

---

---

**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: June 30, 2022

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

Commission File Number: 001-39101

**Baudax Bio, Inc.**

(Exact name of registrant as specified in its charter)

Pennsylvania  
(State or other jurisdiction of  
incorporation or organization)  
  
490 Lapp Road, Malvern, Pennsylvania  
(Address of principal executive offices)

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

19355  
(Zip Code)

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

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

<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 August 9, 2022, there were 8,069,001 shares of common stock, par value \$0.01 per share, outstanding.

---

---

**TABLE OF CONTENTS**  
**Index**

	<b>Page</b>
<u>Forward-Looking Statements</u>	3
<u>PART I. FINANCIAL INFORMATION</u>	5
Item 1. <u>Consolidated Financial Statements (Unaudited)</u>	5
Item 2. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	31
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	41
Item 4. <u>Controls and Procedures</u>	41
<u>PART II. OTHER INFORMATION</u>	42
Item 1. <u>Legal Proceedings</u>	42
Item 1A. <u>Risk Factors</u>	42
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	43
Item 3. <u>Defaults Upon Senior Securities</u>	43
Item 4. <u>Mine Safety Disclosures</u>	44
Item 5. <u>Other Information</u>	44
Item 6. <u>Exhibits</u>	44
<u>SIGNATURES</u>	45

### Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q, or Quarterly Report, contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this Quarterly Report regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “will,” “would,” “could,” “should,” “potential,” “seek,” “evaluate,” “pursue,” “continue,” “design,” “impact,” “affect,” “forecast,” “target,” “outlook,” “initiative,” “objective,” “designed,” “priorities,” “goal,” or the negative of such terms and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements are based on assumptions and expectations that may not be realized and are inherently subject to risks, uncertainties and other factors, many of which cannot be predicted with accuracy and some of which might not even be anticipated.

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

- our estimates regarding expenses, revenue, capital requirements and timing and availability of and the need for additional financing;
- our ability to continue as a going concern for the next twelve months;
- our ability to operate under significant indebtedness;
- our ability to maintain the listing of our common stock on the Nasdaq Capital Market;
- our ability to maintain regulatory approval for ANJESO<sup>®</sup> (meloxicam) injection, or ANJESO, and obtain regulatory approval for any other product candidates that we may develop, and any related restrictions, limitations, or warnings in the label of any approved product candidates;
- our ability to successfully manage the timing, costs and other aspects of the commercialization of ANJESO, including maintaining an acceptable price for and adequate coverage and reimbursement of ANJESO;
- our ability to successfully market, commercialize and achieve broad market acceptance for ANJESO and any of our other product candidates once approved;
- the acceptance of ANJESO by the medical community, including physicians, patients, healthcare providers and hospital formularies and grow market demand;
- our ability and that of our third-party manufacturers to successfully scale-up our commercial manufacturing process for ANJESO;
- the results, timing and outcome of our clinical trials of our product candidates, and any future clinical trials and preclinical studies;
- our ability to source materials needed for our drug candidates, optimize formulations for stability and other characteristics;
- our relationships with Alkermes plc, or Alkermes, other third parties, licensors, collaborators, and our employees;
- potential indemnification liabilities we may owe to Societal CDMO, Inc., or Societal CDMO, formerly Recro Pharma, Inc., after the separation of Societal CDMO’s acute care business and transfer of such assets to us, or the Separation;
- the effects of changes in our effective tax rate due to changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities, tax impacts and net operating loss utilization related to the Separation from Societal CDMO and changes in the tax laws;
- our ability to comply with the regulatory schemes applicable to our business and other regulatory developments in the United States and foreign countries;
- the performance of third-parties upon which we depend, including third-party contract research organizations, or CROs, and third-party suppliers, manufacturers including Alkermes and Patheon UK Limited, group purchasing organizations, distributors, supply chain and logistics providers;
- our ability to obtain and maintain patent protection and defend our intellectual property rights against third-parties;
- our ability to maintain our relationships, profitability and contracts with our key commercial partners;
- our ability to defend any material litigation filed against us and avoid liabilities resulting from any material litigation, including any liabilities associated with the ongoing securities class action filed against Societal CDMO for which we have agreed to indemnify Societal CDMO;

- our ability to recruit or retain key scientific, technical, commercial, and management personnel or to retain our executive officers;
- our ability to raise future financing and attain profitability for continued development of our business and commercialization or other monetization 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;
- the volatility of capital markets and other macroeconomic factors, including inflation, geopolitical tensions or the outbreak or escalation of hostilities or war;
- our ability to operate under increased leverage and comply with associated lending covenants; to pay existing required interest and principal amortization payments when due; and/or to obtain acceptable refinancing alternatives; and
- our expectations regarding the impact of the ongoing COVID-19 pandemic including, but not limited to, the emergence of variants of the virus, the availability and efficacy 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, including but not limited to manufacturing components and raw materials, 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, 2021 filed with the SEC on March 16, 2022, or the 2021 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

(amounts in thousands, except share and per share data)	June 30, 2022 Unaudited	December 31, 2021
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 5,210	\$ 15,891
Accounts receivable, net	616	542
Inventory	5,255	5,002
Prepaid expenses and other current assets	1,398	2,059
Total current assets	12,479	23,494
Property, plant and equipment, net	4,941	5,015
Intangible assets, net	20,390	21,678
Goodwill	2,127	2,127
Other long-term assets	897	963
Total assets	<u>\$ 40,834</u>	<u>\$ 53,277</u>
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 3,064	\$ 1,468
Accrued expenses and other current liabilities	3,812	5,540
Current portion of long-term debt, net	3,611	2,222
Current portion of contingent consideration	7,694	6,416
Total current liabilities	18,181	15,646
Long-term debt, net	5,099	6,309
Long-term portion of contingent consideration	12,692	17,446
Other long-term liabilities	632	650
Total liabilities	36,604	40,051
Commitments and contingencies (Note 12)		
Shareholders' equity:		
Preferred stock, \$0.01 par value. Authorized, 10,000,000 shares; issued and outstanding, 0 shares at June 30, 2022 and 8,289 shares at December 31, 2021	—	—
Common stock, \$0.01 par value. Authorized, 190,000,000 shares; issued and outstanding, 8,068,853 shares at June 30, 2022 and 2,807,239 shares at December 31, 2021	81	28
Additional paid-in capital	156,578	145,287
Accumulated deficit	(152,429)	(132,089)
Total shareholders' equity	4,230	13,226
Total liabilities and shareholders' equity	<u>\$ 40,834</u>	<u>\$ 53,277</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 June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue, net	\$ 300	\$ 201	\$ 722	\$ 399
Operating expenses:				
Cost of sales	361	586	1,009	1,407
Research and development	912	857	2,205	1,965
Selling, general and administrative	4,029	10,608	18,219	22,696
Amortization of intangible assets	644	644	1,288	1,288
Change in warrant valuation	(1)	(59)	(6)	(41)
Change in contingent consideration valuation	1,327	3,881	(2,476)	5,722
Total operating expenses	7,272	16,517	20,239	33,037
Operating loss	(6,972)	(16,316)	(19,517)	(32,638)
Other expense:				
Other (expense) income, net	(559)	987	(823)	397
Net loss	<u>\$ (7,531)</u>	<u>\$ (15,329)</u>	<u>\$ (20,340)</u>	<u>\$ (32,241)</u>
Per share information:				
Net loss per share of common stock, basic	<u>\$ (1.05)</u>	<u>\$ (7.17)</u>	<u>\$ (3.63)</u>	<u>\$ (16.43)</u>
Net loss per share of common stock, diluted	<u>\$ (1.05)</u>	<u>\$ (7.18)</u>	<u>\$ (3.63)</u>	<u>\$ (16.43)</u>
Weighted average common shares outstanding, basic	<u>7,181,640</u>	<u>2,137,191</u>	<u>5,610,037</u>	<u>1,962,655</u>
Weighted average common shares outstanding, diluted	<u>7,181,640</u>	<u>2,138,100</u>	<u>5,610,037</u>	<u>1,962,655</u>

See accompanying notes to consolidated financial statements.

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

For the Six Months Ended June 30, 2022

(amounts in thousands, except share data)	Preferred Stock		Common Stock		Additional paid-in capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balance, December 31, 2021	8,289	\$ —	2,807,239	\$ 28	\$ 145,287	\$ (132,089)	\$ 13,226
Stock-based compensation expense	—	—	—	—	521	—	521
Issuance of common stock and warrants for public offering, net	—	—	3,508,772	35	8,784	—	8,819
Issuance of common stock and warrants for registered direct offerings, net	—	—	—	—	(13)	—	(13)
Issuance of shares pursuant to vesting of restricted stock units, net of shares withheld for income taxes	—	—	2,234	—	(1)	—	(1)
Conversion of preferred stock	(8,289)	—	94,734	1	(1)	—	—
Net loss	—	—	—	—	—	(12,809)	(12,809)
Balance, March 31, 2022	<u>—</u>	<u>\$ —</u>	<u>6,412,979</u>	<u>\$ 64</u>	<u>\$ 154,577</u>	<u>\$ (144,898)</u>	<u>\$ 9,743</u>
Stock-based compensation expense	—	—	—	—	325	—	325
Issuance of common stock and warrants for public offering, net	—	—	—	—	(28)	—	(28)
Issuance of common stock and warrants for registered direct offerings and private placements, net	—	—	1,646,091	16	1,704	—	1,720
Issuance of shares pursuant to vesting of restricted stock units, net of shares withheld for income taxes	—	—	9,783	1	—	—	1
Net loss	—	—	—	—	—	(7,531)	(7,531)
Balance, June 30, 2022	<u>—</u>	<u>\$ —</u>	<u>8,068,853</u>	<u>\$ 81</u>	<u>\$ 156,578</u>	<u>\$ (152,429)</u>	<u>\$ 4,230</u>

See accompanying notes to consolidated financial statements.

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

For the Six Months Ended June 30, 2021

(amounts in thousands, except share data)	Preferred Stock		Common Stock		Additional paid-in capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balance, December 31, 2020	—	\$ —	1,391,099	\$ 14	\$ 97,507	\$ (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	—	—	314,286	3	16,424	—	16,427
Issuance of shares pursuant to vesting of restricted stock units, net of shares withheld for income taxes	—	—	1,205	—	(41)	—	(41)
Exercise of warrants	—	—	297,484	3	12,152	—	12,155
Net loss	—	—	—	—	—	(16,912)	(16,912)
Balance, March 31, 2021	—	\$ —	<u>2,004,074</u>	<u>\$ 20</u>	<u>\$ 128,218</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	—	—	400,815	4	10,897	—	10,901
Issuance of shares pursuant to vesting of restricted stock units, net of shares withheld for income taxes	—	—	2,917	—	(5)	—	(5)
Net loss	—	—	—	—	—	(15,329)	(15,329)
Balance, June 30, 2021	—	\$ —	<u>2,407,806</u>	<u>\$ 24</u>	<u>\$ 139,964</u>	<u>\$ (144,561)</u>	<u>\$ (4,573)</u>

See accompanying notes to consolidated financial statements.

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

(amounts in thousands)	For the Six Months Ended June 30,	
	2022	2021
<b>Cash flows from operating activities:</b>		
Net loss	\$ (20,340 )	\$ (32,241 )
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Stock-based compensation	858	3,207
Non-cash interest expense	449	458
Depreciation expense	86	149
Amortization	1,288	1,288
Non-cash loss on retirement of fixed assets	8	—
Gain on extinguishment of debt	—	(1,553 )
Change in warrant valuation	(6 )	(41 )
Change in contingent consideration valuation	(2,476 )	5,722
<b>Changes in operating assets and liabilities:</b>		
Inventory	(253 )	(580 )
Prepaid expenses and other assets	734	1,529
Accounts receivable	(74 )	(168 )
Accounts payable, accrued expenses and other liabilities	(396 )	(1,826 )
Net cash used in operating activities	(20,122 )	(24,056 )
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	(20 )	(76 )
Purchase of short-term investments	—	(12,147 )
Net cash used in investing activities	(20 )	(12,223 )
<b>Cash flows from financing activities:</b>		
Proceeds from public offering, net of transaction costs	8,925	—
Proceeds from registered direct offerings, net of transaction costs	1,816	27,109
Payments on long-term debt	(278 )	—
Proceeds from warrant exercises	—	12,155
Payment of contingent consideration	(1,000 )	(7,869 )
Payments of withholdings on shares withheld for income taxes	(2 )	(46 )
Net cash provided by financing activities	9,461	31,349
Net decrease in cash and cash equivalents	(10,681 )	(4,930 )
Cash and cash equivalents, beginning of period	15,891	30,342
Cash and cash equivalents, end of period	<u>\$ 5,210</u>	<u>\$ 25,412</u>
<b>Supplemental disclosure of cash flow information:</b>		
Offering costs included in accounts payable and accrued expenses	\$ 213	\$ 7

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)

**(1) Background**

Business

Baudax Bio, Inc. (“Baudax Bio” or the “Company”) is a pharmaceutical company primarily focused on innovative products for hospital and related 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, to the hospital and acute care markets.

Baudax Bio launched ANJESO, which is indicated for the management of moderate to severe pain, in 2020. ANJESO is currently approved for use within the Department of Veterans Affairs, the Department of Defense, Indian Health Service, 340B covered entities, and multiple state Medicaid programs.

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

The Separation

Pursuant to the Separation Agreement between Societal CDMO, Inc. (“Societal CDMO”), formerly Recro Pharma, Inc., and Baudax Bio, Societal CDMO 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 Societal CDMO shareholder received one share of the Company’s common stock for every two and one-half shares of Societal CDMO 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.

Reverse Stock Split

On February 16, 2022, the Company effected a reverse split of shares of the Company’s common stock on a 1-for-35 basis (the “Reverse Stock Split”). All issued and outstanding shares of common stock, warrants, common stock options, and unvested restricted stock units and the related per share amounts contained in the financial statements have been retroactively adjusted to reflect this Reverse Stock Split for all periods presented. The par value and authorized shares of common stock were not adjusted as a result of the Reverse Stock Split. Additionally, the authorized, issued and outstanding shares of preferred stock and their related per share amount, other than the conversion price per share, was not adjusted as a result of the Reverse Stock Split.

**(2) Development Activity Risks, Liquidity and Going Concern**

The Company has incurred operating losses and negative cash flows since inception and has an accumulated deficit of \$152,429 as of June 30, 2022.

The Company has raised funds from debt and equity transactions and will be required to raise additional funds to continue to operate as a standalone entity. In order to fund development activities, clinical and pre-clinical testing, modest commercialization of ANJESO and, if approved, commercialization of the Company’s other product candidates, the Company will require significant additional funding. The Company could delay clinical trial activity or reduce funding of specific programs in order to reduce cash needs. Insufficient funds may cause the Company to delay, reduce the scope of or eliminate one or more of its development, commercialization, or expansion activities. The Company may raise such funds, if available, through debt financings, bank or other loans, through strategic research and development, licensing (including out-licensing) and/or marketing arrangements or through public or private sales of equity or debt securities from time to time. Financing may not be available on acceptable terms, or at all, and failure to raise capital when needed could materially adversely impact the Company’s growth plans and its financial condition or results of operations and ability to continue as a going concern. 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.

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

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. Based on the Company’s available cash and cash equivalents as of June 30, 2022, 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 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. The Company is not expected to be able to maintain its minimum liquidity covenant over the next twelve months without additional inflows of funds or capital financing. The consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates continuity of operations, the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

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

The accompanying unaudited consolidated 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 six months ended June 30, 2022 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2022.

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, 2021 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 to be cash equivalents. 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) Investments***

Investments generally consist of government money market funds and commercial paper with maturity of greater than three months when acquired and does not meet the definition of a cash or cash equivalents. The Company has historically classified its entire investment portfolio as available-for-sale debt securities and is carried at fair value with unrealized gains and losses included in comprehensive loss in the consolidated statement of operations and realized gains and losses included in other income/expense, if applicable.

The Company uses benchmark inputs and industry standard analytical models to derive the fair value of its commercial paper.

***(e) 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.

***(f) Goodwill and Intangible Assets***

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

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

The Company performs its annual goodwill impairment test as of November 30<sup>th</sup>, or whenever an event or change in circumstances occurs that would require reassessment of the recoverability of goodwill. In performing the evaluation, the Company assesses qualitative factors such as overall financial performance of its reporting unit, anticipated changes in industry and market conditions, including recent tax reform, intellectual property protection, and competitive environments. The Company performed an impairment test as of June 30, 2022 after identifying indicators of impairment. There was no impairment to goodwill based on the analysis.

The Company's intangible asset is classified as an asset resulting from R&D activities. The Company determined the useful life of its asset resulting from R&D activities to be approximately 10 years, which is based on the remaining patent life and is being amortized on a straight-line basis. The Company is required to review the carrying value of assets resulting from R&D activities for recoverability whenever events occur or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. The Company performed an impairment test as of June 30, 2022 after identifying indicators of impairment. There was no impairment to intangible assets based on the analysis as of June 30, 2022.

***(g) Revenue Recognition***

The Company sells ANJESO in the U.S. through a single third-party logistics provider ("3PL"), which takes title to and control of the goods, and is considered the customer. 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-user 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.

**(h) Concentration of Credit Risk**

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash, cash equivalents, short-term investments, and accounts receivable. The Company manages its cash, cash equivalents and short-term investments based on established guidelines relative to diversification and maturities to maintain safety and liquidity. The Company's accounts receivable balance as of June 30, 2022 and December 31, 2021 is compromised solely from transactions with the Company's 3PL.

**(i) Research and Development**

Research and development costs for the Company's proprietary products/product candidates are charged to expense as incurred. Research and development expenses consist 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, 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 and milestone payments made to third parties who perform research and development services on the Company's behalf are expensed as services are rendered. Costs incurred in obtaining product technology licenses are charged to research and development expense as acquired in-process research and development ("IPR&D") if the technology licensed has not reached technological feasibility and has no alternative future use.

**(j) Stock-Based Awards**

Share-based compensation included in the consolidated financial statements 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. The Company has never declared or paid dividends and has no plans to do so in the foreseeable future, therefore the dividend yield is zero.

**(k) Income Taxes**

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax 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.

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

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

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

Net loss per common share is computed using the two-class method required due to the participating nature of the Series A Preferred Stock (as defined and discussed in Note 13(b)). Except with respect to voting and conversion, the rights of the holders of the Company's common stock and the Company's Series A Preferred Stock are identical. Each class of shares has the same rights to dividends. Although the Preferred Stock are participating securities, such securities do not participate in net losses and therefore do not impact the Company's net loss per share calculation as of June 30, 2022.

Basic net loss per common share is determined by dividing net loss attributable to common shareholders by the weighted average common shares outstanding during the period. Diluted net loss per common share is determined using the weighted average common shares outstanding during the period plus the weighted average number of shares of common shares that would be issued assuming exercise or conversion of all potentially dilutive instruments. Outstanding warrants, common stock options and unvested restricted stock units are excluded from the calculation of diluted net loss per share when their effect would be anti-dilutive.

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
<b>Basic Loss Per Share</b>				
Net loss	\$ (7,531)	\$ (15,329)	\$ (20,340)	\$ (32,241)
Weighted average common shares outstanding, basic	7,181,640	2,137,191	5,610,037	1,962,655
Net loss per share of common stock, basic	<u>\$ (1.05)</u>	<u>\$ (7.17)</u>	<u>\$ (3.63)</u>	<u>\$ (16.43)</u>
<b>Diluted Loss Per Share</b>				
Net loss	\$ (7,531)	\$ (15,329)	\$ (20,340)	\$ (32,241)
Change in warrant valuation	—	(17)	—	—
Diluted net loss	<u>\$ (7,531)</u>	<u>\$ (15,346)</u>	<u>\$ (20,340)</u>	<u>\$ (32,241)</u>
Weighted average common shares outstanding, basic	7,181,640	2,137,191	5,610,037	1,962,655
Dilutive effect of warrants	—	909	—	—
Weighted average common shares outstanding, diluted	<u>7,181,640</u>	<u>2,138,100</u>	<u>5,610,037</u>	<u>1,962,655</u>
Net loss per share of common stock, diluted	<u>\$ (1.05)</u>	<u>\$ (7.18)</u>	<u>\$ (3.63)</u>	<u>\$ (16.43)</u>

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

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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Options and restricted stock units outstanding	613,580	146,399	613,580	146,399
Warrants	7,065,509	299,006	7,065,509	299,925

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

**(m) Recent Accounting Pronouncements**

*Recently Adopted Accounting Pronouncements*

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 reducing the number of accounting models available for convertible debt instruments. ASU 2020-06 also eliminates the treasury stock method to calculate diluted earnings per share for convertible instruments and requires the use of the if-converted method. 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 adopted this guidance as of January 1, 2022, using the full retrospective method of adoption. The adoption eliminated the presentation of the beneficial conversion feature on the consolidated statement of operations and had no other material impact to the Company.

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 adopted this guidance as of January 1, 2022, using the prospective method of adoption. This adoption did not have a material impact to the Company or its disclosures.

In November 2021, the FASB issued ASU No. 2021-10, “*Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance*,” or ASU 2021-10. ASU 2021-10 requires entities to provide disclosures on government assistance transactions for annual reporting periods. The disclosures include information around the nature of the transaction, the related accounting policies used to account for the transaction, the effect of the transaction on the entity’s financial statements, and any significant terms and conditions of the agreements, including commitments and contingencies. ASU 2021-10 is effective for fiscal years beginning after December 15, 2021 and early adoption is permitted. The Company adopted this guidance as of January 1, 2022, using the prospective method of adoption. This adoption did not have a material impact to the Company or its disclosures.

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

*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.

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

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

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

	Fair value measurements at reporting date using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
<b>At June 30, 2022:</b>			
Assets:			
Cash equivalents (See Note 5)			
Money market mutual funds	\$ 3,613	\$ —	\$ —
Total cash equivalents	\$ 3,613	\$ —	\$ —
Liabilities:			
Warrants (See Note 13(c))	\$ —	\$ —	\$ 1
Contingent consideration (See Note 12(b))	—	—	20,386
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 20,387</u>
<b>At December 31, 2021:</b>			
Assets:			
Cash equivalents (See Note 5)			
Money market mutual funds	\$ 10,110	\$ —	\$ —
Total cash equivalents	\$ 10,110	\$ —	\$ —
Liabilities:			
Warrants (See Note 13(c))	\$ —	\$ —	\$ 7
Contingent consideration (See Note 12(b))	—	—	23,862
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 23,869</u>

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

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, 2020	\$ 65	\$ 65,043
Payment of contingent consideration	—	(7,869)
Remeasurement	(58)	(33,312)
Balance at December 31, 2021	\$ 7	\$ 23,862
Payment of contingent consideration	—	(1,000)
Remeasurement	(6)	(2,476)
Total at June 30, 2022	<u>\$ 1</u>	<u>\$ 20,386</u>
Current portion as of June 30, 2022	\$ —	\$ 7,694
Long-term portion as of June 30, 2022	1	12,692

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, which currently do 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 June 30, 2022, the fair value calculations used a discount rate of 35.00%.

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 June 30, 2022. 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 June 30, 2022, 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 June 30, 2022 due to the fact that the debt arrangements reflect market terms from recent transactions.

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

**(5) Cash Equivalents**

The following is a summary of cash equivalents:

Description	Amortized Cost	June 30, 2022 Gross Unrealized		Estimated Fair Value
		Gain	Loss	
Money market mutual funds	\$ 3,613	\$ —	\$ —	\$ 3,613
Total cash equivalents	<u>\$ 3,613</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 3,613</u>

Description	Amortized Cost	December 31, 2021 Gross Unrealized		Estimated Fair Value
		Gain	Loss	
Money market mutual funds	\$ 10,110	\$ —	\$ —	\$ 10,110
Total cash equivalents	<u>\$ 10,110</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 10,110</u>

As of June 30, 2022 and December 31, 2021, the Company's cash equivalents had maturities of one month.

**(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:

	June 30, 2022	December 31, 2021
Raw materials	\$ 26	\$ 53
Sub-assemblies	4,011	4,656
Finished goods	1,655	645
	5,692	5,354
Provision for inventory obsolescence	(437 )	(352 )
Inventory	<u>\$ 5,255</u>	<u>\$ 5,002</u>

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

Property, plant and equipment consists of the following:

	June 30, 2022	December 31, 2021
Building and improvements	\$ 166	\$ 196
Furniture, office and computer equipment	841	952
Manufacturing and laboratory equipment	717	717
Construction in progress	4,642	4,622
	6,366	6,487
Less: accumulated depreciation	1,425	1,472
Property, plant and equipment, net	<u>\$ 4,941</u>	<u>\$ 5,015</u>

Depreciation expense for the three and six months ended June 30, 2022 was \$43 and \$86, respectively. Depreciation expense for the three and six months ended June 30, 2021 was \$63 and \$149, respectively.

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

**(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. 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 twelve 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 June 30, 2022, undiscounted future lease payments for non-cancellable operating leases are as follows:

	Lease payments	
Remainder of 2022	\$	211
2023		270
2024		278
2025		278
2026		287
2027		295
Total lease payments		1,619
Less imputed interest		(754 )
Total operating lease liability	\$	<u>865</u>

As of June 30, 2022, 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:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating lease cost	\$ 71	\$ 89	\$ 145	\$ 177
Short-term lease cost	35	39	73	78
Total lease cost	<u>\$ 106</u>	<u>\$ 128</u>	<u>\$ 218</u>	<u>\$ 255</u>

Cash paid for amounts included in the measurement of lease liabilities, which is included in operating cash flows, was \$187 and \$171 for the six months ended June 30, 2022 and 2021, respectively.

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

**(9) Intangible Assets**

The following represents the balances of the intangible assets:

	June 30, 2022	December 31, 2021
Asset resulting from R&D activities	\$ 26,400	\$ 26,400
Accumulated Amortization	(6,010)	(4,722)
Intangible assets, net	<u>\$ 20,390</u>	<u>\$ 21,678</u>

Amortization expense for the three and six months ended June 30, 2022 was \$644 and \$1,288, respectively. Amortization expense for the three and six months ended June 30, 2021 was \$644 and \$1,288, respectively.

As of June 30, 2022, future amortization expense is as follows:

	Amortization
Remainder of 2022	\$ 1,288
2023	2,576
2024	2,576
2025	2,576
2026	2,576
2027 and thereafter	8,798
Total	<u>\$ 20,390</u>

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

Accrued expenses and other current liabilities consist of the following:

	June 30, 2022	December 31, 2021
Payroll and related costs	\$ 2,685	\$ 3,516
Professional and consulting fees	409	1,071
Other research and development costs	288	157
Interest payable	109	116
Other	321	680
	<u>\$ 3,812</u>	<u>\$ 5,540</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 \$25 remains accrued and unpaid as of June 30, 2022.

In March 2022, the Company implemented a reduction in force impacting approximately 66 employees and resulted in a charge of \$4,148, primarily related to severance, of which \$1,874 remains accrued and unpaid as of June 30, 2022.

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

**(11) Debt**

The following table summarizes the components of the carrying value of debt:

	June 30, 2022	December 31, 2021
Credit Agreement	\$ 9,722	\$ 10,000
Unamortized deferred issuance costs	(1,162)	(1,583)
Exit fee accretion	150	114
Total debt	<u>\$ 8,710</u>	<u>\$ 8,531</u>
Current portion	\$ 3,611	\$ 2,222
Long-term portion, net	5,099	6,309

**(a) 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 June 30, 2022, no funds have been drawn from the additional tranches.

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.

**BAUDAX BIO, INC.**

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

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 June 30, 2022, 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 (the "Minimum Liquidity Covenant") 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 June 30, 2022, the Company was in compliance with the Minimum Liquidity Covenant as the minimum EBITDA criteria is not applicable until additional tranches are drawn. As of June 30, 2022, borrowings under the Credit Agreement are classified based on their schedule maturities.

On August 1, 2022, the Company entered into Amendment No. 1 and Waiver to Credit Agreement, or the Amendment, with MAM Eagle Lender. Pursuant to the terms of the Amendment, the lenders waived any default under the credit agreement (including the imposition of a default interest rate with respect to the default) resulting from our failure to comply with the Minimum Liquidity Covenant. In addition, the Amendment, among other items, (i) provides that 30% of any cash proceeds received by the Company from certain potential strategic licensing transactions shall be used to prepay amounts outstanding under the credit agreement; and (ii) decreases the amount of cash the Company is required to maintain pursuant to the Minimum Liquidity Covenant to \$3,000 for a period beginning on August 1, 2022, and ending on August 31, 2022, at which point the amount required pursuant to the Minimum Liquidity Covenant shall increase to \$5,000.

As a result of the liquidity conditions discussed in Note 2, the Company is not expected to be able to comply with the Minimum Liquidity Covenant, as amended, over the next twelve months without additional capital financing. If the Company is unable to maintain its Minimum Liquidity Covenant, it is reasonably possible that the Lenders could demand repayment of the borrowings under the Credit Agreement during the next twelve months.

In connection with the Credit Agreement, the Company issued a warrant to MAM Eagle Lender, LLC to purchase 15,060 shares of the Company's common stock, at an exercise price equal to \$160.65 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 June 30, 2022, 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 \$209 and \$421 for the three and six months ended June 30, 2022, respectively, and \$211 and \$422 for the three and six months ended June 30, 2021, respectively.

**(12) Commitments and Contingencies**

**(a) Licenses and Supply Agreements**

The Company is party to an exclusive license with Orion Corporation, a company incorporated under the laws of Finland (“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 (\$21,420 as of June 30, 2022) 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 June 30, 2022, 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 (\$12,749 as of June 30, 2022) 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 June 30, 2022, no such milestones have been achieved.

In June 2017, the Company acquired the exclusive global rights to two novel neuromuscular blocking agents (“NMBs”) and a proprietary reversal agent from Cornell University (“Cornell”). The NMBs and reversal agent are referred to herein as the NMB Related Compounds. The NMB Related Compounds include one novel intermediate-acting NMB that has initiated Phase I clinical trials and two other agents, a novel short-acting NMB, and a rapid-acting reversal agent specific to these NMBs. The Company is obligated to make: (i) an annual license maintenance fee payment to Cornell in the remaining range of \$70 to \$125 until the first commercial sale of the NMB Related Compounds; and (ii) milestone payments to Cornell upon the achievement of certain milestones, up to a maximum, for each NMB 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 NMB Related Compound at a rate ranging from low to mid-single digits, depending on the applicable NMB Related Compounds and whether there is a valid patent claim in the applicable country, subject to an annual minimum royalty amount. Further, the Company reimburses Cornell for its ongoing patent costs related to prosecution and maintenance of the patents related to the Cornell patents for the NMB Related Compounds. Through June 30, 2022, no such milestones have been achieved.

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

The Company is party to a Master Manufacturing Services Agreement and Product Agreement with Patheon UK Limited, a company incorporated under the laws of England (“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, Societal CDMO 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.

**BAUDAX BIO, INC.**

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

Based on the amended terms of the Alkermes agreement, the contingent consideration consists of four separate components. The first component was (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, which was paid in three installments during 2020 and 2021, 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 Company paid \$1,000 of the second payment, which was due in the first quarter of 2022, and will make monthly payments of \$200 thereafter until the second payment is fully paid, as agreed between the Company and Alkermes. The third component consists of three potential payments, based on the achievement of specified annual revenue targets, which currently do 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, which is paid quarterly.

As of June 30, 2022, the Company has paid \$22,429 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. The Company accrues for any legal costs as they are incurred. 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 Societal CDMO of all of Societal CDMO's obligations in connection with a securities class action lawsuit (the "Securities Litigation") and agreed to indemnify Societal CDMO for all liabilities related to the Securities Litigation.

On May 31, 2018, the Securities Litigation was filed against Societal CDMO and certain of Societal CDMO'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 Societal CDMO 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, Societal CDMO filed a motion to dismiss the amended complaint in its entirety, which the lead plaintiff opposed on April 9, 2019. On May 9, 2019, Societal CDMO 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. Societal CDMO 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, Societal CDMO filed a reply in support of the motion to dismiss. On March 1, 2021, Societal CDMO's second motion to dismiss was denied. On June 21, 2021, the defendants filed an answer and affirmative defenses to the second amended complaint. Since then, the parties have been engaged in discovery, which concluded by March 15, 2022. On September 30, 2021, the plaintiff filed a motion for class certification and appointment of class representative. Societal CDMO filed an opposition to the plaintiff's motion on November 30, 2021. On January 6, 2022, the plaintiff filed a reply in support of the motion for class certification.

On March 24, 2022, the plaintiff informed the Court that the parties had reached an agreement-in-principle to settle the Securities Litigation and requested that the court stay all deadlines. On May 10, 2022, plaintiff filed an unopposed motion for preliminary approval of the class action settlement. The Court entered an order preliminarily approving the settlement and providing for notice on May 12, 2022. A hearing for final approval of the settlement is set for October 26, 2022.

**(d) Purchase Commitments**

As of June 30, 2022, the Company had outstanding non-cancelable and cancelable purchase commitments in the aggregate amount of \$4,621 primarily related to manufacturing and development activities and other goods and services. 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 an employment agreement with one of its named executive officers. As of June 30, 2022, this employment agreement provided for, among other things, annual base salary in an aggregate amount of not less than \$927, from that date through December 2023.

**(13) Capital Structure**

*(a) Common Stock*

On November 21, 2019, the Company separated from Societal CDMO as a result of a special dividend distribution of all the outstanding shares of its common stock to Societal CDMO shareholders. On the distribution date, each Societal CDMO shareholder received one share of Baudax Bio's common stock for every two and one-half shares of Societal CDMO common stock held of record at the close of business on November 15, 2019. Upon the Distribution, 268,473 shares of common stock were issued, of which 1,311 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 12,628 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.

On March 26, 2020, the Company closed an underwritten public offering of 219,780 shares of its common stock, Series A Warrants to purchase 219,780 shares of common stock (the "March Series A Warrants") and Series B Warrants to purchase 219,780 shares of common stock (the "March Series B Warrants"), at an exercise price of \$160.65 per share for the March Series A Warrants and at an exercise price of \$113.75 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 81,429 shares of its common stock, warrants to purchase 289,330 shares of common stock (the "November Series A Warrants") at an exercise price of \$42.00 per share, pre-funded warrants to purchase 207,902 shares of common stock (the "November Series B Warrants") at an exercise price of \$0.35 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 17,357 shares of common stock (the "November Placement Agent Warrants") at an exercise price of \$51.84375 per share.

On December 18, 2020, the Company closed a registered direct offering of 121,428 shares of its common stock, warrants to purchase 294,298 shares of common stock (the "December Series A Warrants") at an exercise price of \$41.30 per share, pre-funded warrants to purchase 172,869 shares of common stock (the "December Series B Warrants") at an exercise price of \$0.35 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 17,654 shares of common stock (the "December Placement Agent Warrants") at an exercise price of \$50.96875 per share.

On February 8, 2021, the Company closed a registered direct offering of 314,286 shares of common stock (the "February Offering") at an offering price of \$56.00 per share for net proceeds to the Company of \$16,187. 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 18,854 shares of common stock (the "February Placement Agent Warrants") at an exercise price of \$70.00 per share.

**BAUDAX BIO, INC.**

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

On May 31, 2021, the Company closed a registered direct offering of 400,815 shares of common stock (the “May Offering”) at an offering price of \$29.75 per share and warrants to purchase 400,812 shares of common stock (the “May Warrants”) at an exercise price of \$31.50 per share, for net proceeds to the Company of \$10,861. 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 24,046 shares of common stock (the “May Placement Agent Warrants”) at an exercise price of \$37.1875 per share. The May Warrants and May Placement Agent Warrants were exercisable on the six-month anniversary of the closing date of the May Offering.

On December 28, 2021, the Company closed a registered direct offering (the “December 2021 Offering”) of 42,289.3 shares of the Company’s Series A Preferred Stock, par value \$0.01 per share (the “Preferred Stock”), at a stated value of \$100.00 per share and warrants to purchase 362,479 shares of common stock of the Company (the “December 2021 Warrants”) for net proceeds of \$3,658. The shares of Preferred Stock are convertible, on the date after the issuance thereof, into an aggregate of 483,306 shares of common stock at a conversion price of \$8.75 per share, of which 34,000 shares of Preferred Stock were converted to common stock on December 29, 2021 and the remaining were converted in the first quarter of 2022. The Preferred Stock have no voting rights, other than the right to vote as a class on certain matters, and each share of Preferred Stock will have the right to cast 3,571 votes per share of Preferred Stock on an amendment to the Company’s Amended and Restated Articles of Incorporation, as amended, to effect a reverse stock split of the Company’s outstanding shares of common stock by a ratio to be determined by the Board of Directors of the Company, voting together with the common stock as a single class; and in accordance with Nasdaq Stock Market LLC Listing Rules, the votes cast by holders of the Preferred Stock must be counted by the Company in the same proportion as the aggregate shares of Common Stock voted on the proposal. The holders of Preferred Stock are entitled to dividends, on an as-if converted basis, equal to dividends actually paid, if any, on shares of common stock. The Company recognized a beneficial conversion charge of \$2,422 during the year ended December 31, 2021, which represents the in-the-money value of the conversion rate as of the date of issuance. As compensation to the Placement Agent, the Company agreed to pay the Placement Agent a cash fee of 7.0% of the gross proceeds raised in the December 2021 Offering, plus a management fee equal to 1.0% of the gross proceeds raised in the December 2021 Offering and reimbursement of certain expenses and legal fees. The Company also issued to designees of the Placement Agent warrants to purchase 28,996 shares of common stock (the “December 2021 Placement Agent Warrants”). The December 2021 Warrants and the December 2021 Placement Agent Warrants have an exercise price of \$11.20 per share and were exercisable upon the six-month anniversary of their issuance.

On March 1, 2022, the Company closed an underwritten public offering of 1,831,631 shares of its common stock, pre-funded warrants to purchase 1,677,141 shares of common stock at an exercise price of \$0.01 per share and warrants to purchase 3,508,772 shares of common stock at an exercise price of \$3.25 per share, as well as up to 526,315 additional shares of common stock and/or additional warrants to purchase up to 526,315 shares of common stock, which may be purchased pursuant to a 30-day option to purchase additional securities granted to H.C. Wainwright & Co., LLC (the “Underwriter”) by the Company. The public offering price for each share of common stock and accompanying warrant to purchase one share of common stock was \$2.85, and the public offering price for each pre-funded warrant and accompanying warrant was \$2.84. As compensation to the Underwriter, the Company agreed to pay to the Underwriter a cash fee of 7.0% of the gross proceeds, plus a cash management fee equal to 1.0% of the gross proceeds and reimbursement of certain expenses and legal fees. The Company also issued to designees of the Underwriter warrants to purchase 210,526 shares of common stock at an exercise price of \$3.5625 per share. On February 28, 2022, the Underwriter partially exercised its option to purchase an additional 113,896 warrants. Net proceeds to the Company, after deducting underwriting discounts and commissions and offering expenses, was \$8,791.

On May 17, 2022, the Company entered into a securities purchase agreement with institutional investors named therein, pursuant to which the Company agreed to issue and sell, in a registered direct offering (the “May 2022 Offering”), 1,646,091 shares of the Company’s common stock, par value \$0.01 per share, and, in a concurrent private placement, warrants exercisable for up to an aggregate of 1,646,091 shares of Common Stock at a combined offering price of \$1.215 per share and associated warrant. The warrants have an exercise price of \$1.09 per share. Each warrant is exercisable for one share of common stock and was exercisable immediately upon issuance. The warrants will have a term of five years from the issuance date. As compensation to H.C. Wainwright & Co., LLC as placement agent in connection with the offering, the Company agreed to pay to the placement agent a cash fee of 7.0% of the aggregate gross proceeds raised in the offering, plus a management fee equal to 1.0% of the gross proceeds raised in the offering and certain expenses. The Company also issued to designees of the placement agent warrants to purchase up to 6.0% of the aggregate number of shares of common stock sold in the transactions, or warrants to purchase up to 98,765 shares of common stock. The placement agent warrants have substantially the same terms as the warrants, except that the placement agent warrants have an exercise price equal to 125%

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

of the offering price per share (or \$1.5188 per share). The placement agent warrants will expire on May 17, 2027. Net proceeds to the Company, after deducting underwriting discounts and commissions and offering expenses, was \$1,720.

**(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 June 30, 2022, no shares of preferred stock were issued or outstanding.

See Note 13(a) for additional information regarding the December 2021 Offering.

**(c) Warrants**

On May 29, 2020, in connection with the Credit Agreement, the Company issued a warrant to MAM Eagle Lender, LLC to purchase 15,060 shares of common stock, at an exercise price equal to \$160.65 per share (see Note 11(b)).

On October 19, 2020, the Company entered into Warrant Exchange Agreements (each, an “Exchange Agreement”) with certain holders (each, a “Holder”) of the Company’s outstanding March Series A Warrants and March Series B Warrants. Pursuant to the Exchange Agreements, the Holders, at their election, agreed to a cashless exchange of either all of their March Series A Warrants or March Series B Warrants, in each case for 0.0057 shares of the Company’s common stock per warrant (rounded up to the nearest whole share) (the “Exchange”). The Company issued 33,908 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 \$0.35, 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 294,298 shares of common stock of the Company (the “January Warrants”) at an offering price of \$4.375 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 \$41.30 per warrant. The January Warrants have an exercise price of \$56.00 per share.

As compensation to the 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 17,654 shares of common stock (the “January Placement Agent Warrants”) at an exercise price of \$70.00 per share.

During the year ended December 31, 2020, the Company issued 252,476 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 207,902 shares of common stock upon exercise of the November Series B Warrants for proceeds of \$73 and 172,869 shares of common stock upon exercise of the December Series B Warrants for proceeds of \$60.

During the year ended December 31, 2021, the Company issued 3,189 shares of common stock upon exercise of the March Series B Warrants for net proceeds of \$1 and 294,298 shares of common stock upon exercise of the December Series A Warrants for proceeds of \$12,155.

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

As of June 30, 2022, 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)	919	\$ 0.35	March 26, 2025
MAM Eagle Lender Warrant	15,060	\$ 160.65	May 29, 2027
November Series A Warrants	289,330	\$ 42.00	November 24, 2025
November Placement Warrants	17,357	\$ 51.84375	November 24, 2025
December Placement Warrants	17,654	\$ 50.96875	December 18, 2025
January Warrants	294,298	\$ 56.00	January 21, 2026
January Placement Warrants	17,654	\$ 70.00	January 21, 2026
February Placement Warrants	18,854	\$ 70.00	February 8, 2026
May Warrants	400,812	\$ 31.50	June 1, 2027
May Placement Warrants	24,046	\$ 37.1875	May 31, 2026
December 2021 Warrants	362,479	\$ 11.20	June 27, 2027
December 2021 Placement Agent Warrants	28,996	\$ 11.20	December 27, 2026
March 2022 Warrants	3,622,668	\$ 3.25	March 1, 2027
March 2022 Underwriter Warrants	210,526	\$ 3.56	February 24, 2027
May 2022 Warrants	1,646,091	\$ 1.09	May 19, 2027
May 2022 Placement Agent Warrants	98,765	\$ 1.52	May 17, 2027

With the exception of the March Series A Warrants to purchase 919 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.

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

	June 30, 2022 Series A Warrants
Fair value	\$ 1
Expected dividend yield	— %
Expected volatility	79.89 %
Risk-free interest rates	2.99 %
Remaining contractual term	2.7 years

**(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 an initial total of 85,714 shares of common stock. On December 1<sup>st</sup> of each year, pursuant to the "Evergreen" provision of the 2019 Plan, the number of shares available under the plan shall be increased by an amount equal to 5% of the outstanding common stock on December 1<sup>st</sup> of that year or such lower amount as determined by the Board of Directors. In December 2021, the number of shares available for issuance under the 2019 Plan was increased by 120,605. The total number of shares authorized for issuance under the 2019 Plan as of June 30, 2022 is 263,167. As of June 30, 2022, 112,019 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. There were no options granted during the six months ended June 30, 2022. The weighted average grant-date fair value of options awarded to employees during the six months ended June 30, 2021 was \$27.45.

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

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:

	June 30, 2021
Expected option life	5.5 years
Expected volatility	75.37%
Risk-free interest rate	0.78%
Expected dividend yield	—

The following table summarizes Baudax Bio stock option activity during the six months ended June 30, 2022:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life
Balance, December 31, 2021	125,418	\$ 76.05	8.6 years
Expired/forfeited/cancelled	(35,756 )	\$ 49.85	
Balance, June 30, 2022	<u>89,662</u>	\$ 86.50	7.6 years
Vested	61,610	\$ 85.63	7.1 years
Vested and expected to vest	89,662	\$ 86.50	7.6 years

Included in the table above are 6,106 stock options outstanding as of June 30, 2022 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 six months ended June 30, 2022:

	Number of shares	Weighted average grant date fair value
Balance, December 31, 2021	41,069	\$ 63.79
Granted	501,209	0.76
Vested and settled	(11,337 )	44.77
Expired/forfeited/cancelled	(7,023 )	57.22
Balance, June 30, 2022	<u>523,918</u>	<u>\$ 3.99</u>
Expected to vest	508,792	

In June 2022, the Company granted 501,209 time-based RSUs, which may be settled in cash, stock, or a combination of cash and stock, solely at the election of the Company. These awards are classified as Other long-term liabilities on the Consolidated Balance Sheet due to insufficient shares available for grant in the 2019 Plan.

Included in the table above are 683 time-based RSUs outstanding as of June 30, 2022 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 six months ended June 30, 2022 and 2021 was \$858 and \$3,207, respectively, which for the current year also includes expense for the liability classified awards.

As of June 30, 2022, there was \$2,374 of unrecognized compensation expense related to unvested options and time-based RSUs that are expected to vest and will be expensed over a weighted average period of 2.0 years. As of June 30, 2022, there was \$450 of unrecognized compensation expense related to unvested performance-based RSUs.

The aggregate intrinsic value represents the total amount by which the fair value of the common stock subject to options exceeds the exercise price of the related options. As of June 30, 2022, there was no aggregate intrinsic value of the vested and unvested options.

**(15) Related Party Transactions**

Societal CDMO became a related party to the Company following the Separation. As part of the Separation, the Company entered into a transition services agreement with Societal CDMO, which terminated on December 31, 2020. Under the transition services agreement, the Company provided certain services to Societal CDMO, each related to corporate functions, which were charged to Societal CDMO.

In connection with the Separation, Societal CDMO and Baudax Bio 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 Societal CDMO equity awards.

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

**(16) Retirement Plan**

The Company has a voluntary 401(k) Savings Plan (the "401(k) Plan") in which all employees are eligible to participate. The Company's policy is to match 100% of the employee contributions up to a maximum of 5% of employee compensation. Total Company contributions to the 401(k) plan for the three months ended June 30, 2022 and 2021 were \$51 and \$151, respectively. Total Company contributions to the 401(k) plan for the six months ended June 30, 2022 and 2021 were \$341 and \$421, 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, 2021 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, 2021, filed with the SEC on March 16, 2022. 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 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 United States. ANJESO is the first and only 24-hour, intravenous, or IV, analgesia agent. ANJESO is a cyclooxygenase-2, or COX-2, preferential, non-steroidal anti-inflammatory, or 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 two Phase IIIb programs evaluating ANJESO clinical safety and efficacy along with its health economic impacts in specific surgical settings.

We utilize our internal field team and collaborate with contracted third parties, to market ANJESO to health care professionals at key targeted institutions for the commercialization of ANJESO in the United States. The Centers for Medicare and Medicaid Services, or CMS, established a unique J-code for ANJESO in the fourth quarter of 2020. ANJESO has transitional pass-through status under traditional Medicare plans for a period of 3 years, thereby providing separate reimbursement for ANJESO when used for surgical procedures in the outpatient setting. 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 three integrated delivery networks that serves over twelve million patients nationwide, for availability of ANJESO to their member institutions and with a leading operator of surgical facilities and ancillary services nationally, with over 150 locations nationwide. In addition, ANJESO is currently approved for use within the Department of Veterans Affairs, the Department of Defense, Indian Health Service, 340B covered entities, and multiple state Medicaid programs. We are continuing to evaluate strategic partnerships for the commercialization of ANJESO both in the United States and outside the United States.

We have seen continued growth of ANJESO in the second quarter of 2022 through deepening usage at existing accounts, particularly in the hospital setting where we saw a growth of 12% in vials sold to hospitals compared to the first quarter of 2022. Further, this growth came through the addition of several new key accounts as well as a resurgence by some accounts that ordered early on in the commercialization of ANJESO. The second quarter of 2022 was our second best quarter since launch, a decrease of 9% from the first quarter of 2022, which was our strongest quarter to date. The number of vials sold to end-users increased approximately 67% in the second quarter of 2022 compared to the second quarter of prior year.

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 commercialization activities 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.

Our pipeline also includes other early-stage product candidates, including two novel NMBs and a related proprietary chemical reversal agent and Dex-IN, a proprietary intranasal formulation of dexmedetomidine, or Dex, an alpha-2 adrenergic agonist that we are evaluating for possible partnering.

## **COVID-19 Impact**

Our efforts to commercialize ANJESO were impacted in 2020, 2021, and continue to impact us in 2022 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, and any new and potentially more virulent variants that may emerge. Intermittent impacts in the reduction of elective surgeries have occurred and this has had an impact in the recent quarter, especially in January and February. Overall, many centers have yet returned to pre-COVID levels of surgeries even where the impact of COVID-19 and its variants have not been as great. 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 has impacted and will continue to impact our marketing and commercialization efforts. Further, hospitals and ambulatory surgical centers 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 have 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.

## **2022 Reduction in Force**

Due to our current cash position, in March of 2022, we implemented a reduction in workforce by approximately 66 employees (representing approximately 80% of our total workforce), including 43 members of our sales force. The reorganization was substantially completed by the end of the second quarter and approximately \$4.1 million of charges were incurred for severance and other related costs. The reduction in force was designed to substantially reduce our operational expenses and conserve cash resources.

## **Financial Overview**

### ***Revenue***

We sell ANJESO in the U.S. through a single third-party logistics provider, or 3PL, which takes title to and control of the goods, and is considered our customer. 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-user 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 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 commercialization 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 pediatric development of ANJESO and the NMB portfolio activities. These expenses consist primarily of:

- expenses incurred under agreements with investigative sites, consultants and other service providers that conduct or support our clinical and pre-clinical trials;
- the cost of acquiring and manufacturing clinical trial drug supply and related manufacturing services and pre-commercial product validation and inventory manufacturing expenses;
- costs related to facilities, depreciation and other allocated expenses;
- acquired in-process research and development;
- costs associated with regulatory activities and responses to the FDA; and
- salaries and related costs for personnel in research and development and pre-commercial regulatory functions.

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

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

- the costs, timing and outcome of regulatory review of a product candidate;
- the duration of clinical trials, which varies substantially according to the type, complexity and novelty of the product candidate;
- substantial requirements on the introduction of pharmaceutical products imposed by the FDA and comparable agencies in foreign countries, which require lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures;
- the possibility that data obtained from pre-clinical and clinical activities at any step in the testing process may be adverse and lead to discontinuation or redirection of development activity or may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval;
- risk involved with development of manufacturing processes, FDA pre-approval inspection practices and successful completion of manufacturing batches for clinical development and other regulatory purposes;
- the emergence of competing technologies and products, including obtaining and maintaining patent protections, and other adverse market developments, which could impede our commercial efforts; and
- the other risks disclosed in the sections titled “Risk Factors” of our 2021 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 commercialization scale-up of our other product candidates. We may elect to seek collaborative relationships in order to provide us with a diversified revenue stream and to help facilitate the development and commercialization of our product candidate pipeline.

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

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

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

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance and information technology functions, as well as the commercial portion of the medical affairs and regulatory 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.

Our selling, general and administrative expenses decreased in the quarter ended June 30, 2022 as a result of a reduction in personnel and marketing costs, and we expect our selling, general and administrative expenses to remain relatively constant in the near term.

### ***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 Societal CDMO'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, \$3.6 million paid in 2020, another \$1.4 million paid in 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 and a partial payment was made on the second payment of \$1.0 million, which was due in the first quarter of 2022, with monthly payments of \$0.2 million paid thereafter until fully paid, 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), which is paid quarterly. 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 June 30, 2022 recorded a \$20.4 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 June 30, 2022, we have paid \$22.4 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 was fully forgiven during the year ended December 31, 2021.

### ***Income Taxation***

We maintained a valuation allowance against our deferred tax assets as of June 30, 2022 and 2021.

## Results of Operations

### Comparison of the Three Months Ended June 30, 2022 and 2021

	Three Months Ended June 30,	
	2022	2021
	(amounts in thousands)	
Revenue, net	\$ 300	\$ 201
Operating expenses:		
Cost of sales	361	586
Research and development	912	857
Selling, general and administrative	4,029	10,608
Amortization of intangible assets	644	644
Change in warrant valuation	(1)	(59)
Change in contingent consideration valuation	1,327	3,881
Total operating expenses	7,272	16,517
Operating loss	(6,972)	(16,316)
Other expense:		
Other expense, net	(559)	987
Net loss	<u>\$ (7,531)</u>	<u>\$ (15,329)</u>

**Revenue, net.** For the three months ended June 30, 2022 and 2021, net product revenue was \$0.3 million and \$0.2 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 \$0.1 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 \$0.4 million and \$0.6 million for the three months ended June 30, 2022 and 2021, respectively, 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 June 30, 2022 and 2021 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. The decrease of \$0.2 million was primarily a result of the reduction in manufacturing costs, including production and storage costs, in the current year compared to the prior year of \$0.2 million.

**Research and Development.** Our research and development expenses were \$0.9 million for each of the three months ended June 30, 2022 and 2021, respectively. There was no significant change in the comparable periods.

**Selling, General and Administrative.** Our selling, general and administrative expenses were \$4.0 million and \$10.6 million for the three months ended June 30, 2022 and 2021, respectively. The decrease of \$6.6 million was primarily a result of a reduction in personnel costs of \$3.9 million, a decrease in marketing costs of \$1.3 million, a decrease in public company costs of \$1.0 million, and a decrease in both consulting and travel expenses of \$0.2 million.

**Amortization of Intangible Assets.** Amortization expense was \$0.6 million for each of the three months ended June 30, 2022 and 2021, which was related to the amortization of our intangible asset resulting from research and development activities over its estimated useful life.

**Change in Contingent Consideration Valuation.** The change in contingent consideration valuation was an increase in value of \$1.3 million for the three months ended June 30, 2022 and an increase in value of \$3.9 million for the three months ended June 30, 2021. 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 June 30, 2022 was primarily due to the time value of money as we progress closer to payment of the contingent consideration liability. The increase in contingent consideration valuation for the three months ended June 30, 2021 was primarily due to the time value of money and change in interest rates.

**Other Expense, net.** Other expense was \$0.6 million for the three months ended June 30, 2022 and other income was \$1.0 million for the three months ended June 30, 2021. The change in other income (expense) of \$1.6 million was primarily due to the gain on extinguishment of the PPP Loan of \$1.6 million in the previous year upon the approval of our application for forgiveness.

Comparison of the Six Months Ended June 30, 2022 and 2021

	Six Months Ended June 30,	
	2022	2021
	(amounts in thousands)	
Revenue, net	\$ 722	\$ 399
Operating expenses:		
Cost of sales	1,009	1,407
Research and development	2,205	1,965
Selling, general and administrative	18,219	22,696
Amortization of intangible assets	1,288	1,288
Change in warrant valuation	(6)	(41)
Change in contingent consideration valuation	(2,476)	5,722
Total operating expenses	20,239	33,037
Operating loss	(19,517)	(32,638)
Other expense:		
Other expense, net	(823)	397
Net loss	<u>\$ (20,340)</u>	<u>\$ (32,241)</u>

**Revenue, net.** For the six months ended June 30, 2022 and 2021, 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 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 \$1.0 million and \$1.4 million for the six months ended June 30, 2022 and 2021, respectively, 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 six months ended June 30, 2022 and 2021 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. The decrease of \$0.4 million was primarily a result of the reduction in scrap expense recorded in the current year compared to the prior year of \$0.2 million and a decrease in manufacturing costs, including reductions in production and storage costs, of \$0.2 million.

**Research and Development.** Our research and development expenses were \$2.2 million and \$2.0 million for the six months ended June 30, 2022 and 2021, respectively. The increase of \$0.2 million was primarily due to an increase in clinical trials costs associated with our ANJESO pediatric program of \$0.2 million.

**Selling, General and Administrative.** Our selling, general and administrative expenses were \$18.2 million and \$22.7 million for the six months ended June 30, 2022 and 2021, respectively. The decrease of \$4.5 million was primarily a result of a reduction in personnel costs of \$1.6 million, a decrease in public company costs of \$1.4 million, a decrease in marketing costs of \$1.1 million, and a decrease in consulting expenses of \$0.4 million.

**Amortization of Intangible Assets.** Amortization expense was \$1.3 million for each of the six months ended June 30, 2022 and 2021, which was related to the amortization of our intangible asset resulting from research and development activities over its estimated useful life.

**Change in Contingent Consideration Valuation.** The change in contingent consideration valuation was a decrease in value of \$2.5 million for the six months ended June 30, 2022 and an increase in value of \$5.7 million for the six months ended June 30, 2021. The non-cash charge for contingent consideration in each period related to the revaluation of the probability-adjusted fair value of the Alkermes Transaction payment obligation. The decrease in contingent consideration value for the six months ended June 30, 2022 was primarily due to updated forecasts for ANJESO due to the significant reduction of our commercial team, partially offset by the increase for the time value of money. The increase in contingent consideration valuation for the six months ended June 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.

**Other Expense, net.** Other expense was \$0.8 million for the six months ended June 30, 2022 and other income was \$0.4 million for the six months ended June 30, 2021. The change in other income (expense) of \$1.2 million was primarily due to the gain on extinguishment of the PPP Loan of \$1.6 million in the previous year upon the approval of our application for forgiveness, partially offset by other income in the current year for the settlement of a patent infringement claim of \$0.3 million.

## Liquidity and Capital Resources

As of June 30, 2022, we had \$5.2 million in cash and cash equivalents.

On May 17, 2022, we closed a registered direct offering of 1,646,091 shares of our common stock, par value \$0.01 per share, and in a concurrent private placements, warrants exercisable for up to an aggregate of 1,646,091 shares of common stock at a combined offering price of \$1.215 per share and associated warrant. The warrants have an exercise price of \$1.09 per share. Each warrant is exercisable for one share of common stock and was exercisable immediately upon issuance. The warrants have a term of five years from the issuance date. As compensation to H.C. Wainwright & Co., LLC as placement agent in connection with the offering, we agreed to pay to the placement agent a cash fee of 7.0% of the aggregate gross proceeds raised in the offering, plus a management fee equal to 1.0% of the gross proceeds raised in the offering and certain expenses. We also issued to designees of the placement agent warrants to purchase up to 6.0% of the aggregate number of shares of common stock sold in the transactions, or warrants to purchase up to 98,765 shares of common stock. The placement agent warrants have substantially the same terms as the warrants, except that the placement agent warrants have an exercise price equal to 125% of the offering price per share (or \$1.5188 per share). The placement agent warrants will expire on May 17, 2027. Net proceeds, after deducting underwriting discounts and commissions and offering expenses, was \$1.7 million.

On March 1, 2022, we closed an underwritten public offering of 1,831,631 shares of common stock, pre-funded warrants to purchase 1,677,141 shares of common stock at an exercise price of \$0.01 per share and warrants to purchase 3,508,772 shares of common stock at an exercise price of \$3.25 per share, as well as up to 526,315 additional shares of common stock and/or additional warrants to purchase up to 526,315 shares of common stock which may be purchased pursuant to a 30-day option to purchase additional securities granted to H.C. Wainwright & Co., LLC (the "Underwriter") by us. The public offering price for each share of common stock and accompanying warrant to purchase one share of common stock was \$2.85, and the public offering price for each pre-funded warrant and accompanying warrant was \$2.84. As compensation to the Underwriter, we agreed to pay to the Underwriter a cash fee of 7.0% of the gross proceeds, plus a cash management fee equal to 1.0% of the gross proceeds and reimbursement of certain expenses and legal fees. We also issued to designees of the Underwriter warrants to purchase 210,526 shares of common stock at an exercise price of \$3.5625 per share. On February 28, 2022, the Underwriter partially exercised its option to purchase an additional 113,896 warrants. Net proceeds, after deducting underwriting discounts and commissions and offering expenses, was \$8.8 million.

On December 28, 2021, we closed a registered direct offering of 42,289.3 shares of Series A Preferred Stock, par value \$0.01 per share, or the Preferred Stock, and warrants to purchase 362,479 shares of common stock, or the December 2021 Warrants, for net proceeds of \$3.7 million. The shares of Preferred Stock will have a stated value of \$100.00 per share and are convertible, on the date after the issuance thereof, into an aggregate of 483,306 shares of common stock at a conversion price of \$8.75 per share. As compensation to H.C. Wainwright & Co., LLC, or the Placement Agent, we agreed to pay the Placement Agent a cash fee of 7.0% of the gross proceeds raised in the December 2021 Offering, plus a management fee equal to 1.0% of the gross proceeds raised in the December 2021 Offering and reimbursement of certain expenses and legal fees. We also issued to designees of the Placement Agent warrants to purchase 28,996 shares of common stock, or the December 2021 Placement Agent Warrants. The December 2021 Warrants and the December 2021 Placement Agent Warrants have an exercise price of \$11.20 per share and will be exercisable upon the six-month anniversary of their issuance.

On May 31, 2021, we closed a registered direct offering of 400,815 shares of common stock, or the May Offering, at an offering price of \$29.75 per share and warrants to purchase 400,812 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 the Placement Agent, 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 24,076 shares of common stock (the "May Placement Agent Warrants") at an exercise price of \$37.1875 per share. The May Warrants and May Placement Agent Warrants were 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 314,286 shares of common stock, or the February Offering, at an offering price of \$56.00 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 18,854 shares of common stock, or the February Placement Agent Warrants. The February Placement Agent Warrants have an exercise price of \$70.00 per share.

On January 21, 2021, we entered into an agreement to issue and sell warrants exercisable for an aggregate of 294,298 shares of common stock, or the January Warrants, at an offering price of \$4.375 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 \$41.30 per warrant. The January Warrants have an exercise price of \$56.00 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 17654 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 \$70.00 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 August 1, 2022, we entered into Amendment No. 1 and Waiver to Credit Agreement, or the Amendment, with MAM Eagle Lender. Pursuant to the terms of the Amendment, the lenders waived any default under the credit agreement (including the imposition of a default interest rate with respect to the default) resulting from our failure to comply with the minimum cash covenant, or the Minimum Liquidity Covenant, which requires us to maintain at least \$5.0 million in a liquidity account. In addition, the Amendment, among other items, (i) provides that 30% of any cash proceeds received by us from certain potential strategic licensing transactions shall be used to prepay amounts outstanding under the credit agreement; and (ii) decreases the amount of cash we are required to maintain pursuant to the Minimum Liquidity Covenant to \$3.0 million for a period beginning on August 1, 2022, and ending on August 31, 2022, at which point the amount required pursuant to the Minimum Liquidity Covenant shall increase to \$5.0 million.

On May 8, 2020, we entered into a promissory note for \$1.5 million under the PPP of the CARES Act administered by the SBA. We have used the loan proceeds for covered payroll costs in accordance with the relevant terms and conditions of the CARES Act. This Loan may be partially or fully forgiven if we comply with the provisions of the CARES Act including the use of Loan proceeds for payroll costs, rent, utilities, and other expenses, and at least 60% of the loan proceeds must be for payroll costs as defined by the CARES Act. During the year ended December 31, 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 \$1.5 million and accrued interest. As a result, we recognized a gain on extinguishment of the PPP Loan of \$1.5 million during the year ended December 31, 2021.

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

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 June 30, 2022, we will need to raise additional capital in the next twelve months to continue as a going concern.

#### **Sources and Uses of Cash**

Cash used in operations was \$20.1 million and \$24.1 million for the six months ended June 30, 2022 and 2021, respectively, which represents our operating losses less our non-cash items including: stock-based compensation, non-cash interest expense, depreciation, amortization, changes in warrant valuations, and changes in fair value of contingent consideration, as well as changes in operating assets and liabilities.

There was no significant cash used in investing activities for the six months ended June 30, 2022. Cash used in investing activities for the six months ended June 30, 2021 was \$12.2 million, which was primarily due to purchases of short-term investments in the current year.

There was \$9.5 million of cash provided by financing activities in the six months ended June 30, 2022 consisting of net proceeds of \$8.9 million from a public offering of common stock and warrants and \$1.8 million of net proceeds from a registered direct offering of common stock and concurrent private placement of warrants, partially offset by a payment of contingent consideration of \$1.0 million and payments on long-term debt of \$0.2 million. There was \$31.3 million of cash provided by financing activities for the six months ended June 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 \$7.8 million.

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

- our relationships with third parties, licensors, collaborators, and our employees;
- our ability to continue to operate as a standalone company and execute our strategic priorities;
- potential indemnification liabilities we may owe to Societal CDMO;
- the timing of the Alkermes Transaction milestone payments and other contingent consideration;
- the costs of manufacturing and modest commercialization activities, for ANJESO;
- the level of market acceptance of ANJESO;
- the scope, progress, results, and costs of development for our other product candidates;
- the cost, timing and outcome of regulatory review of our other product candidates;
- the cost of manufacturing scale-up, acquiring drug product and other capital equipment for our other product candidates;
- the extent to which we in-license, acquire or invest in products, businesses and technologies;
- our ability to raise additional funds through equity or debt financings or the sale of certain assets;
- our ability to comply with our debt covenants;
- our ability to achieve certain milestones to access and draw down additional tranches of debt under the Credit Agreement;
- the extent to which holders of our warrants exercise their warrants resulting in the payment of cash proceeds to us;
- the costs of preparing, submitting and prosecuting patent applications and maintaining, enforcing and defending intellectual property claims; and
- the effect of any changes in our effective tax rate due to changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities, tax impacts and net operating loss utilization related to the Separation and changes in tax laws.

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

## Contractual Commitments

The table below reflects our contractual commitments as of June 30, 2022:

Contractual Obligations	Total	Payments Due by Period (in 000s)			
		Less than 1 year	1-3 years	3-5 years	More than 5 years
<b>Debt Obligations (1):</b>					
Debt	\$ 9,722	\$ 3,611	\$ 6,111	\$ —	\$ —
Interest on Debt	2,140	1,182	958	—	—
<b>Purchase Obligations (2):</b>	\$ 4,621	\$ 819	\$ 126	\$ 18	\$ —
Operating Leases (3)	1,619	345	552	573	149
<b>Other Long-Term Liabilities:</b>					
Other License Commitments and Milestone payments (4), (5)	50,565	80	190	125	—
Alkermes Payments (6)	117,571	9,029	22,114	6,429	—
Employment Agreements (7)	927	618	309	—	—
<b>Total Contractual Obligations</b>	<u>\$ 187,165</u>	<u>\$ 15,684</u>	<u>\$ 30,360</u>	<u>\$ 7,145</u>	<u>\$ 149</u>

(1)Debt obligations consist of principal, an exit fee of 2.5% of that principal and interest on the \$9.7 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 manufacturing and development activities and other goods or services. The timing of certain purchase commitments totaling \$3,658 cannot be estimated in the table above as it is dependent on sales launch trajectory, development progression or the outcome of other strategic evaluations and as such is only included in the total. 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. See Note 8 to the Consolidated Financial Statements included in this Quarterly Report.

(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 that may arise based on meeting certain milestones. We are unable to reliably estimate the timing of these payments totaling \$34,170 because they are dependent on the type and complexity of the clinical studies and intended uses of the products, which have not been established, and as such are only included in the total. In accordance with U.S. GAAP, these obligations are not recorded on our Consolidated Balance Sheets.

(5)We license the neuromuscular blocking agents, or NMBs, 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 NMBs. The amount reflects only payment obligations that are fixed and determinable. We are unable to reliably estimate the timing of certain of these payments totaling \$16,000 because they are dependent on the type and complexity of the clinical studies and intended uses of the products, which have not been established, and as such are only included in the total. 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 and in some instances may only arise based on meeting certain commercial milestones. We are unable to reliably estimate the timing of these payments totaling \$79,999 because they are in some instances, events that are not in our control and dependent on the commercial success of the product and as such are only included in the total. 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 an employment agreement with one of our named executive officers. As of June 30, 2022, this employment agreement provided for, among other things, annual base salaries in an aggregate amount of not less than this amount, from that date through December 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.

### **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 2021 Annual Report. In the six months ended June 30, 2022, there were no significant changes to the application of critical accounting policies previously disclosed in our 2021 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 June 30, 2022. 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 June 30, 2022, 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 Societal CDMO and certain of Societal CDMO'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 Societal CDMO concerning the NDA for injectable meloxicam. The complaint seeks unspecified damages, interest, attorneys' fees and other costs. On December 10, 2018, 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, Societal CDMO filed a motion to dismiss the amended complaint in its entirety, which the lead plaintiff opposed on April 9, 2019. On May 9, 2019, the Company filed its response and briefing was completed on the motion to dismiss. In response to questions from the 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. Societal CDMO filed a motion to dismiss the second amended complaint on June 18, 2020. The plaintiff filed an opposition to Societal CDMO's motion to dismiss on August 17, 2020. On September 16, 2020, Societal CDMO filed a reply in support of the motion to dismiss. On March 1, 2021, Societal CDMO's second motion to dismiss was denied. On June 21, 2021, the defendants filed an answer and affirmative defenses to the second amended complaint. Since then, the parties have been engaged in discovery, which must conclude by March 15, 2022. On September 30, 2021, the plaintiff filed a motion for class certification and appointment of class representative. Societal CDMO filed an opposition to the plaintiff's motion on November 30, 2021. On January 6, 2022, the plaintiff filed a reply in support of the motion for class certification. In connection with the Separation, we accepted assignment by Societal CDMO of all of Societal CDMO's obligations in connection with the Securities Litigation and agreed to indemnify Societal CDMO for all liabilities related to the Securities Litigation.

On March 24, 2022, plaintiff informed the Court that the parties had reached an agreement-in-principle to settle the Securities Litigation and requested that the court stay all deadlines. On May 10, 2022, plaintiff filed an unopposed motion for preliminary approval of the class action settlement. The Court entered an order preliminarily approving the settlement and providing for notice on May 12, 2022. A hearing for final approval of the settlement is set for October 26, 2022.

### Item 1A. Risk Factors.

Except as set forth below, there have been no material changes in the risk factors disclosed in our 2021 Annual Report.

#### Risks Related to Our Finances and Capital Requirements

***Our losses, negative cash flows from operations and accumulated deficit raise substantial doubt about our ability to continue as a going concern absent obtaining adequate new debt or equity financings.***

Management has concluded that substantial doubt exists about our ability to continue as a going concern for the next twelve months from the date of this Quarterly Report on Form 10-Q. As of June 30, 2022, we had an accumulated deficit of \$152.4 million, cash and cash equivalents of \$5.2 million and current liabilities of \$18.2 million. Based on available resources, we believe that our cash and cash equivalents on hand are sufficient to fund our currently anticipated operating and capital requirements through the third quarter of 2022.

We did not become a revenue-generating company until the second quarter of 2020, following the commercial launch of ANJESO. We expect to continue to incur losses for the foreseeable future as we continue our efforts to monetize ANJESO and develop our other current and future product candidates. We have also incurred significant indebtedness. As of June 30, 2022, we had an outstanding balance of \$9.7 million under our credit facility with MAM Eagle Lender. These factors, individually and collectively, raise substantial doubt about our ability to continue as a going concern, and therefore, could materially limit our ability to raise additional funds through an issuance of debt or equity securities or otherwise.

Our forecast of the period of time through which our financial resources will be adequate to support our operating requirements is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section and Part I, Item 1A "Risk Factors" of our Annual Report on Form 10-K filed with the SEC on March 16, 2022, as revised or supplemented by our subsequent quarterly reports on Form 10-Q or our current reports on Form 8-K, each as filed with the SEC. We have based this estimate on a number of assumptions that may prove to be wrong, and changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. Our inability to obtain additional funding when we need it could seriously harm our business.

***We have incurred significant indebtedness, which could adversely affect our business, including as a result of any default thereof.***

As of June 30, 2022, we had an outstanding balance of \$9.7 million under our credit agreement with MAM Eagle Lender. Our indebtedness could have important consequences to our shareholders. For example, it:

- increases our vulnerability to adverse general economic and industry conditions;
- limits our flexibility in planning for, or reacting to, changes in our business or the industries in which we operate;
- reduces proceeds we may receive as a result of any sale;
- limits our ability to obtain additional financing or refinancing in the future for working capital, clinical trials, research and development, or other purposes; and
- places us at a competitive disadvantage compared to our competitors that have less indebtedness.

Any of the above-listed factors could materially adversely affect our business, financial condition, results of operations and cash flows.

Our credit agreement with MAM Eagle Lender also contains certain financial and other covenants, and includes limitations on, among other things, additional indebtedness, paying dividends in certain circumstances, and making certain acquisitions and investments. The credit agreement provides for certain mandatory prepayment events, including with respect to the net proceeds of asset sales, extraordinary receipts, casualty payments and other specified events, based on the terms of the credit agreement with MAM Eagle Lender.

On August 1, 2022, we entered into Amendment No. 1 and Waiver to Credit Agreement, or the Amendment, with MAM Eagle Lender. Pursuant to the terms of the Amendment, the lenders waived any default under the credit agreement (including the imposition of a default interest rate with respect to the default) resulting from our failure to comply with the minimum cash covenant, or the Minimum Liquidity Covenant, which requires us to maintain at least \$5.0 million in a liquidity account. In addition, the Amendment, among other items, (i) provides that 30% of any cash proceeds received by us from certain potential strategic licensing transactions shall be used to prepay amounts outstanding under the credit agreement; and (ii) decreases the amount of cash we are required to maintain pursuant to the Minimum Liquidity Covenant to \$3.0 million for a period beginning on August 1, 2022, and ending on August 31, 2022, at which point the amount required pursuant to the Minimum Liquidity Covenant shall increase to \$5.0 million.

Any failure to comply with the terms, covenants and conditions of the credit agreement, as amended, including the Minimum Liquidity Covenant, may result in an event of default under such agreement, which could have a material adverse effect on our business, financial condition and results of operation, and could result in the filing of a voluntary or involuntary bankruptcy petition.

***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 and our ability to raise funding.***

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 July 6, 2022, 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 listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2), or "Rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were given 180 calendar days, or until January 2, 2023, to regain compliance with Rule 5550(a)(2). As of the date of this Quarterly Report on Form 10-Q, we were not in compliance with Rule 5550(a)(2).

There can be no assurance that we will be able to achieve and maintain compliance with Rule 555(a)(2) or the other Nasdaq listing requirements. If we do not achieve and maintain 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, except as set forth in a Form 8-K filed on May 18, 2022.

## **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**

<b>Exhibit No.</b>	<b>Description</b>	<b>Method of Filing</b>
4.1	<a href="#"><u>Form of Warrant, issued May 17, 2022.</u></a>	Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on May 18, 2022 (File No. 001-39101).
4.2	<a href="#"><u>Form of Placement Agent Warrant, issued May 17, 2022.</u></a>	Incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on May 18, 2022 (File No. 001-39101).
31.1	<a href="#"><u>Rule 13a-14(a)/15d-14(a) certification of Principal Executive Officer.</u></a>	Filed herewith.
31.2	<a href="#"><u>Rule 13a-14(a)/15d-14(a) certification of Principal Financial and Accounting Officer.</u></a>	Filed herewith.
32.1	<a href="#"><u>Section 1350 certification, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u></a>	Filed herewith.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	Filed herewith.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	Filed herewith.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	Filed herewith.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	Filed herewith.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	Filed herewith.
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).	Filed herewith.

**SIGNATURES**

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

**BAUDAX BIO, INC.**

Date: August 11, 2022

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

Date: August 11, 2022

By: /s/ Jillian Dilmore  
Jillian Dilmore  
Corporate Controller  
(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: August 11, 2022

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

---



## CERTIFICATION

I, Jillian Dilmore, 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: August 11, 2022

/s/ Jillian Dilmore  
Jillian Dilmore  
Corporate Controller  
(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 June 30, 2022, 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: August 11, 2022

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

/s/ Jillian Dilmore  
Jillian Dilmore  
Corporate Controller  
(Principal Financial and Accounting Officer)

---

