,000 of term A loans and $52,000 of term B loans, all of which mature on December 31, 2023.

The Credit Agreement has been amended six times, twice during 2021:

- the fifth amendment in February 2021 resulted in a reduction of $16,000 principal, a reduction of 1.5% in the stated interest rate, and a $160 settlement of accrued exit fees in exchange for $10,100 of cash and $9,271, or 2,202,420 shares, of common stock issued, as well as certain other changes to the terms of the debt. Of the total common stock issued, $6,060 was applied to the principal balance and accrued exit fee, and substantially all of the remainder was added to unamortized deferred financing costs and will be amortized as interest over the remaining term of the debt.

- The sixth amendment in August 2021 provided (i) Athyrium's consent regarding (i) the acquisition of IriSys and certain resulting changes to the Credit Agreement, (ii) for the inclusion of an updated fee letter of $500 in connection with the sixth amendment; and (iii) an extension of the maturity date of the term loans from March 31, 2023 to December 31, 2023.

The term loans under the Credit Agreement bear a rate of interest equal to the three-month LIBOR rate, with a 1% floor plus 8.25% per annum. The term loans require the Company to pay a 1% exit fee on all repayments. At September 30, 2021, the aggregate exit fee payable was $1,000, and the cumulative exit fee accreted was $627. The exit fees are being accreted to the carrying amount of the debt using the effective interest method over the term of the loan. In addition, if the Company makes any prepayments prior to maturity, the Company would be subject to the following prepayment premiums as a percentage of the amount repaid: (i) term A loans at 2.5% through March 31, 2022 with no penalty thereafter; and (ii) term B loans at 5.0% through March 31, 2022 and 2.5% thereafter.

The Credit Agreement contains certain usual and customary affirmative and negative covenants, as well as financial covenants that the Company will need to satisfy on a monthly and quarterly basis, including maintaining a permitted net leverage ratio (which is the Company's indebtedness under the Credit Agreement, net of cash and cash equivalents, divided by EBITDA, each as defined in the Credit Agreement) and liquidity amount. As of September 30, 2021, the Company was in compliance with its covenants under the Credit Agreement.

In connection with the Credit Agreement, the Company issued warrants to each of Athyrium and its affiliate, Athyrium Opportunities II Acquisition LP ("Athyrium II"), to purchase an aggregate of 348,664 shares of the Company's common stock with an exercise price of $1.73 per share. See note 10 for additional information. The warrants are exercisable through November 17, 2024.

In connection with the Credit Agreement and the six subsequent amendments, the Company has paid financing costs, has incurred costs to record and subsequently to adjust the value of the warrants described above and has been accreting the exit fee described above. These costs are being recognized in interest expense using the effective interest method over the term of the Credit Agreement, resulting in non-cash interest expense of $1,389 and $1,303 in the third quarters of 2021 and 2020, respectively, and $4,469 and $4,222 in the first nine months of 2021 and 2020, respectively.

At September 30, 2021, the overall effective interest rate, including cash paid for interest and non-cash interest expense, was 13.8%.

Note with former equity holder of IriSys

In connection with the acquisition of IriSys (see note 3), the Company issued a subordinated promissory note to a former equity holder of Irisys in the aggregate principal amount of $6,117 (the "Note"). The Note is unsecured, has a three-year term, and bears interest at a rate of 6% per annum. The Note must be repaid in three equal annual installments through its maturity date, August 13, 2024. The Note may be prepaid in whole or in part at any time prior to the maturity date. The Note is expressly subordinated in right of payment and priority to the term loans under the Credit Agreement with Athyrium.

The Note was initially recognized at fair value as part of the consideration paid for the acquisition of IriSys, resulting in an original discount recognized of $877 that is being recognized as interest expense using the effective interest method over the term of the Note. At September 30, 2021, the overall effective interest rate, including the amortization of the original discount, was 13.0%.

The former equity holder of IriSys beneficially owns more than 10% of the Company's common stock and became a related party as a result of the acquisition (see notes 3 and 10). The Company has accrued interest of $49 for the three and nine months ended September 30, 2021 that will become payable to the former equity holder of IriSys on the first anniversary of the acquisition.

Other

In connection with the acquisition of IriSys (see note 3), the Company assumed a loan with a carrying value of $415 at September 30, 2021.

In May 2020, the Company entered into a $4,416 promissory note with PNC Bank under the Small Business Administration ("SBA") Paycheck Protection Program of the Coronavirus Aid, Relief and Economic Security Act of 2020 (the "PPP Note"). Shortly after entering into the note, the Company prepaid $1,100 of principal to comply with guidance from the SBA that limited the amount that could be borrowed at that time. The note had a two-year term and a stated rate of interest of 1.0% per annum, which accrued and would have become payable beginning September 2021.

In October 2020, the Company submitted a forgiveness application for the PPP Note, and in June 2021, the PPP Note and all accrued interest thereon was forgiven. Upon receiving the decision, the Company recorded a gain on extinguishment of debt of $3,352, consisting of forgiveness of $3,316 of principal and $36 of accrued interest.

(10) Shareholders' equity or deficit

Capital raises

The following table presents the Company's capital raises since its initial public offering:

	Date or period	Shares of common stock issued	Gross proceeds	Offering expenses	Net proceeds
Initial public offering	March 12, 2014	4,312,500	$ 34,500	$ (4,244)	$ 30,256
Private placement	July 7, 2015	1,379,311	16,000	(1,188)	14,812
Underwritten public offering	August 19, 2016	1,986,666	14,900	(1,533)	13,367
Underwritten public offering	December 16, 2016	6,670,000	40,020	(3,132)	36,888
2018 common stock purchase agreement with Aspire Capital	Year ended December 31, 2018	1,950,000	16,999	—	16,999
2019 common stock purchase agreement with Aspire Capital	Fourth quarter 2020	4,690,972	11,172	(78)	11,094
Underwritten public offering	May 12, 2021	15,333,332	34,500	(2,397)	32,103

Shares issuable to former equity holders of IriSys

As part of the consideration paid for the acquisition of IriSys (see note 3), the Company agreed to issue 9,302,718 shares of its common stock on the six month anniversary of the Closing and incurred costs of approximately $600 to file a registration statement on Form S-3 in connection with the resale of such shares with the SEC in September 2021. The fair value of the forward contract was estimated to be $20,931 based on the closing price of the Company's common stock on the acquisition date discounted for a lack of marketability. The Company recognized the instrument as shareholders' equity at fair value as of the acquisition date.

Aspire common stock purchase agreement

The Company is currently party to an amended common stock purchase agreement with Aspire Capital Fund LLC ("Aspire Capital") originally entered into during 2019, and most recently amended in February 2021 (as amended, the "2019 Common Stock Purchase Agreement"). The 2019 Common Stock Purchase Agreement provides that, upon the terms and subject to the conditions and limitations set forth in the agreement, Aspire Capital is committed to purchase, at the Company's sole election, up to an aggregate value of $41,172 in shares of common stock. As of September 30, 2021, there is availability to issue up to $30,000 or 6,199,299 shares of common stock under the 2019 Common Stock Purchase Agreement.

Athyrium stock issuance agreement

In February 2021, the Company entered into a stock issuance agreement with Athyrium in connection with an amendment to its Credit Agreement. See note 9 for additional details.

Warrants

At September 30, 2021, warrants to purchase 348,664 shares of common stock were outstanding. The warrants are held by Athyrium, equity-classified, exercisable at $1.73 per share and expire in November 2024. See note 9 for additional details.

(11) Revenue recognition

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. 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.

The following table presents changes in contract assets and liabilities:

	Contract assets	Contract liabilities
Balance at December 31, 2020	$ 7,330	$ 2,695
Changes to the beginning balance of contract assets arising from:		
Reclassification to receivables as a result of rights to consideration becoming unconditional	(8,774)	—
Changes in estimate	1,508	—
Contract assets recognized since beginning of period, net of reclassification to receivables and changes in estimates	6,745	—
Changes to contract liabilities:		
Amounts billed in advance of contract performance	—	4,097
Revenue recognized	—	(4,391)
Acquisition of IriSys	505	930
Balance at September 30, 2021	$ 7,314	$ 3,331
Less: noncurrent portion	—	(1,015)
Current portion	$ 7,314	$ 2,316

The following table disaggregates revenue by timing of revenue recognition:

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Point in time	$ 14,361	$ 17,827	$ 45,947	$ 53,247
Over time	3,876	1,460	7,110	3,339
Total	$ 18,237	$ 19,287	$ 53,057	$ 56,586

The Company's payment terms for manufacturing revenue and development services are typically 30 to 45 days. Profit-sharing 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.

(12) Stock-based compensation

In October 2013, the Company established an equity incentive plan that has been subsequently amended and restated to become the 2018 Amended and Restated Equity Incentive Plan (the "A&R Plan") At September 30, 2021, a total of 2,431,418 shares were available for future grants under the A&R Plan. On December 1st of each year, pursuant to the "Evergreen" provision of the A&R Plan, the number of shares available under the A&R 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.

Stock options

Stock options are exercisable generally for a period of 10 years from the date of grant and generally vest over four years.

The following table presents information about the fair value of stock options granted:

	Nine months ended September 30,	
	2021	**2020**
Weighted average grant date fair value	$ 1.78	$ 8.24
Assumptions used to determine fair value:		
Range of expected option life	5.5 - 6 years	5.5 - 6 years
Expected volatility	79 - 81%	75 - 81%
Risk-free interest rate	0.7 - 1.2%	0.3 - 1.4%
Expected dividend yield	—	—

The intrinsic value of options exercised was negligible in the first nine months of 2021 and $1,058 in the first nine months of 2020.

The following table presents information about stock option balances and activity:

	Number of shares	**Weighted average exercise price**	**Aggregate intrinsic value**	**Weighted average remaining contractual life**
Balance, December 31, 2020	3,907,010	$ 8.03		
Granted	1,575,534	2.64		
Exercised	(80)	2.31		
Forfeited or expired	(185,172)	6.48		
Balance, September 30, 2021	5,297,292	6.48	$ 1	6.0 years
Exercisable	3,268,854	8.05	—	3.9 years

Included in the table above are 903,542 options outstanding as of September 30, 2021 that were granted outside the A&R Plan. The grants were made pursuant to the NASDAQ inducement grant exception in accordance with NASDAQ Listing Rule 5635(c)(4).

Restricted stock units

Restricted stock units ("RSUs") vest over six months to four years depending on the purpose of the award. The fair value of RSUs on the date of grant is measured as the closing price of the Company's common stock on that date. The weighted average grant-date fair value of RSUs awarded to employees was $3.49 in the first nine months of 2021 and $15.11 in the first nine months of 2020. The fair value of RSUs vested was $1,868 in the first nine months of 2021 and $3,246 in the first nine months of 2020.

The following table presents information about recent RSU activity:

	Number of shares	**Weighted average grant date fair value**
Balance, December 31, 2020	1,516,819	$ 5.67
Granted	743,956	3.49
Vested	(680,194)	7.89
Forfeited	(106,408)	9.26
Balance, September 30, 2021	1,474,173	3.29

Included in the table above are 232,822 time-based RSUs outstanding at September 30, 2021 that were granted outside of the A&R Plan. The grants were made pursuant to the NASDAQ inducement grant exception in accordance with NASDAQ Listing Rule 5635(c)(4).

Other information

The following table presents the classification of stock-based compensation expense:

	Nine months ended September 30,	
	2021	**2020**
Cost of sales	$ 3,081	$ 2,293
Selling, general and administrative expenses	3,300	5,793
Total	$ 6,381	$ 8,086

As of September 30, 2021, there was $8,232 of unrecognized compensation expense related to unvested options and RSUs that are expected to vest and will be expensed over a weighted average period of 2.5 years.

(13) 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 and certain warrants. 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.

Items measured at fair value on a recurring basis

Cash equivalents of $15,411 at September 30, 2021 and $6,583 at December 31, 2020 consisted entirely of money market mutual funds whose fair value were determined using Level 1 measurements.

Fair value disclosures

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 September 30, 2021, 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. The carrying values of these accounts approximate fair value due to their short-term nature.

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 its debt, a level 2 measurement, approximated fair value at September 30, 2021 due to the recent issuances and amendment of those instruments and taking into consideration management's current evaluation of market conditions.

(14) Leases

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. Options to extend the lease are included in the lease term if the options are reasonably certain to be exercised. Operating lease expense is recognized on a straight-line basis over the lease term.

Operating lease balances are presented as separate captions on the balance sheets. Finance lease assets are included in property, plant and equipment. Finance lease liabilities are included in debt.

The Company is party to two operating leases for development facilities in California and Georgia that end in 2031 and 2025, respectively, as well as other immaterial operating leases for office space, storage and office equipment. The development facility leases each include options to extend, none of which are included in the lease terms. Short-term and variable lease costs were not material for the periods presented. The development facility leases do not provide an implicit rate, so the Company uses its incremental borrowing rate to discount the lease liabilities.

Undiscounted future lease payments for the two development leases, which were the only material noncancelable leases at September 30, 2021, were as follows:

Twelve months ended September 30,		
2022	$	1,130
2023		1,158
2024		1,186
2025		1,189
2026		1,089
Thereafter		5,086
Total lease payments		10,838
Less imputed interest		(4,842)
Total operating lease liabilities	$	5,996

At September 30, 2021, the weighted average remaining lease term was 8.9 years, and the weighted average discount rate was 14.2%. For the third quarter, total lease cost was $161 in 2021 and $76 in 2020. For the nine months ended September 30, total lease cost was $347 in 2021 and $234 in 2020.

Item 2. Management's discussion and analysis of financial condition and results of operations

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited consolidated financial statements and notes thereto in Part I, Item 1 of this Quarterly Report on Form 10-Q, or Quarterly Report, and the audited consolidated financial statements and notes thereto for the year ended December 31, 2020 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 for the year ended December 31, 2020 filed with the SEC on February 26, 2021, or Annual Report.

In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions and other factors that could cause actual results to differ materially from those made, projected or implied in the forward-looking statements. Our actual results may differ materially from those discussed below. Please see "Forward-Looking Statements" and "Risk Factors" included in Part I, Item 1A of our Annual Report for factors that could cause or contribute to such differences.

Cautionary note regarding forward-looking statements

This Quarterly Report contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this Quarterly Report regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "will," "would" "could," "should," "potential," "seek," "evaluate," "pursue," "continue," "design," "impact," "affect," "forecast," "target," "outlook," "initiative," "objective," "designed," "priorities," "goal," or the negative of such terms and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements are based on assumptions and expectations that may not be realized and are inherently

subject to risks, uncertainties and other factors, many of which cannot be predicted with accuracy and some of which might not even be anticipated.

The forward-looking statements in this Quarterly Report include, among other things, statements about:

- our estimates regarding expenses, future revenue, cash flow, capital requirements and timing and availability of and the need for additional financing;
- our ability to maintain or expand our relationships, profitability and contracts with our key commercial partners, including the impact of changes in consumer demand for the products we manufacture for our commercial partners;
- our ability to grow and diversify our business with new customers, including our ability to meet desired project outcomes with development customers;
- the extent to which the ongoing COVID-19 pandemic continues to disrupt our business operations and financial condition and the business operations and financial condition of our customers and suppliers, including our ability to initiate and continue relationships with third-party clinical research organizations and manufacturers and third-party logistics providers given recent supply chain challenges;
- our ability to operate under increased leverage and associated lending covenants; to pay existing required interest and principal amortization payments when due; and/or to obtain acceptable refinancing alternatives;
- the performance of third-party suppliers upon which we depend for Active Pharmaceutical Ingredients, or APIs, excipients, capsules, reagents, etc., and other third parties involved with maintenance of our facilities and equipment;
- our ability to obtain and maintain patent protection for applicable products and defend our intellectual property rights against third-parties;
- pharmaceutical industry market forces that may impact our commercial customers' success and continued demand for the products we produce;
- our ability to recruit and retain key scientific, technical, business development, and management personnel and our executive officers, including as a result of our enforcement of state and federal vaccine mandates;
- 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 other relevant regulatory authorities applicable to our business; and
- our ability to integrate the IriSys business successfully and the risk that we may not realize the expected benefits of such acquisition.

We may not achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the Annual Report, particularly under "Risk Factors," that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, collaborations or investments we may make. You should read this Quarterly Report and the documents that we incorporate by reference herein completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements.

Overview

We are a dedicated contract development and manufacturing organization, or CDMO, dedicated to solving complex formulation and manufacturing challenges primarily in small molecule therapeutic development. We leverage our formulation and development expertise to develop and manufacture pharmaceutical products using proprietary delivery technologies and know-how for partners who develop and commercialize or plan to commercialize these products. In 2020, we launched our clinical trials support services capabilities, which includes preparation of clinical trial supplies, as well as specialized services dedicated to the development and Good Manufacturing Practices, or GMP, of high-potency products. In August 2021, we acquired IriSys, a San Diego-based CDMO that possesses capabilities that complement and expand those of Recro. We operate a 97,000 square foot, DEA-licensed manufacturing facility in Gainesville, Georgia, a 24,000 square foot development, high-potency product and clinical packaging facility in Gainesville, Georgia that we opened in October 2018, and a 24,500 square foot development and cGMP facility in San Diego, California that was part of the IriSys acquisition. We currently develop and/or manufacture the following key products with our key commercial partners: Ritalin LA®, Focalin XR®, Verelan PM®, Verelan SR®, Verapamil PM, Verapamil SR, and Donnatal®, as well as supporting development stage products.

Our manufacturing and development capabilities include formulation, product development from formulation through clinical trial and commercial manufacturing, and specialized capabilities for solid oral dosage forms, extended release and controlled substance manufacturing, as well as high potency development and manufacturing. With the acquisition of IriSys, our capabilities have been expanded beyond oral solid dose to include sterile injectables oral liquids, tablets, topicals, liquid/powder filled capsules, ophthalmic droppers, liposomes and nano/microparticles. In addition, the acquisition adds new capabilities in the areas of aseptic fill/finish and lyophilization and established bi-coastal footprint from which to better serve clients within the U.S., as well as globally. In a typical collaboration, we work with our partners to develop product candidates, or new formulations of existing product candidates, and may license certain intellectual property to such partners. We also typically exclusively manufacture and supply clinical and commercial supplies of these proprietary products and product candidates.

We have used cash flow generated by our business primarily to fund the growth of our CDMO business, to fund a historical acute care research and development business that was spun off in 2019, and to make payments under our credit facility. We believe our business will continue to contribute cash to fund our growth, make payments under our credit facility and other general corporate purposes.

COVID-19

We continue to closely monitor developments related to the COVID-19 pandemic, which continues to have adverse effects on the U.S. and world economies, including the commercial activities of our customers and their peers. While we are committed to continue providing essential pharmaceutical products to our customers, we are also taking all necessary measures to protect the health and safety of our employees. These developments include:

Operations. We are continuing to follow appropriate safety protocols including strict social distancing and other protective measures for employees supporting essential operations at our plant. We are also supporting continued remote work arrangements for other personnel not required to work on site.

Business development. We continue to experience lower than expected growth in our development business, which we believe is partially attributable to COVID-19. We have responded to these challenges by adopting new methods for meeting and contacting customers. Meanwhile, some customers have begun easing restrictions, but these measures vary among customers and from state to state. Other customers continue to delay their development plans for a variety of reasons such as concerns about the timing of clinical trials.

Manufacturing demand. We believe that there continues to be lower end-user demand for some of the commercial products we manufacture as compared to periods prior to the onset of the COVID-19 pandemic. Third party national data demonstrates that there was a meaningful impact of COVID-19 on the reduction of total prescriptions filled by patients across most therapeutic areas, including chronic cardiovascular and pediatric medications.

Logistics challenges. As global logistics and supply chain issues continue to present obstacles to the U.S. economy and our business, we will continue to work to overcome these challenges. We also expect to continue facing inflationary pressure on raw materials, labor and logistics. During the three months ended September 30, 2021, we experienced minimal supply chain disruption.

Our sales and manufacturing operations for the nine months ended September 30, 2021 were disrupted as a result of the pandemic because of production slowdowns, stoppages and decreased demand for the products we manufacture. While we are not currently expecting that future results will be materially impacted by the pandemic, there can be no assurance that such future results will not be impacted. While vaccines have proven effective in reducing the severity and mortality of COVID-19, including the variants that have evolved to date, the overall vaccination rate in the United States has not reached the level required for herd immunity. Certain variants of COVID-19, such as the delta variant, are proving to be more easily spread than earlier variants. We may also be adversely impacted by broader economic effects associated with the pandemic such as inflation, changes in laws and general volatility in the markets. The continued low vaccination rate, and the emergence of new variants, which could prove resistant to existing vaccines, could again result in major disruptions to businesses and markets worldwide and our business, results of operations and financial condition could be materially and adversely affected. We will continue to closely monitor any developments.

Financial overview

Revenues

We recognize three types of revenue: manufacturing, profit-sharing and research and development.

Manufacturing

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.

Profit-sharing

We recognize profit-sharing or royalty revenue, collectively referred to as profit-sharing revenue, related to the sale of products by our commercial partners that incorporate our technologies. Profit-sharing revenues are generally recognized under the terms of the applicable license, development and/or supply agreement. For arrangements that include sales-based profit-sharing and the license is deemed to be the predominant item to which the profit-sharing relates, we recognize revenue when the related sales occur by the commercial partner. For arrangements that include sales-based profit-sharing and the license is not deemed to be the predominant item to which the profit-sharing relates, we recognize revenue when the performance obligation to which the profit-sharing has been allocated has been satisfied, which is upon transfer of control of a product to a customer. In these cases, significant judgment is required to calculate the estimated variable consideration from such profit-sharing using the expected value method based on historical commercial partner pricing and deductions. Estimated variable consideration is partially constrained due to the uncertainty of price adjustments made by our commercial partners, which are outside of our control. Factors causing price adjustments by our commercial partners include increased competition in the products' markets, mix of volume between the commercial partners' customers, and changes in government pricing.

Research and development

Research and development revenue includes services associated with formulation, process development, clinical trial material and clinical trial support services, as well as custom development of manufacturing processes and analytical methods for a customer's non-clinical, clinical and commercial products. Such revenues are recognized at a point in time or over time depending on the nature and particular facts and circumstances associated with the contract terms.

In contracts that specify milestones, we evaluate whether the milestones are considered probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. Milestone payments related to arrangements under which we have continuing performance obligations are deferred and recognized over the period of performance. Milestone payments that are not within our control, such as submission for approval to regulators by a commercial partner or approvals from regulators, are not considered probable of being achieved until those submissions are submitted by the customer or approvals are received.

In contracts that require revenue recognition over time, we utilize input or output methods, depending on the specifics of the contract, that compare the cumulative work-in-process to date to the most current estimates for the entire performance obligation. Under these contracts, the customer typically owns the product details and process, which have no alternative use. These projects are customized to each customer to meet its specifications and typically only one performance obligation is included. Each project represents a distinct service that is sold separately and has stand-alone value to the customer. The customer also retains control of its product as the product is being created or enhanced by our services and can make changes to its process or specifications upon request.

Cost of sales and selling, general and administrative expenses

Cost of sales consists of inventory costs, including production wages, material costs and overhead, and other costs related to the recognition of revenue. Selling, general and administrative expenses consists of salaries and related costs for corporate administrative, public company costs, business development personnel as well as legal, patent-related expenses and consulting fees. Public company costs include compliance, auditing services, tax services, insurance and investor relations.

With the August 2021 acquisition of IriSys, we have been integrating and reorganizing our collective employee base to support a multi-site organization. As a result, we are reevaluating our expense classification policies which may result in material reclassification in the fourth quarter of 2021.

We expect our business development expenses to increase during the remainder of 2021 as we continue to expand our sales team in various geographies, in anticipation of business growth from new formulation and development capabilities as well as the expansion of the team through the acquisition of IriSys.

For the first nine months of 2021, we qualified for approximately $4.4 million of federal employee retention credits. The employee retention credits are recognized as offsets to our expenses in the same period that the related employee expenditures are recognized. The expense offset for the three and nine months ended September 30, 2021 was approximately $1.9 million and $3.6 million, respectively, and we expect to recognize an additional expense offset of $0.8 million in the fourth quarter of 2021. We do not expect to qualify for any additional credits based on recent legislative activity.

Amortization of intangible assets

Historically, we recognized amortization expense related to an intangible asset for our profit-sharing and contract manufacturing relationships on a straight-line basis over an estimated useful life of six years. Amortization stopped when the intangible asset reached the end of its useful life in April 2021. With the acquisition of IriSys, we are recognizing amortization expense related to acquired customer relationships, backlog and trademarks and trade names on a straight-line basis over an estimated useful life of 12, 2.4, and 1.5 years, respectively.

Interest expense

Interest expense for the periods presented primarily relates to our Athyrium senior secured term loans and the amortization of related financing costs. In addition, following the acquisition of IriSys, there is additional interest expense related to interest on the sellers note which was a component of the IriSys acquisition purchase price.

Net operating losses and tax carryforwards

As of December 31, 2020, we had federal net operating loss, or NOL, carry forwards of approximately $130.6 million, $122.4 million of which have an indefinite carry forward period. The remaining $8.2 million of federal NOL carry forwards, $127.4 million of state NOL carry forwards and federal and state research and development tax credit carryforwards of $4.4 million are also available to offset future taxable income, but they will begin to expire at various dates beginning in 2028 if not utilized. We believe that it is more likely than not that the deferred income tax assets associated with our U.S. operations will not be realized, and as such, there is a full valuation allowance against our U.S. deferred tax assets.

Results of operations

Comparison of third quarters 2021 and 2020

(in millions)	Three months ended September 30, 2021	2020
Revenue	$ 18.2	$ 19.3
Operating expenses:		
Cost of sales (excluding amortization of intangible assets)	13.2	11.7
Selling, general and administrative	4.6	4.4
Amortization of intangible assets	0.1	0.7
Total operating expenses	17.9	16.8
Operating income (loss)	0.3	2.5
Interest expense	(3.8)	(4.6)
Net loss	$ (3.5)	$ (2.1)

Revenue. The decrease of $1.1 million was primarily the result of decreased product sales due to timing of customer orders. This decrease was partially offset by increases in revenue due to the acquisition of IriSys as well as higher revenues from our clinical trial materials business including revenue from the Otsuka Pharmaceutical Co., Ltd. commercial product tech transfer project.

Cost of sales. The increase of $1.5 million was primarily due to costs from the San Diego facility due to the acquisition of IriSys and is partially offset by lower costs due to certain employment incentive tax credits in 2021.

Selling, general and administrative. The increase of $0.2 million was primarily related to deal and integration costs related to the acquisition of IriSys and business development expenses associated with our San Diego team offset by lower public company costs and stock-based compensation expense.

Amortization of intangible assets. The decrease of $0.6 million was because the amortization of CDMO royalties and contract manufacturing relationships acquired in 2015 ended on April 10, 2021 offset by amortization related to the acquisition of IriSys for acquired customer relationships, backlog and trademarks and trade names.

Interest expense. The decrease of $0.8 million was primarily due to reduced term loan borrowings under the Credit Agreement with Athyrium as well as a decrease in the LIBOR base rate of interest on our term loans under the Credit Agreement. This decrease was partially offset by an increase in interest from the sellers note which was a component of the IriSys acquisition purchase price.

Comparison of first nine months 2021 and 2020

(in millions)	Nine months ended September 30, 2021	2020
Revenue	$ 53.1	$ 56.6
Operating expenses:		
Cost of sales (excluding amortization of intangible assets)	39.8	41.6
Selling, general and administrative	13.1	14.1
Amortization of intangible assets	0.9	2.0
Total operating expenses	53.8	57.7
Operating loss	(0.7)	(1.1)
Interest expense	(11.7)	(14.7)
Gain on extinguishment of debt	3.4	—
Net loss	$ (9.0)	$ (15.8)

Revenue. The decrease of $3.5 million was primarily the result of the discontinuation of two commercial product lines by our commercial partners announced in the first quarter of 2020 as well as decreased product sales from one of our commercial partners due to timing of customer orders. During the 2021 period, increased product sales from one of our commercial partners, increased revenue due to the acquisition of IriSys as well as higher revenues from our clinical trial materials new business growth activities, have partially offset the decrease.

Cost of sales. The decrease of $1.8 million was primarily due to lower commercial manufacturing volumes and reflects lower costs due to the prior year reduction in force as well as certain employment incentive tax credits in 2021 offset by costs from the San Diego facility due to the acquisition of IriSys.

Selling, general and administrative. The decrease of $1.0 million was primarily related to lower public company costs and stock-based compensation expense offset by expenses related to the acquisition of IriSys and business development expenses associated with our San Diego team.

Amortization of intangible assets. The decrease of $1.2 million was because the amortization of CDMO royalties and contract manufacturing relationships acquired in 2015 ended on April 10, 2021 offset by amortization related to the acquisition of IriSys for acquired customer relationships, backlog and trademarks and trade names.

Interest expense. The decrease of $3.0 million was primarily due to reduced term loan borrowings under the Credit Agreement with Athyrium as well as a decrease in the LIBOR base rate of interest on our term loans under the Credit Agreement. This decrease was partially offset by an increase in interest from the sellers note which was a component of the IriSys acquisition purchase price.

Gain on extinguishment of debt. In June 2021, the PPP Note and all accrued interest thereon was forgiven.

Liquidity and capital resources

At September 30, 2021, we had $23.5 million in cash and cash equivalents.

Since our inception, we have financed our operations and capital expenditures primarily from the issuance of equity and debt. During the nine months ended September 30, 2021, our capital expenditures were $2.8 million to scale and support our expansion of capabilities.

We are party to a credit agreement with Athyrium, or the Credit Agreement, which has been fully drawn. The Credit Agreement requires us to repay the outstanding principal amount of $100.0 million on December 31, 2023. The Credit Agreement also includes certain financial covenants that the Company will need to satisfy on a monthly and quarterly basis, including: 1) maintaining a permitted net leverage ratio, calculated as our indebtedness, net of cash and cash equivalents, divided by EBITDA, each as defined in the Credit Agreement; and 2) a minimum amount of cash and cash equivalents on hand.

We are also party to an amended common stock purchase agreement with Aspire Capital Fund LLC, or Aspire Capital. The amended agreement provides that, upon the terms and subject to the conditions and limitations set forth in the agreement, Aspire Capital is committed to purchase, at our sole election, up to an aggregate value of $41.2 million in shares of common stock. As of September 30, 2021, there is availability to issue up to $30.0 million or 6,199,299 shares of common stock under the 2019 Common Stock Purchase Agreement.

In August 2021, we acquired IriSys for $50.2 million by paying $24.0 million in cash, net of cash acquired, and issuing a note and equity with fair values of $5.3 million and $20.9 million, respectively, to the former equity holders of IriSys.

We may require additional financing and if we do, we may raise such additional funds through debt refinancing, bank or other loans, through strategic development, 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. Further, our ability to access capital market or otherwise raise capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. 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 to access capital.

Sources and uses of cash

(amounts in millions)	Nine months ended September 30, 2021	2020
Net cash provided by (used in) continuing operations:		
Operating activities	$ 6.4	$ 6.4
Investing activities	(26.8)	(5.5)
Financing activities	20.1	2.6
Net cash (used in) provided by continuing operations	$ (0.3)	$ 3.5
Net cash used in discontinued operations	$ —	$ (1.2)

Cash flows from operating activities represent our net loss as adjusted for stock-based compensation, depreciation, non-cash interest expense, amortization of intangibles, a gain on extinguishment of debt and changes in operating assets and liabilities. Cash flows from operations were relatively flat for the first nine months of 2021 compared to 2020.

Net cash used in investing activities include $24.0 million paid to acquire IriSys for the first nine months of 2021 and capital expenditures in both periods to scale and support our expansion of capabilities.

Net cash provided by financing activities in the first nine months of 2021 primarily included net proceeds from an issuance of common stock of $32.1 million, partially offset by debt repayments of $10.1 million and financing costs of $1.4 million paid in connection with the debt amendments and common stock issuances.

Net cash used in discontinued operations during 2020 was to settle outstanding liabilities related to our former acute care research and development business.

Forward-looking factors

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

- the extent to which we in-license, acquire or invest in products, businesses and technologies;
- the timing and extent of our manufacturing and capital expenditures;
- our ability to maintain or expand our relationships and contracts with our commercial partners;
- our ability to grow and diversify our business with new customers, including our ability to meet desired project outcomes with development customers;
- our ability to regain profitability;
- our ability to comply with stringent U.S. & foreign government regulation in the manufacture of pharmaceutical products, including cGMP and U.S. DEA requirements;
- our ability to raise additional funds through equity or debt financings or sale of certain assets;
- the costs of preparing, submitting and prosecuting patent applications and maintaining, enforcing and defending intellectual property claims; and
- the extent to which health epidemics and other outbreaks of communicable diseases, including the ongoing COVID-19 pandemic, could disrupt our operations or materially and adversely affect our business and financial conditions.

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 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 September 30, 2021:

		Payments due by period			
(in millions)	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Debt obligations (1):					
Principal	$ 106.5	$ 2.0	$ 104.1	$ 0.1	$ 0.3
Interest	11.3	5.0	6.1	0.1	0.1
Purchase obligations (2)	4.5	4.0	0.5	—	—
Operating leases (3)	10.8	1.1	2.3	2.3	5.1
Other long-term liabilities (4)	1.3	1.0	0.3	—	—
Total	$ 134.4	$ 13.1	$ 113.3	$ 2.5	$ 5.5

(1) Debt obligations consist of principal, an exit fee of 1% of that principal, and interest on $100.0 million of outstanding term loans under our credit facility with Athyrium, $6.1 million of notes issued to the former members of IriSys and a small finance lease. Because the Athyrium term loans bear interest at a variable rate based on LIBOR, we estimated future interest commitments utilizing the LIBOR rate as of September 30, 2021. In accordance with U.S. GAAP, the future interest obligations are not recorded on our consolidated balance sheet.

(2) Purchase obligations consist of cancelable and non-cancelable purchase commitments related to inventory, capital expenditures and other goods or services. In accordance with U.S. GAAP, these obligations are not recorded on our consolidated balance sheets.

(3) We are party to two operating leases for development facilities in California and Georgia that end in 2031 and 2025, respectively. The leases each include options to extend at our discretion.

(4) We have entered into employment agreements with each of our named executive officers that provide for, among other things, severance commitments of up to $1.3 million should we terminate the named executive officers for convenience or if certain events occur following a change in control. In addition, we would be subject to other contingencies of up to $3.6 million in the aggregate if certain events occur following a change in control; because these obligations are contingent, the amounts are not included in the table above.

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

The following supplements the critical accounting policies and estimates disclosed in the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section of our Annual Report.

Business combinations

Business acquisitions are accounted for in accordance with Accounting Standards Codification, or ASC, Topic 805, *Business Combinations*. In purchase accounting, identifiable assets acquired and liabilities assumed, are recognized at their estimated fair values at the acquisition date, and any remaining purchase price is recorded as goodwill. In determining the fair values of the consideration transferred, the assets acquired and the liabilities assumed, we make significant estimates and assumptions, particularly with respect to long-lived tangible and intangible assets. Critical estimates used in valuing tangible and intangible assets include, but are not limited to, future expected cash flows, discount rates, market prices and asset lives.

While we use our best estimates and assumptions as part of the purchase price allocation process to accurately value assets acquired and liabilities assumed at the business acquisition date, our estimates and assumptions are inherently uncertain and subject to refinement. As a result, during the purchase price allocation period, which is generally one year from the business acquisition date, we record adjustments to the assets acquired and liabilities assumed, with the corresponding offset to goodwill. For changes in the valuation of intangible assets between preliminary and final purchase price allocation, the related amortization is adjusted in the period it occurs. Subsequent to the purchase price allocation period any adjustment to assets acquired or liabilities assumed is included in operating results in the period in which the adjustment is determined.

Although our estimates of fair value are based upon assumptions believed to be reasonable, actual results may differ. See note 3 to the consolidated financial statements contained in Part I, Item 1 for more information related to the acquisition of IriSys.

Item 3. Quantitative and qualitative disclosures about market risk

There has been no material change in our assessment of our sensitivity to market risk described in the Annual Report.

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 September 30, 2021. 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 September 30, 2021, 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.

Information regarding legal and regulatory proceedings is set forth in note 8 to our consolidated financial statements included in Part I, Item 1 of this Quarterly Report, and is incorporated by reference herein.

We are also engaged in various other legal actions arising in the ordinary course of our business (such as, for example, proceedings relating to employment matters or the initiation or defense of proceedings relating to intellectual property rights) and, while there can be no assurance, we believe that the ultimate outcome of these other legal actions will not have a material adverse effect on our business, results of operations, financial condition or cash flows.

Item 1A. Risk factors.

In connection with the Acquisition, we have supplemented our risk factors as previously reported in our Annual Report as follows:

The acquisition and integration of IriSys may present many risks and we may not realize the strategic and financial goals that were contemplated at the time we entered into the Purchase Agreement.

We acquired IriSys on August 13, 2021, and we are in the process of integrating IriSys with our Company. The success of the acquisition depends on, among other things, our ability to combine our business with IriSys in a manner that does not materially disrupt existing relationships and allows us to achieve operational synergies. If we are unable to achieve these objectives, the anticipated benefits of the acquisition may not be realized fully or at all or may take longer to realize than expected. In particular, the acquisition may not be accretive to our stock value in the near or long term.

Some of the risks we may face in connection with the acquisition include the following:

- We may not realize the benefits we expect to receive from the transaction, such as anticipated synergies;
- We may have difficulties managing IriSys' business portfolio or retaining key personnel from IriSys;
- We may experience performance shortfalls as a result of the diversion of management's attention from our core business caused by integration efforts;
- The acquisition may not further our business strategy as we expected, we may not successfully integrate IriSys as planned, there could be unanticipated adverse impacts on IriSys' business, or we may otherwise not realize the expected return on our investments, which could adversely affect our business or operating results and potentially cause impairment to assets that we record as a part of an acquisition including intangible assets and goodwill;
- Our operating results or financial condition may be adversely impacted by (i) claims or liabilities related to IriSys' business including, among others, claims from U.S. or international regulatory or other governmental agencies, terminated employees, current or former customers or business partners, or other third parties; (ii) pre-existing contractual relationships of IriSys that we would not have otherwise entered into, the termination or modification of which may be costly or disruptive to our business; (iii) unfavorable accounting treatment as a result of IriSys' practices; (iv) future intellectual property claims or disputes; and (v) the final valuation and accounting treatment of the acquisition and any reclassification or estimates needed to conform presentation between IriSys and Recro;
- Prior to the acquisition, IriSys was not required to maintain an internal control infrastructure that would meet the standards of a public company in the United States, including the requirements of the Sarbanes-Oxley Act of 2002. The costs that we may incur to implement such controls and procedures may be substantial and we could encounter unexpected delays and challenges in this implementation. In addition, we may discover significant deficiencies or material weaknesses in the quality of IriSys' financial and disclosure controls and procedures;
- IriSys operates in segments of the contract development and manufacturing organization market that we have less experience with, and our further expansion of operations into these areas could present various integration challenges and result in increased costs and other unforeseen challenges; and
- We may fail to identify or assess the magnitude of certain liabilities, shortcomings or other circumstances prior to acquiring IriSys, which could result in unexpected litigation or regulatory exposure, unfavorable accounting

treatment, a diversion of management's attention and resources, and other adverse effects on our business, financial condition, and operating results.

If any of these events were to occur, our ability to maintain relationships with customers, suppliers and employees or our ability to achieve the anticipated benefits of the acquisition could be adversely affected, or could reduce our future earnings or otherwise adversely affect our business and financial results and, as a result, adversely affect the market price of our common stock.

In addition, we expect to continue to incur additional costs integrating the operations of IriSys, as well as higher regulatory and personnel costs, which cannot be fully estimated accurately at this time. If the total costs of the integration of our companies exceed the anticipated benefits of the acquisition, our financial results could be adversely affected.

Our future success depends on our ability to attract and retain qualified personnel, which may be affected by recent government vaccine mandates.

As a party to certain contracts with the federal government, we are subject to various federal regulatory requirements including, but not limited to, COVID-19 vaccine mandates. These vaccine mandates present certain risks regarding our ability to attract or retain talent, including the willingness of our employees to comply with such mandates and the potential conflict with actions by certain states in which we operate that are in conflict with the federal mandate. If a significant number of our employees choose not to comply with applicable mandates and we are forced to terminate their employment as a result, our business could be materially harmed. The inability to recruit or the loss of the services of any executive or key employee could impede the progress of our business development, manufacturing, quality, growth and diversification objectives.

Our U.S. government contracts require compliance with numerous laws that may present additional risk and liability.

Through IriSys, we provide services to the National Institutes of Health, a part of the U.S. Department of Health and Human Services. As a result, we must comply with certain laws and regulations relating to the award, administration, and performance of U.S. government contracts. U.S. government contracts typically contain a number of extraordinary provisions that would not typically be found in commercial contracts and which may create a disadvantage and additional risks to us as compared to competitors that do not rely on government contracts. As a U.S. government service provider and subcontractor, we are subject to increased risks of investigation, audit, criminal prosecution, and other legal actions and liabilities to which purely private sector companies are not. The results of any such actions could adversely impact our business and have an adverse effect on our financial performance.

Additionally, a violation of specific laws and regulations could result in the imposition of fines and penalties or the termination of our contracts, as well as suspension or debarment. The suspension or debarment in any particular case may be limited to the facility, contract or subsidiary involved in the violation or could be applied to our entire enterprise in certain severe circumstances. Even a narrow scope suspension or debarment could result in negative publicity that could adversely affect our ability to renew contracts and to secure new contracts, both with the U.S. government and private customers, which could materially and adversely affect our business and results of operations. Fines and penalties could be imposed for failing to follow procurement integrity and bidding rules, employing improper billing practices, receiving or paying kickbacks, or filing false claims, among other potential violations. In addition, we could suffer serious reputational harm and the value of our common stock could be negatively affected if allegations of impropriety related to such contracts are made against us.

Item 2. Unregistered sales of equity securities and use of proceeds.

As previously disclosed on a Current Report on Form 8-K, on August 13, 2021, we entered into a Unit Purchase Agreement, or the Purchase Agreement, in connection with the acquisition of IriSys.

Pursuant to the terms of the Purchase Agreement, we agreed to issue 9,302,718 shares of our common stock to the former equity holders of IriSys (or their permitted designees) on the six-month anniversary of the closing of the acquisition in February 2022.

The offering and sale of such shares was made pursuant to the exemption from the registration requirements of the Securities Act of 1933, as amended, provided by Section 4(a)(2) thereof.

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	Unit Purchase Agreement, dated August 13, 2021, by and among Recro Pharma, Inc., IriSys, LLC, the Sellers (as defined therein), and IriSys, Inc. as the Seller's Representative	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 13, 2021
10.2	Form of Subordinated Promissory Note	Incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on August 13, 2021
10.3	Sixth Amendment to Credit Agreement, dated as of August 13, 2021, by and among Recro Pharma, Inc., certain subsidiaries of Recro Pharma, Inc., named as guarantors therein, the lenders named therein and Athyrium Opportunities III Acquisition LP, as administrative agent	Incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on August 13, 2021
31.1	Rule 13a-14(a)/15d-14(a) certification of Principal Executive Officer	Filed herewith
31.2	Rule 13a-14(a)/15d-14(a) certification of Principal Financial and Accounting Officer	Filed herewith
32.1	Section 1350 certification, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Filed herewith
101 INS	XBRL Instance Document	Filed herewith
101 SCH	XBRL Taxonomy Extension Schema	Filed herewith
101 CAL	XBRL Taxonomy Extension Calculation Linkbase	Filed herewith
101 DEF	XBRL Taxonomy Extension Definition Linkbase	Filed herewith
101 LAB	XBRL Taxonomy Extension Label Linkbase	Filed herewith
101 PRE	XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith

SIGNATURES

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

RECRO PHARMA, INC.

Date: November 9, 2021

By: /s/ J. David Enloe, Jr.
J. David Enloe, Jr.
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 9, 2021

By: /s/ Ryan D. Lake
Ryan D. Lake
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION

I, J. David Enloe, Jr., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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: November 9, 2021

/s/ J. David Enloe, Jr.
J. David Enloe, Jr.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Ryan D. Lake, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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: November 9, 2021

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

Exhibit 32.1

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 quarterly period ended September 30, 2021, 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: November 9, 2021

/s/ J. David Enloe, Jr.
J. David Enloe, Jr.
President and Chief Executive Officer
(Principal Executive Officer)

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