

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

FORM 10-Q

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

For the Quarterly Period Ended: September 30, 2021

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

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)

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

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

19355
(Zip Code)

(484) 395-2440
(Registrant's telephone number, including area code)

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

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

Securities registered pursuant to Section 12(g) of the Act:
None

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of November 2, 2021, there were 84,423,699 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:

- ① our estimates regarding expenses, revenue, capital requirements and timing and availability of and the need for additional financing;
- ① our ability to continue as a going concern for the next 12 months;
- ① our ability to operate under significant indebtedness;
- ① our ability to maintain the listing of our common stock on the Nasdaq Capital Market;
- ① 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;
- ① 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;
- ① our ability to successfully market, commercialize and achieve broad market acceptance for ANJESO and any of our other product candidates once approved;
- ① the acceptance of ANJESO by the medical community, including physicians, patients, healthcare providers and hospital formularies;
- ① our ability and that of our third-party manufacturers to successfully scale-up our commercial manufacturing process for ANJESO;
- ① the results, timing and outcome of our clinical trials of our product candidates, and any future clinical and preclinical studies;
- ① our relationships with Alkermes plc, or Alkermes, other third parties, licensors, collaborators, and our employees;
- ① our ability to operate as a standalone company and execute our strategic priorities;
- ① potential indemnification liabilities we may owe to Recro Pharma, Inc., or Recro, after the separation of Recro’s acute care business and transfer of such assets to us, or the Separation;
- ① 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;
- ① our ability to comply with the regulatory schemes applicable to our business and other regulatory developments in the United States and foreign countries;
- ① 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;
- ① our ability to obtain and maintain patent protection and defend our intellectual property rights against third-parties;
- ① our ability to maintain our relationships, profitability and contracts with our key commercial partners;
- ① 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;
- ① our ability to recruit or retain key scientific, technical, commercial, and management personnel or to retain our executive officers;

- ② 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;
- ② 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
- ② 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 and 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)	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 14,772	\$ 30,342
Short-term investments	10,150	—
Accounts receivable, net	422	51
Inventory	4,310	2,978
Prepaid expenses and other current assets	1,484	3,346
Total current assets	31,138	36,717
Property, plant and equipment, net	4,933	5,052
Intangible assets, net	22,322	24,254
Goodwill	2,127	2,127
Other long-term assets	979	583
Total assets	<u>\$ 61,499</u>	<u>\$ 68,733</u>
Liabilities and Shareholders' Deficit		
Current liabilities:		
Accounts payable	\$ 1,819	\$ 3,653
Accrued expenses and other current liabilities	4,568	5,326
Current portion of long-term debt, net	1,389	683
Current portion of contingent consideration	6,666	8,467
Total current liabilities	14,442	18,129
Long-term debt, net	6,913	8,469
Long-term portion of contingent consideration	60,059	56,576
Other long-term liabilities	813	358
Total liabilities	82,227	83,532
Commitments and contingencies (Note 12)		
Shareholders' deficit:		
Preferred stock, \$0.01 par value. Authorized, 10,000,000 shares; none issued and outstanding	—	—
Common stock, \$0.01 par value. Authorized, 190,000,000 shares; issued and outstanding, 84,423,342 shares at September 30, 2021 and 48,688,480 shares at December 31, 2020	844	487
Additional paid-in capital	139,951	97,034
Accumulated deficit	(161,523)	(112,320)
Total shareholders' deficit	(20,728)	(14,799)
Total liabilities and shareholders' deficit	<u>\$ 61,499</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 September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue, net	\$ 281	\$ 68	\$ 680	\$ 417
Operating expenses:				
Cost of sales	462	540	1,869	1,190
Research and development	658	1,469	2,623	5,889
Selling, general and administrative	11,074	13,763	33,770	33,026
Amortization of intangible assets	644	643	1,932	1,502
Change in warrant valuation	(6)	(11,182)	(47)	2,863
Change in contingent consideration valuation	3,829	(17,427)	9,551	14,252
Total operating expenses	16,661	(12,194)	49,698	58,722
Operating (loss) income	(16,380)	12,262	(49,018)	(58,305)
Other expense:				
Other expense, net	(582)	(577)	(185)	(753)
Net (loss) income	<u>\$ (16,962)</u>	<u>\$ 11,685</u>	<u>\$ (49,203)</u>	<u>\$ (59,058)</u>
Per share information:				
Net (loss) income per share of common stock, basic	<u>\$ (0.20)</u>	<u>\$ 0.64</u>	<u>\$ (0.66)</u>	<u>\$ (3.84)</u>
Net (loss) income per share of common stock, diluted	<u>\$ (0.20)</u>	<u>\$ 0.62</u>	<u>\$ (0.66)</u>	<u>\$ (3.84)</u>
Weighted average common shares outstanding, basic	<u>84,400,156</u>	<u>18,374,604</u>	<u>74,008,574</u>	<u>15,366,861</u>
Weighted average common shares outstanding, diluted	<u>84,400,156</u>	<u>18,768,376</u>	<u>74,008,574</u>	<u>15,366,861</u>

See accompanying notes to consolidated financial statements.

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

For the Nine Months Ended September 30, 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>
Stock-based compensation expense	—	—	854	—	854
Issuance of common stock and warrants for registered direct offerings, net	14,028,520	141	10,760	—	10,901
Issuance of shares pursuant to vesting of restricted stock units, net of shares withheld for income taxes	102,094	1	(6)	—	(5)
Net loss	—	—	—	(15,329)	(15,329)
Balance, June 30, 2021	<u>84,273,222</u>	<u>\$ 843</u>	<u>\$ 139,145</u>	<u>\$ (144,561)</u>	<u>\$ (4,573)</u>
Stock-based compensation expense	—	—	874	—	874
Issuance of common stock and warrants for registered direct offerings, net	—	—	(38)	—	(38)
Issuance of restricted stock units, net of shares withheld for income taxes	150,120	1	(30)	—	(29)
Net loss	—	—	—	(16,962)	(16,962)
Balance, September 30, 2021	<u>84,423,342</u>	<u>\$ 844</u>	<u>\$ 139,951</u>	<u>\$ (161,523)</u>	<u>\$ (20,728)</u>

See accompanying notes to consolidated financial statements.

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

For the Nine Months Ended September 30, 2020

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

See accompanying notes to consolidated financial statements.

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

(amounts in thousands)	For the Nine Months Ended September 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (49,203)	\$ (59,058)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	4,132	7,431
Non-cash interest expense	673	306
Gain on extinguishment of debt	(1,553)	—
Depreciation expense	195	315
Amortization	1,932	1,502
Change in warrant valuation	(47)	2,863
Change in contingent consideration valuation	9,551	14,252
Changes in operating assets and liabilities:		
Inventory	(1,332)	(1,784)
Prepaid expenses and other assets	1,474	(90)
Accounts receivable	(371)	—
Accounts payable, accrued expenses and other liabilities	(2,075)	4,837
Net cash used in operating activities	(36,624)	(29,426)
Cash flows from investing activities:		
Purchase of property and equipment	(76)	(307)
Purchase of short-term investments	(19,641)	—
Proceeds from maturity of short-term investments	9,500	—
Net cash used in investing activities	(10,217)	(307)
Cash flows from financing activities:		
Proceeds from issuance of long-term debt, net of transaction costs	—	10,041
Proceeds from equity facility, net of transaction costs	—	3,612
Proceeds from public offering, net of transaction costs	—	23,085
Proceeds from registered direct offerings, net of transaction costs	27,059	—
Proceeds from warrant exercises	12,155	2,458
Payment of contingent consideration	(7,869)	(2,500)
Payments of withholdings on shares withheld for income taxes	(74)	(95)
Net cash provided by financing activities	31,271	36,601
Net (decrease) increase in cash and cash equivalents	(15,570)	6,868
Cash and cash equivalents, beginning of period	30,342	17,740
Cash and cash equivalents, end of period	<u>\$ 14,772</u>	<u>\$ 24,608</u>
Supplemental disclosure of cash flow information:		
Purchase of property, plant and equipment included in accrued expenses and accounts payable	\$ —	\$ 22
Fair value of warrants issued in connection with public offering	\$ —	\$ 8,111
Fair value of warrants issued in connection with financing facility	\$ —	\$ 1,423
Right-of-use assets acquired	\$ 575	\$ —

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

Baudax Bio, Inc. (“Baudax Bio” or the “Company”) is a pharmaceutical company primarily focused on commercializing and developing 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.

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.

Business

Baudax Bio launched ANJESO, which is indicated for the management of moderate to severe pain in 2020, and the Centers for Medicare and Medicaid Services (“CMS”) granted a J-code to ANJESO in the fourth quarter of 2020.

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.

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 \$161,523 as of September 30, 2021.

The Company has raised funds from debt and equity transactions and will likely 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. In addition, development activities, clinical and pre-clinical testing and, if approved, commercialization of the Company’s other product candidates, will likely 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 September 30, 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 and nine months ended September 30, 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.

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. There were no indicators of impairment since our last impairment test.

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

As of September 30, 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.

(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 of internal costs and 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 project. 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 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.

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(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.

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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) Income Per Common Share

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

For purposes of calculating basic and diluted (loss) income 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) income 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) income per share:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Basic (Loss) Income Per Share				
Net (loss) income	\$ (16,962)	\$ 11,685	\$ (49,203)	\$ (59,058)
Weighted average common shares outstanding, basic	84,400,156	18,374,604	74,008,574	15,366,861
Net (loss) income per share of common stock, basic	<u>\$ (0.20)</u>	<u>\$ 0.64</u>	<u>\$ (0.66)</u>	<u>\$ (3.84)</u>
Diluted (Loss) Income Per Share				
Net (loss) income	\$ (16,962)	\$ 11,685	\$ (49,203)	\$ (59,058)
Change in warrant valuation	—	—	—	—
Diluted net (loss) income	<u>\$ (16,962)</u>	<u>\$ 11,685</u>	<u>\$ (49,203)</u>	<u>\$ (59,058)</u>
Weighted average common shares outstanding, basic	84,400,156	18,374,604	74,008,574	15,366,861
Dilutive effect of warrants	—	—	—	—
Dilutive effect of equity awards, based on treasury stock method	—	393,772	—	—
Weighted average common shares outstanding, diluted	<u>84,400,156</u>	<u>18,768,376</u>	<u>74,008,574</u>	<u>15,366,861</u>
Net (loss) income per share of common stock, diluted	<u>\$ (0.20)</u>	<u>\$ 0.62</u>	<u>\$ (0.66)</u>	<u>\$ (3.84)</u>

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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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Options and restricted stock units outstanding	4,794,738	2,098,316	4,794,738	1,694,889
Warrants	38,360,429	15,107,100	38,360,429	15,199,605

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.

In May 2021, the FASB issued ASU No. 2021-04, “*Earnings Per Share (Topic 260), Debt – Modifications and Extinguishments (Subtopic 470-50), Compensation – Stock Compensation (Topic 718), and Derivatives and Hedging – Contracts in Entity’s Own Equity (Subtopic 815-40): Issuer’s Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*,” or ASU 2021-04. ASU 2021-04 clarifies and reduces diversity in an issuer’s accounting for modifications or exchanges of freestanding equity-classified written call options, such as warrants, that remain equity classified after modification or exchange. ASU 2021-04 is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years and early adoption is permitted. 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:

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

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

	Fair value measurements at reporting date using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
At September 30, 2021:			
Assets:			
Cash equivalents (See Note 5)			
Money market mutual funds	\$ 12,262	\$ —	\$ —
Commercial paper	—	1,500	—
Total cash equivalents	\$ 12,262	\$ 1,500	\$ —
Short-term investments (See Note 5)			
Commercial paper	—	10,150	—
Total financial assets	\$ 12,262	\$ 11,650	\$ —
Liabilities:			
Warrants (See Note 13(c))	\$ —	\$ —	\$ 18
Contingent consideration (See Note 12(b))	—	—	66,725
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 66,743</u>
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
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 65,108</u>

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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	—	(7,869)
Remeasurement	(47)	9,551
Total at September 30, 2021	<u>\$ 18</u>	<u>\$ 66,725</u>
Current portion as of September 30, 2021	\$ —	\$ 6,666
Long-term portion as of September 30, 2021	18	60,059

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 \$45,000 payable in seven equal annual payments of approximately \$6,400 of which the first payment was made 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 September 30, 2021, the fair value calculations used discount rates in the range of 17.53% to 36.46%, with a weighted average of 27.53%.

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 September 30, 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 September 30, 2021, the financial assets and liabilities recorded on the Consolidated Balance Sheets that are not measured at fair value on a recurring basis include accounts receivable, accounts payable and accrued expenses, 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 September 30, 2021 due to the fact that the debt arrangements reflect market terms from recent transactions.

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Note 5: Cash Equivalents and Short-Term Investments

Short-term investments consist of government money market funds and commercial paper with original maturities of greater than three months. 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 carried 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	Amortized Cost	September 30, 2021 Gross Unrealized		Estimated Fair Value
		Gain	Loss	
Money market mutual funds	\$ 12,262	\$ —	\$ —	\$ 12,262
Commercial paper	11,650	—	—	11,650
Total cash equivalents and short-term investments	\$ 23,912	\$ —	\$ —	\$ 23,912

Description	Amortized Cost	December 31, 2020 Gross Unrealized		Estimated Fair Value
		Gain	Loss	
Money market mutual funds	\$ 24,210	\$ —	\$ —	\$ 24,210
Commercial paper	4,500	—	—	4,500
Total cash equivalents and short-term investments	\$ 28,710	\$ —	\$ —	\$ 28,710

Short-term investments are included in cash and cash equivalents when their original maturities are three months or less when acquired. As of September 30, 2021 and December 31, 2020, the Company's cash equivalents and short-term investments had maturities of one to four months. The Company uses benchmark inputs and industry standard analytical models to derive the fair value of its commercial paper.

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 consists of the following:

	September 30, 2021	December 31, 2020
Raw materials	\$ 13	\$ 130
Sub-assemblies	3,997	2,476
Finished goods	654	928
	4,664	3,534
Provision for inventory obsolescence	(354)	(556)
Inventory	\$ 4,310	\$ 2,978

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Note 7: Property, Plant and Equipment

Property, plant and equipment consists of the following:

	September 30, 2021	December 31, 2020
Building and improvements	\$ 196	\$ 196
Furniture, office and computer equipment	969	934
Manufacturing and laboratory equipment	717	717
Construction in progress	4,494	4,453
	6,376	6,300
Less: accumulated depreciation	1,443	1,248
Property, plant and equipment, net	<u>\$ 4,933</u>	<u>\$ 5,052</u>

Depreciation expense for the three and nine months ended September 30, 2021 was \$46 and \$195, respectively. Depreciation expense for the three and nine months ended September 30, 2020 was \$104 and \$315, 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 6 years, which was extended during the three months ended September 30, 2021. Most leases contain specific renewal options where notice to renew must be provided in advance of lease expiration or automatic renewals where no advance notice is required. Periods covered by an option to extend the lease were included in the non-cancellable lease term when exercise of the option was determined to be reasonably certain. Costs determined to be variable and not based on an index or rate were not included in the measurement of operating lease liabilities. As most leases do not provide an implicit rate, the Company's effective interest rate was used to discount its lease liabilities.

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

As of September 30, 2021, undiscounted future lease payments for non-cancellable operating leases are as follows:

	Lease payments	
Remainder of 2021	\$	158
2022		383
2023		270
2024		278
2025 and thereafter		858
Total lease payments		1,947
Less imputed interest		(941)
Total operating lease liability	\$	<u>1,006</u>

As of September 30, 2021, the weighted average remaining lease term was 6 years and the weighted average discount rate was 23%.

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

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating lease cost	\$ 79	\$ 87	\$ 255	\$ 306
Short-term lease cost	52	38	130	68
Total lease cost	<u>\$ 131</u>	<u>\$ 125</u>	<u>\$ 385</u>	<u>\$ 374</u>

Cash paid for amounts included in the measurement of lease liabilities, which is included in operating cash flows, was \$258 and \$78 for the nine months ended September 30, 2021 and 2020, respectively.

Note 9: Intangible Assets

The following represents the balance of the intangible assets at September 30, 2021:

	September 30, 2021	December 31, 2020
Asset resulting from R&D activities	\$ 26,400	\$ 26,400
Accumulated Amortization	(4,078)	(2,146)
Intangible assets, net	<u>\$ 22,322</u>	<u>\$ 24,254</u>

Amortization expense for the three and nine months ended September 30, 2021 was \$644 and \$1,932, respectively. Amortization expense for the three and nine months ended September 30, 2020 was \$643 and \$1,502, respectively.

As of September 30, 2021, future amortization expense is as follows:

	Amortization	
Remainder of 2021	\$	644
2022		2,576
2023		2,576
2024		2,576
2025 and thereafter		13,950
Total	<u>\$</u>	<u>22,322</u>

Note 10: Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	September 30, 2021	December 31, 2020
Payroll and related costs	\$ 2,409	\$ 3,177
Guarantee liability	635	422
Professional and consulting fees	545	802
Other research and development costs	142	243
Interest payable	113	126
Stock-based compensation	111	—
Other	613	556
	<u>\$ 4,568</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 \$117 remains accrued and unpaid as of September 30, 2021.

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Note 11: Debt

The following table summarizes the components of the carrying value of debt as of September 30, 2021:

	September 30, 2021	December 31, 2020
Paycheck Protection Program Loan	\$ —	\$ 1,537
Credit Agreement	10,000	10,000
Unamortized deferred issuance costs	(1,794)	(2,427)
Exit fee accretion	96	42
Total debt	\$ 8,302	\$ 9,152
Current portion	\$ 1,389	\$ 683
Long-term portion, net	6,913	8,469

(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.

During the nine months ended September 30, 2021, the Company received a Notice of PPP Forgiveness Payment from the SBA regarding the approval of their application for forgiveness of the PPP Loan of \$1,537 and accrued interest. As a result, the Company recognized a gain on extinguishment of the PPP Loan of \$1,553 during the nine months ended September 30, 2021.

(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”). As of September 30, 2021, no funds have been drawn from the additional tranches.

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

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

Subject to certain exceptions, the Company is required to make mandatory prepayments of the Term Loans, with the proceeds of asset sales, extraordinary receipts, debt issuances and specified other events. The Company may make voluntary prepayments in whole or in part, subject to a prepayment premium equal to (i) with respect to any prepayment paid on or prior to the third anniversary of the Tranche One Loan (or, in the case of each of the Tranche Two Loans, Tranche Three Loans, Tranche Four Loans or Tranche Five Loans, the third anniversary of the date each such loan is funded), the remaining scheduled payments of interest that would have accrued on the Term Loans being prepaid, repaid or accelerated, but that remained unpaid, in no event to be less than 5.0% of the principal amount of the Term Loan being prepaid, and (ii) with respect to any prepayment paid after the third but prior to the fourth anniversary of the Tranche One Loan (or, in the case of each of the Tranche Two Loans, Tranche Three Loans, Tranche Four Loans or Tranche Five Loans, the fourth anniversary of the date each such loan is funded), 3.0% of the principal amount of the Term Loan being prepaid. In addition, an exit fee will be due and payable upon prepayment or repayment of the Term Loans (including, without limitation, on the Maturity Date) equal to the lesser of 2.5% of the sum of the aggregate principal amount of the Term Loans advanced or approved to be advanced by the Lenders and \$700; provided that such exit fee will be equal to \$700 if fee is paid in conjunction with a change of control that occurs in connection with the payoff or within 6 months thereof. As of September 30, 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 September 30, 2021, the Company was in compliance with the required covenants for minimum liquidity as the minimum EBITDA criteria is not applicable until additional tranches are drawn. As of September 30, 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.

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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 September 30, 2021, the effective interest rate was 22.67%, which takes into consideration the non-cash amortization of the debt issuance costs and accretion of the exit fee. The Company recorded debt issuance cost amortization related to the Credit Agreement of \$211 and \$633 for the three and nine months ended September 30, 2021, respectively. The Company recorded debt issuance cost amortization related to the Credit Agreement of \$211 and \$281 for the three and nine months ended September 30, 2020, respectively.

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 (\$23,756 as of September 30, 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 September 30, 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 (\$14,140 as of September 30, 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 September 30, 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.

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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 December 20, 2020; and (iii) \$1,440 paid June 18, 2021. In consideration of amending the timing of this development milestone earn-out payment, the Company paid Alkermes a one-time, non-refundable and non-creditable fee of \$285 at the time of entering into the Amendment to the Purchase and Sale Agreement.

As of September 30, 2021, the Company has paid \$21,429 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. In connection with the Separation, the Company accepted assignment by Recro of all of Recro’s obligations in connection with a securities class action lawsuit (the “Securities Litigation”) and agreed to indemnify Recro for all liabilities related to the Securities Litigation.

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On May 31, 2018, 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. On June 21, 2021, the defendants filed an answer and affirmative defenses to the second amended complaint. A Preliminary Pretrial Conference was held on August 3, 2021. The parties have begun discovery and class certification briefing, which the Court has ordered to be completed by December 30, 2021. All expert and fact discovery must be completed by March 15, 2022. The Company has recorded a liability equal to the estimated fair value of the indemnification to Recro related to this Securities Litigation. The Company believes that the lawsuit is without merit and intends to vigorously defend against it, 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. As of September 30, 2021, the Company has recorded a guarantee liability of \$635, which represents the present value estimate of our expected obligation related to this matter.

(d) Purchase Commitments

As of September 30, 2021, the Company had outstanding non-cancelable and cancelable purchase commitments in the aggregate amount of \$6,231 related to inventory and other goods and services, predominantly manufacturing 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 September 30, 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 March 2023.

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 190,000,000 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 "ATM Facility") 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. On May 27, 2021, the Company voluntarily terminated the ATM Facility with the Agent. During the term of the ATM Facility, the Company sold an aggregate of 441,967 shares of common stock under the ATM Facility for net proceeds of \$3,612. The Agent was paid a sales commission of 3% for such sales under the ATM Facility. The ATM Facility was terminable at will by the Company with no penalty.

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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 \$1.48125 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 for net proceeds to the Company of \$16,173. 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.

On May 31, 2021, the Company closed a registered direct offering of 14,028,520 shares of common stock (the "May Offering") at an offering price of \$0.85 per share and warrants to purchase 14,028,520 shares of common stock (the "May Warrants") at an exercise price of \$0.90 per share, for net proceeds to the Company of \$10,900. 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 May Offering, plus a management fee equal to 1.0% of the gross proceeds raised in the May Offering and reimbursement of certain expenses and legal fees. The Company also issued to designees of the Placement Agent warrants to purchase 841,711 shares of common stock (the "May Placement Agent Warrants") at an exercise price of \$1.0625 per share. The May Warrants and May Placement Agent Warrants will be exercisable on the six-month anniversary of the closing date of the May Offering.

(b) Preferred Stock

The Company is authorized to issue 10,000,000 shares of preferred stock, with a par value of \$0.01 per share. As of September 30, 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)).

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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 \$60.

During the nine months ended September 30, 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 \$12,155.

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As of September 30, 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
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
February Placement Warrants	660,000	\$ 2.00	February 8, 2026
May Warrants	14,028,520	\$ 0.90	June 1, 2027
May Placement Warrants	841,711	\$ 1.06250	May 31, 2026

With the exception of the March Series A 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.

	September 30, 2021
	Series A Warrants
Fair value	\$ 18
Expected dividend yield	— %
Expected volatility	77.37 %
Risk-free interest rates	.76 %
Remaining contractual term	3.5 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 3,000,000 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 September 30, 2021 is 4,989,706. As of September 30, 2021, 251,754 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 nine months ended September 30, 2021 and 2020 was \$0.72 and \$2.22, respectively.

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Under the 2019 Plan, the fair value of the Baudax Bio options was estimated on the date of grant using a Black-Scholes option pricing model with the following weighted average assumptions:

	September 30,	
	2021	2020
Expected option life	5.6 years	6 years
Expected volatility	75.16%	73.77%
Risk-free interest rate	0.84%	0.41%
Expected dividend yield	—	—

The following table summarizes Baudax Bio stock option activity during the nine months ended September 30, 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	1,737,563	\$ 1.17	
Expired/forfeited/cancelled	(417,519)	\$ 1.74	
Balance, September 30, 2021	3,604,342	\$ 2.33	8.4 years
Vested	1,254,511	\$ 2.92	7.2 years
Vested and expected to vest	3,604,342	\$ 2.33	8.4 years

Included in the table above are 799,065 stock options outstanding as of September 30, 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 nine months ended September 30, 2021:

	Number of shares
Balance, December 31, 2020	991,012
Granted	683,143
Vested and settled	(366,866)
Expired/forfeited/cancelled	(116,893)
Balance, September 30, 2021	1,190,396
Expected to vest	1,190,396

Included in the table above are 241,612 time-based RSUs outstanding as of September 30, 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 nine months ended September 30, 2021 and 2020 was \$4,132 and \$7,431, respectively. For the current year, this represents stock-based compensation for the Baudax Bio awards, including \$228 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 September 30, 2021, there was \$4,618 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 2.2 years. As of September 30, 2021, there was \$1,683 of unrecognized compensation expense related to unvested performance-based RSUs.

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The aggregate intrinsic value represents the total amount by which the fair value of the common stock subject to options exceeds the exercise price of the related options. As of September 30, 2021, there was no aggregate intrinsic value of the vested and unvested options.

Note 15: Related Party Transactions

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 and nine months ended September 30, 2020, the Company recorded income of \$516 and \$1,548, respectively, related to the transition services agreement, which is recorded as a reduction in selling, general and administrative expenses 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 September 30, 2021 and 2020 were \$148 and \$188, respectively. Total Company contributions to the 401(k) plan for the nine months ended September 30, 2021 and 2020 were \$569 and \$449, 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 commercializing and developing 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.

In mid-2020, we launched our first commercial product ANJESO 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. The clinical dosing portion of the BX1000 dose escalation study has been completed and is in the data analysis stage. We continue to evaluate strategic partnerships to commercialize ANJESO outside of the United States.

During the third quarter of 2021, despite the COVID-19 delta impact during July and August affecting over 40% of our business, we continued to see solid growth in the total number of vials sold to end-users. Demand for ANJESO demonstrated strong growth and deepening usage patterns based on several key quarter-over-quarter metrics. Despite extensive outbreaks of COVID-19 delta variant in much of the south and selected other regions, and its impact on elective surgeries in July and August, there was growth in estimated end-user demand units sold to all customers in the third quarter of 2021 compared to the second quarter of 2021 of approximately 16% and vials sold to end-user hospitals and ambulatory surgery centers (ASCs) combined was up 17% in the same period. Vials sold to existing hospitals increased 11% and vials sold to existing ASCs increased 66% from the third quarter of 2021 compared the second quarter of 2021. In addition, the month of September 2021 was our single largest month of ANJESO end-user demand units sold launch-to-date for the product.

The Centers for Medicare and Medicaid Services, or CMS, granted a J-code to ANJESO in the fourth quarter of 2020. 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 September 2021, we signed an agreement for terms of availability with a leading operator of surgical facilities and ancillary services nationally, with over 150 locations nationwide, which became effective October 1, 2021.

Our costs consist primarily of expenses incurred in conducting our manufacturing, commercialization of ANJESO, public company and personnel costs, clinical trials and preclinical studies, and regulatory activities. 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 in 2021 on a variable basis depending on the timing, location and extent of the outbreaks. There may continue to be impact from the COVID-19 pandemic, particularly in light of the surge of new COVID-19 cases relating to new variants, such as the delta variant. Intermittent impacts in the reduction of elective surgeries have occurred and this has had an impact in the recent quarter, especially in July and August. Overall, many centers have yet returned to pre-COVID levels of surgeries even where COVID-19 and its variants have not been as impactful. In addition, COVID-19 has impacted revenue for many 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. Further, hospitals may experience staffing shortages as a result of employee non-compliance with government or employer mandated vaccination requirements, which could reduce the number of elective surgeries that can be performed at hospitals with staffing shortages. We believe a reduction in elective surgeries during the COVID-19 pandemic has impacted and may continue to impact 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, including for personal protective equipment, and ventilators, and this impact may result in ongoing decreased revenue. If fewer elective procedures are being performed, we believe this may negatively impact ANJESO growth rates. In addition, in some areas the absence of hospital formulary meetings where new drugs can be adopted has had ongoing variable impact on 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 products scheduled to be reviewed, we believe we will make progress with having ANJESO added to additional hospital formularies over 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 became an independent public company whose shares of common stock are trading under the symbol “BXRX” on The Nasdaq Capital Market.

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 that over time, product costs in cost of sales will increase as sales increase and inventory associated with the units manufactured prior to FDA approval are sold.

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:

- ① expenses incurred under agreements with investigative sites, consultants and other service providers that conduct or support our clinical and pre-clinical trials;
- ① the cost of acquiring and manufacturing clinical trial drug supply and related manufacturing services and pre-commercial product validation and inventory manufacturing expenses;
- ① costs related to facilities, depreciation and other allocated expenses;
- ① acquired in-process research and development;
- ① costs associated with regulatory activities and responses to the FDA; and
- ① 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 development products, analysis and testing of product candidates and patent costs. We expense costs related to clinical inventory and development 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 required for ANJESO, which 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 for our product candidates 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:

- ① the costs, timing and outcome of regulatory review of a product candidate;
- ① the duration of clinical trials, which varies substantially according to the type, complexity and novelty of the product candidate;
- ① 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;
- ① 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;
- ① 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;
- ① 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
- ① 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 benefits of ANJESO and educational programs for health care professionals.

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 impact to the 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 September 30, 2021 recorded a \$66.7 million payment obligation, representing the estimated probability adjusted fair value of the liability. Each reporting period, we revalue this estimated obligation with changes in fair value recognized as a non-cash operating expense or gain. As of September 30, 2021, we have paid \$21.4 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"), which has been fully forgiven as of September 30, 2021.

Income Taxation

We maintained a valuation allowance against our deferred tax assets as of September 30, 2021 and 2020.

Results of Operations

Comparison of the Three Months Ended September 30, 2021 and 2020

	Three Months Ended September 30,	
	2021	2020
	(amounts in thousands)	
Revenue, net	\$ 281	\$ 68
Operating expenses:		
Cost of sales	462	540
Research and development	658	1,469
Selling, general and administrative	11,074	13,763
Amortization of intangible assets	644	643
Change in warrant valuation	(6)	(11,182)
Change in contingent consideration valuation	3,829	(17,427)
Total operating expenses	16,661	(12,194)
Operating (loss) income	(16,380)	12,262
Other expense:		
Other expense, net	(582)	(577)
Net (loss) income	\$ (16,962)	\$ 11,685

Revenue, net. For the three months ended September 30, 2021 and 2020, net product revenue was \$0.3 million and \$0.1 million, respectively, related to sales of ANJESO in the U.S. While utilizing the title model of distribution, product revenue is recognized as shipments are made to our 3PL provider. The increase of \$0.2 million was attributable to securing additional formulary approvals and generating trial and adoption of ANJESO, as well as increased end-user demand leading to increased purchasing by direct customers.

Cost of Sales. Our cost of sales was \$0.5 million for both the three months ended September 30, 2021 and 2020, 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 September 30, 2021 and 2020 were expensed prior to FDA approval of ANJESO in February 2020, and therefore are not included in cost of sales during the related periods. We expect that over time, product costs in cost of sales will increase as sales increase and inventory associated with the units manufactured prior to FDA approval are sold.

Research and Development. Our research and development expenses were \$0.7 million and \$1.5 million for the three months ended September 30, 2021 and 2020, respectively. The decrease of \$0.8 million was primarily due to a decrease in personnel costs of \$0.5 million as well as a decrease in clinical costs of \$0.5 million, which were partially offset by an increase in pre-clinical costs of \$0.2 million.

Selling, General and Administrative. Our selling, general and administrative expenses were \$11.1 million and \$13.8 million for the three months ended September 30, 2021 and 2020, respectively. The decrease of \$2.7 million was primarily due to decrease in personnel costs of \$3.1 million and a decrease in public company and other related costs of \$0.2 million, which was partially offset by an increase of \$0.5 million as the three months ended September 30, 2020 included 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 each of the three months ended September 30, 2021 and 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 September 30, 2021. Our warrant valuation decreased \$11.2 million for the three months ended September 30, 2020 due to a decrease in the Black-Scholes values as a result of a decrease in our stock price for the related period.

Change in Contingent Consideration Valuation. The change in contingent consideration valuation was an increase in value of \$3.8 million for the three months ended September 30, 2021 and an decrease in value of \$17.4 million for the three months ended September 30, 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 September 30, 2021 was primarily due to the time value of money as we progress closer to payment of the contingent consideration liability. The decrease in contingent consideration valuation for the three months ended September 30, 2020 was primarily due to the adjusted timing of estimated milestone and royalty payments due to updated forecasts reflecting an estimate of the launch trajectory of ANJESO.

Other Expense, net. Other expense was \$0.6 million for each of the three months ended September 30, 2021 and 2020, which was related to the interest expense incurred on our Credit Agreement with MAM Eagle Lender and the amortization of related financing costs.

Comparison of the Nine Months Ended September 30, 2021 and 2020

	Nine Months Ended September 30,	
	2021	2020
	(amounts in thousands)	
Revenue, net	\$ 680	\$ 417
Operating expenses:		
Cost of sales	1,869	1,190
Research and development	2,623	5,889
Selling, general and administrative	33,770	33,026
Amortization of intangible assets	1,932	1,502
Change in warrant valuation	(47)	2,863
Change in contingent consideration valuation	9,551	14,252
Total operating expenses	49,698	58,722
Operating loss	(49,018)	(58,305)
Other expense:		
Other expense, net	(185)	(753)
Net loss	<u>\$ (49,203)</u>	<u>\$ (59,058)</u>

Revenue, net. For the nine months ended September 30, 2021 and 2020, net product revenue was \$0.7 million and \$0.4 million, respectively, related to sales of ANJESO in the U.S. While utilizing the title model of distribution, product revenue is recognized as shipments are made to our 3PL provider. The increase of \$0.3 million was attributable to securing additional formulary approvals and generating trial and adoptions of ANJESO, as well as increased end-user demand leading to increased purchasing by direct customers.

Cost of Sales. Our cost of sales was \$1.9 million and \$1.2 million for the nine months ended September 30, 2021 and 2020, respectively, and consists of product costs, royalty expense and certain fixed costs associated with the manufacturing of ANJESO including supply chain and quality costs. Based on our policy, we expense costs associated with the manufacturing of our products as research and development prior to regulatory approval. Certain product costs of ANJESO units recognized as revenue during the nine months ended September 30, 2021 and 2020 were expensed prior to FDA approval of ANJESO in February 2020, and therefore are not included in cost of sales during the related periods. We expect that over time, product costs in cost of sales will increase as sales increase and inventory associated with the units manufactured prior to FDA approval are sold.

Research and Development. Our research and development expenses were \$2.6 million and \$5.9 million for the nine months ended September 30, 2021 and 2020, respectively. The decrease of \$3.3 million was primarily due to a decrease in personnel costs of \$2.6 million, a decrease of \$0.8 million in pre-commercialization manufacturing costs for ANJESO and a decrease of \$0.1 million in clinical costs. This was partially offset by an increase in pre-clinical costs of \$0.2 million.

Selling, General and Administrative. Our selling, general and administrative expenses were \$33.8 million and \$33.0 million for the nine months ended September 30, 2021 and 2020, respectively. The increase of \$0.8 million was primarily a result of the prior period including \$1.5 million in reimbursed general and administrative expenses related to the Transition Services Agreement with Recro Pharma, which ended on December 31, 2020. This increase as well as an increase in public company costs of \$1.2 million were partially offset by a decrease in personnel expenses of \$1.9 million.

Amortization of Intangible Assets. Amortization expense was \$1.9 million and \$1.5 million for the nine months ended September 30, 2021 and 2020, respectively, 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 nine months ended September 30, 2021. Our warrant valuation increased \$2.9 million for the nine months ended September 30, 2020 due to an increase in the Black-Scholes values as a result of an increase in our stock price for the related period.

Change in Contingent Consideration Valuation. The change in contingent consideration valuation was an increase in value of \$9.6 million for the nine months ended September 30, 2021 as compared to an increase in value of \$14.3 million for the nine months ended September 30, 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 nine months ended September 30, 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 nine months ended September 30, 2020 was primarily due to the increase in the probability of success of milestones tied to the FDA approval of ANJESO, partially offset by a decrease due to updated forecasts reflecting an estimate of the launch trajectory in the third quarter of 2020.

Other Expense, net. Other expense for the nine months ended September 30, 2021 was \$0.2 million compared to other expense of \$0.8 million for the nine months ended September 30, 2020. The change in other expense of \$0.6 million was due to the gain on extinguishment of the PPP Loan of \$1.5 million upon the approval of our application for forgiveness in the current year, partially offset by an increase of \$0.9 million in interest expense and debt issuance cost amortization related to our Credit Agreement with MAM Eagle Lender.

Liquidity and Capital Resources

As of September 30, 2021, we had \$24.9 million in cash, cash equivalents and short-term investments.

On May 31, 2021, we closed a registered direct offering of 14,028,520 shares of common stock, or the May Offering, at an offering price of \$0.85 per share and warrants to purchase 14,028,520 shares of common stock, or the May Warrants, at an exercise price of \$0.90 per share, for net proceeds of \$10.9 million. As compensation to H.C. Wainwright & Co., LLC, or the Placement Agent, as placement agent in connection with the May Offering, we agreed to pay the Placement Agent a cash fee of 6.0% of the gross proceeds raised in the May Offering, plus a management fee equal to 1.0% of the gross proceeds raised in the May Offering and reimbursement of certain expenses and legal fees. We also issued to designees of the Placement Agent warrants to purchase 841,711 shares of common stock (the "May Placement Agent Warrants") at an exercise price of \$1.0625 per share. The May Warrants and May Placement Agent Warrants will be exercisable on the six-month anniversary of the closing date of the May Offering.

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, for net proceeds of \$16.2 million. As compensation to the Placement Agent, 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.

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. During the nine months ended September 30, 2021, we received a Notice of PPP Forgiveness Payment from the SBA regarding the approval of our application for forgiveness of the PPP Loan of \$1,537 and accrued interest. As a result, we recognized a gain on extinguishment of the PPP Loan of \$1,553 during the nine months ended September 30, 2021.

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 Facility. On May 27, 2021, we voluntarily terminated the ATM Facility with the Agent. During the term of the ATM Facility, we sold an aggregate of 441,967 shares of common stock under the ATM Facility for net proceeds of \$3.6 million, none of which were sold in the nine months ended September 30, 2021. The Agent was paid a sales commission of 3% for such sales under the Sales Agreement. The ATM Facility was terminable at will by the Company with no penalty.

We expect to seek additional funding to sustain our future operations and while we have successfully raised capital in the past, the ability to raise capital in future periods is not assured. Based on our available cash as of September 30, 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 \$36.6 million and \$29.4 million for the nine months ended September 30, 2021 and 2020, respectively, which represents our operating losses less our non-cash items including: stock-based compensation, non-cash interest expense, gain on extinguishment of debt in the current year, depreciation, amortization, changes in warrant valuations, and changes in fair value of contingent consideration, as well as changes in operating assets and liabilities. The increase in cash used from operations was primarily due to decreases in accounts payable, which was partially offset by a decrease in operating loss.

Cash used in investing activities was \$10.2 million for the nine months ended September 30, 2021, which was primarily due to purchases of short-term investments in the current year, partially offset by the maturities of these short-term investments. Cash used in investing activities for the nine months ended September 30, 2020 was \$0.3 million, which was primarily due to capital expenditures.

There was \$31.3 million of cash provided by financing activities in the nine months ended September 30, 2021 consisting of net proceeds of \$27.1 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 \$7.9 million. There was \$36.6 million of cash provided by financing activities for the nine months ended September 30, 2020 from net proceeds of the public offering of \$23.1 million, net proceeds of \$1.5 million from the issuance of the PPP Loan, net proceeds of \$8.5 million from the incurrence of long-term debt under the Credit Agreement with MAM Eagle Lender, net proceeds of \$3.6 million from our ATM Facility, and net proceeds of \$2.5 million from warrant exercises, partially offset by a payment of contingent consideration of \$2.5 million.

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

- ① our relationships with third parties, licensors, collaborators, and our employees;
- ① our ability to continue to operate as a standalone company and execute our strategic priorities;
- ① potential indemnification liabilities we may owe to Recro;
- ① the timing of the Alkermes Transaction milestone payments and other contingent consideration;
- ① the costs of continued manufacturing scale-up and commercialization activities, for ANJESO;
- ① the level of market acceptance of ANJESO;
- ① the scope, progress, results, and costs of development for our other product candidates;
- ① the cost, timing and outcome of regulatory review of our other product candidates;
- ① the cost of manufacturing scale-up, acquiring drug product and other capital equipment for our other product candidates;
- ① the extent to which we in-license, acquire or invest in products, businesses and technologies;
- ① our ability to raise additional funds through equity or debt financings or the sale of certain assets;
- ① our ability to achieve certain milestones to access and draw down additional tranches of debt under the Credit Agreement;
- ① the extent to which holders of our warrants exercise their warrants resulting in the payment of cash proceeds to us;
- ① our ability to have sufficient authorized shares of our common stock available;
- ① the ability to effectuate a reverse stock split or other similar change to our capital structure;
- ① the costs of preparing, submitting and prosecuting patent applications and maintaining, enforcing and defending intellectual property claims; and
- ① 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, short-term investments, debt, equity financing, sale of assets or out-licensing revenue or a combination thereof to fund our operations or product acquisitions. If we increase our debt levels, we might be restricted in our ability to raise additional capital and might be subject to financial and restrictive covenants. Our shareholders may experience dilution as a result of the issuance of additional equity or debt securities. This dilution may be significant depending upon the amount of equity or debt securities that we issue and the prices at which we issue any securities.

Contractual Commitments

The table below reflects our contractual commitments as of September 30, 2021:

Contractual Obligations	Total	Payments Due by Period (in 000s)			
		Less than 1 year	1-3 years	3-5 years	More than 5 years
Debt Obligations (1):					
Debt	\$ 10,000	\$ 1,389	\$ 6,667	\$ 1,944	\$ —
Interest on Debt	3,160	1,372	1,651	137	—
Purchase Obligations (2):					
Operating Leases (3)	\$ 6,231	\$ 1,616	\$ 388	\$ 21	\$ —
Other Long-Term Liabilities:					
Other License Commitments and Milestone payments (4), (5)	54,365	—	240	225	—
Alkermes Payments (6)	118,571	6,429	19,286	12,857	—
Employment Agreements (7)	1,317	1,008	309	—	—
Total Contractual Obligations	\$ 195,591	\$ 12,258	\$ 29,117	\$ 15,744	\$ 367

(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 accordance with U.S. GAAP, the future interest obligations are not recorded on our Consolidated Balance Sheet. See Note 11 to the Consolidated 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 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 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 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 Financial Statements included in this Quarterly Report.

(7) We have entered into employment agreements with certain of our named executive officers. As of September 30, 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 March 2023. In accordance with U.S. GAAP, these obligations are not recorded on our Consolidated Balance Sheets. See Note 12(e) to the Consolidated 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 nine months ended September 30, 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 September 30, 2021. We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure.

A control system, no matter how well conceived and operated, can provide only reasonable, and not absolute, assurance that the objectives of the control system will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. However, our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives. Based on the evaluation of our disclosure controls and procedures as of September 30, 2021, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

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

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

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. On June 21, 2021, the defendants filed an answer and affirmative defenses to the second amended complaint. A Preliminary Pretrial Conference was held on August 3, 2021. The parties have begun discovery and class certification briefing, which the Court has ordered to be completed by December 30, 2021. All expert and fact discovery must be completed by March 15, 2022. In connection with the Separation, 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. As of September 30, 2021, the Company has recorded a guarantee liability of \$635, which represents the present value estimate of our expected obligation related to this matter.

Item 1A. Risk Factors.

Except as set forth below, there have been no material changes in the risk factors disclosed in our 2020 Annual Report and Quarterly Reports for the quarters ended March 31, 2021 and June 30, 2021.

If we are unable to regain compliance with the listing standards of Nasdaq, our common stock may become delisted, which could have a material adverse effect on the liquidity of our common stock.

The listing standards of the Nasdaq Capital Market provide that a company, in order to qualify for continued listing, must maintain a minimum closing bid price of \$1.00 and satisfy standards relative to minimum shareholders' equity, minimum market value of publicly held shares and various additional requirements. On June 17, 2021, we received a deficiency letter from the Listing Qualifications Department of Nasdaq, or the Staff, notifying us that, for the last 30 consecutive business days, the bid price for our common stock had closed below the minimum \$1.00 per share requirement for continued inclusion on the Nasdaq Capital Market.

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have been provided a period of 180 calendar days, or until December 14, 2021, in which to regain compliance. In order to regain compliance with the minimum bid price requirement, the closing bid price of our common stock must be at least \$1.00 per share for a minimum of ten consecutive business days during this 180-day period. In the event that we do not regain compliance within this 180-day period, we may be eligible to seek an additional compliance period of 180 calendar days if we (i) meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the bid price requirement, and (ii) provide written notice to Nasdaq of our intent to cure the deficiency during this second compliance period, including by effecting a reverse stock split, if necessary. However, if it appears to the Staff that we will not be able to cure the deficiency, or if we are otherwise not eligible, Nasdaq will provide notice to us that we will not be eligible for the additional compliance period and our common stock will be subject to delisting. We would then be entitled to appeal the determination to a Nasdaq Listing Qualifications Panel and request a hearing.

There can be no assurance that we will be able to regain compliance with the minimum bid price requirement or maintain compliance with the other Nasdaq listing requirements. If we do not regain compliance with the Nasdaq continuing listing requirements, our common stock will be delisted from the Nasdaq Capital Market and it could be more difficult to buy or sell our securities and to obtain accurate quotations, and the price of our common stock could suffer a material decline. In addition, a delisting would impair our ability to raise capital through the public markets, could deter broker-dealers from making a market in or otherwise seeking or generating interest in our securities and might deter certain institutions and persons from investing in our securities at all.

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
3.1	<u>Articles of Amendment to the Amended and Restated Articles of Incorporation of Baudax Bio, Inc.</u>	Incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on August 11, 2021 (File No. 001-39101).
31.1	<u>Rule 13a-14(a)/15d-14(a) certification of Principal Executive Officer.</u>	Filed herewith.
31.2	<u>Rule 13a-14(a)/15d-14(a) certification of Principal Financial and Accounting Officer.</u>	Filed herewith.
32.1	<u>Section 1350 certification, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>	Filed herewith.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	Filed herewith.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	Filed herewith.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	Filed herewith.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	Filed herewith.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	Filed herewith.
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).	Filed herewith.

SIGNATURES

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

BAUDAX BIO, INC.

Date: November 4, 2021

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

Date: November 4, 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: November 4, 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: November 4, 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 September 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to such officer's knowledge:

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

Date: November 4, 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)
