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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 10-Q**

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

For the Quarterly Period Ended: September 30, 2020

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

Commission File Number: 001-39101

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**Baudax Bio, Inc.**

(Exact name of registrant as specified in its charter)

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Pennsylvania  
(State or other jurisdiction of  
incorporation or organization)

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

47-4639500  
(I.R.S. Employer  
Identification No.)

19355  
(Zip Code)

(484) 395-2440

(Registrant's telephone number, including area code)

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

Title of Each Class  
Common Stock, par value \$0.01

Trading Symbol  
BXXRX

Name of Exchange on Which Registered  
Nasdaq Capital Market

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

None

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Non-accelerated filer

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 5, 2020, there were 26,238,825 shares of common stock, par value \$0.01 per share, outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

**BAUDAX BIO, INC.**  
Consolidated Balance Sheets  
(Unaudited)

(amounts in thousands, except share and per share data)	September 30, 2020	December 31, 2019
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 24,608	\$ 17,740
Inventory	1,784	—
Prepaid expenses and other current assets	2,563	2,395
Total current assets	28,955	20,135
Property, plant and equipment, net	4,835	4,821
Intangible assets, net	24,898	26,400
Goodwill	2,127	2,127
Other long-term assets	652	730
Total assets	<u>\$ 61,467</u>	<u>\$ 54,213</u>
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,782	\$ 271
Accrued expenses and other current liabilities	7,292	3,850
Current portion of long-term debt, net	171	—
Current portion of contingent consideration	10,677	3,592
Total current liabilities	19,922	7,713
Long-term debt, net	8,753	—
Warrant liability	10,228	—
Long-term portion of contingent consideration	67,433	62,766
Other long-term liabilities	361	455
Total liabilities	<u>106,697</u>	<u>70,934</u>
Commitments and contingencies (Note 12)		
Shareholders' equity:		
Preferred stock, \$0.01 par value. Authorized, 10,000,000 shares; none issued and outstanding	—	—
Common stock, \$0.01 par value. Authorized, 100,000,000 shares; issued and outstanding, 18,374,604 shares at September 30, 2020 and 9,350,709 shares at December 31, 2019	184	94
Additional paid-in capital	49,864	19,405
Accumulated deficit	(95,278)	(36,220)
Total shareholders' equity (deficit)	(45,230)	(16,721)
Total liabilities and shareholders' equity	<u>\$ 61,467</u>	<u>\$ 54,213</u>

See accompanying notes to consolidated and combined financial statements.

**BAUDAX BIO, INC.**  
Consolidated and Combined Statements of Operations  
(Unaudited)

(amounts in thousands, except share and per share data)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue, net	\$ 68	\$ —	\$ 417	\$ —
<b>Operating expenses:</b>				
Cost of sales	540	—	1,190	—
Research and development	1,469	1,845	5,889	18,578
Selling, general and administrative	13,763	4,524	33,026	21,809
Amortization of intangible assets	643	—	1,502	—
Change in warrant valuation	(11,182)	—	2,863	—
Change in contingent consideration valuation	(17,427)	3,909	14,252	(15,241)
Total operating expenses	(12,194)	10,278	58,722	25,146
Operating income (loss)	12,262	(10,278)	(58,305)	(25,146)
<b>Other expense:</b>				
Other expense	(577)	(37)	(753)	(86)
Net income (loss)	\$ 11,685	\$ (10,315)	\$ (59,058)	\$ (25,232)
<b>Per share information:</b>				
Net income (loss) per share of common stock, basic	\$ 0.64	\$ (1.10)	\$ (3.84)	\$ (2.70)
Net income (loss) per share of common stock, dilutive	\$ 0.62	\$ (1.10)	\$ (3.84)	\$ (2.70)
Weighted average common shares outstanding, basic	18,374,604	9,350,709	15,366,861	9,350,709
Weighted average common shares outstanding, diluted	18,768,376	9,350,709	15,366,861	9,350,709

See accompanying notes to consolidated and combined financial statements.

**BAUDAX BIO, INC.**  
Consolidated and Combined Statements of Shareholders' Equity  
(Unaudited)

**For the Nine Months Ended September 30, 2020**

(amounts in thousands, except share data)	Common Stock		Additional paid-in capital	Accumulated Deficit	Total
	Shares	Amount			
Balance, December 31, 2019	9,350,709	\$ 94	\$ 19,405	\$ (36,220)	\$ (16,721)
Recro Pharma allocation - stock-based compensation	—	—	456	—	456
Stock-based compensation expense	—	—	2,177	—	2,177
Issuance of common stock and warrants for public offering, net	7,692,308	77	14,899	—	14,976
Sale of common stock under equity facility, net of transaction costs	441,967	4	3,608	—	3,612
Issuance of common stock upon Separation	45,874	1	—	—	1
Issuance of restricted stock units, net of shares withheld for income taxes	39,130	—	(95)	—	(95)
Net loss	—	—	—	(40,298)	(40,298)
Balance, March 31, 2020	<u>17,569,988</u>	<u>\$ 176</u>	<u>\$ 40,450</u>	<u>\$ (76,518)</u>	<u>\$ (35,892)</u>
Recro Pharma allocation - stock-based compensation	—	—	445	—	445
Stock-based compensation expense	—	—	1,864	—	1,864
Stock issuance costs	—	—	(3)	—	(3)
Warrants issued in connection with financing facility	—	—	1,423	—	1,423
Exercise of warrants	804,616	8	3,196	—	3,204
Net loss	—	—	—	(30,445)	(30,445)
Balance, June 30, 2020	<u>18,374,604</u>	<u>\$ 184</u>	<u>\$ 47,375</u>	<u>\$ (106,963)</u>	<u>\$ (59,404)</u>
Recro Pharma allocation - stock-based compensation	—	—	444	—	444
Stock-based compensation expense	—	—	2,045	—	2,045
Net income	—	—	—	11,685	11,685
Balance, September 30, 2020	<u>18,374,604</u>	<u>\$ 184</u>	<u>\$ 49,864</u>	<u>\$ (95,278)</u>	<u>\$ (45,230)</u>

**For the Nine Months Ended September 30, 2019**

(amounts in thousands, except share data)	Parent Company Net Investment
Balance, December 31, 2018	\$ (68,347)
Net loss	(4,335)
Net transfer from parent	19,823
Parent allocation - share-based compensation	1,527
Balance, March 31, 2019	<u>\$ (51,332)</u>
Net loss	(10,582)
Net transfer from parent	31,052
Parent allocation - share-based compensation	1,675
Balance, June 30, 2019	<u>\$ (29,187)</u>
Net loss	(10,315)
Net transfer from parent	3,027
Parent allocation - share-based compensation	1,052
Balance, September 30, 2019	<u>\$ (35,423)</u>

See accompanying notes to consolidated and combined financial statements.

**BAUDAX BIO, INC.**  
Consolidated and Combined Statements of Cash Flows  
(Unaudited)

(amounts in thousands)	For the Nine Months Ended September 30,	
	2020	2019
<b>Cash flows from operating activities:</b>		
Net loss	\$ (59,058 )	\$ (25,232 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	7,431	4,254
Non-cash interest expense	306	—
Depreciation expense	315	369
Amortization	1,502	—
Change in warrant valuation	2,863	—
Change in contingent consideration valuation	14,252	(15,241 )
Changes in operating assets and liabilities:		
Inventory	(1,784 )	—
Prepaid expenses and other current assets	(90 )	1,199
Accounts payable, accrued expenses and other liabilities	4,837	(7,453 )
Net cash used in operating activities	(29,426 )	(42,104 )
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	(307 )	(1,633 )
Acquisition of license agreement	—	(165 )
Net cash used in investing activities	(307 )	(1,798 )
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of long-term debt, net of transaction costs	10,041	—
Proceeds from public offering, net of transaction costs	23,085	—
Proceeds from equity facility, net of transaction costs	3,612	—
Proceeds from warrant exercises	2,458	—
Investment from parent company	—	53,902
Payments of withholdings on shares withheld for income taxes	(95 )	—
Payment of contingent consideration	(2,500 )	(10,000 )
Net cash provided by financing activities	36,601	43,902
Net increase in cash and cash equivalents	6,868	—
Cash and cash equivalents, beginning of period	17,740	—
Cash and cash equivalents, end of period	\$ 24,608	\$ —
<b>Supplemental disclosure of cash flow information:</b>		
Purchase of property, plant and equipment included in accrued expenses and accounts payable	\$ 22	\$ —
Fair value of warrants issued in connection with public offering	\$ 8,111	\$ —
Fair value of warrants issued in connection with financing facility	\$ 1,423	\$ —

See accompanying notes to consolidated and combined financial statements.

**BAUDAX BIO, INC.**

Notes to the Consolidated and Combined Financial Statements  
(amounts in thousands, except share and per share data)  
(Unaudited)

**(1) Background**

Business

Baudax Bio, Inc. (“Baudax Bio” or the “Company”) is a pharmaceutical company primarily focused on developing and commercializing innovative products for acute care settings. Baudax Bio believes it can bring valuable therapeutic options for patients, prescribers and payers, such as its lead product, ANJESO® (meloxicam) injection, to the acute care markets.

On February 20, 2020, the Company announced that the U.S. Food and Drug Administration (“FDA”) approved the New Drug Application (“NDA”) for ANJESO, which is indicated for the management of moderate to severe pain, alone or in combination with other non-NSAID analgesics. On June 15, 2020, Baudax Bio announced the commercial launch of ANJESO and that the Centers for Medicare and Medicaid Services (“CMS”) approved transitional pass-through status and established a new reimbursement C-code for ANJESO.

On August 6, 2020, the Company announced CMS established a new permanent J-code for ANJESO facilitating reimbursement in the hospital outpatient, ambulatory surgery center and physician office settings of care. The code, J1738 (Injection, meloxicam, 1 mg), took effect on October 1, 2020 and replaced the previously issued C-code.

The Separation

Pursuant to the Separation Agreement between Recro Pharma, Inc. (“Recro”) and Baudax Bio, Recro transferred the assets, liabilities, and operations of its Acute Care business to the Company (the “Separation”) and, on November 21, 2019, the distribution date, each Recro shareholder received one share of the Company’s common stock for every two and one-half shares of Recro common stock held of record at the close of business on November 15, 2019, the record date for the distribution (the “Distribution”). Additionally, Recro contributed \$19,000 of cash to Baudax Bio in connection with the Separation. Following the Distribution and Separation, Baudax Bio operates as a separate, independent company. References to “the Company” represent Baudax Bio or the Acute Care Business of Recro for periods prior to the Separation.

Basis of Presentation Related to the Separation

For all periods prior to the Separation, the accompanying combined financial statements represent the Acute Care Business of Recro and are derived from Recro’s consolidated financial statements. The Acute Care Business of Recro did not consist of a separate, standalone group of legal entities for public company reporting and certain other corporate functions in the periods prior to the Separation and, accordingly, allocations were required through the Distribution date. These combined financial statements, prior to the Separation, reflect the Company’s historical financial position, results of operations and cash flows as the business was operated as part of Recro prior to the Separation, in conformity with U.S. generally accepted accounting principles (“U.S. GAAP”). See Note 15 for a description of the agreements entered into between Recro and Baudax Bio following the Separation.

Prior to the Separation, the combined financial statements include certain assets and liabilities that had historically been held at the Recro corporate level, but which were specifically identifiable or allocable to the Company. All intracompany transactions and accounts have been eliminated. All intercompany transactions between the Company and Recro are considered to be effectively settled in the combined financial statements at the time the transaction was recorded. The total net effect of the settlement of these intercompany transactions was reflected in the combined statements of cash flows as a financing activity and in the combined balance sheet as parent company net investment. The Company did not record interest expense on amounts funded by Recro. Long-term debt held at the Recro corporate level was retained by Recro and was not assumed by the Company.

Historically, certain corporate level activity costs have been incurred and reported within the legal entity that includes the Recro Acute Care Business. The Company’s combined financial statements, prior to the Separation, include an allocation of these expenses related to these certain Recro corporate functions, including senior management, legal, human resources, finance, and information technology through the distribution date. These expenses are included in selling, general and administrative expense and have been allocated based on direct usage or benefit where identifiable, with the remainder allocated on a pro rata basis of expenses, headcount, or other measures. The Company considers the expense allocation methodology and results to be reasonable for all periods presented prior to the Separation, however, the allocations may not be indicative of the actual expense that would have been incurred had the Company operated as an independent, publicly-traded company for the periods presented prior to the Separation. For the three and nine months ended September 30, 2019, a total of \$1,516 and \$6,467, respectively, of these costs have been allocated to Recro’s contract manufacturing and development segment (the “CDMO business”).

The income tax amounts in the combined financial statements for periods prior to the Separation have been calculated based on a separate return methodology and are presented as if the Company was a standalone taxpayer in each of its tax jurisdictions prior to

the Separation. Because of the Company's history of losses as a standalone entity, a full valuation allowance is recorded against deferred tax assets in all periods presented.

Upon the Separation, the Company adopted its own share-based compensation plan. Recro maintains its stock-based compensation plan at a corporate level. Certain of the Company's employees participated in Recro's stock-based compensation plans prior to the Separation and a portion of the cost of those plans is included in the Company's combined financial statements using an allocation methodology similar to the methodology used to allocate the cash compensation of the related employees.

The parent company net investment balances in these combined financial statements represents the accumulated deficit of the Recro Acute Care Business and the net funding provided to the Company, which are reflected as net transfers from parent in the Combined Statements of Parent Company Net Investment prior to the Separation.

Subsequent to the Separation, the accompanying consolidated financial statements are presented on a consolidated basis and include all of the accounts and operations of Baudax Bio and its subsidiaries. The consolidated financial statements reflect the financial position, results of operations and cash flows of Baudax Bio in accordance with U.S. GAAP. All significant intercompany accounts and transactions are eliminated in consolidation.

The Company has determined that it operates in a single segment involved in the commercialization and development of innovative products for hospital and other acute care settings.

## **(2) Development-Stage Risks and Liquidity**

The Company has incurred losses from operations since inception and has an accumulated deficit of \$5,278 as of September 30, 2020.

The Company has a history of operating losses and negative cash flows while operating as part of Recro and, accordingly, was dependent upon Recro for its capital funding and liquidity needs. Recro contributed \$19,000 to the Company immediately prior to the Distribution. Recro has not committed any additional funding to the Company beyond the \$19,000 that was contributed as of the Distribution date. The Company has raised additional funds from debt and equity transactions as a standalone entity and will be required to raise additional funds to continue to operate as a standalone entity. The Company's ability to generate cash inflows is highly dependent on the commercialization of ANJESO and there can be no assurance that ANJESO can be successfully commercialized. In addition, development activities, clinical and pre-clinical testing and, if approved, commercialization of the Company's other product candidates, will require significant additional funding. The Company could delay clinical trial activity or reduce funding of specific programs in order to reduce cash needs. Insufficient funds may cause the Company to delay, reduce the scope of or eliminate one or more of its development, commercialization, or expansion activities. The Company may raise such funds, if available, through debt financings, bank or other loans, through strategic research and development, licensing (including out-licensing) and/or marketing arrangements or through public or private sales of equity or debt securities from time to time. Financing may not be available on acceptable terms, or at all, and failure to raise capital when needed could materially adversely impact the Company's growth plans and its financial condition or results of operations. Additional debt or equity financing, if available, may be dilutive to holders of the Company's common stock and may involve significant cash payment obligations and covenants that restrict the Company's ability to operate its business.

The Company follows the provisions of Financial Accounting Standards Board ("FASB"), Accounting Standards Codification ("ASC"), Topic 205-40, "*Presentation of Financial Statements — Going Concern*", or ASC 205-40, which requires management to assess the Company's ability to continue as a going concern for one year after the date the consolidated financial statements are issued. The Company expects to seek additional funding to sustain its future operations and while the Company has successfully raised capital in the past, the ability to raise capital in future periods is not assured. Based on the Company's available cash as of September 30, 2020, management has concluded that substantial doubt exists about the Company's ability to continue as a going concern for one year from the date these financial statements are issued. The consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates continuity of operations, the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

## **(3) Summary of Significant Accounting Principles**

### **(a) Basis of Presentation**

The accompanying unaudited consolidated and combined financial statements of the Company and its subsidiaries have been prepared in accordance with U.S. GAAP, for interim financial information and with the instructions of Form 10-Q and Article 10 of Regulation S-X and, therefore, do not include all of the information and notes required by U.S. GAAP for complete annual financial statements. In the opinion of management, the accompanying consolidated and combined financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company's results for the interim periods.



Operating results for the three and nine months ended September 30, 2020 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2020.

The accompanying unaudited interim consolidated and combined financial statements should be read in conjunction with the annual audited financial statements and related notes as of and for the year ended December 31, 2019 included in the Company's Form 10-K.

**(b) Use of Estimates**

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

**(c) Cash and Cash Equivalents**

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

**(d) Property and Equipment**

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

**(e) Business Combinations**

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

**(f) Goodwill and Intangible Assets**

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

The one-step quantitative test calculates the amount of goodwill impairment as the excess of a reporting unit's carrying amount over its fair value, not to exceed the total amount of goodwill allocated to the reporting unit. The Company has one reporting unit.

As of September 30, 2020, the Company's intangible asset is classified as an asset resulting from R&D activities. Historically, prior to receiving FDA approval, the intangible asset was classified as an IPR&D asset. Intangible assets related to IPR&D are considered indefinite-lived intangible assets and are assessed for impairment annually or more frequently if impairment indicators exist. If the associated research and development effort is abandoned, the related assets will be written-off, and the Company will record a noncash impairment loss on its Consolidated and Combined Statements of Operations. For those compounds that reach commercialization, the IPR&D assets will be amortized over their estimated useful lives. The Company determined the useful life of its asset resulting from R&D activities to be approximately 10 years, which is based on the remaining patent life and will be amortized on a straight-line basis. The Company is required to review the carrying value of assets resulting from R&D activities for recoverability whenever events occur or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable.

The Company performs its annual goodwill impairment test as of November 30<sup>th</sup>, or whenever an event or change in circumstances occurs that would require reassessment of the recoverability of goodwill. In performing the evaluation, the Company assesses qualitative factors such as overall financial performance of its reporting unit, anticipated changes in industry and market conditions, intellectual property protection, and competitive environments. Due to the global market disruption from COVID-19 in March 2020, an indicator of potential impairment, the Company performed an impairment test as of March 31, 2020, which indicated that there was no impairment of goodwill or intangible assets resulting from R&D activities. There have been no additional triggering events as of September 30, 2020. The Company will perform its annual goodwill impairment test as of November 30, 2020.

**(g) Revenue Recognition**

Subsequent to regulatory approval for ANJESO from the FDA, the Company began selling ANJESO in the U.S. through a single third-party logistics provider (“3PL”) which takes title to and control of the goods. The Company recognizes revenue from ANJESO product sales at the point the title to the product is transferred to the customer and the customer obtains control of the product. The transaction price that is recognized as revenue for products includes an estimate of variable consideration for reserves, which result from discounts, returns, chargebacks, rebates and other allowances that are offered within contracts between us and our end-customers, wholesalers, group purchasing organizations and other indirect customers. Our payment terms are generally between thirty to ninety days.

The Company’s estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of its anticipated performance and all information (historical, current and forecasted) that is reasonably available. These reserves reflect the Company’s best estimate of the amount of consideration to which the Company is entitled based on the terms of the contracts. The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price only to the extent that is considered probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company’s estimates. If actual results in the future vary from the Company’s estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

**(h) 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 balance is compromised solely from transactions with the Company’s 3PL.

**(i) Research and Development**

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

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

**(j) Stock-Based Awards**

Baudax Awards

Share-based compensation included in the consolidated financial statements following the Separation is based upon the Baudax Bio, Inc. 2019 Equity Incentive Plan (the “2019 Plan”). The plan includes grants of stock options, time-based vesting restricted stock units (“RSUs”) and performance-based RSUs. The Company measures employee stock-based awards at grant-date fair value and recognizes employee compensation expense on a straight-line basis over the vesting period of the award. The Company accounts for forfeitures as they occur.

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

The expected life of stock options was estimated using the "simplified method," as the Company has limited historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock options grants. The simplified method is based on the average of the vesting tranches and the contractual life of each grant. For stock price volatility, the Company uses an average of its peer group's volatility 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.

#### Recro Awards

The Recro Pharma, Inc. 2018 Amended and Restated Equity Incentive Plan (the "Recro Equity Plan") includes stock options, time-based vesting RSUs and performance-based vesting RSUs granted to the Company's employees prior to the Separation. The consolidated and combined financial statements reflect share-based compensation expense based on an allocation of a portion of Recro share-based compensation issued to the Company's employees based on where their services are performed.

Recro 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. Forfeitures are accounted for 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. Recro uses the Black-Scholes option pricing model to value its stock option awards. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. As a result, if factors change and/or management uses different assumptions, stock-based compensation expense could be materially different for future awards.

The expected life of stock options was estimated using the "simplified method," as Recro has limited historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock options grants. The simplified method is based on the average of the vesting tranches and the contractual life of each grant. For stock price volatility, Recro 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.

#### **(k) Income Taxes**

The income tax amounts in these consolidated and combined financial statements for periods prior to the Separation have been calculated based on a separate return methodology and presented as if the Company was a standalone taxpayer in each of its tax jurisdictions. 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. Because of the Company's history of losses as a standalone entity, a full valuation allowance is recorded against deferred tax assets in all periods presented.

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

#### **(l) Net Income (Loss) Per Common Share**

Basic net income (loss) per common share is determined by dividing net income (loss) applicable to common shareholders by the weighted average common shares outstanding during the period. Outstanding warrants, common stock options and unvested restricted stock units are excluded from the calculation of diluted net income (loss) per share when their effect would be anti-dilutive.

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

Prior to the distribution date of November 21, 2019, there were no Baudax Bio shares outstanding, as such, the shares outstanding immediately after the Distribution were used to calculate the net loss per share for all pre-Separation periods presented.

The following table reconciles the shares used in the calculation of basic net income per share to those used for diluted net income per share:

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
<b>Basic and Diluted Income (Loss) Per Share</b>				
Net income (loss)	\$ 11,685	\$ (10,315)	\$ (59,058)	\$ (25,232)
Weighted average common shares outstanding, basic	18,374,604	9,350,709	15,366,861	9,350,709
Dilutive effect of equity awards, based on the treasury stock method	393,772	—	—	—
Weighted average common shares outstanding, diluted	<u>18,768,376</u>	<u>9,350,709</u>	<u>15,366,861</u>	<u>9,350,709</u>

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Options and restricted stock units outstanding	2,098,316	—	1,694,889	—
Warrants	15,107,100	—	15,199,605	—

Amounts in the table above reflect the common stock equivalents of the noted instruments. For the three and nine months ended September 30, 2019, there were no outstanding warrants, common stock options or unvested restricted stock units.

**(m) Recent Accounting Pronouncements**

*Recently Adopted Accounting Pronouncements*

In February 2016, the FASB issued ASU No. 2016-02, “Leases (Topic 842),” or ASU 2016-02. ASU 2016-02 establishes a wholesale change to lease accounting and introduces a lease model that brings most leases on the balance sheet. It also eliminates the required use of bright-line tests in current U.S. GAAP for determining lease classification. In July 2018, the FASB issued ASU No. 2018-11, Leases (“Topic 842”), *Targeted Improvements*, which provides an alternative transition method permitting the recognition of a cumulative-effect adjustment on the date of adoption rather than restating comparative periods in transition as originally prescribed by Topic 842. The new guidance is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted. The Company adopted this guidance as of January 1, 2019. The Company elected the optional transition method to account for the impact of the adoption with a cumulative-effect adjustment in the period of adoption and did not restate prior periods. The Company opted to elect the package of practical expedients to not reassess prior conclusions related to contracts containing leases, lease classification and initial direct costs, and certain other practical expedients, including the use of hindsight to determine the lease term for existing leases and in assessing impairment of the right-of-use asset, and the exception for short-term leases. For its current classes of underlying assets, the Company did not elect the practical expedient under which the lease components would not be separated from the nonlease components. At January 1, 2019, the Company recorded a right-of-use asset of \$1,174 and an operating lease liability of \$1,219. For additional information regarding how the Company is accounting for leases under the new guidance, refer to Note 8.

In August 2018, the FASB issued ASU 2018-13, “Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement,” or ASU 2018-13. ASU 2018-13 removes, modifies and adds certain disclosure requirements in Topic 820 “Fair Value Measurement”. ASU 2018-13 eliminates certain disclosures related to transfers and the valuations process, clarifies the measurement uncertainty disclosure, and requires additional disclosures for Level 3 fair value measurements, including the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. ASU 2018-13 is effective for fiscal years, and interim periods within those fiscal

years, beginning after December 15, 2019 with early adoption permitted. The Company adopted this guidance as of January 1, 2020. The adoption did not have a material impact to the Company or its disclosures.

#### *Accounting Pronouncements Not Yet Adopted*

In June 2016, the FASB issued ASU No. 2016-13, “*Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*,” or ASU 2016-13. ASU 2016-13 requires companies to measure credit losses utilizing a methodology that reflects expected credit losses and requires consideration of a range of reasonable information to estimate credit losses on certain types of financial instruments, including trade receivables and available-for-sale debt securities. ASU 2016-13 is effective for fiscal years beginning after December 15, 2022, including those interim periods within those fiscal years. The Company is currently assessing the impact of adopting this standard, but based on a preliminary assessment, does not expect the adoption of this guidance to have a material impact on its consolidated financial statements.

In August 2020, the FASB issued ASU No. 2020-06, “*Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity*,” or ASU 2020-06. ASU 2020-06 simplifies accounting for convertible instruments by removing major separation models required under current GAAP. ASU 2020-06 removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception, which will permit more equity contracts to qualify for such exception. ASU 2020-06 also simplifies the diluted earnings per share calculation in certain areas. ASU 2020-06 is effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years and early adoption is permitted in annual reporting periods ending after December 15, 2020. The Company is currently assessing the impact of adopting this standard.

#### **(4) 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 and contingent consideration. The Company’s assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of financial assets and financial liabilities and their placement within the fair value hierarchy. Categorization is based on a three-tier valuation hierarchy, which prioritizes the inputs used in measuring fair value, as follows:

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

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

	Fair value measurements at reporting date using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
At September 30, 2020:			
Assets:			
Cash equivalents (See Note 5)			
Money market mutual funds	\$ 22,910	\$ —	\$ —
Total cash equivalents	<u>\$ 22,910</u>	<u>\$ —</u>	<u>\$ —</u>
Liabilities:			
Warrants (See Note 13(c))	\$ —	\$ —	\$ 10,228
Contingent consideration (See Note 12(b))	—	—	78,110
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 88,338</u>
At December 31, 2019:			
Assets:			
Cash equivalents (See Note 5)			
Money market mutual funds	\$ 16,514	\$ —	\$ —
Total cash equivalents	<u>\$ 16,514</u>	<u>\$ —</u>	<u>\$ —</u>
Liabilities:			
Contingent consideration (See Note 12(b))	\$ —	\$ —	\$ 66,358
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 66,358</u>

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

The reconciliation of liabilities measured at fair value on a recurring basis using unobservable inputs (Level 3) is as follows:

	Warrants	Contingent Consideration
Balance at December 31, 2019	\$ —	\$ 66,358
Additions	8,111	—
Exercise of warrants	(746)	—
Payment of contingent consideration	—	(2,500)
Remeasurement	2,863	14,252
Total at September 30, 2020	<u>\$ 10,228</u>	<u>\$ 78,110</u>
Current portion as of September 30, 2020	\$ —	\$ 10,677
Long-term portion as of September 30, 2020	10,228	67,433

The current portion of the contingent consideration represents the estimated probability adjusted fair value that is expected to become payable within one year as of September 30, 2020.

The fair value of the contingent consideration liability is measured as the reporting date using inputs and assumptions as of the date of the financial statements. Events and circumstances impacting the fair value of the liability that occur after the balance sheet date, but before the date that the financial statements are available to be issued are adjusted in the period during which such events and circumstances occur. The fair value of the second contingent consideration component is estimated by applying a risk-adjusted discount rate to the probability-adjusted contingent payments and the expected payment dates. The fair value of the third contingent consideration component is estimated using the Monte Carlo simulation method and applying a risk-adjusted discount rate to the potential payments resulting from probability-weighted revenue projections based upon the expected revenue target attainment dates. The fair value of the fourth contingent consideration component is estimated by applying a risk-adjusted discount rate to the

potential payments resulting from probability-weighted revenue projections and the defined royalty percentage. As of September 30, 2020, the fair value calculations used discount rates in the range of 15.42% to 33.94%, with a weighted average of 23.35%.

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

The Company follows the disclosure provisions of FASB ASC Topic 825, "Financial Instruments", for disclosure purposes for financial assets and financial liabilities that are not measured at fair value. As of September 30, 2020, the financial assets and liabilities recorded on the Consolidated Balance Sheets that are not measured at fair value on a recurring basis include accounts receivable, accounts payable and accrued expenses and approximate fair value due to the short-term nature of these instruments. The fair value of 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 debt approximated fair value at September 30, 2020 due to the fact that the debt arrangements reflect market terms from recent transactions.

**(5) Cash Equivalents**

Cash equivalents as of September 30, 2020 include money market funds. The following is a summary of cash equivalents:

Description	September 30, 2020			Estimated Fair Value
	Amortized Cost	Gross Unrealized		
		Gain	Loss	
Money market mutual funds	\$ 22,910	\$ —	\$ —	\$ 22,910
Total cash equivalents	\$ 22,910	\$ —	\$ —	\$ 22,910

Description	December 31, 2019			Estimated Fair Value
	Amortized Cost	Gross Unrealized		
		Gain	Loss	
Money market mutual funds	\$ 16,514	\$ —	\$ —	\$ 16,514
Total cash equivalents	\$ 16,514	\$ —	\$ —	\$ 16,514

**(6) Inventory**

Inventory is stated at the lower of cost and net realizable value. Cost is determined using the first-in, first-out method. The Company expensed costs related to inventory within the Research and development line in the Consolidated and Combined Statements of Operations until it received approval from the FDA to market a product, at which time the Company commenced capitalization of costs relating to that product. Adjustments to inventory are determined at the raw material, sub-assemblies and finished goods levels to reflect obsolescence or impaired balances.

Inventory was as follows:

	September 30, 2020	December 31, 2019
Raw materials	\$ 67	\$ —
Sub-assemblies	796	—
Finished goods	921	—
	\$ 1,784	\$ —

(7) **Property, Plant and Equipment**

Property, plant and equipment consists of the following:

	September 30, 2020	December 31, 2019
Building and improvements	\$ 196	\$ 196
Furniture, office and computer equipment	935	902
Manufacturing and laboratory equipment	717	717
Construction in progress	4,142	3,846
	<u>5,990</u>	<u>5,661</u>
Less: accumulated depreciation	1,155	840
Property, plant and equipment, net	<u>\$ 4,835</u>	<u>\$ 4,821</u>

Depreciation expense for the three and nine months ended September 30, 2020 was \$104 and \$315, respectively. Depreciation expense for the three and nine months ended September 30, 2019 was \$123 and \$369, respectively.

(8) **Leases**

The Company is a party to various operating leases in Malvern, Pennsylvania, and Dublin, Ireland for office space and office equipment. Right-of-use assets are recorded on the Consolidated Balance Sheet in other long-term assets. Operating lease liabilities are recorded on the Consolidated Balance Sheet in accrued expenses and other current liabilities and other long-term liabilities, based on the timing of expected cash payments.

The Company determines if an arrangement is a lease at inception. The arrangement is a lease if it conveys the right to the Company to control the use of identified property, plant, or equipment for a period of time in exchange for consideration. Lease terms vary based on the nature of operations. The current leased facility recorded on the Consolidated Balance Sheet is classified as an operating lease with a remaining lease term of 2 years. Most leases contain specific renewal options where notice to renew must be provided in advance of lease expiration or automatic renewals where no advance notice is required. Periods covered by an option to extend the lease were included in the non-cancellable lease term when exercise of the option was determined to be reasonably certain. Costs determined to be variable and not based on an index or rate were not included in the measurement of operating lease liabilities. As most leases do not provide an implicit rate, the Company's effective interest rate was used to discount its lease liabilities.

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

As of September 30, 2020, undiscounted future lease payments for non-cancellable operating leases are as follows:

	Lease payments	
Remainder of 2020	\$	127
2021		367
2022		373
Total lease payments		<u>867</u>
Less imputed interest		<u>(172)</u>
Total operating lease liability	\$	<u>695</u>

As of September 30, 2020, the weighted average remaining lease term was 2 years and the weighted average discount rate was 16%.

The components of the Company's lease cost were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating lease cost	\$ 87	\$ 121	\$ 306	\$ 363
Short-term lease cost	38	-	68	14
Total lease cost	<u>\$ 125</u>	<u>\$ 121</u>	<u>\$ 374</u>	<u>\$ 377</u>



Cash paid for amounts included in the measurement of lease liabilities, which is included in operating cash flows, was \$78 and \$344 for the nine months ended September 30, 2020 and 2019, respectively.

**(9) Intangible Assets**

The following represents the balance of the intangible assets at September 30, 2020:

	Cost	Accumulated Amortization	Net Intangible Assets
Asset resulting from R&D activities	\$ 26,400	\$ 1,502	\$ 24,898
Total	<u>\$ 26,400</u>	<u>\$ 1,502</u>	<u>\$ 24,898</u>

Amortization expense for the three and nine months ended September 30, 2020 was \$643 and \$1,502, respectively. There was no amortization expense for the three and nine months ended September 30, 2019.

As of September 30, 2020, future amortization expense is as follows:

	Amortization
Remainder of 2020	\$ 644
2021	2,576
2022	2,576
2023	2,576
2024 and thereafter	16,526
Total	<u>\$ 24,898</u>

**(10) Accrued Expenses and Other Current Liabilities**

Accrued expenses and other current liabilities consist of the following:

	September 30, 2020	December 31, 2019
Payroll and related costs	\$ 3,936	\$ 2,181
Inventory	1,014	0
Professional and consulting fees	667	209
Research and development costs	272	538
Guarantee liability	443	548
Interest payable	119	—
Other	841	374
	<u>\$ 7,292</u>	<u>\$ 3,850</u>

**(11) Debt**

The following table summarizes the components of the carrying value of debt as of September 30, 2020:

Paycheck Protection Program Loan	\$ 1,537
Credit Agreement	10,000
Unamortized deferred issuance costs	(2,637)
Exit fee accretion	24
Total debt	<u>\$ 8,924</u>
Current portion as of September 30, 2020	\$ 171
Long-term portion, net as of September 30, 2020	8,753

**(a) Paycheck Protection Program Loan**

On April 13, 2020, the Company applied to PNC Bank, National Association (the “Lender”) under the Small Business Administration (the “SBA”) Paycheck Protection Program (“PPP”) of the Coronavirus Aid, Relief and Economic Security Act of 2020 (the “CARES Act”) for a loan of \$ 1,537 (the “Loan”). On May 8, 2020, the Company entered into a promissory note with respect to the Loan in favor of the Lender (the “PPP Note”). The Company has used the proceeds of the Loan for covered payroll costs in accordance with the relevant terms and conditions of the CARES Act.

The PPP Note has a two-year term, matures on May 8, 2022, and bears interest at a stated rate of 1.0% per annum. Monthly principal and interest payments, less the amount of any potential forgiveness (discussed below), will commence on the earlier of September 15, 2021, or the date on which a forgiveness decision is received from the Lender. The Company did not provide any collateral or guarantees for the Loan, nor did the Company pay any facility charge to obtain the Loan. The PPP Note provides for customary events of default, including, among others, those relating to failure to make payment, bankruptcy, breaches of representations and material adverse effects. The Company may prepay the principal of the Loan at any time without incurring any prepayment charges.

The Loan may be partially or fully forgiven if the Company complies with the provisions of the CARES Act including the use of Loan proceeds for payroll costs, rent, utilities and certain other expenses, and at least 60% of the Loan proceeds must be used for payroll costs as defined by the CARES Act. Any forgiveness of the Loan will be subject to approval by the SBA and the Lender will require the Company to apply for such treatment in the future. According to the terms of the Credit Agreement, as defined below, if any amount less than \$1,100 is not forgiven, the Company will be required to promptly repay the unforgiven amount of the PPP Note that is less than \$1,100.

**(b) Credit Agreement**

On May 29, 2020 (the “Credit Agreement Closing Date”), the Company entered into a \$50,000 Credit Agreement (the “Credit Agreement”) by and among the Company, Wilmington Trust, National Association, in its capacity as the agent (“Agent”), and MAM Eagle Lender, LLC, as the lender (together with any other lenders under the Credit Agreement from time to time, collectively, the “Lenders”). The Credit Agreement provides for a term loan in the original principal amount of \$10,000 (the “Tranche One Loans”) funded on the Credit Agreement Closing Date. Pursuant to the terms of the Credit Agreement, there are four additional tranches of term loans, in an aggregate original principal amount of \$40,000 (the “Tranche Two Loans”, “Tranche Three Loans”, “Tranche Four Loans” and the “Tranche Five Loans”, and collectively with the Tranche One Loans, the “Term Loans” and each a “Term Loan”).

The Tranche Two Loans in an amount not to exceed \$5,000 may be drawn upon on or before August 29, 2021 provided that the Company generates at least \$5,000 in net revenue in the three consecutive calendar months immediately preceding the date such Tranche Two Loans are funded. The Tranche Two Loans may also be drawn on a subsequent date with the satisfaction of the conditions for the Tranche Three Loans, Tranche Four Loans, or Tranche Five Loans, as applicable, provided that the Tranche Two Loans may not be drawn more than once. The Tranche Three Loans in an amount not to exceed \$5,000 may be drawn upon on or before November 29, 2021 provided that the Company generates at least \$10,000 in net revenue in the three consecutive calendar months immediately preceding such date such Tranche Three Loans are funded. The Tranche Three Loans may also be drawn on a subsequent date with the satisfaction of the conditions for the Tranche Four Loans or Tranche Five Loans, as applicable, provided that the Tranche Three Loans may not be drawn more than once. The Tranche Four Loans in an amount not to exceed \$10,000 may be drawn upon, subject to the consent of the Lenders, on or before August 29, 2022 provided that the Company generates at least \$20,000 in net revenue in the three consecutive calendar months immediately preceding the date such Tranche Four Loans are funded. The Tranche Four Loans may also be drawn on a subsequent date with the satisfaction of the conditions for the Tranche Five Loans provided that the Tranche Four Loans may not be drawn more than once. The Tranche Five Loans in an amount not to exceed \$20,000 may be drawn upon, subject to the consent of the Lenders, on or before March 1, 2023 provided that the Company generates at least \$100,000 in net revenue in the twelve consecutive calendar months immediately preceding the date such Tranche Five Loans are funded.

The Term Loans will bear interest at a per annum rate equal to 13.5%, with monthly, interest-only payments until the date that is three years prior to the Maturity Date (as defined below) (the “Amortization Date”). The maturity date of the Credit Agreement is May 29, 2025, but may be extended to May 29, 2026 provided that the EBITDA (as defined in the Credit Agreement) for the consecutive twelve month period ending on or immediately prior to May 29, 2022 is greater than \$10,000 (such date, “Maturity Date”). Beginning on the Amortization Date, the Company will be obligated to pay amortization payments (in addition to the interest stated above) on such date and each month thereafter in equal month installments of principal based on an amortization schedule of thirty-six months. Any unpaid principal amount of the Term Loans is due and payable on the Maturity Date.

Subject to certain exceptions, the Company is required to make mandatory prepayments of the Term Loans, with the proceeds of asset sales, extraordinary receipts, debt issuances and specified other events. The Company may make voluntary prepayments in whole or in part, subject to a prepayment premium equal to (i) with respect to any prepayment paid on or

prior to the third anniversary of the Tranche One Loan (or, in the case of each of the Tranche Two Loans, Tranche Three Loans, Tranche Four Loans or Tranche Five Loans, the third anniversary of the date each such loan is funded), the remaining scheduled payments of interest that would have accrued on the Term Loans being prepaid, repaid or accelerated, but that remained unpaid, in no event to be less than 5.0% of the principal amount of the Term Loan being prepaid, and (ii) with respect to any prepayment paid after the third but prior to the fourth anniversary of the Tranche One Loan (or, in the case of each of the Tranche Two Loans, Tranche Three Loans, Tranche Four Loans or Tranche Five Loans, the fourth anniversary of the date each such loan is funded), 3.0% of the principal amount of the Term Loan being prepaid. In addition, an exit fee will be due and payable upon prepayment or repayment of the Term Loans (including, without limitation, on the Maturity Date) equal to the lesser of 2.5% of the sum of the aggregate principal amount of the Term Loans advanced or approved to be advanced by the Lenders and \$700; provided that such exit fee will be equal to \$700 if fee is paid in conjunction with a change of control that occurs in connection with the payoff or within 6 months thereof. As of September 30, 2020, the Company will have to pay a 2.5% exit fee, which is \$250 at the current outstanding loan balance and is being accreted to the carrying amount of the debt using the effective interest method over the term of the loan.

The Credit Agreement contains certain usual and customary affirmative and negative covenants, as well as financial covenants including a minimum liquidity requirement of \$5,000 at all times and minimum EBITDA levels that the Company may need to satisfy on a quarterly basis beginning in September 2021, subject to borrowing levels. As of September 30, 2020, the Company was in compliance with the required covenants. As of September 30, 2020, borrowings under the Credit Agreement are classified based on their schedule maturities. As a result of the liquidity conditions discussed in Note 2, the Company is not expected to be able to maintain its minimum liquidity covenant over the next twelve months without additional capital financing. If the Company is unable to maintain its minimum liquidity covenant, it is reasonably possible that the Lenders could demand repayment of the borrowings under the Credit Agreement during the next twelve months.

In connection with the Credit Agreement, the Company issued a warrant to MAM Eagle Lender, LLC to purchase 527,100 shares of the Company's common stock, at an exercise price equal to \$4.59 per share. See Note 13(c) for additional information. The warrant is exercisable through May 29, 2027.

In addition, the Company recorded debt issuance costs for the Credit Agreement of \$1,496 and the fair value of warrants of \$1,423, which are being amortized using the effective interest method over the term of Credit Agreement. Debt issuance cost amortization is included in interest expense within the Consolidated and Combined Statements of Operations. As of September 30, 2020, the effective interest rate was 22.66%, which takes into consideration the non-cash amortization of the debt issuance costs and accretion of the exit fee. The Company recorded debt issuance cost amortization related to the Credit Agreement of \$211 and \$281 for the three and nine months ended September 30, 2020.

## **(12) Commitments and Contingencies**

### **(a) Licenses and Supply Agreements**

The Company is party to an exclusive license with Orion for the development and commercialization of Dexmedetomidine for use in the treatment of pain in humans in any dosage form for transdermal, transmucosal (including sublingual and intranasal), topical, enteral or pulmonary (inhalational) delivery, but specifically excluding delivery vehicles for administration by injection or infusion, worldwide, except for Europe, Turkey and the CIS (currently includes Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine and Uzbekistan), referred to herein as the Territory. The Company is required to pay Orion lump sum payments of up to €20,500 (\$24,033 as of September 30, 2020) on the achievement of certain developmental and commercial milestones, as well as a royalty on net sales during the term, which varies from 10% to 20% depending on annual sales levels. Through September 30, 2020, no such milestones have been achieved.

The Company is also party to an exclusive license agreement with Orion for the development and commercialization of Fadolmidine for use as a human therapeutic, in any dosage form in the Territory. The Company is required to pay Orion lump sum payments of up to €12,200 (\$14,304 as of September 30, 2020) on achievement of certain developmental and commercial milestones, as well as a royalty on net sales during the term, which varies from 10% to 15% depending on annual sales levels. Through September 30, 2020, no such milestones have been achieved.

In June 2017, the Company acquired the exclusive global rights to two novel neuromuscular blocking agents ("NMBAs") and a proprietary reversal agent from Cornell University ("Cornell"). The NMBAs and reversal agent are referred to herein as the NMBA Related Compounds. The NMBA Related Compounds include one novel intermediate-acting NMBA that has initiated Phase I clinical trials and two other agents, a novel short-acting NMBA, and a rapid-acting reversal agent specific to these NMBAs. The Company is obligated to make: (i) an annual license maintenance fee payment to Cornell until the first commercial sale of the NMBA Related Compounds; and (ii) milestone payments to Cornell upon the achievement of certain milestones, up to a maximum, for each NMBA Related Compound, of \$5,000 for U.S. regulatory approval and commercialization milestones and \$3,000 for European regulatory approval and commercialization milestones. The Company

is obligated to pay Cornell royalties on net sales of the NMBA Related Compound at a rate ranging from low to mid-single digits, depending on the applicable NMBA Related Compounds and whether there is a valid patent claim in the applicable country, subject to an annual minimum royalty amount. Further, the Company will reimburse Cornell ongoing patent costs related to prosecution and maintenance of the patents related to the Cornell patents for the NMBA Related Compounds.

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

The Company is party to a Master Manufacturing Services Agreement and Product Agreement with Patheon, collectively the Patheon Agreements, pursuant to which Patheon provides sterile fill-finish of injectable meloxicam drug product at its Monza, Italy manufacturing site. The Company has agreed to purchase a certain percentage of its annual requirements of finished injectable meloxicam from Patheon during the term of the Patheon Agreements.

**(b) Contingent Consideration for the Alkermes Transaction**

On April 10, 2015, Recro completed the acquisition of a manufacturing facility in Gainesville, Georgia and the licensing and commercialization rights to injectable meloxicam (the “Alkermes Transaction”). Pursuant to the purchase and sale agreement and subsequent amendment with Alkermes, as amended, governing the Alkermes Transaction, the Company agreed to pay to Alkermes up to an additional \$140,000 in milestone payments including \$50,000 upon regulatory approval payable over a seven-year period, as well as net sales milestones related to injectable meloxicam and royalties on future product sales of injectable meloxicam.

Based on the amended terms of the Alkermes agreement, the contingent consideration consists of four separate components. The first component is (i) a \$5,000 payment made in the first quarter of 2019 and (ii) a \$5,000 payment made in the second quarter of 2019. The second components are payable upon regulatory approval and include (i) a \$5,000 payment due within 180 days following regulatory approval for ANJESO, of which timing of payment was amended as noted below, and (ii) \$45,000 payable in seven equal annual payments of approximately \$6,400 beginning on the first anniversary of such approval. The third component consists of three potential payments, based on the achievement of specified annual revenue targets, the last of which represents over 60% of these milestone payments and currently does not have a fair value assigned to its achievement. The fourth component consists of a royalty payment between 10% and 12% (subject to a 30% reduction when no longer covered by patent) for a defined term on future injectable meloxicam net sales.

In August 2020, the Company entered in to an Amendment to the Purchase and Sale Agreement that restructured the timing of payment of the \$5,000 milestone development earn-out consideration due to Alkermes as a result of achievement of approval of the NDA for ANJESO to be paid in three installments of (i) \$ 2,500 paid August 18, 2020; (ii) \$1,060 on or prior to December 20, 2020; and (iii) \$1,440 on or prior to June 20, 2021. In consideration of amending the timing of this development milestone earn-out payment, the Company paid Alkermes a one-time, non-refundable and non-creditable fee of \$285 at the time of entering into the Amendment to the Purchase and Sale Agreement.

As of September 30, 2020, the Company has paid \$12,500 in milestone payments to Alkermes.

**(c) Litigation**

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

On May 31, 2018, a securities class action lawsuit (the “Securities Litigation”) was filed against Recro and certain of Recro’s officers and directors in the U.S. District Court for the Eastern District of Pennsylvania (Case No. 2:18-cv-02279-MMB) that purported to state a claim for alleged violations of Section 10(b) and 20(a) of the Exchange Act and Rule 10(b)(5) promulgated thereunder, based on statements made by Recro concerning the NDA for ANJESO. 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, Recro filed a motion to dismiss the amended complaint in its entirety, which the lead plaintiff opposed on April 9, 2019. On May 9, 2019, Recro filed its response and briefing was completed on the motion to dismiss. In response to questions from the Judge, the parties submitted supplemental briefs with regard to the motion to dismiss the amended complaint during the fall of 2019. On February 18, 2020, the motion to dismiss was granted without prejudice. On April 25, 2020, the plaintiff filed a second amended complaint. Recro filed a motion to dismiss the second

amended complaint on June 18, 2020. The plaintiff filed an opposition to the motion to dismiss on August 17, 2020. On September 16, 2020, Recro filed a reply in support of the motion to dismiss. In connection with the Separation, the Company accepted assignment by Recro of all of Recro's obligations in connection with the Securities Litigation and agreed to indemnify Recro for all liabilities related to the Securities Litigation. The Company has recorded a liability equal to the estimated fair value of the indemnification to Recro related to this Securities Litigation. The Company believes that the lawsuit is without merit and intends to vigorously defend against it. At this time, no assessment can be made as to its likely outcome or whether the outcome will be material to the Company.

**(d) Purchase Commitments**

As of September 30, 2020, the Company had outstanding non-cancelable and cancelable purchase commitments in the aggregate amount of \$10,840 related to inventory and other goods and services, including commercial activities and manufacturing scale-up. The timing of certain purchase commitments cannot be estimated as it is dependent on sales launch trajectory or the outcome of other strategic evaluations and agreements.

**(e) Certain Compensation and Employment Agreements**

The Company has entered into employment agreements with certain of its named executive officers. As of September 30, 2020, these employment agreements provided for, among other things, annual base salaries in an aggregate amount of not less than \$1,327, from that date through March 2022.

**(13) Capital Structure**

**(a) Common Stock**

On November 21, 2019, the Company separated from Recro as a result of a special dividend distribution of all the outstanding shares of its common stock to Recro shareholders. On the distribution date, each Recro shareholder received one share of Baudax Bio's common stock for every two and one-half shares of Recro common stock held of record at the close of business on November 15, 2019. Upon the Distribution, 9,396,583 shares of common stock were issued, of which 45,874 were distributed after December 31, 2019.

The Company is authorized to issue 100,000,000 shares of common stock, with a par value of \$0.01 per share.

On February 13, 2020, the Company entered into a Sales Agreement (the "Sales Agreement") with JMP Securities LLC, as sales agent (the "Agent"), pursuant to which the Company may, from time to time, issue and sell shares of its common stock, par value \$0.01 per share, in an aggregate offering price of up to \$25,000 through the Agent. As of September 30, 2020, 441,967 shares of common stock have been sold under the Sales Agreement for net proceeds of \$3,612. The Agent was paid a sales commission of 3% for such sales under the Sales Agreement.

On March 26, 2020, the Company closed an underwritten public offering of 7,692,308 shares of its common stock, Series A Warrants to purchase 7,692,308 shares of common stock (the "Series A Warrants") and Series B Warrants to purchase 7,692,308 shares of common stock (the "Series B Warrants"), at an exercise price of \$4.59 per share for Series A Warrants and at an exercise price of \$3.25 per share for Series B Warrants, for net proceeds to the Company of \$23,085, after deducting underwriting discounts and commissions and offering expenses.

**(b) Preferred Stock**

The Company is authorized to issue 10,000,000 shares of preferred stock, with a par value of \$0.01 per share. As of September 30, 2020, no preferred stock was issued or outstanding.

**(c) Warrants**

On May 29, 2020, in connection with the Credit Agreement, the Company issued a warrant to MAM Eagle Lender, LLC to purchase 527,100 shares of common stock, at an exercise price equal to \$4.59 per share.

During the nine months ended September 30, 2020, the Company issued 804,616 shares of common stock upon exercise of Series B Warrants for net proceeds of \$2,458.

As of September 30, 2020, the Company had the following warrants outstanding to purchase shares of the Company's common stock:

	Number of Shares	Exercise Price per Share	Expiration Date
Series A Warrants	7,692,308	\$ 4.59	March 26, 2025
Series B Warrants	6,887,692	\$ 3.25	April 26, 2021
MAM Eagle Lender Warrant	527,100	\$ 4.59	May 29, 2027

The Series A Warrants to purchase 7,692,308 shares of common stock and Series B Warrants to purchase 6,887,692 shares of common stock related to the public offering are liability classified as they contain antidilution provisions that do not meet the standard definition of antidilution provisions. The warrant to purchase 527,100 shares of common stock is equity classified.

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

	September 30, 2020	
	Series A Warrants	Series B Warrants
Fair value	\$ 6,857	\$ 3,371
Expected dividend yield	— %	— %
Expected volatility	73.86 %	101.47 %
Risk-free interest rates	.28 %	.11 %
Remaining contractual term	4.5 years	0.6 years

On October 19, 2020, the Company entered into Warrant Exchange Agreements (each, an "Exchange Agreement") with certain holders (each, a "Holder") of the Company's outstanding Series A Warrants and Series B Warrants. Pursuant to the Exchange Agreements, the Holders, at their election, agreed to a cashless exchange of either all of their Series A Warrants or Series B Warrants, in each case for 0.2 shares of the Company's common stock per warrant (rounded up to the nearest whole share) (the "Exchange"). No Holder exchanged both series of warrants in the Exchange. The closings of the exchanges contemplated by the Exchange Agreements occurred on October 21, 2020. The Company issued 1,186,774 shares of its common stock to the participating Holders as a result of the Exchange. Series A Warrants and Series B Warrants to purchase 8,646,154 shares of the Company's common stock were outstanding immediately after the Exchange.

As a result of the Exchange, pursuant to certain price adjustment provisions in the warrants, the exercise price of each of the Series A Warrants or Series B Warrants (including warrants held by holders not participating in the Exchange) that were not exchanged were adjusted to par value, or \$0.01, for each share of common stock underlying such warrant. Pursuant to the Exchange Agreements, any outstanding warrant held by a Holder participating in the Exchange (i) was amended to remove certain anti-dilution and variable pricing protections and (ii) in the case of Series A Warrants not exchanged by a participating Holder, was amended to adjust the expiration date of such Series A Warrants to April 26, 2021 (which is the expiration date of the Series B Warrants).

As of November 5, 2020, the Company issued 6,677,447 shares of its common stock upon the exercise of its Series A Warrants and Series B Warrants subsequent to the Exchange. As of November 5, 2020, there were 64,738 Series A Warrants outstanding and 1,903,969 Series B Warrants outstanding.

#### (14) Stock-Based Compensation

The Company has adopted the 2019 Plan, which allows for the grant of stock options, stock appreciation rights and stock awards for a total of 8,000,000 shares of common stock. On December 1<sup>st</sup> of each year, pursuant to the "Evergreen" provision of the 2019 Plan, the number of shares available under the plan shall be increased by an amount equal to 5% of the outstanding common stock on December 1<sup>st</sup> of that year or such lower amount as determined by the Board of Directors. In December 2019, the number of shares available for issuance under the 2019 Plan was increased by 467,535. The total number of shares authorized for issuance under the 2019 plan as of September 30, 2020 is 3,467,535. As of September 30, 2020, 1,076,396 shares are available for future grants under the 2019 Plan.

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 weighted average grant-date fair value of the Baudax Bio options awarded to employees during nine months ended September 30, 2020 was \$2.22. Under the 2019 Plan, the fair value of the Baudax Bio options was estimated on the date of grant using a Black-Scholes option pricing model with the following weighted average assumptions:

	September 30, 2020
Range of expected option life	6 years
Expected volatility	73.77%
Risk-free interest rate	.41%
Expected dividend yield	—

Certain employees of the Company participated in the Recro Equity Plan. The combined financial statements prior to the Separation reflect stock-based compensation expense related to Recro stock options and RSUs issued to the Company's employees as well as an allocation of a portion of Recro share-based compensation issued to corporate employees and members of the Board of Directors until the Separation date. The weighted average grant-date fair value of the options awarded to employees under the Recro Equity Plan during the nine months ended September 30, 2019 was \$5.53.

Under the Recro Equity Plan for the nine months ended September 30, 2019, the fair value of the options granted to employees of the Company was estimated on the date of grant using a Black-Scholes option pricing model with the following weighted average assumptions:

	September 30, 2019
Range of expected option life	6 years
Expected volatility	79.96%
Risk-free interest rate	2.60%
Expected dividend yield	—

The following table summarizes Baudax Bio stock option activity during the nine months ended September 30, 2020:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life
Balance, December 31, 2019	643,879	\$ 6.33	9.9 years
Granted	840,299	\$ 3.48	
Expired/forfeited/cancelled	(22,500)	\$ 4.15	
Balance, September 30, 2020	1,461,678	\$ 4.72	9.5 years
Vested	120,720	\$ 6.33	9.2 years
Vested and expected to vest	1,461,678	\$ 4.72	9.5 years

Included in the table above are 634,503 stock options outstanding as of September 30, 2020 that were granted outside of the plan. The grants were made pursuant to the Nasdaq inducement grant exception in accordance with Nasdaq Listing Rule 5635(c)(4).

Restricted Stock Units (RSUs):

The following table summarizes the Baudax Bio RSUs activity during the nine months ended September 30, 2020:

	Number of shares
Balance, December 31, 2019	1,380,030
Granted	377,351
Vested and settled	(50,240)
Expired/forfeited/cancelled	(6,000)
Balance, September 30, 2020	1,701,141
Expected to vest	1,701,141

Included in the table above are 176,307 time-based RSUs outstanding as of September 30, 2020 that were granted outside of the plan. The grants were made pursuant to the Nasdaq inducement grant exception in accordance with Nasdaq Listing Rule 5635(c)(4).

Stock-Based Compensation Expense:

Stock-based compensation expense for the nine months ended September 30, 2020 and 2019 was \$7,431 and \$4,254, respectively. For the current year, this represents stock-based compensation from the 2019 Plan as well as stock-based compensation from the Recro Equity Plan for certain Baudax Bio employees who are continuing to vest in their Recro awards but are not performing services to Recro. For the prior year, this represents the allocated portion of Recro stock-based compensation expense for employees of the Company.

As of September 30, 2020, there was \$10,720 of unrecognized compensation expense related to unvested options and time-based RSUs that are expected to vest and will be expensed over a weighted average period of 2.6 years, which includes stock-based compensation from the 2019 Plan as well as the Recro Equity Plan for certain employees of the Company.

The aggregate intrinsic value represents the total amount by which the fair value of the common stock subject to options exceeds the exercise price of the related options. As of September 30, 2020, the aggregate intrinsic value of the unvested options was \$66. There was no aggregate intrinsic value of the vested options.

**(15) Related Party Transactions**

A Non-Executive Director of the Company's Irish subsidiary is a Managing Director and a majority shareholder of HiTech Health Ltd ("HiTech Health"), a consultancy firm for the biotech, pharmaceutical and medical device industry. Since 2016, HiTech Health has provided the Company with certain consulting services and in November 2017 both parties entered into a Service Agreement to engage in both regulatory and supply chain project support and consultancy. In consideration for such services, the Company recorded \$5 and \$11 for the three months ended September 30, 2020 and 2019, respectively. For the nine months ended September 30, 2020 and 2019, the Company recorded \$133 and \$115, in consideration for such services, respectively. A portion of the amount relates to consultancy services provided by the Non-Executive Director.

Recro became a related party to the Company following the Separation. As part of the Separation, the Company entered into a transition services agreement with Recro. Under the transition services agreement, the Company provides certain services to Recro, each related to corporate functions, and are charged to Recro. Additionally, Recro may incur expenses that are directly related to the Company after the Separation, which are billed to the Company. For the three and nine months ended September 30, 2020, the Company recorded income of \$516 and \$1,548, respectively, related to the transition services agreement, which is recorded as a reduction in selling, general and administrative expenses. The Company recorded a net payable of \$39 for activities with Recro as of September 30, 2020.

In connection with the Separation, Recro and Baudax entered into an Employee Matters Agreement. The Employee Matters Agreement allocates liabilities and responsibilities relating to employee compensation and benefits plans and programs and other related matters in connection with the Distribution including, without limitation, the treatment of outstanding Recro equity awards.

In connection with the Separation, Recro and Baudax entered into a Tax Matters Agreement that governs the parties' respective rights, responsibilities and obligations with respect to taxes, tax attributes, the preparation and filing of tax returns, the control of audits and other tax proceedings and other matters regarding taxes for any tax period ending on or before the Distribution date, as well as tax periods beginning after the Distribution date.

**(16) Retirement Plan**

The Company has a voluntary 401(k) Savings Plan (the "401(k) Plan") in which all employees are eligible to participate. The Company's policy is to match 100% of the employee contributions up to a maximum of 5% of employee compensation. Total Company contributions to the 401(k) plan for the three months ended September 30, 2020 and 2019 were \$188 and \$45, respectively. Total Company contributions to the 401(k) plan for the nine months ended September 30, 2020 and 2019 were \$449 and \$281, respectively.

**(17) Subsequent Events**

On November 9, 2020, the Company implemented a strategic restructuring initiative, and corresponding reduction in workforce, aimed at reducing operating expenses, while maintaining key personnel needed to successfully commercialize ANJESO. The Company is taking this action in our efforts to control operating expenses during the pandemic. The restructuring initiative includes a reduction of workforce of approximately 40 positions. The Company estimates that it will incur approximately \$1,500 of costs in connection with the reduction in workforce related to severance pay and other related termination benefits. The Company communicated the workforce reduction on November 9, 2020 and expects the majority of the costs to be incurred during the quarter ending December 31, 2020. The Company expects to complete the strategic restructuring initiative and corresponding reduction in workforce during the quarter ending December 31, 2020.





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

*The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the interim unaudited financial statements contained in Part I, Item 1 of this Quarterly Report, and the audited financial statements and notes thereto for the year ended December 31, 2019 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, 2019, filed with the SEC on February 13, 2020. As used in this Quarterly Report, unless the context suggests otherwise, "we," "us," "our," the "Company" or "Baudax Bio" refer to Baudax Bio, Inc. and its consolidated subsidiaries.*

### Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q, or Quarterly Report, contains 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.

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

- our estimates regarding expenses, revenue, capital requirements and timing and availability of and the need for additional financing;
- our ability to maintain regulatory approval for ANJESO® (meloxicam) injection, or ANJESO, and any other product candidates that we may develop, and any related restrictions, limitations, or warnings in the label of any approved product candidates;
- our ability to successfully manage the timing, costs and other aspects of the commercial launch of ANJESO, including setting an acceptable price for and obtaining adequate coverage and reimbursement of ANJESO;
- our ability to successfully market, commercialize and achieve broad market acceptance for ANJESO and any of our other product candidates once approved;
- the acceptance of ANJESO by the medical community, including physicians, patients, healthcare providers and hospital formularies;
- our ability and that of our third-party manufacturers to successfully scale-up our commercial manufacturing process for ANJESO;
- the results, timing and outcome of our clinical trials of our product candidates, and any future clinical and preclinical studies;
- our relationships with Recro Pharma, Inc., or Recro, Alkermes plc, or Alkermes, other third parties, licensors, collaborators, and our employees;
- our ability to operate as a standalone company and execute our strategic priorities;
- potential indemnification liabilities we may owe to Recro after the separation of Recro's acute care business and transfer of such assets to us, or the Separation;
- the effects of changes in our effective tax rate due to changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities, tax impacts and net operating loss utilization related to the separation from Recro and changes in the tax laws;
- our ability to comply with the regulatory schemes applicable to our business and other regulatory developments in the United States and foreign countries;
- the performance of third-parties upon which we depend, including third-party contract research organizations, or CROs, and third-party suppliers, manufacturers including Alkermes and Patheon UK Limited, group purchasing organizations, distributors, and logistics providers;
- our ability to obtain and maintain patent protection and defend our intellectual property rights against third-parties;
- our ability to maintain our relationships, profitability and contracts with our key commercial partners;
- our ability to defend any material litigation filed against us and avoid liabilities resulting from any material litigation, including any liabilities associated with the ongoing securities class action filed against Recro for which we have agreed to indemnify Recro;

- our ability to recruit or retain key scientific, technical, commercial, and management personnel or to retain our executive officers;
- our ability to raise future financing and attain profitability for continued development of our business and commercialization of ANJESO and our product candidates and to meet any required debt payments, and any milestone payments owing to Alkermes, or our other licensing and collaboration partners;
- our ability to operate under increased leverage and associated lending covenants; to pay existing required interest and principal amortization payments when due; and/or to obtain acceptable refinancing alternatives; and
- our expectations regarding the impact of the ongoing coronavirus 2019, or COVID-19, pandemic including, but not limited to, the expected duration of disruption and immediate and long-term delays, disruption in the commercial launch of ANJESO, our ability to access hospital systems and formulary committees, manufacturing and supply chain interruptions, adverse effects on healthcare systems and disruption of the global economy, and the overall impact of the COVID-19 pandemic on our business, financial condition and results of operations.

Any forward-looking statements that we make in this Quarterly Report speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this Quarterly Report or to reflect the occurrence of unanticipated events. Comparisons of results for current and any prior periods are not intended to express any future trends or indications of future performance, unless expressed as such, and should only be viewed as historical data.

You should also read carefully the factors described in the “Risk Factors” included in Part II, Item 1A of this Quarterly Report, Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2019 filed with the SEC on February 13, 2020, or the 2019 Annual Report, Part II, Item 1A of our Quarterly Report on Form 10-Q for the three months ended March 31, 2020 filed with the SEC on May 8, 2020, or the Q1 Quarterly Report, and Part II, Item 1A of our Quarterly Report on Form 10-Q for the three and six months ended June 30, 2020 filed with the SEC on August 10, 2020, or the Q2 Quarterly Report, to better understand significant risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements in this Quarterly Report and you should not place undue reliance on any forward-looking statements.

## Overview

We are a pharmaceutical company primarily focused on developing and commercializing innovative products for hospital and related acute care settings. We believe that we can bring valuable therapeutic options for patients, prescribers and payers to the hospital and related acute care markets.

Our first commercial product, ANJESO, had its New Drug Application, or NDA, approved by the United States Food and Drug Administration, or FDA, on February 20, 2020 for the management of moderate to severe pain, alone or in combination with other non-NSAID analgesics. ANJESO is a once daily intravenous, or IV, NSAID with preferential Cox-2 activity, which has successfully completed three Phase III studies, including two pivotal efficacy trials, a large double-blind Phase III safety trial and other safety studies for the management of moderate to severe pain. Overall, the total NDA program included over 1,400 patients. We have established sales management, marketing and reimbursement functions in connection with the commercialization of ANJESO in the United States.

We commenced our commercial launch of ANJESO in June of 2020 with a sales team of sales representatives and collaborate with third parties who market ANJESO to health care professionals at our called-on institutions. We continue to evaluate strategic partnerships to commercialize ANJESO outside of the United States. In August 2020, the Centers for Medicare and Medicaid Services (“CMS”) established a new permanent J-code for ANJESO, which became effective on October 1, 2020, facilitating reimbursement in the hospital outpatient, ambulatory surgery center and physician office settings of care. We have also entered into agreements with leading group purchasing organizations in the U.S., like Vizient Inc., and Premier Inc., and with one of the top 3 integrated delivery networks for terms for availability of ANJESO to their member institutions. Over 50 institutions have added ANJESO to their formulary and the number of vials sold to end-customers (e.g. hospitals and ambulatory surgical centers) has increased almost three-fold in the third quarter of 2020 versus the second quarter of 2020. The average monthly orders per account has increased over 125% since launch and the re-order rate is approximately 50% with a deepening usage pattern.

Our costs consist primarily of expenses incurred in conducting our manufacturing scale-up, commercialization of ANJESO, clinical trials and preclinical studies, regulatory activities, and public company and personnel costs. We expect to incur significant and increasing operating losses for at least the next few years. We expect substantially all of our operating losses to result from costs incurred in connection with our commercialization activities, including manufacturing costs, and development programs, including our clinical, non-clinical and formulation development activities. Our expenses over the next several years are expected to relate to the commercialization of ANJESO and continuing to develop our other current and future product candidates. In addition, we may incur costs associated with the acquisition or in-license of products and successful commercialization of the acquired or in-licensed products.

## **COVID-19 Impact**

Our efforts to commercialize ANJESO have been impacted and may continue to be impacted by the COVID-19 pandemic. Hospitals have reduced elective surgeries and many have not yet returned to their prior number of surgeries even where the pandemic has, for a time, abated. In addition, COVID-19 has, in many cases, impacted revenue for hospitals, reduced staffing, diverted resources from other normal activities to patients suffering from COVID-19 and limited hospital access for nonpatients, including our sales professionals, which we believe is impacting our marketing and commercialization efforts. We believe a reduction in elective surgeries during the COVID-19 pandemic has caused and may continue to result in decreased demand for ANJESO.

We anticipate that many hospitals and health care providers will continue to suffer negative financial consequences due to an increase in unexpected costs, personal protective equipment and ventilators, along with a dramatic reduction in revenue due to fewer elective procedures being performed, which may result in a decreased demand for ANJESO. While access restrictions have eased in some locations, cycling spikes of COVID-19 cases in certain states or regions may further impact our sales force as access to hospitals may be restricted and elective surgeries may be limited in those areas. In addition, the absence of hospital formulary meetings where new drugs can be adopted has impacted our efforts to commercialize ANJESO. Many hospital formularies recently resumed meetings after a 6-month absence. Despite the existence of a backlog of agents scheduled to be reviewed, we believe we will make progress getting ANJESO added to additional hospital formularies in the near term. Due to the rapidly evolving environment, continued uncertainties from the impact of the COVID-19 global pandemic, and the recent regional outbreaks that are impacting the recovery, we cannot estimate the full extent to which our commercialization of ANJESO and financial results may be adversely impacted.

## **Separation from Recro Pharma, Inc.**

In August 2019, Recro announced its plans to separate its acute care business from its contract manufacturing and development business through a pro rata distribution of our common stock to shareholders of Recro. As a part of the Separation, Recro transferred the assets, liabilities and operations of its acute care segment to us, pursuant to the terms of a Separation Agreement. On November 21, 2019, the distribution date, each Recro shareholder received one share of our common stock for every two and one-half shares of Recro common stock held of record at the close of business on November 15, 2019, the record date for the Distribution. As a result of the Distribution, we are now an independent public company whose shares of common stock are trading under the symbol “BXRX” on The Nasdaq Capital Market, or Nasdaq.

Our historical combined financial statements for periods prior to the Separation have been prepared on a stand-alone basis and are derived from Recro’s consolidated financial statements and accounting records and are presented in conformity with U.S. GAAP. Our financial position, results of operations and cash flows historically operated as part of Recro’s financial position, results of operations and cash flows prior to and until the Distribution to Recro’s shareholders. These historical combined financial statements for periods prior to the Separation may not be indicative of our future performance and do not necessarily reflect what our combined results of operations, financial condition and cash flows would have been had we operated as a separate company during the periods presented.

## Financial Overview

### Revenue

Subsequent to regulatory approval for ANJESO from the FDA, we began selling ANJESO in the U.S. through a single third-party logistics provider, or 3PL, which takes title to and control of the goods. We recognize revenue from ANJESO product sales at the point the title to the product is transferred to the customer and the customer obtains control of the product. The transaction price that is recognized as revenue for products includes an estimate of variable consideration for reserves, which result from discounts, returns, chargebacks, rebates and other allowances that are offered within contracts between us and our end-customers, wholesalers, group purchasing organizations and other indirect customers.

Our estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of its anticipated performance and all information (historical, current and forecasted) that is reasonably available. These reserves reflect our best estimate of the amount of consideration to which we are entitled based on the terms of the contracts. The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price only to the extent that is considered probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

### Cost of Sales

Cost of sales includes manufacturing costs, transportation and freight, royalty expense, qualification costs for a secondary manufacturing suite for increased available capacity to meet anticipated demand and indirect overhead costs associated with the manufacturing and distribution of ANJESO including supply chain and quality personnel costs. Cost of sales may also include period costs related to certain manufacturing services and inventory adjustment charges. We expensed a significant portion of the cost of producing ANJESO that we are using in the commercial launch as research and development expense prior to the regulatory approval of ANJESO. We expect cost of sales to increase as we deplete these inventories.

### Research and Development Expenses

Research and development expenses currently consist primarily of costs incurred in connection with the development of ANJESO and other pipeline activities. These expenses consist primarily of:

- expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and a substantial portion of our preclinical studies;
- the cost of acquiring and manufacturing clinical trial drug supply and related manufacturing services and pre-commercial product validation and inventory manufacturing expenses;
- costs related to facilities, depreciation and other allocated expenses;
- acquired in-process research and development;
- costs associated with non-clinical and pre-commercial regulatory activities; and
- salaries and related costs for personnel in research and development and pre-commercial regulatory functions.

The majority of our external research and development costs have related to clinical trials, manufacturing of drug supply for pre-commercial products, analysis and testing of product candidates and patent costs. We expense costs related to clinical inventory and pre-commercial inventory until we receive approval from the FDA to market a product, at which time we commence capitalization of costs relating to that product to inventory. Costs related to facilities, depreciation and support are not charged to specific programs. Subsequent to regulatory approval of ANJESO, we allocated or recategorized certain personnel and overhead expenses related to medical affairs, supply chain, quality and regulatory support functions that had previously been recorded within research and development to cost of sales or selling, general and administrative expenses in support of the commercial launch of ANJESO. Pre-commercial activities directly utilizing personnel and overhead expenses from the medical affairs, supply chain, quality and regulatory support function continue to be recorded within research and development.

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

- the costs, timing and outcome of regulatory review of a product candidate;
- the duration of clinical trials, which varies substantially according to the type, complexity and novelty of the product candidate;

- substantial requirements on the introduction of pharmaceutical products imposed by the FDA and comparable agencies in foreign countries, which require lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures;
- the possibility that data obtained from pre-clinical and clinical activities at any step in the testing process may be adverse and lead to discontinuation or redirection of development activity or may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval;
- risk involved with development of manufacturing processes, FDA pre-approval inspection practices and successful completion of manufacturing batches for clinical development and other regulatory purposes;
- the emergence of competing technologies and products, including obtaining and maintaining patent protections, and other adverse market developments, which could impede our commercial efforts; and
- the other risks disclosed in the sections titled “Risk Factors” of our 2019 Annual Report, Q1 Quarterly Report, Q2 Quarterly Report, and this Quarterly Report.

Development timelines, probability of success and development costs vary widely. As a result of the uncertainties discussed above, we will assess our product candidate’s commercial potential and our available capital resources. As a result of these uncertainties surrounding the timing and outcome of any approval, we are currently unable to estimate precisely when, if ever, any of our product candidates will generate revenues and cash flows.

We expect our research and development costs to relate to ANJESO, including required pediatric post-marketing studies, as well as development and commercialization scale-up of our other product candidates. We may elect to seek collaborative relationships in order to provide us with a diversified revenue stream and to help facilitate the development and commercialization of our product candidate pipeline.

#### ***Selling, General and Administrative Expenses***

Selling, general and administrative expenses consist of sales and marketing expenses and general and administrative expenses.

Sales and marketing expenses primarily consist of compensation and benefits for our sales force and personnel that support our sales and marketing efforts as well as third party consulting costs for the promotion and sale of ANJESO. In addition, sales and marketing expenses include expenses related to communicating the clinical and economic benefits of ANJESO and educational programs for our indirect customers.

General and administrative expenses consist principally of salaries and related costs for personnel in executive, medical affairs, regulatory, finance and information technology functions. General and administrative expenses also include public company costs, directors and officers insurance, professional fees for legal, including patent-related expenses, consulting, auditing, and tax services.

We expect our selling, general and administrative expenses to increase in the future as a result of our commercial launch of ANJESO.

#### ***2020 Reduction in Force***

Due to the impacts of COVID-19 and the resultant slower than expected commercial ramp of ANJESO, in November of 2020, we implemented a reduction in workforce by approximately 40 employees. We expect that the reorganization will result in annualized savings of an estimated \$10.6 million in personnel and other related costs. There were also significant cost reductions made for 2021 manufacturing and launch related activities. We estimate that the reorganization will be substantially completed in November 2020 and that it will incur approximately \$1.5 million of charges for severance and other costs, primarily during the fourth quarter of 2020.

#### ***2019 Reduction in Force***

Following the receipt of a second complete response letter from the FDA with regard to IV meloxicam in March of 2019, we implemented a strategic restructuring initiative, and corresponding reduction in workforce, aimed at reducing operating expenses, while maintaining key personnel needed to select a partner and obtain FDA approval of IV meloxicam. The restructuring initiative included a reduction of approximately 50 positions. In connection with the strategic restructuring plan, we incurred approximately \$7.2 million of costs, all of which were incurred in the first half of 2019. These costs included severance and related termination benefits and canceled marketing and production costs.

#### ***Change in Fair Value of Contingent Consideration***

In connection with the Separation, we entered into an Assignment and a Partial Assignment, Assumption and Bifurcation Agreement, or the Alkermes Agreements, relating to the Purchase and Sale Agreement for the acquisition of certain assets, including the worldwide rights to injectable meloxicam and Recro’s development, formulation and manufacturing business from Alkermes, or the Alkermes Transaction, as amended in December 2018 and August 2020. Pursuant to the Alkermes Agreements, we are required to pay up to \$140.0 million in milestone payments, including \$10.0 million that was paid during 2019, another \$2.5 million paid within 180 days of

approval of ANJESO, \$1.1 million due December 20, 2020, \$1.4 million due June 20, 2021, and \$45.0 million over seven years beginning one year after approval, as well as net sales milestones and a royalty percentage of future product net sales related to injectable meloxicam between 10% and 12% (subject to a 30% reduction when no longer covered by patent). The estimated fair value of the initial \$54.6 million payment obligation was recorded as part of the purchase price for the Alkermes Transaction. We have continued to reevaluate the fair value each subsequent period and as of September 30, 2020 recorded a \$78.1 million payment obligation, representing the estimated probability adjusted fair value of the liability. Each reporting period, we revalue this estimated obligation with changes in fair value recognized as a non-cash operating expense or gain. As of September 30, 2020, we have paid \$12.5 million in milestone payments to Alkermes.

#### **Interest Expense**

Interest expense for the periods presented primarily includes interest expense incurred on our Credit Agreement with MAM Eagle Lender, the amortization of related financing costs, and interest expense on a promissory note with PNC Bank under the Paycheck Protection Program (“PPP”) of the Coronavirus Aid, Relief and Economic Security Act of 2020 (the “CARES Act”) administered by the Small Business Administration (the “SBA”).

#### **Income Taxation**

We maintained a valuation allowance against our deferred tax assets as of September 30, 2020 and 2019.

#### **Results of Operations**

##### **Comparison of the Three Months Ended September 30, 2020 and 2019**

	<b>Three Months Ended September 30,</b>	
	<b>2020</b>	<b>2019</b>
	<b>(amounts in thousands)</b>	
Revenue, net	\$ 68	\$ —
Operating expenses:		
Cost of sales	540	—
Research and development	1,469	1,845
Selling, general and administrative	13,763	4,524
Amortization of intangible assets	643	—
Change in warrant valuation	(11,182)	—
Change in contingent consideration valuation	(17,427)	3,909
Total operating expenses	(12,194)	10,278
Operating loss (loss)	12,262	(10,278)
Other expense:		
Other expense, net	(577)	(37)
Net income (loss)	<u>\$ 11,685</u>	<u>\$ (10,315)</u>

**Revenue, net.** For the three months ended September 30, 2020, net product revenue was \$0.1 million, related to sales of ANJESO in the U.S. While in the title model of distribution, product revenue represents shipments to our third-party logistics (“3PL”) provider. As the second quarter of 2020 included stocking orders to our 3PL, the third quarter revenue is not a reflection of units sold to the end customers. The number of vials sold to end customers (e.g., hospitals, ambulatory surgical centers) has increased almost three-fold in the third quarter of 2020 versus the second quarter of 2020. For the three months ended September 30, 2019, we did not recognize any product revenue.

**Cost of sales.** Our cost of sales was \$0.5 million for the three months ended September 30, 2020 and consists of product costs, royalty expense and certain fixed costs associated with the manufacturing of ANJESO including supply chain and quality costs. Based on our policy, we expense costs associated with the manufacturing of our products as research and development prior to regulatory approval. Certain product costs of ANJESO units recognized as revenue during the three months ended September 30, 2020 were incurred prior to FDA approval of ANJESO in February 2020, and therefore are not included in cost of sales during the period. We expect over time cost of sales will increase as we build new inventory not expensed during the pre-approval period and deplete our initial inventory levels. No product cost of sales was recorded for the three months ended September 30, 2019.

**Research and Development.** Our research and development expenses were \$1.5 million and \$1.8 million for the three months ended September 30, 2020 and 2019, respectively. The decrease of \$0.3 million primarily resulted from a decrease in personnel and overhead expenses of \$0.5 million as we allocated or recategorized certain expenses related to supply chain, regulatory, quality and

medical affairs associated with support of the commercial launch of ANJESO and a decrease in pre-commercialization manufacturing and clinical costs for ANJESO of \$0.4 million. These decreases were offset by a \$0.6 million increase in other development costs.

**Selling, General and Administrative.** Our selling, general and administrative expenses were \$13.8 million and \$4.5 million for the three months ended September 30, 2020 and 2019, respectively. The increase of \$9.3 million was primarily due to increased selling and marketing expenses in connection with the commercial launch of ANJESO. Selling and marketing expenses of \$7.6 million for the three months ended September 30, 2020 increased \$6.8 million due to increased personnel costs of \$4.9 million and increased commercial costs of \$1.9 million. General and administrative expenses of \$6.2 million for the three months ended September 30, 2020 increased \$2.5 million primarily due to increased personnel costs, over half of which was attributed to medical affairs field personnel and regulatory support functions that had previously been recorded within research and development expense in the prior year period.

**Amortization of Intangible Assets.** Amortization expense was \$0.6 million for the three months ended September 30, 2020, which was related to the amortization of our intangible asset resulting from research and development activities over its estimated useful life. There was no amortization expense for the three months ended September 30, 2019.

**Change in Warrant Valuation.** The change in warrant valuation was a decrease in value of \$11.2 million for the three months ended September 30, 2020 due to a decrease in the Black-Scholes values as a result of a decrease in our stock price.

**Change in Contingent Consideration Valuation.** The change in contingent consideration valuation was a decrease in value of \$17.4 million for the three months ended September 30, 2020 and an increase in value of \$3.9 million for the three months ended September 30, 2019. The non-cash charge for contingent consideration in each period related to the revaluation of the probability-adjusted fair value of the Alkermes Transaction payment obligation. The decrease in contingent consideration value for the three months ended September 30, 2020 was primarily due to the adjusted timing of estimated milestone and royalty payments due to updated forecasts reflecting an estimate of the launch trajectory of ANJESO. The increase in contingent consideration valuation for the three months ended September 30, 2019 was due to the time value of money associated with the fair value at that time.

**Comparison of the Nine Months Ended September 30, 2020 and 2019**

	Nine Months Ended September 30,	
	2020	2019
	(amounts in thousands)	
Revenue, net	\$ 417	\$ —
Operating expenses:		
Cost of sales	1,190	—
Research and development	5,889	18,578
Selling, general and administrative	33,026	21,809
Amortization of intangible assets	1,502	—
Change in warrant valuation	2,863	—
Change in contingent consideration valuation	14,252	(15,241)
Total operating expenses	58,722	25,146
Operating loss	(58,305)	(25,146)
Other expense:		
Other expense, net	(753)	(86)
Net loss	\$ (59,058)	\$ (25,232)

**Revenue, net.** For the nine months ended September 30, 2020, net product revenue was \$0.4 million, related to sales of ANJESO in the U.S. For the nine months ended September 30, 2019, we did not recognize any product revenue.

**Cost of sales.** Our cost of sales was \$1.2 million for the nine months ended September 30, 2020 and consists of product costs, royalty expense and certain fixed costs associated with the manufacturing of ANJESO including supply chain and quality costs. Based on our policy, we expense costs associated with the manufacturing of our products as research and development prior to regulatory approval. Certain product costs of ANJESO units recognized as revenue during the nine months ended September 30, 2020 were incurred prior to FDA approval of ANJESO in February 2020, and therefore are not included in cost of sales during the period. We expect over time cost of sales will increase as we build new inventory not expensed during the pre-approval period and deplete our initial inventory levels. No product cost of sales was recorded for the nine months ended September 30, 2019.

**Research and Development.** Our research and development expenses were \$5.9 million and \$18.6 million for the nine months ended September 30, 2020 and 2019, respectively, a decrease of \$12.7 million. Excluding \$2.8 million of costs associated with the 2019



strategic restructuring initiative recorded in the nine months ended September 30, 2019, the decrease of \$9.9 million resulted from a decrease in pre-commercialization manufacturing and clinical costs for IV meloxicam of \$6.6 million, a decrease in personnel and overhead expenses of \$1.7 million as we re-allocated costs related to supply chain, regulatory, quality and medical affairs associated with support of the commercial launch of ANJESO and a decrease in other development costs of \$1.6 million.

**Selling, General and Administrative.** Our selling, general and administrative expenses were \$33.0 million and \$21.8 million for the nine months ended September 30, 2020 and 2019, respectively. Excluding \$4.4 million of costs associated with the 2019 strategic restructuring initiative recorded in the nine months ended September 30, 2019, the increase of \$15.6 million was primarily due to increased selling and marketing expenses in connection with the commercial launch of ANJESO. Selling and marketing expenses of \$16.5 million for the nine months ended September 30, 2020 increased \$10.1 million due to increased personnel costs of \$6.6 million and increased commercial costs of \$3.5 million. General and administrative expenses of \$16.5 million for the nine months ended September 30, 2020 increased \$5.5 million primarily due to increased personnel costs of \$4.9 million, over half of which was attributed to medical affairs field personnel and regulatory support functions that had previously been recorded within research and development expense in the prior year period, and increased public company costs of approximately \$0.6 million as the prior year costs represent an allocated portion of the costs in the historical combined financial statements of us and Recro prior to the Separation.

**Amortization of Intangible Assets.** Amortization expense was \$1.5 million for the nine months ended September 30, 2020, which was related to the amortization of our intangible asset resulting from research and development activities over its estimated useful life. There was no amortization expense for the nine months ended September 30, 2019.

**Change in Warrant Valuation.** The change in warrant valuation was an increase of \$2.9 million for the nine months ended September 30, 2020, related to the warrants sold as part of the March 26, 2020 underwritten public offering and represents an increase in the Black-Scholes values as a result of an increase in our stock price.

**Change in Contingent Consideration Valuation.** The change in contingent consideration valuation was an increase in value of \$14.3 million for the nine months ended September 30, 2020 as compared to a decrease in value of \$15.2 million for the nine months ended September 30, 2019. The non-cash charge for contingent consideration in each period related to the revaluation of the probability-adjusted fair value of the Alkermes Transaction payment obligation. The increase in contingent consideration value for the nine months ended September 30, 2020 was primarily due to the increase in probability of success of milestones tied to the FDA approval of ANJESO, partially offset by a decrease due to updated forecasts reflecting an estimate of the launch trajectory in the third quarter of 2020. The decrease in contingent consideration valuation for the nine months ended September 30, 2019 was due to the adjusted timing of estimated milestone and royalty payments after receipt of the second CRL from the FDA in March 2019.

### **Liquidity and Capital Resources**

As of September 30, 2020, we had \$24.6 million in cash and cash equivalents. Historically, the primary source of liquidity for our business was cash flow provided to us from Recro. Prior to the Separation, transfers of cash to and from Recro were reflected in Net Parent Investment in the historical combined balance sheets, statements of cash flows and statements of changes in Net Parent Investment. We have not reported cash or cash equivalents for the periods presented in the combined balance sheets prior to the Separation.

On May 29, 2020, we entered in a \$50.0 million Credit Agreement with MAM Eagle Lender, pursuant to which we have drawn \$10.0 million as of the date of this Quarterly Report and may draw upon four additional tranches of term loans. The Tranche Two Loans in an amount not to exceed \$5.0 million may be drawn upon on or before August 29, 2021 provided that we generate at least \$5.0 million in net revenue in the three consecutive calendar months immediately preceding the date such Tranche Two Loans are funded. The Tranche Two Loans may also be drawn on a subsequent date with the satisfaction of the conditions for the Tranche Three Loans, Tranche Four Loans, or Tranche Five Loans, as applicable, provided that the Tranche Two Loans may not be drawn more than once. The Tranche Three Loans in an amount not to exceed \$5.0 million may be drawn upon on or before November 29, 2021 provided that we generate at least \$10.0 in net revenue in the three consecutive calendar months immediately preceding such date such Tranche Three Loans are funded. The Tranche Three Loans may also be drawn on a subsequent date with the satisfaction of the conditions for the Tranche Four Loans or Tranche Five Loans, as applicable, provided that the Tranche Three Loans may not be drawn more than once. The Tranche Four Loans in an amount not to exceed \$10.0 million may be drawn upon, subject to the consent of the Lenders, on or before August 29, 2022 provided that we generate at least \$20.0 million in net revenue in the three consecutive calendar months immediately preceding the date such Tranche Four Loans are funded. The Tranche Four Loans may also be drawn on a subsequent date with the satisfaction of the conditions for the Tranche Five Loans provided that the Tranche Four Loans may not be drawn more than once. The Tranche Five Loans in an amount not to exceed \$20.0 million may be drawn upon, subject to the consent of the Lenders, on or before March 1, 2023 provided that we generate at least \$100.0 million in net revenue in the twelve consecutive calendar months immediately preceding the date such Tranche Five Loans are funded.

On May 8, 2020, we entered into a promissory note for \$1.5 million under the PPP of the CARES Act administered by the SBA. We have used the loan proceeds for covered payroll costs in accordance with the relevant terms and conditions of the CARES Act. This Loan may be partially or fully forgiven if we comply with the provisions of the CARES Act including the use of Loan proceeds for

payroll costs, rent, utilities and other expenses, and at least 60% of the loan proceeds must be used for payroll costs as defined by the CARES Act. Any forgiveness of the Loan will be subject to approval by the SBA and the Lender will require us to apply for such treatment in the future. Should we meet the requirements for forgiveness, we would extinguish the note upon receiving legal release from PNC Bank and record a gain on extinguishment in the period. We expect that the full \$1.5 million balance of the PPP Note will be forgiven, however, no assurance can be given that we will obtain forgiveness of the PPP Note in whole or in part.

On March 26, 2020, we closed an underwritten public offering of 7,692,308 shares of our common stock, Series A Warrants to purchase 7,692,308 shares of our common stock (the "Series A Warrants") at an exercise price of \$4.59 per share and Series B Warrants to purchase 7,692,308 shares of our common stock (the "Series B Warrants") at an exercise price of \$3.25 per share, resulting in \$23.1 million of net proceeds, after deducting underwriting discounts and commissions and estimated offering expenses. Subsequent to the closing of the underwritten public offering, the exercise of warrants related to the transaction has provided net proceeds of an additional \$2.5 million. In October 2020, we executed Warrant Exchange Agreements with certain holders of our Series A Warrants and Series B Warrants. As of November 5, 2020, we have issued 7.9 million shares of our common stock in exchange for, or upon the exercise thereafter of, the Series A Warrants and Series B Warrants. As of November 5, 2020, there were 64,738 Series A Warrants outstanding and 1,903,969 Series B Warrants outstanding. See Note 13(c) to the Consolidated and Combined Financial Statements included in this Quarterly Report for additional information.

On February 13, 2020, we entered into a Sales Agreement with JMP Securities LLC, as sales agent, or the Agent, pursuant to which we may, from time to time, issue and sell shares of our common stock, in an aggregate offering price of up to \$25.0 million through the Agent, or the ATM Program. As of September 30, 2020, 441,967 shares have been sold under the ATM Program for net proceeds of \$3.6 million. The Agent was paid a sales commission of 3% for such sales under the Sales Agreement.

Under the terms of the Separation Agreement, Recro made a cash capital contribution of \$19.0 million to us to fund our initial operations. Subsequent to the Separation, we no longer participate in Recro's centralized cash management or benefit from direct funding from Recro. We have raised additional funds from debt and equity transactions as a standalone entity and will be required to raise additional funds needed to continue to operate as a standalone entity. Our ability to fund our operations and capital needs will depend on our ability to raise additional funds through debt financings, bank or other loans, licensing, including out-licensing activities, sale of assets and/or marketing arrangements, the exercise of our short-dated warrants, 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 access to capital.

We expect to seek additional funding to sustain our future operations and while we have successfully raised capital in the past, the ability to raise capital in future periods is not assured. Based on our available cash as of September 30, 2020, we have concluded that substantial doubt exists about our ability to continue as a going concern for one year from the date our consolidated financial statements are issued. See "Item 1A – Risk Factors" in the Quarterly Report for more information.

We anticipate that our principal uses of cash in the future will be primarily to launch and commercialize ANJESO and to fund our operations, pipeline development activities, working capital needs, capital expenditures and other general corporate purposes.

#### Sources and Uses of Cash

Cash used in operations was \$29.4 million and \$42.1 million for the nine months ended September 30, 2020 and 2019, respectively, which represents our operating losses less our non-cash items including: stock-based compensation, non-cash interest expense, depreciation, amortization, changes in warrant valuations, and changes in fair value of contingent consideration, as well as changes in operating assets and liabilities.

Cash used in investing activities was \$0.3 million and \$1.8 million for the nine months ended September 30, 2020 and 2019, respectively, which was primarily due to capital expenditures of \$0.3 million and \$1.6 million in the same periods, respectively.

There was \$36.6 million of cash provided by financing activities in the nine months ended September 30, 2020 consisting of net proceeds of \$23.1 million from the public offering of common stock and warrants, net proceeds of \$1.5 million from the issuance of the PPP Loan, net proceeds of \$8.5 million from the incurrence of long-term debt under the Credit Agreement with MAM Eagle Lender, net proceeds of \$3.6 million from our ATM Program, and net proceeds of \$2.5 million from warrant exercises, partially offset by a payment of contingent consideration of \$2.5 million. There was \$43.9 million of cash provided by financing activities for the nine months ended September 30, 2019 from net proceeds of \$53.9 million from parent company investment, partially offset by a payment of contingent consideration of \$10.0 million.

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

- our relationships with Recro, third parties, licensors, collaborators, and our employees;
- our ability to continue to operate as a standalone company and execute our strategic priorities;

- potential indemnification liabilities we may owe to Recro;
- the timing of the Alkermes Transaction milestone payments and other contingent consideration;
- the costs of continued manufacturing scale-up and commercialization activities, for ANJESO;
- the level of market acceptance of ANJESO;
- the scope, progress, results and costs of development for our other product candidates;
- the cost, timing and outcome of regulatory review of our other product candidates;
- the cost of manufacturing scale-up, acquiring drug product and other capital equipment for our other product candidates;
- the extent to which we in-license, acquire or invest in products, businesses and technologies;
- our ability to raise additional funds through equity or debt financings or the sale of certain assets;
- our ability to achieve certain milestones to access and draw down additional tranches of debt under the Credit Agreement;
- the costs of preparing, submitting and prosecuting patent applications and maintaining, enforcing and defending intellectual property claims; and
- the effect of any changes in our effective tax rate due to changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities, tax impacts and net operating loss utilization related to the Separation and changes in tax laws.

We might use existing cash and cash equivalents on hand, debt, equity financing, sale of assets or out-licensing revenue or a combination thereof to fund our operations or product acquisitions. If we increase our debt levels, we might be restricted in our ability to raise additional capital and might be subject to financial and restrictive covenants. Our shareholders may experience dilution as a result of the issuance of additional equity or debt securities. This dilution may be significant depending upon the amount of equity or debt securities that we issue and the prices at which we issue any securities.

#### Contractual Commitments

The table below reflects our contractual commitments as of September 30, 2020:

Contractual Obligations	Payments Due by Period (in 000s)				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
<b>Debt Obligations (1):</b>					
Debt	\$ 11,537	\$ 171	\$ 6,088	\$ 5,278	\$ —
Interest on Debt	4,550	1,385	2,430	735	—
<b>Purchase Obligations (2):</b>	\$ 10,840	\$ 4,824	\$ 2,989	\$ —	\$ —
Operating Leases (3)	867	403	464	—	—
<b>Other Long-Term Liabilities:</b>					
Other License Commitments and Milestone payments (4), (5)	54,855	60	150	190	125
Alkermes Payments (6)	127,500	8,929	12,857	12,857	12,857
Employment Agreements (7)	1,327	1,018	309	—	—
<b>Total Contractual Obligations</b>	<u>\$ 211,476</u>	<u>\$ 16,790</u>	<u>\$ 25,287</u>	<u>\$ 19,060</u>	<u>\$ 12,982</u>

- (1) Debt obligations consist of principal, an exit fee of 2.5% of that principal and interest on the \$10.0 million outstanding term loan under our Credit Agreement in addition to principal and interest on a \$1.5 million promissory note under the SBA Paycheck Protection Program of the CARES Act. In accordance with U.S. GAAP, the future interest obligations are not recorded on our Consolidated Balance Sheet. See Note 11 to the Consolidated and Combined Financial Statements included in this Quarterly Report.

- (2) These obligations consist of cancelable and non-cancelable purchase commitments related to inventory and other goods or services. The timing of certain purchase commitments cannot be estimated as it is dependent on sales launch trajectory or the outcome of other strategic evaluations. In accordance with U.S. GAAP, these obligations are not recorded on our Consolidated Balance Sheets. See Note 12(d) to the Consolidated and Combined Financial Statements included in this Quarterly Report.
- (3) We have become party to certain operating leases for the leased space in Malvern, Pennsylvania, and Dublin, Ireland, as well as for office equipment, for which the minimum lease payments are presented.
- (4) We are party to exclusive licenses with Orion for the development and commercialization of certain pipeline product candidates, under which we may be required to make certain milestone and royalty payments to Orion. See Note 12(a) to the Consolidated and Combined Financial Statements included in the Quarterly Report. The amount reflects only payment obligations that are fixed and determinable. We are unable to reliably estimate the timing of these payments because they are dependent on the type and complexity of the clinical studies and intended uses of the products, which have not been established. In accordance with U.S. GAAP, these obligations are not recorded on our Consolidated Balance Sheets.
- (5) We license the neuromuscular blocking agents, or NMBAs, from Cornell University pursuant to a license agreement under which we are obligated to make annual license maintenance fee payments, milestone payments and patent cost payments and to pay royalties on net sales of the NMBAs. The amount reflects only payment obligations that are fixed and determinable. We are unable to reliably estimate the timing of certain of these payments because they are dependent on the type and complexity of the clinical studies and intended uses of the products, which have not been established. In accordance with U.S. GAAP, certain of these obligations are not recorded on our Consolidated Balance Sheets. See 12(a) to the Consolidated and Combined Financial Statements included in this Quarterly Report.
- (6) Pursuant to the purchase and sale agreement governing the Alkermes Transaction, we agreed to pay to Alkermes milestone and royalty payments. The amount reflects only payment obligations that are fixed and determinable. We are unable to reliably estimate the timing of some of these payments because they are in some instances, dependent on the commercial success of the product. In accordance with U.S. GAAP, the fair value of these obligations is recorded as contingent consideration on our Consolidated Balance Sheets. See Note 12(b) to the Consolidated and Combined Financial Statements included in this Quarterly Report.
- (7) We have entered into employment agreements with certain of our named executive officers. As of September 30, 2020, these employment agreements provided for, among other things, annual base salaries in an aggregate amount of not less than this amount, from that date through March 2022. In accordance with U.S. GAAP, these obligations are not recorded on our Consolidated Balance Sheets. See Note 12(e) to the Consolidated and Combined Financial Statements included in this Quarterly Report.

#### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K.

#### **Critical Accounting Policies and Estimates**

Our critical accounting policies and estimates are disclosed in the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section of our 2019 Annual Report. In the nine months ended September 30, 2020, there were changes to the application of critical accounting policies previously disclosed in our 2019 Annual Report related to the launch of ANJESO and the related revenue recognition, as described below.

*Revenue Recognition*— Subsequent to regulatory approval for ANJESO from the FDA, we began selling ANJESO in the U.S. through a single third-party logistics provider, or 3PL, which takes title to and control of the goods. We recognize revenue from ANJESO product sales at the point the title to the product is transferred to the customer and the customer obtains control of the product. The transaction price that is recognized as revenue for products includes an estimate of variable consideration for reserves which result from discounts, returns, chargebacks, rebates and other allowances that are offered within contracts between us and our end-customers, wholesalers, group purchasing organizations and other indirect customers. Our payment terms are generally between thirty to ninety days.

Our estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of its anticipated performance and all information (historical, current and forecasted) that is reasonably available. The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is considered probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. These reserves reflect our best estimate of the amount of consideration to which we are entitled based on the terms of the contracts. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

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

Not applicable.

**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, 2020. 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, 2020, 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.

We are involved, from time to time, in various claims and legal proceedings arising in the ordinary course of its business. Except as disclosed below, we are 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, or the Securities Litigation, was filed against Recro and certain of Recro's officers and directors in the U.S. District Court for the Eastern District of Pennsylvania (Case No. 2:18-cv-02279-MMB) that purported to state a claim for alleged violations of Section 10(b) and 20(a) of the Exchange Act and Rule 10(b)(5) promulgated thereunder, based on statements made by Recro concerning the NDA for ANJESO. 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, Recro filed a motion to dismiss the amended complaint in its entirety, which the lead plaintiff opposed on April 9, 2019. On May 9, 2019, Recro filed its response and briefing was completed on the motion to dismiss. In response to questions from the Judge, the parties submitted supplemental briefs with regard to the motion to dismiss the amended complaint during the fall of 2019. On February 18, 2020, the motion to dismiss was granted without prejudice. On April 25, 2020, the plaintiff filed a second amended complaint. Recro filed a motion to dismiss the second amended complaint on June 18, 2020. The plaintiff filed an opposition to Recro's motion to dismiss on August 17, 2020. On September 16, 2020, Recro filed a reply in support of the motion to dismiss. In connection with the Separation, we accepted assignment by Recro of all of Recro's obligations in connection with the Securities Litigation and agreed to indemnify Recro for all liabilities related to the Securities Litigation. Recro and we believe that the lawsuit is without merit and intend to vigorously defend against it. At this time, no assessment can be made as to its likely outcome or whether the outcome will be material to us.

### Item 1A. Risk Factors.

*You should carefully consider the risk factors described in our 2019 Annual Report, our Q1 Quarterly Report, and our Q2 Quarterly Report, under the caption "Item 1A. Risk Factors." Except as set forth below, there have been no material changes in our risk factors disclosed in our 2019 Annual Report, our Q1 Quarterly Report, and our Q2 Quarterly Report.*

#### ***Our ability to continue as a going concern is in substantial doubt absent obtaining adequate new debt or equity financings.***

Management has concluded that substantial doubt exists about our ability to continue as a going concern for the next 12 months from the date of the financial statements included in this report. As of September 30, 2020, we had an accumulated deficit of \$95.3 million, cash and cash equivalents of \$24.6 million and current liabilities of \$1.8 million. Based on available resources, we believe that our cash and cash equivalents on hand, consisting of funds raised by financing activities in the nine months ended September 30, 2020 are sufficient to fund our currently anticipated operating and capital requirements into the first quarter of 2021, however, our current capital resources are not sufficient to support our planned operations for the next 12 months from the date of the financial statements included in this report.

We did not become a revenue-generating company until the second quarter of 2020, following the commercial launch of ANJESO. We expect our expenses relating to the commercialization of ANJESO, including those related to personnel, marketing and selling, to increase. We expect to continue to incur losses for the foreseeable future as we continue our efforts to commercialize ANJESO and develop our other current and future product candidates. We have also incurred significant indebtedness. As of September 30, 2020, we had an outstanding balance under our PPP Note of approximately \$1.5 million, of which we cannot assure forgiveness in whole or in part, and an outstanding balance of \$10 million under our credit facility with MAM Eagle Lender. These factors, individually and collectively, raise substantial doubt about our ability to continue as a going concern, and therefore, could materially limit our ability to raise additional funds through an issuance of debt or equity securities or otherwise.

There can be no assurance that we will be able to raise sufficient additional capital on acceptable terms or at all. If such additional financing is not available on satisfactory terms, or is not available in sufficient amounts, we may be required to delay, limit or eliminate the development of business opportunities and our ability to achieve our business objectives, our competitiveness, and our business, financial condition and results of operations will be materially adversely affected. In addition, the impact of the COVID-19 pandemic on the global financial markets may reduce our ability to access capital, which could negatively affect our liquidity and ability to continue as a going concern. In addition, the perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

### Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

### Item 3. Defaults Upon Senior Securities.

None.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

On November 9, 2020, the Company implemented a strategic restructuring initiative, and corresponding reduction in workforce, aimed at reducing operating expenses, while maintaining key personnel needed to successfully commercialize ANJESO. The Company is taking this action in our efforts to control operating expenses during the pandemic. The restructuring initiative includes a reduction of workforce of approximately 40 positions. The Company estimates that it will incur approximately \$1.5 million of costs in connection with the reduction in workforce related to severance pay and other related termination benefits. The Company communicated the workforce reduction on November 9, 2020 and expects the majority of the costs to be incurred during the quarter ending December 31, 2020. The Company expects to complete the strategic restructuring initiative and corresponding reduction in workforce during the quarter ending December 31, 2020.

**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	<a href="#"><u>Third Amendment to the Purchase and Sale Agreement, dated August 17, 2020 by and among Alkermes Pharma Ireland Limited, Daravita Limited, Alkermes US Holdings, Inc. and Baudax Bio, Inc.</u></a>	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 21, 2020 (File No. 001-39101).
10.2	<a href="#"><u>Third Amendment to License Agreement, dated August 17, 2020, by and among Alkermes Pharma Ireland Limited, Recro Gainesville LLC and Baudax Bio, Inc.</u></a>	Incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on August 21, 2020 (File No. 001-39101).
10.3	<a href="#"><u>Form of Warrant Exchange Agreement</u></a>	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on form 8-K filed on October 20, 2020 (File No. 001-39101).
31.1	<a href="#"><u>Rule 13a-14(a)/15d-14(a) certification of Principal Executive Officer.</u></a>	Filed herewith.
31.2	<a href="#"><u>Rule 13a-14(a)/15d-14(a) certification of Principal Financial and Accounting Officer.</u></a>	Filed herewith.
32.1	<a href="#"><u>Section 1350 certification, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u></a>	Filed herewith.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	Filed herewith.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	Filed herewith.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	Filed herewith.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	Filed herewith.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	Filed herewith.
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).	Filed herewith.



**SIGNATURES**

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

**BAUDAX BIO, INC.**

Date: November 9, 2020

By: /s/ Gerri A. Henwood

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

Date: November 9, 2020

By: /s/ Ryan D. Lake

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

## CERTIFICATION

I, Gerri A. Henwood, certify that:

1. I have reviewed this Quarterly Report of Baudax Bio, 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, 2020

/s/ Gerri A. Henwood

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

## CERTIFICATION

I, Ryan D. Lake, certify that:

1. I have reviewed this Quarterly Report of Baudax Bio, 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, 2020

/s/ Ryan D. Lake

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

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

In connection with the Quarterly Report of Baudax Bio, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2020, 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, 2020

/s/ Gerri A. Henwood

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

/s/ Ryan D. Lake

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