

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

FORM 10-Q

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

For the Quarterly Period Ended: March 31, 2021

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

Commission File Number: 001-39101

Baudax Bio, Inc.

(Exact name of registrant as specified in its charter)

Pennsylvania
(State or other jurisdiction of
incorporation or organization)

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

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

19355
(Zip Code)

(484) 395-2440

(Registrant's telephone number, including area code)

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 May 3, 2021, there were 70,152,898 shares of common stock, par value \$0.01 per share, outstanding.

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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 continue as a going concern for the next 12 months;
- our ability to operate under significant indebtedness and obtain forgiveness of our Paycheck Protection Program, or PPP, Loan;
- our ability to maintain regulatory approval for ANJESO® (meloxicam) injection, or ANJESO, and obtain regulatory approval for 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 commercialization 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 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 Pharma, Inc. (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 availability of vaccines for COVID-19 and peoples' willingness to avail themselves of such vaccines, the expected duration of disruption and immediate and long-term delays, disruption in the commercialization 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, 2020 filed with the SEC on February 16, 2021, or the 2020 Annual 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.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

BAUDAX BIO, INC.
Consolidated Balance Sheets
(Unaudited)

(amounts in thousands, except share and per share data)	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 30,690	\$ 30,342
Short-term investments	7,495	—
Accounts receivable, net	163	51
Inventory, net	2,773	2,978
Prepaid expenses and other current assets	2,569	3,346
Total current assets	43,690	36,717
Property, plant and equipment, net	5,039	5,052
Intangible assets, net	23,610	24,254
Goodwill	2,127	2,127
Other long-term assets	520	583
Total assets	<u>\$ 74,986</u>	<u>\$ 68,733</u>
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,140	\$ 3,653
Accrued expenses and other current liabilities	4,680	5,326
Current portion of long-term debt, net	1,196	683
Current portion of contingent consideration	7,107	8,467
Total current liabilities	14,123	18,129
Long-term debt, net	8,185	8,469
Warrant liability	83	65
Long-term portion of contingent consideration	53,348	56,576
Other long-term liabilities	241	293
Total liabilities	<u>75,980</u>	<u>83,532</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, 70,142,608 shares at March 31, 2021 and 48,688,480 shares at December 31, 2020	701	487
Additional paid-in capital	127,537	97,034
Accumulated deficit	(129,232)	(112,320)
Total shareholders' equity (deficit)	(994)	(14,799)
Total liabilities and shareholders' equity	<u>\$ 74,986</u>	<u>\$ 68,733</u>

See accompanying notes to consolidated financial statements.

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

(amounts in thousands, except share and per share data)	For the Three Months Ended March 31,	
	2021	2020
Revenue, net	\$ 198	\$ —
Operating expenses:		
Cost of sales	821	—
Research and development	1,108	3,070
Selling, general and administrative	12,088	8,046
Amortization of intangible assets	644	215
Change in warrant valuation	18	1,378
Change in contingent consideration valuation	1,841	27,626
Total operating expenses	16,520	40,335
Operating loss	(16,322)	(40,335)
Other expense:		
Interest and other expense	(590)	37
Net loss	\$ (16,912)	\$ (40,298)
Per share information:		
Net loss per share of common stock, basic and diluted	\$ (0.27)	\$ (4.03)
Weighted average common shares outstanding, basic and diluted	62,584,129	10,001,228

See accompanying notes to consolidated financial statements.

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

For the Three Months Ended March 31, 2021

(amounts in thousands, except share data)	Common Stock		Additional paid-in capital	Accumulated Deficit	Total
	Shares	Amount			
Balance, December 31, 2020	48,688,480	\$ 487	\$ 97,034	\$ (112,320)	\$ (14,799)
Recro Pharma allocation - stock-based compensation	—	—	1,201	—	1,201
Stock-based compensation expense	—	—	975	—	975
Issuance of common stock and warrants for registered direct offerings, net	11,000,000	110	16,317	—	16,427
Issuance of shares pursuant to vesting of restricted stock units, net of shares withheld for income taxes	42,159	—	(41)	—	(41)
Exercise of warrants	10,411,969	104	12,051	—	12,155
Net loss	—	—	—	(16,912)	(16,912)
Balance, March 31, 2021	<u>70,142,608</u>	<u>\$ 701</u>	<u>\$ 127,537</u>	<u>\$ (129,232)</u>	<u>\$ (994)</u>

For the Three Months Ended March 31, 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 shares pursuant to vesting 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>

See accompanying notes to consolidated financial statements.

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

(amounts in thousands)	For the Three Months Ended March 31,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (16,912)	\$ (40,298)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,304	2,633
Non-cash interest expense	229	—
Depreciation expense	86	105
Amortization	644	215
Change in warrant valuation	18	1,378
Change in contingent consideration valuation	1,841	27,626
Changes in operating assets and liabilities:		
Inventory	205	—
Prepaid expenses and other current assets	777	184
Right-of-use asset	63	99
Accounts receivable	(112)	—
Accounts payable, accrued expenses and other liabilities	(3,081)	1,848
Operating lease liability	(67)	(104)
Net cash used in operating activities	(14,005)	(6,314)
Cash flows from investing activities:		
Purchase of property and equipment	(73)	—
Purchase of short-term investments	(7,495)	—
Net cash used in investing activities	(7,568)	—
Cash flows from financing activities:		
Proceeds from equity facility, net of transaction costs	—	3,612
Proceeds from public offering, net of transaction costs	—	23,341
Proceeds from registered direct offerings, net of transaction costs	16,236	—
Proceeds from warrant exercises	12,155	—
Payment of contingent consideration	(6,429)	—
Payments of withholdings on shares withheld for income taxes	(41)	(95)
Net cash provided by financing activities	21,921	26,858
Net increase in cash and cash equivalents	348	20,544
Cash and cash equivalents, beginning of period	30,342	17,740
Cash and cash equivalents, end of period	\$ 30,690	\$ 38,284
Supplemental disclosure of cash flow information:		
Fair value of warrants issued in connection with public offering	\$ —	\$ 8,111
Offering costs included in accounts payable and accrued expenses	\$ 38	\$ 254

See accompanying notes to consolidated financial statements.

BAUDAX BIO, INC.
Notes to the Consolidated Financial Statements
(amounts in thousands, except share and per share data)
(Unaudited)

Note 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 to patients, prescribers and payers, such as its lead product, ANJESO® (meloxicam) injection.

In June 2020, Baudax Bio announced the commercial launch of ANJESO, which is indicated for the management of moderate to severe pain, alone or in combination with other non-NSAID analgesics and that the Centers for Medicare and Medicaid Services (“CMS”) approved transitional pass-through status and established a new reimbursement C-code for ANJESO.

In October 2020, the J-code for ANJESO facilitating reimbursement in the hospital outpatient, ambulatory surgery center and physician office settings of care took effect and replaced the previously issued C-code.

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.

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”). Following the Distribution and Separation, Baudax Bio operates as a separate, independent company.

Note 2: Development-Stage Risks, Liquidity and Going Concern

The Company has incurred operating losses and negative cash flows since inception and has an accumulated deficit of \$29,232 as of March 31, 2021.

The Company has raised funds from debt and equity transactions 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, which is in its early launch stage. 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, cash equivalents and short-term investments as of March 31, 2021, 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.

Note 3: Summary of Significant Accounting Principles

(a) Basis of Presentation

The accompanying unaudited consolidated financial statements of the Company and its subsidiaries have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"), for interim financial information 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 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 months ended March 31, 2021 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2021.

The accompanying unaudited interim consolidated financial statements should be read in conjunction with the annual audited financial statements and related notes as of and for the year ended December 31, 2020 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 represents 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 remaining lease term or useful life for leasehold improvements. Repairs and maintenance costs are expensed as incurred.

(e) 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 March 31, 2021, the Company's intangible asset is classified as an asset resulting from R&D activities. 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 is being 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 30th, 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, including recent tax reform, intellectual property protection, and competitive environments. As a result of the latest impairment tests, November 30, 2020, the Company determined that there was no impairment to goodwill or intangible assets. Additionally, there were no indicators of impairment as of March 31, 2021.

(f) 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 the Company and end-customers, wholesalers, group purchasing organizations and other indirect customers. The Company’s 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.

(g) Concentration of Credit Risk

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

The Company’s accounts receivable balance is compromised solely from transactions with the Company’s 3PL.

(h) 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 in-process research and development (“IPR&D”) if the technology licensed has not reached technological feasibility and has no alternative future use.

(i) 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 grants of stock options, time-based vesting RSUs and performance-based vesting RSUs granted to the Company’s employees prior to the Separation. The consolidated 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.

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.

(j) Income Taxes

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

(k) Net Loss Per Common Share

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

For purposes of calculating basic and diluted loss per common share, the denominator includes the weighted average common shares outstanding, the weighted average common stock equivalents for warrants priced at par value, or \$0.01, as the underlying common shares will be issued for little cash consideration and the conditions for the issuance of the underlying common shares are met when such warrants are issued, and, with regard to diluted loss per common share, the number of common stock equivalents if the inclusion of such common stock equivalents would be dilutive.

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

	Three Months Ended March 31,	
	2021	2020
Basic and Diluted Loss Per Share		
Net loss	\$ (16,912)	\$ (40,298)
Weighted average common shares outstanding, basic and diluted	62,584,129	10,001,228
Net loss per share of common stock, basic and diluted	<u>\$ (0.27)</u>	<u>\$ (4.03)</u>

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

	Three Months Ended March 31,	
	2021	2020
Options and restricted stock units outstanding	4,314,310	2,320,480
Warrants	22,862,636	15,384,616

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

(l) Recent Accounting Pronouncements

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.

Note 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, short-term investments, warrants, 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 March 31, 2021:			
Assets:			
Cash equivalents (See Note 5)			
Money market mutual funds	\$ 12,794	\$ —	\$ —
Commercial paper	—	15,221	—
Total cash equivalents	\$ 12,794	\$ 15,221	\$ —
Short-term investments (See Note 5)			
Commercial paper	—	7,495	—
Total financial assets	\$ 12,794	\$ 22,716	\$ —
Liabilities:			
Warrants (See Note 13(c))	\$ —	\$ —	\$ 83
Contingent consideration (See Note 12(b))	—	—	60,455
	\$ —	\$ —	\$ 60,538
At December 31, 2020:			
Assets:			
Cash equivalents (See Note 5)			
Money market mutual funds	\$ 24,210	\$ —	\$ —
Commercial paper	—	4,500	—
Total cash equivalents	\$ 24,210	\$ 4,500	\$ —
Liabilities:			
Warrants (See Note 13(c))	\$ —	\$ —	\$ 65
Contingent consideration (See Note 12(b))	—	—	65,043
	\$ —	\$ —	\$ 65,108

The reconciliation of the warrant liability and contingent consideration 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	(2,922)	—
Payment of contingent consideration	—	(3,560)
Remeasurement	16,734	2,245
Reclassification to equity upon warrant exchange	(21,858)	—
Balance at December 31, 2020	\$ 65	\$ 65,043
Payment of contingent consideration	—	(6,429)
Remeasurement	18	1,841
Total at March 31, 2021	\$ 83	\$ 60,455
Current portion as of March 31, 2021	\$ —	\$ 7,107
Long-term portion as of March 31, 2021	83	53,348

See Note 13(c) for the significant assumptions and inputs used to determine the fair value of liability classified warrants.

Based on the amended terms of the Alkermes agreement (see Note 12(b)), the remaining contingent consideration payments include the second components, which became payable upon regulatory approval, and includes remaining payments of \$1,440 due on or prior to June 20, 2021 and \$45,000 payable in seven equal annual payments of approximately \$6,400 beginning in February 2021, 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. The fair value of the remaining second consideration component is estimated by applying a risk-adjusted discount rate to the scheduled remaining payments. 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 March 31, 2021, the fair value calculations used discount rates in the range of 17.47% to 36.67%, with a weighted average of 27.03%.

The fair value of the contingent consideration liability is measured using inputs and assumptions as of the date of the financial statements. 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 March 31, 2021. 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.

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 March 31, 2021, the financial assets and liabilities recorded on the Consolidated Balance Sheets that are not measured at fair value on a recurring basis include accounts receivable, accounts payable and accrued expenses, which 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 March 31, 2021 due to the fact that the debt arrangements reflect market terms from recent transactions.

Note 5: Cash Equivalents and Short-Term Investments

Short-term investments as of March 31, 2021 consist of government money market funds and commercial paper. A portion of short-term investments is included in cash and cash equivalents due to its original maturity of three months or less when acquired. In accordance with FASB ASC Topic 320, “*Investments – Debt and Equity Securities*,” the Company has classified its entire investment portfolio as available-for-sale securities with secondary or resale markets, and, as such, its portfolio is reported at fair value with unrealized gains and losses included in Comprehensive Income in stockholders’ equity and realized gains and losses included in other income/expense, if applicable. The following is a summary of cash equivalents and short-term investments:

Description	March 31, 2021			
	Amortized Cost	Gross Unrealized		Estimated Fair Value
		Gain	Loss	
Money market mutual funds	\$ 12,794	\$ —	\$ —	\$ 12,794
Commercial paper	22,716	—	—	22,716
Total cash equivalents	<u>\$ 35,510</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 35,510</u>

Description	December 31, 2020			
	Amortized Cost	Gross Unrealized		Estimated Fair Value
		Gain	Loss	
Money market mutual funds	\$ 24,210	\$ —	\$ —	\$ 24,210
Commercial paper	4,500	—	—	4,500
Total cash equivalents	<u>\$ 28,710</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 28,710</u>

Short-term investments are included in cash and cash equivalents when their original maturities are three months or less when acquired. As of March 31, 2021 and December 31, 2020, the Company’s cash equivalents had maturities of one to three months. To derive the fair value of its commercial paper, the Company uses benchmark inputs and industry standard analytical models.

Note 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 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:

	March 31, 2021	December 31, 2020
Raw materials	\$ 68	\$ 130
Sub-assemblies	2,482	2,476
Finished goods	788	928
	3,338	3,534
Provision for inventory obsolescence	(565)	(556)
	<u>\$ 2,773</u>	<u>\$ 2,978</u>

Note 7: Property, Plant and Equipment

Property, plant and equipment consists of the following:

	<u>March 31, 2021</u>	<u>December 31, 2020</u>
Building and improvements	\$ 196	\$ 196
Furniture, office and computer equipment	934	934
Manufacturing and laboratory equipment	717	717
Construction in progress	4,526	4,453
	<u>6,373</u>	<u>6,300</u>
Less: accumulated depreciation	1,334	1,248
Property, plant and equipment, net	<u>\$ 5,039</u>	<u>\$ 5,052</u>

Depreciation expense for the three months ended March 31, 2021 and 2020 was \$86 and \$105, respectively.

Note 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 March 31, 2021, undiscounted future lease payments for non-cancellable operating leases are as follows:

	<u>Lease payments</u>	
Remainder of 2021	\$	272
2022		373
Total lease payments		<u>645</u>
Less imputed interest		(86)
Total operating lease liability	<u>\$</u>	<u>559</u>

As of March 31, 2021, 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:

	<u>Three Months Ended March 31,</u>	
	<u>2021</u>	<u>2020</u>
Operating lease cost	\$ 89	\$ 122
Short-term lease cost	39	-
Total lease cost	<u>\$ 128</u>	<u>\$ 122</u>

Note 9: Intangible Assets

The following represents the balance of the intangible assets at March 31, 2021:

	Cost	Accumulated Amortization	Net Intangible Assets
Asset resulting from R&D activities	\$ 26,400	\$ 2,790	\$ 23,610
Total	<u>\$ 26,400</u>	<u>\$ 2,790</u>	<u>\$ 23,610</u>

Amortization expense for the three months ended March 31, 2021 and 2020 was \$644 and \$215, respectively.

As of March 31, 2021, future amortization expense is as follows:

	Amortization
Remainder of 2021	\$ 1,932
2022	2,576
2023	2,576
2024	2,576
2025 and thereafter	13,950
Total	<u>\$ 23,610</u>

Note 10: Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	March 31, 2021	December 31, 2020
Payroll and related costs	\$ 2,007	\$ 3,177
Professional and consulting fees	884	802
Guarantee liability	772	422
Other research and development costs	258	243
Interest payable	130	126
Stock-based compensation	111	—
Other	518	556
	<u>\$ 4,680</u>	<u>\$ 5,326</u>

In November 2020, the Company implemented a reduction in force impacting approximately 40 employees and resulted in a charge of \$1,753, primarily related to severance, of which \$359 remains accrued and unpaid as of March 31, 2021.

Note 11: Debt

The following table summarizes the components of the carrying value of debt as of March 31, 2021:

Paycheck Protection Program Loan	\$ 1,537
Credit Agreement	10,000
Unamortized deferred issuance costs	(2,216)
Exit fee accretion	60
Total debt	<u>\$ 9,381</u>
Current portion as of March 31, 2021	\$ 1,196
Long-term portion, net as of March 31, 2021	8,185

(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 Loan”).

The PPP Loan 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 PPP Loan, nor did the Company pay any facility charge to obtain the PPP Loan. The PPP Loan 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 PPP Loan at any time without incurring any prepayment charges.

The PPP Loan may be partially or fully forgiven if the Company complies with the provisions of the CARES Act and related guidance including using the PPP Loan proceeds for covered payroll costs, rent, utilities, and certain other expenses, and using at least 60% of the PPP Loan proceeds to pay covered payroll costs as defined by the CARES Act. Any forgiveness of the PPP 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 Loan 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 3.5%, 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 March 31, 2021, 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 March 31, 2021, the Company was in compliance with the required covenants. As of March 31, 2021, 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.

The Company recorded debt issuance costs for the Credit Agreement of \$1,496 plus 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 Statements of Operations. As of March 31, 2021, the effective interest rate was 23.12%, 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 for the three months ended March 31, 2021.

Note 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 (\$24,039 as of March 31, 2021) 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 March 31, 2021, 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 (\$14,308 as of March 31, 2021) 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 March 31, 2021, 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 a New Drug Application (“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 \$60,000 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 became payable upon regulatory approval in February 2020 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, of which the first payment was made in the first quarter of 2021. 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 into 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 paid on 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 March 31, 2021, the Company has paid \$19,989 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. On March 1, 2021, Recro’s second motion to dismiss was denied. The parties are engaged in discussions to see if the matter can be resolved, and all deadlines in the case have been continued until June 21, 2021. 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. Recro and the Company has recorded a liability equal to the estimated fair value of the indemnification to Recro related to this Securities Litigation. The Company believe that the lawsuit is without merit and intends to vigorously defend against it, unless and until a resolution satisfactory to Recro and the Company can be achieved. 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 March 31, 2021, the Company had outstanding non-cancelable and cancelable purchase commitments in the aggregate amount of \$6,680 related to inventory and other goods and services, including manufacturing and clinical activities. The timing of certain purchase commitments cannot be estimated as it is dependent on 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 March 31, 2021, these employment agreements provided for, among other things, annual base salaries in an aggregate amount of not less than \$1,317, from that date through September 2022.

Note 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 March 31, 2021, 441,967 shares of common stock have been sold under the Sales Agreement for net proceeds of \$3,612, none of which were sold in the three months ended March 31, 2021. 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 “March Series A Warrants”) and Series B Warrants to purchase 7,692,308 shares of common stock (the “March Series B Warrants”), at an exercise price of \$4.59 per share for the March Series A Warrants and at an exercise price of \$3.25 per share for the March Series B Warrants, for net proceeds to the Company of \$23,085, after deducting underwriting discounts and commissions and offering expenses.

On November 24, 2020, the Company closed a registered direct offering of 2,850,000 shares of its common stock, warrants to purchase 10,126,583 shares of common stock (the “November Series A Warrants”) at an exercise price of \$ 1.20 per share, pre-funded warrants to purchase 7,276,583 shares of common stock (the “November Series B Warrants”) at an exercise price of \$0.01 per share, for net proceeds to the Company of \$10,763. As compensation to H.C. Wainwright & Co., LLC (the “Placement Agent”) as placement agent, the Company agreed to pay to the Placement Agent a cash fee of 6.0% of the aggregate gross proceeds, plus a management fee equal to 1.0% of the gross proceeds and reimbursement of certain expenses and legal fees. The Company also issued warrants to purchase 607,595 shares of common stock (the “November Placement Agent Warrants”) at an exercise price of \$.48125 per share.

On December 18, 2020, the Company closed a registered direct offering of 4,250,000 shares of its common stock, warrants to purchase 10,300,430 shares of common stock (the “December Series A Warrants”) at an exercise price of \$ 1.18 per share, pre-funded warrants to purchase 6,050,430 shares of common stock (the “December Series B Warrants”) at an exercise price of \$0.01 per share, for net proceeds to the Company of \$10,933. As compensation to the Placement Agent, the Company agreed to pay to the Placement Agent a cash fee of 6.0% of the aggregate gross proceeds, plus a management fee equal to 1.0% of the gross proceeds and reimbursement of certain expenses and legal fees. The Company also issued warrants to purchase 618,026 shares of common stock (the “December Placement Agent Warrants”) at an exercise price of \$1.45625 per share.

On February 8, 2021, the Company closed a registered direct offering of 11,000,000 shares of common stock (the “February Offering”) at an offering price of \$1.60 per share. As compensation to the Placement Agent, the Company agreed to pay the Placement Agent a cash fee of 6.0% of the gross proceeds raised in the February Offering, plus a management fee equal to 1.0% of the gross proceeds raised in the February Offering and reimbursement of certain expenses and legal fees. The Company also issued to designees of the Placement Agent warrants to purchase 660,000 shares of common stock (the “February Placement Agent Warrants”) at an exercise price of \$2.00 per share. The February Placement Agent Warrants will be exercisable immediately upon approval by the Company’s board of directors and shareholders of an increase in the number of shares of the Company’s authorized common stock.

(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 March 31, 2021, 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 (see Note 11(b)).

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 March Series A Warrants and March Series B Warrants. Pursuant to the Exchange Agreements, the Holders, at their election, agreed to a cashless exchange of either all of their March Series A Warrants or March 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”). The Company issued 1,186,774 shares of its common stock to the participating Holders as a result of the Exchange.

As a result of the Exchange, pursuant to certain price adjustment provisions in the warrants, the exercise price of each of the March Series A Warrants or March 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 March Series A Warrants not exchanged by a participating Holder, was amended to adjust the expiration date of such March Series A Warrants to April 26, 2021 (which is the expiration date of the March Series B Warrants). The March Series A and Series B warrants were liability classified prior to the Exchange because they contained anti-dilution provisions that did not meet the standard definition of anti-dilution provisions. The Company recorded a mark-to-market adjustment to record the March Series A and Series B warrant at their fair values immediately prior to the Exchange and then reclassified the remaining balance of \$21,858 to equity as a result of the issuance of shares and the removal of the anti-dilution and variable pricing protections in the Exchange.

On January 21, 2021, the Company entered into an agreement with an institutional investor, pursuant to which the Company agreed to issue and sell, in an offering (the “January Offering”), warrants exercisable for an aggregate of 10,300,430 shares of common stock of the Company (the “January Warrants”) at an offering price of \$0.125 per warrant in exchange for the exercise of the institutional investor’s existing December Series A warrants that were issued to them on December 21, 2020, at an exercise price of \$1.18 per warrant. The January Warrants have an exercise price of \$1.60 per share.

As compensation to the Placement Agent, as placement agent in connection with the January Offering, the Company agreed to pay to the Placement Agent a cash fee of 6.0% of the aggregate gross proceeds raised in the January Offering (including the proceeds relating to the exercise of the December Series A Warrants), plus a management fee equal to 1.0% of the gross proceeds raised in the January Offering (including the proceeds relating to the exercise of the December Series A Warrants) and reimbursement of certain expenses and legal fees. The Company also issued to designees of the Placement Agent warrants to purchase 618,026 shares of common stock (the "January Placement Agent Warrants") at an exercise price of \$2.00 per share.

During the year ended December 31, 2020, the Company issued 8,836,663 shares of common stock upon exercise of the March Series A and Series B Warrants for net proceeds of \$2,538.

During the year ended December 31, 2020, the Company issued 7,276,583 shares of common stock upon exercise of the November Series B Warrants for proceeds of \$73 and 6,050,430 shares of common stock upon exercise of the December Series B Warrants for proceeds of \$0.

During the three months ended March 31, 2021, the Company issued 111,539 shares of common stock upon exercise of the March Series B Warrants for net proceeds of \$1 and 10,300,430 shares of common stock upon exercise of the December Series A Warrants for proceeds of \$2,155.

As of March 31, 2021, 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
March Series A Warrants (non-participating holders)	32,438	\$ 0.01	March 26, 2025
March Series B Warrants (non-participating holders)	32,438	\$ 0.01	April 26, 2021
March Series A and Series B Warrants (participating holders)	437,692	\$ 0.01	April 26, 2021
MAM Eagle Lender Warrant	527,100	\$ 4.59	May 29, 2027
November Series A Warrants	10,126,583	\$ 1.20	November 24, 2025
November Placement Warrants	607,595	\$ 1.48125	November 24, 2025
December Placement Warrants	618,026	\$ 1.45625	December 18, 2025
January Warrants	10,300,430	\$ 1.60	January 21, 2026
January Placement Warrants	618,026	\$ 2.00	January 21, 2026

With the exception of the March Series A Warrants to purchase 32,438 shares of common stock and March Series B Warrants to purchase 32,438 shares of common stock related to the public offering and held by non-participating investors in the Exchange that are liability classified as they contain antidilution provisions that do not meet the standard definition of antidilution provisions, the remaining warrants outstanding are equity classified. There were 470,130 warrants to purchase shares of common stock that were unexercised at the expiration date and as a result cancelled as of April 26, 2021.

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

	March 31, 2021	
	Series A Warrants	Series B Warrants
Fair value	\$ 42	\$ 41
Expected dividend yield	— %	— %
Expected volatility	76.25 %	59.57 %
Risk-free interest rates	.64 %	.01 %
Remaining contractual term	4.0 years	0.1 years

Note 14: Stock-Based Compensation

The Company has adopted the 2019 Plan that 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 1st 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 1st of that year or such lower amount as determined by the Board of Directors. In December 2020, the number of shares available for issuance under the 2019 Plan was increased by 1,522,171. The total number of shares authorized for issuance under the 2019 Plan as of March 31, 2021 is 4,989,706. As of March 31, 2021, 748,715 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 the three months ended March 31, 2021 and 2020 was \$0.79 and \$1.58, respectively.

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:

	March 31,	
	2021	2020
Expected option life	5.5 years	6 years
Expected volatility	75.68%	72.85%
Risk-free interest rate	0.68%	0.46%
Expected dividend yield	—	—

The following table summarizes Baudax Bio stock option activity during the three months ended March 31, 2021:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life
Balance, December 31, 2020	2,284,298	\$ 3.10	9.1 years
Granted	994,877	\$ 1.28	
Expired/forfeited/cancelled	(101,852)	\$ 1.76	
Balance, March 31, 2021	<u>3,177,323</u>	\$ 2.58	8.6 years
Vested	429,292	\$ 4.47	5.4 years
Vested and expected to vest	3,177,323	\$ 2.58	8.6 years

Included in the table above are 355,503 stock options outstanding as of March 31, 2021 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 Baudax Bio RSUs activity during the three months ended March 31, 2021:

	Number of shares
Balance, December 31, 2020	991,012
Granted	265,046
Vested and settled	(87,509)
Expired/forfeited/cancelled	(31,562)
Balance, March 31, 2021	<u>1,136,987</u>
Expected to vest	1,136,987

Included in the table above are 191,208 time-based RSUs outstanding as of March 31, 2021 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 three months ended March 31, 2021 and 2020 was \$2,304 and \$2,633, respectively. For the current year, this represents stock-based compensation for the Baudax Bio awards, including \$128 of liability-classified awards, as well as stock-based compensation from the Recro Equity Plan for the acceleration of vesting for Baudax Bio employees in their Recro awards. For the prior 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 were continuing to vest in their Recro awards but were not performing services to Recro.

As of March 31, 2021, there was \$5,931 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 2.0 years. As of March 31, 2021, there was \$1,783 of unrecognized compensation expense related to unvested performance-based RSUs.

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 March 31, 2021, the aggregate intrinsic value of the unvested options was \$196. There was no aggregate intrinsic value of the vested options.

Note 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 \$17 and \$88 for the three months ended March 31, 2021 and 2020, 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, which terminated on December 31, 2020. Under the transition services agreement, the Company provided certain services to Recro, each related to corporate functions, which were 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 months ended March 31, 2020, the Company recorded income of \$516 related to the transition services agreement, which is recorded as a reduction in selling, general and administrative expenses in the prior year.

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.

Note 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 March 31, 2021 and 2020 were \$270 and \$141, respectively.

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the interim unaudited financial statements contained in Part I, Item 1 of this Quarterly Report, and the audited financial statements and notes thereto for the year ended December 31, 2020 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on February 16, 2021. 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.

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.

The launch of our first commercial product ANJESO began in mid-2020 in the U.S. ANJESO is the first and only 24-hour, intravenous (IV) COX-2 preferential non-steroidal anti-inflammatory (NSAID) for the management of moderate to severe pain, which can be administered alone or in combination with other non-NSAID analgesics. We have successfully completed three Phase III clinical trials, including two pivotal efficacy trials, a large double-blind Phase III safety trial and a Phase IIIb program evaluating ANJESO and its health economic impact in specific surgical settings. In addition to ANJESO, we have a pipeline of other innovative pharmaceutical assets including two novel neuromuscular blocking agents (NMBAs) and a proprietary chemical reversal agent specific to these NMBAs, which is currently in preclinical studies. We continue to evaluate strategic partnerships to commercialize ANJESO outside of the United States.

Effective October 2020, the Centers for Medicare and Medicaid Services, or CMS, established a new permanent J-code for ANJESO, 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., including Vizient Inc., Premier Inc., and HealthTrust, as well as one of the top 3 integrated delivery networks for terms for availability of ANJESO to their member institutions. In the first quarter of 2021 we have seen more meaningful progress in deepening usage of ANJESO in early users as reflected in sales to existing hospitals and ambulatory surgery centers, which doubled in the first quarter of 2021 compared to the fourth quarter of 2020. The number of vials sold to end-customers has increased 40% in the first quarter of 2021 versus the fourth quarter of 2020 and the re-order rate was nearly 70% for the same comparable period. During the first quarter, formulary wins grew by 22 institutions, for a total of 90 institutions as of March 31, 2021, an increase of over 30% from the fourth quarter of 2020.

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 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 primarily 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. Even as vaccines for COVID-19 are being rolled out, an average of over 50,000 new cases are being reported in the United States every day. 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, caused a reduction in hospital staffing, lead to a diversion in resources from other normal activities to patients suffering from COVID-19 and caused a limitation in 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 an ongoing 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, or longer, 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.

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 product costs, 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 CROs, 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 commercialization 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 2020 Annual 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 other related activities 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 officer’s 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 in manufacturing and launch related activities. The reorganization was completed in November 2020 and we incurred approximately \$1.7 million of charges for severance and other costs relating to such reorganization activities during the fourth quarter of 2020.

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 \$3.6 million paid in 2020, \$1.4 million which becomes due June 20, 2021, and \$45.0 million over seven years beginning one year after approval, of which the first payment was made in the first quarter of 2021, 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 March 31, 2021 recorded a \$60.5 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 March 31, 2021, we have paid \$20.0 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 March 31, 2021 and 2020.

Results of Operations

Comparison of the Three Months Ended March 31, 2021 and 2020

	Three Months Ended March 31,	
	2021	2020
	(amounts in thousands)	
Revenue, net	\$ 198	\$ —
Operating expenses:		
Cost of sales	821	—
Research and development	1,108	3,070
Selling, general and administrative	12,088	8,046
Amortization of intangible assets	644	215
Change in warrant valuation	18	1,378
Change in contingent consideration valuation	1,841	27,626
Total operating expenses	16,520	40,335
Operating loss	(16,322)	(40,335)
Other expense:		
Interest and other expense	(590)	37
Net loss	\$ (16,912)	\$ (40,298)

Revenue, net. For the three months ended March 31, 2021, net product revenue was \$0.2 million, related to sales of ANJESO in the U.S. While utilizing the title model of distribution, product revenue represents shipments to our 3PL provider. For the three months ended March 31, 2020, we did not recognize any product revenue.

Cost of sales. Our cost of sales was \$0.8 million for the three months ended March 31, 2021 and consists of product costs, royalty expense and certain fixed costs associated with the manufacturing of ANJESO, including supply chain and quality costs. We expensed 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 March 31, 2021 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 that over time, our cost of sales will increase as sales increase and as inventory values change to include all direct and indirect costs and expenses post FDA approval. No product cost of sales was recorded for the three months ended March 31, 2020.

Research and Development. Our research and development expenses were \$1.1 million and \$3.1 million for the three months ended March 31, 2021 and 2020, respectively. The decrease of \$2.0 million was primarily due to a decrease of \$1.7 million as a result of re-allocating costs related to supply chain, regulatory, quality, and medical affairs associated with support of the commercial launch of ANJESO from research and development expense to cost of sales and selling, general and administrative expense and a decrease in personnel costs of \$0.3 million.

Selling, General and Administrative. Our selling, general and administrative expenses were \$12.1 million and \$8.0 million for the three months ended March 31, 2021 and 2020, respectively. The increase of \$4.1 million was primarily due to the commercial launch of ANJESO, specifically, an increase in personnel related costs of \$1.6 million, an increase of \$1.3 million attributable to medical affairs and regulatory support reallocated from research and development expense post FDA approval, an increase of \$0.3 million in public company costs and an increase of \$0.3 million in marketing costs. In addition, the first quarter of 2020 included \$0.5 million in reimbursed general and administrative expenses related to the Transition Services Agreement with Recro Pharma, which ended on December 31, 2020.

Amortization of Intangible Assets. Amortization expense was \$0.6 million for the three months ended March 31, 2021 and \$0.2 million for the three months ended March 31, 2020, which was related to the amortization of our intangible asset resulting from research and development activities over its estimated useful life beginning in the first quarter of fiscal 2020.

Change in Warrant Valuation. There was not a material change in warrant valuation for the three months ended March 31, 2021. Our warrant valuation increased \$1.4 million for the three months ended March 31, 2020 due to an increase in the Black-Scholes values.

Change in Contingent Consideration Valuation. The change in contingent consideration valuation was an increase in value of \$1.8 million for the three months ended March 31, 2021 and an increase in value of \$27.6 million for the three months ended March 31, 2020. 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 three months ended March 31, 2021 was primarily due to the time value of money and change in interest rates, partially offset by 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 March 31, 2020 was primarily due to the increase in probability of success of milestones tied to the FDA approval of ANJESO during the first quarter of fiscal 2020.

Liquidity and Capital Resources

As of March 31, 2021, we had \$38.2 million in cash, cash equivalents and short-term investments.

On February 8, 2021, we entered into an agreement to issue and sell 11,000,000 shares of common stock, or the February Offering, at an offering price of \$1.60 per share. As compensation to H.C. Wainwright & Co., LLC, or the Placement Agent, as placement agent in connection with the February Offering, we agreed to pay the Placement Agent a cash fee of 6.0% of the gross proceeds raised in the February Offering, plus a management fee equal to 1.0% of the gross proceeds raised in the February Offering and reimbursement of certain expenses and legal fees. We also issued to designees of the Placement Agent warrants to purchase up to 660,000 shares of common stock, or the February Placement Agent Warrants. The February Placement Agent Warrants have an exercise price of \$2.00 per share. The February Placement Agent Warrants will be exercisable immediately upon approval by our board of directors and shareholders of an increase in the number of shares of our authorized common stock.

On January 21, 2021, we entered into an agreement to issue and sell warrants exercisable for an aggregate of 10,300,430 shares of common stock or the January Warrants, at an offering price of \$0.125 per warrant in exchange for the exercise of the institutional investor's existing December Series A warrants that were issued to them on December 21, 2020, at an exercise price of \$1.18 per warrant. The January Warrants have an exercise price of \$1.60 per share. The January Warrants are immediately exercisable and will expire five years from the issuance date. As compensation to the Placement Agent, we agreed to pay a cash fee of 6.0% of the aggregate gross proceeds raised in the January Offering (including the proceeds relating to the exercise of the December Series A Warrants), plus a management fee equal to 1.0% of the gross proceeds raised in the January Offering (including the proceeds relating to the exercise of the December Series A Warrants) and reimbursement of certain expenses and legal fees. We also issued to designees of the Placement Agent warrants to purchase up to 618,026 shares of common stock, or the January Placement Agent Warrants. The January Placement Agent Warrants have substantially the same terms as the January Warrants, except that the January Placement Agent Warrants have an exercise price equal to \$2.00 per share.

On November 24, 2020, we closed a registered direct offering of 2,850,000 shares of common stock, warrants to purchase 10,126,583 shares of common stock, or the November Series A Warrants, at an exercise price of \$1.20 per share, pre-funded warrants to purchase 7,276,583 shares of common stock, or the November Series B Warrants, at an exercise price of \$0.01 per share, for net proceeds of \$10.8 million. As compensation to the Placement Agent, we agreed to pay to the Placement Agent a cash fee of 6.0% of the aggregate gross proceeds, plus a management fee equal to 1.0% of the gross proceeds and reimbursement of certain expenses and legal fees. We also issued warrants to purchase 607,595 shares of common stock, or the November Placement Agent Warrants, at an exercise price of \$1.48125 per share.

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 million 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 and related guidance. Accordingly, this Loan may be partially or fully forgiven if we are deemed to have complied 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 is 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 Loan will be forgiven, however, no assurance can be given that we will obtain forgiveness of the PPP Loan in whole or in part.

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 March 31, 2021, 441,967 shares have been sold under the ATM Program for net proceeds of \$3.6 million, none of which were sold in the three months ended March 31, 2021. The Agent was paid a sales commission of 3% for such sales under the Sales Agreement.

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 March 31, 2021, we will need to raise additional capital in the next twelve months to continue as a going concern.

We anticipate that our principal uses of cash in the future will be primarily to 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 \$14.0 million and \$6.3 million for the three months ended March 31, 2021 and 2020, 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 \$7.6 million for the three months ended March 31, 2021, which was primarily due to purchases of short-term investments. There was no cash used in investing activities for the three months ended March 31, 2020

There was \$21.9 million of cash provided by financing activities in the three months ended March 31, 2021 consisting of net proceeds of \$16.2 million from registered direct offerings of common stock and warrants and net proceeds of \$12.2 million from warrant exercises, partially offset by a payment of contingent consideration of \$6.4 million. There was \$26.9 million of cash provided by financing activities for the three months ended March 31, 2020 from net proceeds of the public offering of \$23.3 million and net proceeds of our equity facility of \$3.6 million.

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

- our relationships with 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 extent to which holders of our warrants exercise their warrants resulting in the payment of cash proceeds to us;
- our ability to have sufficient authorized shares of our common stock available;
- the ability to effectuate a reverse stock split or other similar change to our capital structure;
- 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 March 31, 2021:

Contractual Obligations	Payments Due by Period (in 000s)				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Debt Obligations (1):					
Debt	\$ 11,537	\$ 1,196	\$ 6,730	\$ 3,611	\$ —
Interest on Debt	3,873	1,395	2,099	379	—
Purchase Obligations (2):	\$ 6,680	\$ 3,202	\$ 451	\$ —	\$ —
Operating Leases (3)	711	431	280	—	—
Other Long-Term Liabilities:					
Other License Commitments and Milestone payments (4), (5)	54,875	60	150	190	125
Alkermes Payments (6)	120,011	7,869	19,286	12,857	—
Employment Agreements (7)	1,317	1,008	309	—	—
Total Contractual Obligations	\$ 199,004	\$ 15,161	\$ 29,305	\$ 17,037	\$ 125

- (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 March 31, 2021, 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 September 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 2020 Annual Report. In the three months ended March 31, 2021, there were no significant changes to the application of critical accounting policies previously disclosed in our 2020 Annual Report.

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 March 31, 2021. We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure.

A control system, no matter how well conceived and operated, can provide only reasonable, and not absolute, assurance that the objectives of the control system will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. However, our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives. Based on the evaluation of our disclosure controls and procedures as of March 31, 2021, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

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. On March 1, 2021, Recro's second motion to dismiss was denied. The parties are engaged in discussions to see if the matter can be resolved, and all deadlines in the case have been continued until June 21, 2021. 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, unless and until a resolution satisfactory to Recro and us can be achieved. 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.

There have been no material changes in our risk factors as previously disclosed in our 2020 Annual Report.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

(a) The following exhibits are filed herewith or incorporated by reference herein:

EXHIBIT INDEX

Exhibit No.	Description	Method of Filing
4.1	Form of Series C Warrant, issued January 25, 2021.	Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on January 22, 2021 (File No. 001-39101).
4.2	Form of Placement Agent Warrant, issued January 25, 2021.	Incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on January 22, 2021 (File No. 001-39101).
4.3	Form of Placement Agent Warrant, issued February 10, 2021.	Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on February 9, 2021 (File No. 001-39101).
10.1	Employment Agreement, dated March 8, 2021, between Baudax Bio, Inc. and Richard S. Casten.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 11, 2021 (File No. 001-39101).
31.1	Rule 13a-14(a)/15d-14(a) certification of Principal Executive Officer.	Filed herewith.
31.2	Rule 13a-14(a)/15d-14(a) certification of Principal Financial and Accounting Officer.	Filed herewith.
32.1	Section 1350 certification, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
101.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: May 5, 2021

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

Date: May 5, 2021

By: /s/ Richard S. Casten
Richard S. Casten
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: May 5, 2021

/s/ Gerri A. Henwood

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

CERTIFICATION

I, Richard S. Casten, 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: May 5, 2021

/s/ Richard S. Casten

Richard S. Casten
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 March 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to such officer's knowledge:

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

Date: May 5, 2021

/s/ Gerri A. Henwood

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

/s/ Richard S. Casten

Richard S. Casten
Chief Financial Officer
(Principal Financial and Accounting Officer)