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

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2022

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to

Commission File Number 001-39101

Baudax Bio, Inc.

(Exact name of Registrant as specified in its charter)

Pennsylvania	**47-4639500**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
490 Lapp Road, Malvern, Pennsylvania	**19355**
(Address of principal executive offices)	**(Zip Code)**

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

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

Title of each class	Trading Symbol	Name of each exchange on which registered
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 if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

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

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

Large accelerated filer	☐	Accelerated filer	☐	Emerging growth company	☒
Non-accelerated filer	☒	Smaller reporting company	☒		

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 USC. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The Nasdaq Stock Market on June 30, 2022 was $6.8 million. The number of shares of Registrant's Common Stock outstanding as of February 21, 2023, was 2,585,702.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates certain information by reference from the Registrant's proxy statement for the 2023 annual meeting of shareholders to be filed no later than 120 days after the end of the Registrant's fiscal year ended December 31, 2022.

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FORWARD-LOOKING STATEMENTS

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

The forward-looking statements in this Annual Report on Form 10-K and the documents incorporated herein by reference 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 obtain regulatory approval for any 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 market, commercialize and achieve broad market acceptance for any of our product candidates once approved;
- our ability and that of our third-party manufacturers to successfully scale-up our clinical and commercial manufacturing process for future products;
- 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;
- 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's acute care business and transfer of such assets to us, or the Separation, 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 develop relationships with key commercial partners;
- our ability to defend any material litigation filed against us and avoid liabilities resulting from any material litigation;
- our ability to recruit or retain key scientific, technical, and management personnel or to retain our executive officers;
- our ability to raise future financing for continued development of our business 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 due to inflationary pressures, geopolitical tensions or the outbreak 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 alternative, 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, 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.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly under "Risk Factors," that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, collaborations or investments we may make.

You should read this Annual Report on Form 10-K and the documents that we incorporate by reference herein completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements.

Solely for convenience, tradenames referred to in this Annual Report on Form 10-K appear without the ® symbol, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these tradenames. All trademarks, service marks and tradenames included or incorporated by reference in this Annual Report on Form 10-K are the property of their respective owners, including, without limitation, the NanoCrystal® mark owned by Alkermes and/or its affiliates.

PART I

Item 1. Business

Overview

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

We hold exclusive global rights to two new molecular entities, which are centrally acting Neuromuscular Blocking Agents (NMBs), BX1000, an intermediate duration of action NMB currently undergoing a Phase II clinical trial, and BX2000, an ultra-short acting NMB currently undergoing a Phase I clinical trial, as well as a proprietary blockade reversal agent, BX3000, currently being evaluated in preclinical studies intended to support an IND filing in 2023. BX3000 is an agent that is expected to rapidly reverse BX1000 and BX2000 blockade. All three agents are licensed from Cornell University. We believe these agents, when administered in succession, will allow for a rapid onset of centrally acting neuromuscular blockade, followed by a rapid reversal of the neuromuscular blockade with BX3000. These novel agents have the potential to meaningfully reduce time to onset of blocking and of reversal of blockade, reducing time in operating rooms or post operative suites (PACU), resulting in potential clinical and cost advantages, as well as valuable cost savings for hospitals and ambulatory surgical centers.

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 could be administered alone or in combination with other non-NSAID analgesics. We 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's clinical safety and efficacy along with its positive health economic impacts in specific surgical settings. As many sources have documented, many hospitals have suffered great economic impacts associated with the Covid-19 pandemic and with its continuing impact on surgery rates, as well as the impacts of the “Great Resignation” of 2021 and beyond, impacting nursing and other professional staff available to support surgery and post operative care. We believe these market conditions and the ensuing economic hardship that threatens the functioning of numerous well known and highly regarded institutions have impacted the willingness and ability of acute care facilities to use agents that may cost slightly more than available opioid treatments to manage post operative pain, even when these less expensive treatments may prolong hospital stay. These factors influenced the uptake of ANJESO and a number of other non-opioid treatments. The expense of maintaining a commercial presence in an acute care setting that is distressed, as well as maintaining milestone payments due to our licensor during the present and upcoming years caused us to discontinue commercial sales of ANJESO in December of 2022.

Our 2022 costs have consisted primarily of expenses incurred in conducting our manufacturing and commercialization of ANJESO, public company and personnel costs, as well as clinical trials and manufacturing costs for our NMB blocking and reversal agents. 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 development programs, including our clinical, preclinical and manufacturing related activities. Our expenses over the next several years are expected to primarily relate to developing our 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.

Products and Pipeline

Product / Compound	Pre-Clinical	Phase I	Phase II	Phase III	Marketed	Rights
NEUROMUSCULAR BLOCKING AGENTS (NMBs)						World Wide
IV Intermediate-action (BX1000)						
IV Ultra-short action (BX2000)						
NMB REVERSAL (ANESTHESIA)						World Wide
BX3000						

Our Strategy

We believe that we can bring valuable therapeutic options for patients, prescribers and payers to the hospital and acute care markets. We believe we can create value for our shareholders through the development, and potential approval and commercialization of our NMB and NMB reversal agents, as well as any other pipeline product candidates we develop. In addition to our pipeline, we continue to evaluate acquisition and in-licensing opportunities, especially those that can contribute revenue and cash flow.

Our near-term goals include:

•*Leveraging our development experience to progress our NMB blockade and reversal product candidates.* Our clinical stage product pipeline includes proprietary NMB blockade product candidates for use in anesthesia, BX1000 and BX2000, as well as an NMB reversal agent currently in preclinical studies, BX3000. We believe the concurrent development of a blocking agents and reversal agent used safely in the same patient, once certain stand alone and initial combination information is available, will allow our programs to provide clinical, financial, and temporal advantages to patients. We believe such programs can also proceed in a cost effective manner. Our overall goal is to leverage our drug development expertise to safely develop these product candidates for effective use in hospital and acute care settings.

•*Further characterize commercial opportunity for the NMB related franchise with additional market studies with more data from clinical trials to add to the target product profile(s).*

•*Pursuing the license or acquisition of additional products and product candidates.* We are seeking in-license or acquisition opportunities to add commercial or near-commercial products and product candidates to our portfolio. We have the experience of establishing reimbursement and other functions for the commercialization of a product in the United States and we believe we can utilize this infrastructure for the successful commercialization of acquired assets or licensed products.

Our Pipeline Candidates

Our pipeline includes clinical and early-stage product candidates, including the NMB and Reversal agents that we are developing for use in hospital and related settings.

NMBs

Neuromuscular blocking agents are used as muscle paralyzing agents to facilitate intubation and provide skeletal muscle relaxation during surgery or mechanical ventilation. We are developing an intermediate-acting NMB, BX1000, an ultra- short acting NMB, BX2000, and a reversal agent specific to our NMBs, BX3000. The table below summarizes the predicted onset and duration of activity for each NMB based on currently available data, as well as the development status of each NMB:

Compound	Onset Time	Duration of Activity	Status
BX1000	Rapid	Intermediate acting	Phase II expected to be completed in 2023
BX2000	Rapid	Ultra-short acting	Phase I dose escalation expected to be completed in 2023
BX3000	Rapid	Blockade reversal agent	IND filing expected in 2023

In animal models, the proprietary reversal agent acts quickly by chemical reaction to reverse the neuromuscular blockade. We believe that the NMBs can reduce the time required for induction of anesthesia and the reversal agent can reduce the time needed to recover from a NMB dosing post-procedure, while potentially enhancing patient safety and resulting in cost savings for the hospital or other provider.

We have a worldwide, exclusive license to the NMBs and the related reversal agent from Cornell University.

BX1000

We completed a Phase I study in 2021 for BX1000 which evaluated its safety profile when administered with Total Intravenous Anesthesia, as well as the dose response of neuromuscular blockade. We completed a dose-escalation study evaluating BX1000 in a total of 58 healthy volunteers who had already undergone endotracheal intubation while under general anesthesia. After intubation, subjects received a single IV bolus dose of BX1000 and were monitored for neuromuscular blockade and for any changes in vital signs or the presence of adverse events. BX1000 dose-escalations were continued until prespecified effects were observed. Doses of BX1000, up to 0.4 mg/kg, were well tolerated in this study of healthy volunteer subjects. Muscle paralysis was rapidly achieved along with complete spontaneous recovery. Neuromuscular blocking parameters were observed to increase in depth and duration of blockade while the time to onset of blockade was reduced with increasing doses of BX1000. Pharmacokinetic exposures increased with increasing study

doses while elimination of the study compound remained rapid. Evaluation of electrocardiogram data using concentration-QTc modeling did not identify a risk of QTc prolongation within the studied dosing range. We engaged with the FDA regarding the design for the Phase II study in patients undergoing elective hernia and similar abdominal surgical procedures utilizing total intravenous anesthesia, in the fall of 2022, and initiated enrollment in the study in the fourth quarter of 2022. In January 2023, we announced the positive outcome of the interim analysis of the randomized, double blind, active controlled clinical Phase II trial, which compared three doses of BX1000 to a standard dose of rocuronium. The interim analysis was performed without breaking the study blind and was based on the first 20 of the 80 total patients being enrolled to the 4 study arms. The primary efficacy endpoint was the proportion of patients meeting criteria for Good or Excellent intubating conditions using a standardized scale. Additionally, the study is evaluating the safety and tolerability of BX1000 as compared to rocuronium in this patient population. We expect the Phase II study to be complete by the first half of 2023.

The pre-planned interim analysis evaluated intubating conditions for each patient after administration of study drug in a blinded fashion. In the 20 patient cohort, 5 patients per group received one of the study medications. All 20 patients were observed to have met the criteria for Good or Excellent intubating conditions at 60 seconds. Nineteen of the patients were successfully intubated at 60 seconds, with one remaining patient successfully intubated following the assessment at 90 seconds. Study treatments were generally well tolerated with no occurrence of severe or serious adverse events. The blinded interim analysis did not result in the decision to drop any of the four study groups nor any decision to adjust planned study enrollment numbers.

BX2000

We filed an IND for BX2000 in 2020 in order to conduct a first-in-human clinical trial. We conducted an additional toxicology study requested by the FDA in 2021 and in March 2022, FDA notified us that we could proceed with initiation of a first in human, Phase I dose-escalation study in healthy volunteers.

In June of 2022, we announced the completion of dosing of the first cohort of the Phase I dose escalation study for BX2000, which we believe to be a rapid onset, ultra-short acting NMB agent, in healthy volunteers. The study is investigating single, ascending doses of BX2000 administered in a single, intravenous bolus injection compared to placebo. The study is comprised of up to 10 dosing cohorts and each cohort will enroll 8 patients. The study will evaluate the effect of BX2000 on safety, including heart rate, blood pressure, corrected QT interval, pharmacokinetics, and the time course of the neuromuscular blocking profile. Subjects will be monitored at an inpatient facility for 24 hours following administration of BX2000. There are also follow up visits on Day 8 and additional follow ups will take place approximately 2 and 4 weeks after dosing to evaluate the continued safety of study participants.

Enrollment began in the second quarter of 2022 and cohort 2 completed, as planned, in the fourth quarter of 2022. Enrollment in cohort 3 was underway in January 2023 and despite the challenges of enrollment to this type of protocol, we remain optimistic that we will be close to reaching maximum dosage by late 2023 to mid-2024.

BX3000

BX3000 is a small molecule that was designed to induce chemical cleaving of BX1000 and BX2000, resulting in the rapid inactivation of those molecules and thus quickly reversing neuromuscular blockade. We are currently engaged with the pre-clinical toxicity studies needed to support an IND for BX3000 in the summer of 2023. We expect to begin the clinical program for BX3000 in 2023.

Intellectual Property

We license the patents and other intellectual property covering the NMBs and the related reversal agent and related methods of use under a worldwide, exclusive, sublicensable, royalty-bearing license from Cornell. We exclusively license issued patents in the U.S. and other major foreign markets directed to BX1000 that expire in 2027, subject to any applicable extension, along with a pending PCT application directed to certain methods of using BX1000 that, if issued, would expire in 2041, subject to any applicable disclaimer or extension. We exclusively license issued patents in the U.S. and other major foreign markets directed to BX2000 that expire in 2033, subject to any applicable extension, along with a pending PCT application directed to certain methods of using BX-2000 that, if issued, would expire in 2041, subject to any applicable disclaimer or extension. Under the license agreement, we are obligated to pay Cornell (i) an annual license maintenance fee payment which ranges from $15,000 to $125,000 until the first commercial sale of a licensed compound; (ii) milestone payments upon the achievement of certain milestones, up to a maximum, for each NMB, of $5 million for U.S. regulatory approval and commercialization milestones and $3 million for European regulatory approval and commercialization milestones; and (iii) royalties on net sales of the NMBs and the related reversal agent at rates ranging from low to mid-single digits, depending on the applicable licensed compound and whether there is a valid patent claim in the applicable country, subject to an annual minimum royalty amount of $150,000 to $250,000 that increases to between $150,000 to $500,000 after the fourth year of sales. In addition, we will reimburse Cornell for past and ongoing patent costs related to prosecution and maintenance of the patents related to the licensed compounds. The license agreement is terminable by us at any time upon 90 days' written notice and by Cornell upon our material breach, subject to a cure period, and upon our filing any claim asserting the invalidity of any of Cornell's licensed patent rights. The royalty term for each licensed compound expires, on a country-by-country basis, on the later of (i) the expiration date of the longest-lived licensed patent, (ii) the expiration of any granted statutory period of marketing exclusivity, or (iii) the first commercial sale of a generic equivalent of the applicable licensed compound. On the last to expire royalty term the license agreement will automatically convert to a royalty-free nonexclusive license.

We own patents and patent applications directed to the analgesia indication, formulations and intranasal methods of use of dexmedetomidine, or Dex, in the United States and certain major foreign markets. Several patents have issued outside the United States for transmucosal methods, and the resulting patent protection will last into 2030, subject to any disclaimers or extensions. In addition, patents related to intranasal methods has issued in the United States and certain major foreign markets, and the resulting patent protection will last into 2032, subject to any disclaimers or extensions.

We own patents and patent applications for injectable meloxicam, that cover pharmaceutical compositions, including compositions produced using NanoCrystal® technology, method of making injectable meloxicam and method of treating pain with injectable meloxicam. These issued patents expire between 2024 and 2039 in the United States, and the pending applications, if issued, would expire between 2030 and 2039. We also exclusively license from Alkermes, on a perpetual, royalty-free basis, composition and methods of making patents, and patent applications directed to the prevention of flake like aggregates to manufacture and commercialize IV, intramuscular or parenteral meloxicam, which begin to expire in 2030.

We intend to rely on a combination of patents and trade secrets, as well as confidentiality agreements and license agreements, to protect our product candidates. Our patent strategy is designed to facilitate commercialization of our current product candidates and future product candidates, as well as create barriers to entry for third parties. One focus of our claim strategy is on formulation claims and other related claims.

We are seeking patent protection in the United States and internationally for our product candidates. Our policy is to pursue, maintain and defend patent rights and to protect the technology, inventions and improvements that are commercially important to the development of our business. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents granted to us in the future will be commercially useful in protecting our technology. We also intend to rely on trade secrets to protect our product candidates. Our commercial success also depends in part on our non-infringement of the patents or proprietary rights of third parties.

Our success will depend significantly on our ability to:

- obtain and maintain patent and other proprietary protection for our product candidates;
- defend our patents;
- develop trade secrets as needed and preserve the confidentiality of our trade secrets; and
- operate our business without infringing the patents and proprietary rights of third parties.

We have taken steps to build and will continue to build proprietary positions for our product candidates and related technology in the United States and abroad. We note that the patent laws of foreign countries differ from those in the United States, and the degree of protection afforded by foreign patents may be different from the protection offered by United States patents.

Competition

If approved, we believe BX1000 and BX2000 would be competing with succinylcholine or related agent products used as NMBs. These agents were introduced in the 1950s, and while it relaxes and then paralyzes muscles, it causes a type of muscle contraction called

fasciculations before the paralysis stage, which is undesirable. This class of compounds is called depolarizing agents because they mimic the effect of acetylcholine at the nerve junction. Succinylcholine is currently still in use but has been replaced by newer, non-depolarizing agents that do not cause fasciculations and are not associated with malignant hyperthermia or hyperkalemia (elevated potassium levels). Some literature sources report that succinylcholine still accounts for about 25% of instances of use of NMB agents.

An additional category of NMBs that is reported to be widely used is rocuronium bromate, which is also multisource (generic), and was introduced in 1994. It has a rapid onset of action, although not as quick as succinylcholine, and an intermediate duration of action. While these agents do not cause muscle fasciculations, they have been associated with some risk of allergic reactions and anaphylaxis in high-risk patients such as those with asthma. This class of agents, which includes other compounds like rocuronium, is called non-depolarizing and they work by competitive blockade of the neuromuscular junction.

These NMBs, and related analogs, account for the vast majority of neuromuscular blockade agents used in the US and elsewhere.

Reversal agents are drugs given to shorten the period of paralysis, or neuromuscular blockade, and return muscle function to normal. The two most commonly used are neostigmine and sugammadex (Merck's Bridion®).

Manufacturing

We currently rely on contract manufacturers located in Europe to produce drug product for our clinical studies with respect to our product candidates. These contract manufacturers produce drug product under current Good Manufacturing Practices, or cGMP, with oversight by our internal managers. We have identified other potential drug product manufacturers that could satisfy our clinical and commercial requirements, but this would require significant expense and could produce a significant delay in setting up the facility and moving equipment.

Government Regulation

Governmental authorities in the United States at the federal, state and local level, and the equivalent regulatory authorities in other countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, export and import of products such as those we are developing. Our product candidates must be approved by the FDA before they may legally be marketed in the United States. In addition, to the extent we choose to clinically evaluate or market any products in other countries or develop these products for future licensing to third parties, we are subject to a variety of regulatory requirements and to the authority of the competent regulatory authorities of those other countries.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the FDCA, and implementing regulations. The process of obtaining regulatory approvals and ensuring compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process, or after approval, may subject an applicant to administrative enforcement or judicial sanctions. This enforcement could include, without limitation, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, corrective actions, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies, some of which must be conducted according to Good Laboratory Practices regulations;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to the FDA's Good Clinical Practices, or GCPs, to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA for a new drug;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities identified in the NDA;
- review and approval of proposed proprietary name; and
- FDA review and approval of the NDA.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

Once a pharmaceutical product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND. The sponsor must also include a protocol detailing, among other things, the objectives of the initial clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated if the initial clinical trial lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during trials due to safety concerns regarding the product candidate or non-compliance with applicable requirements.

All clinical trials of a product candidate must be conducted under the supervision of one or more qualified investigators, in accordance with GCP regulations. These regulations include the requirement that all research subjects provide informed consent. Further, an IRB must review and approve the plan for any clinical trial before it commences at any institution. The IRB's role is to protect the rights and welfare of human subjects involved in clinical studies by evaluating, among other things, the potential risks and benefits to subjects, processes for obtaining informed consent, monitoring of data to ensure subject safety, and provisions to protect the subjects' privacy. The IRB approves the information regarding the clinical trial and the consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

Once an IND is in effect, each new clinical protocol, and any amendments to the protocol, must be submitted to the IND for FDA review and to the IRBs for approval. Protocols detail, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase I. The product is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing may be conducted in patients.
- Phase II. Phase II trials involve investigations in a limited patient population to identify possible AEs and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted indications and to determine dosage tolerance and optimal dosage and schedule.
- Phase III. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for regulatory approval and product labeling.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA, and safety reports must be submitted to the FDA and the investigators for serious and unexpected side effects. Phase I, Phase II and Phase III testing may not be completed successfully within any specified period, if at all. Results from earlier trials are not necessarily predictive of results from later trials. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the drug, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA for a new drug, requesting approval to market the product.

The submission of an NDA generally is subject to the payment of a substantial user fee for a human drug application.

In addition, under the Pediatric Research Equity Act of 2003, an NDA or supplement to an NDA for a new indication, dosage form, dosing regimen, route of administration, or active ingredient, must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may waive or defer pediatric studies under certain circumstances.

Section 505(b)(2) New Drug Applications. As an alternate path to FDA approval, particularly for modifications to drug products previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA, or a Section 505(b)(2) NDA. Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments, and it permits approval of applications other than those for duplicate products and permits reliance for such approvals on literature or on the FDA's findings of safety and effectiveness of an approved drug product. A Section 505(b)(2) NDA is an application where at least some of the information required for approval comes from clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The FDA requires submission of information needed to support any changes relative to a previously approved drug, known as the reference product, such as published data or new studies conducted by the applicant, including bioavailability or bioequivalence studies, or clinical trials demonstrating safety and effectiveness. The FDA may then approve the Section 505(b)(2) NDA for all or some of the labeled indications for which the reference product has been approved, as well as for any new indication sought by the applicant, unless such indications or uses are protected by patent or exclusivity provisions covering the reference product. To the extent that a Section 505(b)(2) NDA relies on clinical trials conducted for a previously approved drug product or the FDA's prior findings of safety and effectiveness for a previously approved drug product, the Section 505(b)(2) applicant must submit patent certifications in its application with respect to any patents for the reference product that are listed in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the Orange Book. Specifically, the applicant must certify for each listed patent that, in relevant part, (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired but will expire on a particular date and approval is not sought until after patent expiration; or (4) the listed patent is invalid, unenforceable or will not be infringed by the proposed new product. A certification that the new product will not infringe the previously approved product's listed patent or that such patent is invalid or unenforceable is known as a Paragraph IV certification. If the applicant does not challenge one or more listed patents through a Paragraph IV certification, the FDA will not approve the Section 505(b)(2) NDA until all the listed patents claiming the referenced product have expired.

Further, the FDA will also not approve a Section 505(b)(2) NDA until any non-patent exclusivity, such as, for example, five-year exclusivity for obtaining approval of a new chemical entity, three-year exclusivity for an approval based on new clinical trials, or pediatric exclusivity, listed in the Orange Book for the reference product, has expired.

If the Section 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the owner of the reference product and relevant patent holders within 20 days after the Section 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement suit against the Section 505(b)(2) applicant. Under the FDCA, the filing of a patent infringement lawsuit within 45 days of receipt of the notification regarding a Paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA for 30 months, beginning on the date the patent holder receives notice, or until the patent expires or a court deems the patent unenforceable, invalid or not infringed, whichever is earlier. Even if a patent infringement claim is not brought within the 45-day period, a patent infringement claim may be brought under traditional patent law, but it does not invoke the 30-month stay. Moreover, in cases where a Section 505(b)(2) application containing a Paragraph IV certification is submitted after the fourth year of a previously approved drug's five-year exclusivity period, and the patent holder brings suit within 45 days of notice of certification, the 30-month period is automatically extended to prevent approval of the Section 505(b)(2) application until the date that is seven and one-half years after approval of the previously approved reference product. The court also has the ability to shorten or lengthen either the 30-month or the seven and one-half year period if either party is found not to be reasonably cooperating in expediting the litigation. Thus, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its product only to be subject to significant delay and patent litigation before its product may be commercialized. Alternatively, if the NDA applicant or relevant patent holder does not file a patent infringement lawsuit within the specified 45-day period, the FDA may approve the Section 505(b)(2) application at any time, assuming the application is otherwise approvable.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, some pharmaceutical companies and other stakeholders have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505(b)(2) NDA that we submit.

FDA Review of New Drug Applications. The FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. If the FDA does not find an NDA to be sufficiently complete for filing, it may request additional information rather than accepting the NDA for filing. In this event, the sponsor must resubmit the NDA with the additional information. The re-submitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether clinical data demonstrates that a product is safe and effective for its intended use and whether its manufacturing process can assure the product's identity, strength, quality and purity. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. An advisory committee is a panel of independent experts who provide advice and recommendations when requested by the FDA. The FDA is not bound by the recommendation of an advisory committee.

The approval process is lengthy and difficult, and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA will issue a complete response letter, or CRL, if the agency decides not to approve the NDA in its present form. The CRL usually describes all the specific deficiencies that the FDA identified in the NDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the CRL may include recommended actions that the applicant might take to place the application in a condition for approval. If a CRL is issued, the applicant may either resubmit the NDA, addressing all the deficiencies identified in the letter, withdraw the application or request an opportunity for a hearing.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages, or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling, and the agency also may require a REMS if it determines that a REMS is necessary to assure that the benefits of a drug outweigh its risks. In addition, the FDA may require Phase IV testing, which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA approval, and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specific circumstances of FDA marketing approval of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. Subject to certain limitations, the patent term restoration period is generally equal to one-half of the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. However, each phase of the regulatory review period may be reduced by any time that the FDA finds the applicant did act not act with due diligence. Only one patent applicable to an approved drug is eligible for the extension, it must be the first approval of the active ingredient of the product, and the application for the extension must be submitted prior to the expiration of the patent and within sixty days of approval of the drug. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for patents that issue from some of our currently owned or licensed patents or patent applications to add patent life beyond their current expiration dates, depending on the expected length of the clinical trials, the eligibility of the product and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to NDAs for products containing chemical entities never previously approved by the FDA alone or in combination. A new chemical entity means a drug that contains no active moiety that has been approved by the FDA in any application submitted under Section 505(b) of the FDCA. An active moiety is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA, or a Section 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. This exclusivity provision does not prevent the submission or approval of another full Section 505(b)(1) NDA, but such an NDA applicant would be required to conduct its own preclinical and adequate, well-controlled clinical trials to demonstrate safety and effectiveness. The FDCA also provides three years of marketing exclusivity for an NDA, Section 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. Such clinical trials may, for example, support new indications, dosages, routes of administration or strengths of an existing drug, or for a new use. This exclusivity, which is sometimes referred to as clinical investigation exclusivity, prevents the FDA from approving an application under a Section 505(b)(2) NDA or an ANDA for the same conditions of use associated with the new clinical investigations before the expiration of three years from the date of approval. Such three-year exclusivity, however, would not prevent the approval of another application if the applicant submits a Section 505(b)(1) NDA and has conducted its own adequate, well-controlled clinical trials demonstrating safety and efficacy, nor would it prevent approval of an ANDA or a Section 505(b)(2) NDA product that did not incorporate the exclusivity-protected aspects of the approved drug product.

Pediatric exclusivity is another type of exclusivity in the United States. Pediatric exclusivity, if granted, provides an additional six months of exclusivity to any existing exclusivity (*e.g*., three- or five-year exclusivity) or patent protection for a drug. This six-month exclusivity, which runs from the end of other exclusivity or patent protection, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product or a method of using the product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA or an application covered by Section 505(b)(2) of the FDCA. An ANDA provides for marketing of a drug product that has the same active ingredients, generally in the same strengths and dosage form, as the listed drug and has been shown through pharmacokinetic, or PK, testing to be bioequivalent to the listed drug. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are generally not required to conduct, or submit results of, preclinical studies or clinical tests to prove the safety or effectiveness of their drug product. Section 505(b)(2) applications provide for marketing of a drug product that may have the same active ingredients as the listed drug and contains full safety and effectiveness data as an NDA, but at least some of this information comes from studies not conducted by or for the applicant. This alternate regulatory pathway enables the applicant to rely, in part, on the FDA's findings of safety and efficacy for an existing product, or published literature, in support of its application. The FDA may then approve the new drug candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

The ANDA or Section 505(b)(2) applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA or Section 505(b)(2) applicant may also elect to submit a statement certifying that its proposed ANDA label does not contain, or carves out, any language regarding a patented method of use rather than certify to such listed method of use patent. If the applicant does not challenge the listed patents by filing a certification that the listed patent is invalid or will not be infringed by the new product, the ANDA or Section 505(b)(2) application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA or Section 505(b)(2) applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA or Section 505(b)(2) application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or Section 505(b)(2) application until the earliest of 30 months, expiration of the patent, settlement of the lawsuit, and a decision in the infringement case that is favorable to the ANDA or Section 505(b)(2) applicant. This prohibition is generally referred to as the 30-month stay. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.

The ANDA or Section 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Post-Approval Requirements

Any drugs for which we receive FDA approval will be subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other government agencies enforce the laws and regulations prohibiting the false or misleading promotion of drugs. The FDA also limits the promotion of product candidates prior to their approval. With limited exceptions, pre-approval promotion is prohibited under the FDA's regulations.

Further, manufacturers of drugs must continue to comply with cGMP requirements, which are extensive and require considerable time, resources and ongoing investment to ensure compliance. In addition, changes to the manufacturing process may require prior FDA approval before being implemented, and other types of changes to the approved product, such as adding new indications and additional labeling claims, are subject to further FDA review and approval. Drug manufacturers and other entities involved in the manufacturing and distribution of approved drugs, and those supplying products, ingredients, and components of them, are required to list their products and to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, applicable product tracking and tracing requirements, and other laws. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the drug. Manufacturers must establish validated systems to ensure that products meet specifications and regulatory standards and test each product batch or lot prior to its release. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our product candidates. FDA and state inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution or may require substantial resources to correct.

The FDA may withdraw a product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Further, the failure to maintain compliance with regulatory requirements may result in administrative or judicial actions, such as fines, untitled and warning letters, holds on clinical trials, product recalls or seizures, product detention or refusal to permit the import or export of products, refusal to approve pending applications or supplements, restrictions on marketing or manufacturing, consent decrees, injunctions or the imposition of civil or criminal penalties.

From time to time, legislation is drafted, introduced and passed in the U.S. Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, the FDA regulations and policies are often revised or reinterpreted by the agency in ways that may significantly affect our business and our product candidates. It is impossible to predict whether further legislative or FDA regulation or policy changes will be enacted or implemented and what the impact of such changes, if any, may be.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials of our product candidates and commercial sales and distribution of any product for which we obtain regulatory approval outside of the United States. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. As in the United States, post-approval regulatory requirements, such as those regarding product manufacture, marketing or distribution, would apply to any product that is approved outside the United States.

For example, in the European Union, we may submit applications for marketing authorizations either under a centralized, decentralized, or mutual recognition marketing authorization procedure. The centralized procedure provides for the grant of a single marketing authorization for a medicinal product by the European Commission on the basis of a positive opinion by the European Medicines Agency, or the EMA. A centralized marketing authorization is valid for all European Union member states and three of the four European Free Trade Association, or EFTA, States (Iceland, Liechtenstein and Norway). The decentralized procedure and the mutual recognition procedure apply between European Union member states. The decentralized marketing authorization procedure involves the submission of an application for marketing authorization to the competent authority of all European Union member states in which the product is to be marketed. One national competent authority, selected by the applicant, assesses the application for marketing authorization. The competent authorities of the other European Union member states are subsequently required to grant marketing authorization for their territory on the basis of this assessment, except where grounds of potential serious risk to public health require this authorization to be refused. The mutual recognition procedure provides for mutual recognition of marketing authorizations delivered by the national competent authorities of European Union member states by the competent authorities of other European Union member states. The holder of a national marketing authorization may submit an application to the competent authority of a European Union member state requesting that this authority recognize the marketing authorization delivered by the competent authority of another European Union member state for the same medicinal product.

We are also subject to the U.K. Bribery Act, and other third country anti-corruption laws and regulations pertaining to our financial relationships with foreign government officials. The U.K. Bribery Act, which applies to any company incorporated or doing business in the UK, prohibits giving, offering, or promising bribes in the public and private sectors, bribing a foreign public official or private person, and failing to have adequate procedures to prevent bribery amongst employees and other agents. Penalties under the Bribery Act include potentially unlimited fines for companies and criminal sanctions for corporate officers under certain circumstances. Liability in relation to breaches of the U.K. Bribery Act is strict. This means that it is not necessary to demonstrate elements of a corrupt state of mind. However, a defense of having in place adequate procedures designed to prevent bribery is available.

Formulary Approvals and Third-Party Payer Coverage and Reimbursement

In both the United States and foreign markets, our ability to successfully commercialize our product candidates for which we receive regulatory approval, and to attract commercialization partners for our product candidates, depends in significant part on the availability of institutional formulary approvals and on adequate financial coverage and reimbursement from third-party payers, including, in the United States. These payers include CMS, the federal program that runs the Medicare program, and monitors the Medicaid programs offered by each state, as well as national and regional commercial plans. Medicare is a federally funded program managed by CMS through local Medicare Administrative Contractors that administer coverage and reimbursement for certain healthcare items and services furnished to the elderly, disabled and other individuals with certain conditions. Medicaid is an insurance program for certain categories of patients whose income and assets fall below state defined levels that is both federally and state funded and managed by each state. The federal government sets general guidelines for Medicaid and each state creates specific regulations that govern its individual program. Each government or commercial plan has its own process and standards for determining whether it will cover and reimburse a procedure or particular product and how much it will pay for that procedure or product. Commercial plans often rely on the lead of the governmental payers in rendering coverage and reimbursement determinations. Therefore, achieving favorable Medicare coverage and reimbursement is usually an essential component of successfully launching a new product. The competitive position of some of our products will depend, in part, upon the extent of coverage and adequate reimbursement for such products and for the procedures in which such products are used. Reimbursement can be subject to challenge, reduction or denial by government and other commercial plans.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government healthcare programs and other third-party payers are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy, and have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payers are challenging the prices charged for medical products and requiring that drug companies provide them with predetermined discounts from list prices.

The Inflation Reduction Act of 2022 (the "IRA") contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the IRA. The IRA could have the effect of reducing the prices we can charge and reimbursement we receive for our products, if approved, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results of operations, and growth prospects. The effects of the IRA on our business and the pharmaceutical industry in general is not yet known.

Payers also are increasingly changing the metrics for reimbursement rates, such as basing payment on average sales price, or ASP, AMP, and wholesale acquisition cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. CMS surveys and publishes retail community pharmacy acquisition cost information in the form of National Average Drug Acquisition Cost files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates. It may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payers to cover any products.

If we successfully commercialize any of our products, we may participate in the Medicaid Drug Rebate Program. Participation is required for federal funds to be available for our products under Medicaid and Medicare Part B. Under the Medicaid Drug Rebate Program, we would be required to pay a quarterly rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and Part B of the Medicare program.

Federal law requires that any company that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B drug pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients.

Additionally, in order to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, a manufacturer also must participate in the Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program, established by Section 603 of the Veterans Health Care Act of 1992, or VHCA. Under this program, the manufacturer is obligated to make its innovator and single source products available for procurement on an FSS contract and charge a price to four federal agencies, Department of Veterans Affairs, Department of Defense, or DoD, Public Health Service, and Coast Guard, that is no higher than the statutory Federal Ceiling Price. Moreover, pursuant to regulations issued by the DoD's TRICARE Management Activity, now the Defense Health Agency, to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008, manufacturers are required to provide rebates on utilization of their innovator and single source products that are dispensed to TRICARE beneficiaries by TRICARE network retail pharmacies. The formula for determining the rebate is established in the regulations and is based on the difference between the annual non-federal average manufacturer price and the Federal Ceiling Price (these price points are required to be calculated by us under the VHCA). The requirements under the 340B, FSS, and TRICARE programs could reduce the revenue we may generate from any products that are commercialized in the future.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers costs, including research, development, manufacturing, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover costs and may only be temporary. Reimbursement rates vary according to the use of the drug and the clinical setting in which it is used. Product reimbursement may also be incorporated into existing bundled payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or commercial payers and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Limited coverage may impact the demand for, or the price of, any product candidate for which marketing approval is obtained. Third-party payers also may seek additional clinical evidence, including expensive pharmacoeconomic studies, beyond the data required to obtain marketing approval, demonstrating clinical benefits and value in specific patient populations, before covering our products for those patients. If reimbursement is available only for limited indications, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and commercial payers for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

United States Healthcare Reform

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system, including implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs.

In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the Affordable Care Act, was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry, and impose additional health policy reforms.

Among the provisions of the Affordable Care Act that have been implemented since enactment and are of importance to the commercialization of our product and product candidates, if approved, are the following:

- an annual, nondeductible fee on any entity that manufactures, or imports specified branded prescription drugs or biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the U.S. civil False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- requirements to report certain financial arrangements with physicians and teaching hospitals;
- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There have been significant ongoing judicial, administrative, executive and legislative efforts to modify or eliminate the Affordable Care Act. For example, the Tax Act enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code, commonly referred to as the individual mandate. Other legislative changes have been proposed and adopted since passage of the Affordable Care Act. The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of an amount greater than $1.2 trillion for the fiscal years 2012 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions included aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, which went into effect in April 2013. Subsequent litigation extended the 2% reduction, on average, to 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief and Economic Security Act, or the CARES Act, which was designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 to March 31, 2022. From April through June 2022, a 1% reduction was in effect. As of July 2, 2022, the 2% cut resumed. The sequester will remain in place through 2030. On January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

The Affordable Care Act has also been subject to challenges in the courts. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional and remanded the case to the Texas District Court to reconsider its earlier invalidation of the entire Affordable Care Act. An appeal was taken to the U.S. Supreme Court. On June 17, 2021, the Supreme Court ruled that the plaintiffs lacked standing to challenge the law as they had not alleged personal injury traceable to the allegedly unlawful conduct. As a result, the Supreme Court did not rule on the constitutionality of the ACA or any of its provisions.

Further changes to and under the Affordable Care Act remain possible but it is unknown what form any such changes or any law proposed to replace or revise the Affordable Care Act would take, and how or whether it may affect our business in the future. We expect that changes to the Affordable Care Act, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug prices and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry. We also expect that the Affordable Care Act, as well as other healthcare reform measures that have and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for our product and product candidates, if approved. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payers.

Other Healthcare Laws and Compliance Requirements

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our activities will be subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil False Claims Act, and laws and regulations pertaining to limitations on and reporting of healthcare provider payments (physician sunshine laws). These laws and regulations are interpreted and enforced by various federal, state and local authorities including CMS, the Office of Inspector General for the U.S. Department of Health and Human Services, the U.S. Department of Justice, individual U.S. Attorney offices within the Department of Justice, and state and local governments. These laws include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, or arranging for or recommending the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. civil False Claims Act (which can be enforced through "qui tam," or whistleblower actions, by private citizens on behalf of the federal government), prohibits any person from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the U.S. federal government;
- U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal liability and amends provisions on the reporting, investigating, enforcement, and penalizing of civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for healthcare benefits, items or services by a healthcare benefit program, which includes both government and privately funded benefits programs; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- state laws and regulations, including state anti-kickback and false claims laws, that may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payer, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and
- the Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS information related to certain payments made in the preceding calendar year and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; beginning in 2022, applicable manufacturers were required to report such information regarding payments and transfers of value provided, as well as ownership and investment interests held, during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives.

Violations of any of these laws or any other governmental regulations that may apply to us, may subject us to significant civil, criminal and administrative sanctions including penalties, damages, fines, imprisonment, and exclusion from government funded healthcare programs, such as Medicare and Medicaid, and/or adverse publicity.

Moreover, government entities and private litigants have asserted claims under state consumer protection statutes against pharmaceutical and medical device companies for alleged false or misleading statements in connection with the marketing, promotion and/or sale of pharmaceutical and medical device products, including state investigations and litigation by certain government entities regarding the marketing of opioid products.

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or the FCPA, generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our industry is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently, the SEC and Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. Violations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business.

Facilities

Our principal executive offices are located at 490 Lapp Road, Malvern, PA 19355, where we occupy approximately 17,369 square feet of leased laboratory and office space pursuant to an eleven-year lease, which expires on December 31, 2027. We also lease a 4,145 square foot office space in Dublin, Ireland pursuant to a short-term lease.

Corporate Information

We were incorporated under the laws of the Commonwealth of Pennsylvania in September 2019. Our principal executive offices are located at 490 Lapp Road, Malvern, PA 19355, and our telephone number is (484) 395-2440.

Human Capital Resources

In order to achieve the goals and expectations of our Company, it is crucial that we continue to attract and retain top talent. To facilitate talent attraction and retention, we strive to make Baudax Bio a safe and rewarding workplace, with opportunities for our employees to grow and develop in their careers, supported by strong compensation, benefits and health and wellness programs, and by programs that build connections between our employees.

We have implemented COVID-19 policies at our corporate office designed to ensure the safety and well-being of all employees and continue to adapt such policies in connection with evolving local and federal government regulations. We implemented additional safety measures for employees continuing critical on-site work. To reduce risk and promote the safety of our workplace, all of our employees have been encouraged to receive COVID-19 vaccinations and boosters.

As of December 31, 2022, we had 9 full-time employees, of which 1 holds a Pharm.D. None of our employees are represented by a collective bargaining agreement. We believe that we have a good relationship with our employees.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase shareholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Available Information

Our website address is www.baudaxbio.com. Our Annual Report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, any amendments to those reports, proxy and registration statements filed or furnished with the Securities and Exchange Commission, or SEC, are available free of charge through our website. We make these materials available through our website as soon as reasonably practicable after we electronically file such materials with, or furnish such materials to, the SEC. The reports filed with the SEC by our executive officers and directors pursuant to Section 16 under the Exchange Act are also made available, free of charge on our website, as soon as reasonably practicable after copies of those filings are provided to us by those persons. These materials can be accessed through the "Investor Relations" section of our website. The information contained in, or that can be accessed through, our website is not part of this Report.

Item 1A. Risk Factors

Risk Factor Summary

We are providing the following summary of the risk factors contained in this Annual Report on Form 10-K to enhance the readability and accessibility of our risk factor disclosures. We encourage you to carefully review the full risk factors contained in this Annual Report on Form 10-K in their entirety for additional information regarding the material factors that make an investment in our securities speculative or risky. These risks and uncertainties include, among others, the following:

- Our business has incurred significant losses and we expect to continue to incur significant losses for the foreseeable future. We may never achieve profitability and these factors raise substantial doubt about our ability to continue as a going concern absent obtaining adequate new debt or equity financings.
- We will need to raise additional funding to advance our product candidates, which may not be available on acceptable terms, or at all. Failure to obtain capital when needed may force us to delay, limit or terminate our product development efforts or other operations.
- We have incurred significant indebtedness, which could adversely affect our business.
- The COVID-19 pandemic has materially and adversely affected and may continue to materially and adversely affect our financial results.
- We are early in our development efforts of our current pipeline candidates, and our business is dependent on our ability to advance our current and future product candidates through preclinical studies and clinical trials, obtain marketing approval, and ultimately commercialize such product candidates, if approved.
- We are highly dependent on the success of our lead product candidates, BX1000 and BX2000, and our other product candidates.
- Preclinical and clinical development involve a lengthy and expensive process with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current product candidates or any future product candidates, if approved.
- If our license agreement with Cornell University is terminated, we could lose our rights to develop our NMB product candidates.
- We may explore strategic collaborations that may never materialize or we may be required to relinquish important rights to and control over the development and commercialization of our product candidates to any future collaborators.
- Even if we obtain regulatory and marketing approval for a product candidate, our pipeline candidates will remain subject to regulatory oversight.
- If third-party service providers, including carriers, logistics providers and distributors fail to devote sufficient time and resources to pipeline products or their performance is substandard, our successful clinical trials may be delayed, and our costs may be higher than expected.
- We rely on third-party manufacturers and suppliers to produce preclinical and clinical supplies, and, if approved, intend to rely on third-party manufacturers for commercial supplies, of our product candidates.
- We are subject to intense competition and, if we are unable to compete effectively, future products may not reach their commercial potential.
- The regulatory approval processes of the FDA are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- We may be subject to litigation or government investigations for a variety of claims, which could adversely affect our operating results, harm our reputation or otherwise negatively impact our business.

•Our future success depends on our ability to retain and have the full attention of our key executives as well as to attract, retain and motivate other qualified personnel.

•We will need to grow the size of our organization, and we may experience difficulties in managing our growth.

•Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

•The security of our information technology systems may be compromised and if we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions, private litigation and/or adverse publicity, which could negatively affect our operating results and business.

•We own or license numerous pending patent applications and issued patents in the United States. If our pending patent applications fail to issue or if our issued patents are not sufficiently broad, expire or are successfully opposed, invalidated, or rendered unenforceable, our business will be adversely affected.

•The market price for our common stock has been volatile and may continue to fluctuate or may decline significantly in the future.

•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.

Risk Factors

The following risk factors and other information included in this Annual Report on Form 10-K should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations, financial condition, results of operations and future growth prospects. Please see pages 4 and 5 of this Annual Report on Form 10-K for a discussion of some of the forward-looking statements that are qualified by these risk factors. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risks Related to Our Financial Position and Capital Requirements

Our business has incurred significant losses since our inception, and we may continue to incur significant losses for the foreseeable future. We may never achieve profitability.

Our business has incurred operating losses due to costs incurred in connection with our research and development activities, general and administrative expenses, and commercialization expenses associated with our operations. Our net losses for the years ended December 31, 2022 and 2021 were $58.8 million and $19.8 million, respectively. As of December 31, 2022, we had an accumulated deficit of $190.9 million. We launched ANJESO, our first commercial product, in mid-2020, but we have not generated significant revenue from sales of ANJESO, and in December 2022, we announced the discontinuation of the sale of ANJESO and are evaluating commercial partnering options for the product, including divestiture. For the years ended December 31, 2022 and 2021, net product revenue was $1.3 million and $1.1 million, respectively, related to sales of ANJESO in the U.S. Our product candidate pipeline includes early-stage product candidates, including two novel neuromuscular blocking agents, or NMBs, and a related proprietary chemical reversal agent. If our product candidates are not successfully developed and approved, we may never generate any new revenue. All of our product candidates will require the expenditure of substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin realizing product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue our development of, seek regulatory approval for, and potentially commercialize any of our product candidates, if approved, and seek to identify, assess, acquire, in-license, or develop additional product candidates. Our prior losses, combined with expected future losses, have had and will continue to have a negative effect on our stockholders' deficit and working capital.

We expect that it will be several years, if ever, before we have a commercialized product. We anticipate that our expenses will increase substantially if, and as, we:

•continue clinical development of BX1000 and BX2000 and preclinical development of BX3000;

•seek to discover and develop additional product candidates;

•seek regulatory approvals for any of our product candidates that successfully complete clinical trials;

•maintain, expand, protect, and enforce our intellectual property portfolio;

•acquire or in-license other product candidates and technologies;

•out-license or seek other partnering or divestiture for ANJESO; and

•increase our employee headcount and related expenses to support these activities

Because of the numerous risks and uncertainties associated with pharmaceutical product development and commercialization, we are unable to predict the timing or amount of increased expenses, and when, or if, we will be able to generate revenue or achieve or maintain profitability

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 the financial statements included in this Annual Report on Form 10-K. As of December 31, 2022, we had an accumulated deficit of $190.9 million, cash and cash equivalents of $5.3 million and current liabilities of $21.5 million. Based on available resources, we believe that our cash and cash equivalents on hand, consisting of funds raised by financing activities in the year ended December 31, 2022 are sufficient to fund our currently anticipated operating and capital requirements into the second quarter of 2023, however, our current capital resources are not sufficient to support our planned operations for the next twelve months from the date of the financial statements included in this report.

We did not become a revenue-generating company until the second quarter of 2020, following the commercial launch of ANJESO. We have not generated significant revenue from sales of ANJESO, and in December 2022, we announced the discontinuation of the sale of ANJESO and are evaluating commercial partnering options for the product, including divestiture. We expect to continue to incur losses for the foreseeable future as we continue our efforts to develop our current and future product candidates and seek other partnership opportunities for, or the divesture of, ANJESO. We have also incurred significant indebtedness. As of December 31, 2022, we had an outstanding balance of $7.8 million under our credit facility with MAM Eagle Lender. These factors, individually and collectively, raise substantial doubt about our ability to continue as a going concern, and therefore, could materially limit our ability to raise additional funds through an issuance of debt or equity securities or otherwise.

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

We have incurred significant indebtedness, which could adversely affect our business, financial condition, results of operations, and growth prospects, including as a result of any default thereof.

As of December 31, 2022, we had an outstanding balance of $7.8 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, growth prospects 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.

In January 2023, we entered into Amendment No. 4 to Credit Agreement, or the Amendment, with MAM Eagle Lender. Pursuant to the terms of the Amendment, the credit agreement is amended such that we must repay the principal thereunder (i) a payment of principal in the amount of $500,000 on January 3, 2023, (ii) a payment of principal in the amount of $300,000 on February 1, 2023 and March 1, 2023, and (iii) on the interest payment date on April 3, 2023 and on each interest payment date thereafter until the obligations are repaid in full, the principal amount of $500,000.

In addition, the Amendment decreases the minimum cash covenant we are required to maintain under the credit agreement, or the Minimum Liquidity Covenant, to (i) $3.0 million for the period beginning on October 1, 2022, and ending on December 6, 2022, (ii) $4.5 million for the period beginning on December 7, 2022, and ending on January 10, 2023, (iii) $2.225 million for the period beginning on January 11, 2023, and ending on February 28, 2023, and (iv) $3.0 million from and after March 1, 2023. Further, we have agreed that prior to April 30, 2023, we will not, without the prior written consent of MAM Eagle Lender, make or permit any payment under our agreements with Alkermes.

We intend to remain in discussion with MAM Eagle Lender regarding the appropriate cash level for the Minimum Liquidity Covenant, however, 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.

The report of our independent registered accounting firm on our audited financial statements for the fiscal year ended December 31, 2022, contains an explanatory paragraph relating to our ability to continue as a going concern.

The auditor's opinion on our audited financial statements for the year ended December 31, 2022 includes an explanatory paragraph stating that we have incurred recurring losses and negative cash flows and have an accumulated deficit of $190.9 million as of December 31, 2022 that raise substantial doubt about our ability to continue as a going concern. While we believe that we will be able to raise the capital we need to continue our operations, there can be no assurances that we will be successful in these efforts or will be able to resolve our liquidity issues or eliminate our operating losses. If we are unable to obtain sufficient funding, we would need to significantly reduce our operating plans and curtail some or all of our product development activities. Accordingly, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all.

We may not be able to complete a divestiture or commercial partnership for ANJESO.

We have discontinued our sale of ANJESO and are evaluating commercial partnering options for the product, including divestiture. We cannot predict if any such arrangement would be available at all or whether they would be available on commercially reasonable terms. If we are unable to enter into any such arrangement on acceptable terms or at all, or if we are unable to negotiate a favorable agreement in respect of any liabilities we may owe, if any, to Alkermes in connection with such divestiture, we may not be able to generate much, if any, value from this asset.

We will need to raise additional funding to advance our product candidates, which may not be available on acceptable terms, or at all. Failure to obtain capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

Developing and commercializing pharmaceutical products, including conducting preclinical studies and clinical trials and ramping up commercialization and manufacturing activities, is a very time-consuming, expensive, and uncertain process that takes years to complete. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct preclinical and clinical trials of, and seek regulatory and marketing approval for, our product candidates. Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate.

Our research and development expenses increased from $3.1 million for the year ended December 31, 2021 to $3.9 million for the year ended December 31, 2022. As of December 31, 2022, we had cash, and cash equivalents of $5.3 million. Based on our research and development plans, we believe our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditures requirements into the second quarter of 2023.

Attempting to secure additional financing will divert our management from our day-to-day activities, which may impair or delay our ability to develop our product candidates. Raising funds in the current economic environment may present substantial challenges, and future financing may not be available in sufficient amounts or on acceptable terms, if at all. If we are unable to raise capital when needed or on reasonable terms, we may curtail, delay or discontinue our research or development programs or wind down our business. In addition, demands on our cash resources may change as a result of many factors currently unknown to us including, but not limited to, any unforeseen costs we may incur as a result of preclinical study or clinical trial delays due to the ongoing COVID-19

pandemic or other causes, and we may need to seek additional funds sooner than planned. If we are unable to obtain funding on a timely basis or at all, we may be required to significantly curtail or stop one or more of our research or development programs and could have a material adverse effect on our business, operating results and prospects.

Raising additional capital may dilute our existing shareholders, restrict our operations or cause us to relinquish valuable rights.

Until and unless we can generate substantial product revenue, we expect to finance our cash needs through a combination of public or private equity offerings and debt financings. Financing may not be available in sufficient amounts or on reasonable terms. The terms of any financing may harm existing shareholders, and the issuance of additional securities, whether equity or debt, or the possibility of such issuance, may cause the market price of our shares to decline. We have no commitments for any additional financing, and will likely be required to raise such financing through the sale of additional securities. The sale of additional equity or convertible securities may dilute the ownership of existing shareholders. The incurrence of indebtedness would result in increased fixed payment obligations, and we may agree to restrictive covenants, such as limitations on our ability to incur additional debt or limitations on our ability to acquire, sell or license intellectual property rights that could impede our ability to conduct our business.

We may also seek funds through collaborations, strategic alliances, or licensing arrangements with third parties, and such agreements may involve relinquishing valuable rights to our product candidates or technologies, future revenue streams, research programs or products candidates or to grant licenses on terms that may not be favorable to us. Such arrangements will limit our participation in the success of any of our product candidates that receive regulatory approval. Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability.

Risks Related to Clinical Development and Regulatory Approval of our Product Candidates

W*e are early in our development efforts. Our business is dependent on our ability to advance our current and future product candidates through preclinical studies and clinical trials, obtain marketing approval, and ultimately commercialize such product candidates, if approved.*

We are early in our development efforts of our current pipeline candidates, and although we previously obtained approval of ANJESO, all of our current product candidates are still in clinical or preclinical development. We are developing an intermediate-acting NMB, BX1000, an ultra-short acting NMB, BX2000, and BX3000, a reversal agent specific to our NMBs. We have completed a Phase I study in 2021 with BX1000 which evaluated its safety profile when administered with Total Intravenous Anesthesia, and are currently conducting a Phase II study, for which we expect to complete enrollment in March 2023, and report topline results in April 2023. We filed an IND for BX2000 in November 2020 in order to conduct a first-in-human clinical trial. We conducted an additional toxicology study requested by FDA in 2021 and in March 2022, FDA notified us that we could proceed with initiation of a dose-escalation study in healthy volunteers, which commenced in January 2023.

Our ability to generate product revenue from these product candidates if approved, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates if approved, which may never occur. We currently generate no revenue from product sales from these product candidates and we may never be able to develop or commercialize a marketable product.

Each of our product candidates will require additional preclinical and/or clinical development, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, capacity and expertise, building a commercial organization, or successfully outsourcing commercialization, substantial investment, and significant marketing efforts before we generate any revenue from product sales. Our product candidates must be authorized for marketing by the U.S. Food and Drug Administration, or the FDA, or certain other foreign regulatory agencies before we may commercialize our product candidates.

The clinical and commercial success of our product candidates, if approved, will depend on several factors, including the following:

- timely and successful completion of preclinical studies, including toxicology studies, biodistribution studies, and minimally efficacious dose studies in animals, where applicable, and in accordance with Good Laboratory Practices, or GLPs;
- effective INDs or comparable foreign applications that allow commencement of our planned clinical trials or future clinical trials for our product candidates;
- successful enrollment and completion of clinical trials, including under the FDA's GCPs, and GLPs;
- positive results from our future clinical programs that support a finding of safety and effectiveness and an acceptable risk-benefit profile of our product candidates in the intended populations;
- receipt of marketing approvals from applicable regulatory authorities;

•establishment of arrangements with CMOs for clinical supply and, where applicable, commercial manufacturing capabilities;

•establishment and maintenance of patent and trade secret protection, and/or regulatory exclusivity for our product candidates;

•commercial launch of our product candidates, if approved, whether alone or in collaboration with others;

•acceptance of the benefits and use of our product candidates, including method of administration, if and when approved, by patients, the medical community, and third-party payors;

•effective competition with other comparable products;

•establishment and maintenance of healthcare coverage and adequate reimbursement and patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement;

•establishment of a physician training system and network for administration of our product candidates, if approved;

•enforcement and defense of intellectual property rights and claims; and

•maintenance of a continued acceptable safety, tolerability, and efficacy profile of our product candidates, if approved.

If we do not succeed in one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, if approved, which would materially harm our business. If we are unable to advance our product candidates to clinical development, obtain regulatory approval, and ultimately commercialize our product candidates, if approved, or experience significant delays in doing so, our business will be materially harmed.

Our business is highly dependent on the success of our lead product candidates, BX1000 and BX2000, and our other product candidates.

While we have commenced Phase II and Phase I clinical trials for BX1000 and BX2000, respectively, we cannot guarantee that our NMBs or our other product candidates will be approved for commercialization, on a timely basis or at all. We cannot be certain that our NMBs or our other product candidates will be successful in clinical trials or receive regulatory approval. The FDA and other comparable global regulatory authorities can delay, limit, or deny approval of a product candidate for many reasons. Any delay in obtaining, or inability to obtain, applicable regulatory approval will delay or harm our ability to successfully initiate clinical trials and commercialize our NMBs or our other product candidates and materially adversely affect our business, financial condition, results of operations, and growth prospects.

Furthermore, if our clinical trials of our NMBs or our other product candidates encounter safety, efficacy, or manufacturing problems, development delays, regulatory issues, or other problems, our development plans for such product candidates in our pipeline could be significantly impaired, which could materially adversely affect our business, financial condition, results of operations, and growth prospects.

We may also evaluate our product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA or similar regulatory authorities outside of the United States. If the FDA or similar regulatory authorities outside of the United States do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with any product candidate we develop, we may be unable to obtain approval of or market our product candidates.

Preclinical and clinical development involve a lengthy and expensive process with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current product candidates or any future product candidates, if approved.

All of our product candidates are in clinical or preclinical development and their risk of failure is high. It is impossible to predict when or if any of our discovery or product candidates will receive regulatory approval. To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and lengthy, complex, and expensive clinical trials that our product candidates are safe and effective in humans. Clinical testing can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process.

The results of preclinical studies and early clinical trials or early cohorts of our clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials or later cohorts of our clinical trials. The initial cohorts of early-stage clinical trials often involve enrollment of a small number of patients and may not be as predictive as trials with larger cohorts. Additionally, if safety issues arise in an early cohort, we may be delayed or prevented from subsequently expanding into larger trial cohorts. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial

can fail at any stage of testing. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials.

Moreover, clinical data is often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products. A number of companies in our industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unfavorable safety profiles, notwithstanding promising results in earlier trials. There is typically a high rate of failure of product candidates proceeding through clinical trials. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our future clinical trials, if allowed to proceed, will ultimately be successful or support clinical development of our current or any of our future product candidates.

We may experience delays in initiating or completing clinical trials. We also may experience numerous unforeseen events during, or as a result of, any future clinical trials that we could conduct that could delay or prevent our ability to receive marketing approval or commercialize our lead product candidates or any future product candidates, including:

- we may be unable to obtain the necessary funding to commence or complete our planned or ongoing clinical trials;
- regulators or institutional review boards, or IRBs, the FDA, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs as the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- clinical trials of any product candidates may fail to show safety or efficacy, produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs;
- the number of subjects required for clinical trials of any product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- difficulty in attracting enrollment in these clinical trials from subjects that need to agree to be temporarily paralyzed prior to receiving our product candidate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators, IRBs, or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants in our trials are being exposed to unacceptable health risks;
- the cost of clinical trials of any of our product candidates may be greater than we anticipate;
- the quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be inadequate to initiate or complete a given clinical trial;
- our inability to manufacture sufficient quantities of our product candidates for use in clinical trials;
- reports from clinical testing of other therapies may raise safety or efficacy concerns about our product candidates;
- our failure to establish an appropriate safety profile for a product candidate based on clinical or preclinical data for such product candidate as well as data emerging from other studies or trials in the same class as our product candidate; and
- the FDA or applicable foreign regulatory agencies may require us to submit additional data such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the number and location of clinical sites we enroll, the proximity of patients to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the inability to obtain and maintain patient consents, the risk that enrolled participants will drop out before completion, competing clinical trials, and clinicians' patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications being investigated by us, and other factors, such as the ongoing COVID-19 pandemic, over which we have no control. Furthermore, we expect to rely on our collaborators, CROs, and clinical trial sites to ensure the proper and timely conduct of our future

clinical trials, including the patient enrollment process, and we have limited influence over their performance. Additionally, we could encounter delays if treating physicians encounter unresolved ethical issues associated with enrolling patients in future clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles.

We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the institutions in which such trials are being conducted, or the FDA or other regulatory authorities, or if a clinical trial is recommended for suspension or termination by the Data Safety Monitoring Board for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial. Clinical studies may also be delayed or terminated as a result of ambiguous or negative interim results. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

Our product development costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates, if approved, and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition, and results of operations significantly.

The regulatory approval processes of the FDA are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during a product candidate's clinical development and may vary among jurisdictions. It is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA may not accept our NDA filings;
- the FDA may disagree with the design, scope or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA that a product candidate is safe and effective for its proposed indication;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA;
- the FDA may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA may change significantly in a manner rendering our clinical data insufficient for approval.

We cannot be certain that our product candidates will receive regulatory approval. If the markets for patients or indications that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such products, if approved, which could have a material adverse effect on our business, financial condition and results of operations.

We may not be able to file our INDs to commence clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.

Subject to discussions with FDA, we plan to submit an IND for our BX3000 and potentially other product candidates. We cannot be sure that submission of an IND will result in the FDA allowing testing and clinical trials to begin, or that, once begun, issues will not arise that result in suspension or termination of such clinical trials. Additionally, even if such regulatory authorities agree with

the design and implementation of the clinical trials set forth in an IND or clinical trial application, or CTA, we cannot guarantee that such regulatory authorities will not change their requirements in the future.

We may experience difficulties identifying and enrolling patients in our clinical trials. Difficulty in enrolling patients could delay or prevent clinical trials of our NMBs or our other product candidates.

Identifying and qualifying patients to participate in clinical trials of our NMBs is critical to our success. The timing of our clinical trials depends in part on the speed at which we can recruit patients to participate in testing NMBs, and we may experience delays in our clinical trials if we encounter difficulties in enrollment. The eligibility criteria of our clinical trials may limit the pool of available study participants as it will typically require patients undergoing surgeries for which our product candidates are utilized to optimize surgical conditions. We also may not be able to identify, recruit, and enroll a sufficient number of appropriate patients to complete our clinical trials that are willing to agree to be temporarily paralyzed prior to receiving our product candidate because of demographic criteria for prospective patients, the perceived risks and benefits of the product candidate under study, the proximity and availability of clinical trial sites for prospective patients, and the patient referral practices of physicians. The availability and efficacy of competing product candidates and clinical trials can also adversely impact enrollment. If patients are unwilling to participate in our trials for any reason, the timeline for recruiting patients, conducting trials, and obtaining regulatory approval of potential products may be delayed, the commercial prospects of our NMBs or our other product candidates will be harmed, and our ability to generate product revenue from any of these product candidates could be delayed or prevented. Furthermore, our inability to enroll a sufficient number of patients for our clinical trials could result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs and jeopardize our ability to achieve our clinical development timeline and goals, including the dates by which we will commence, complete, and receive results from clinical trials. Enrollment delays in our clinical trials may also jeopardize our ability to commence sales of and generate revenues from our NMBs or our other product candidates. Any of these occurrences may harm our business, financial condition, and prospects significantly.

Interim, topline, or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available or as we make changes to our manufacturing processes and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, topline, or preliminary data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Further, modifications or improvements to our manufacturing processes for a product candidate may result in changes to the characteristics or behavior of the product candidate that could cause our product candidates to perform differently and affect the results of our ongoing clinical trials. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data has been received and fully evaluated. Topline data also remains subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data is available.

Preliminary or interim data from clinical trials is subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Additionally, disclosure of preliminary or interim data by us or by our competitors could result in volatility in the price of our common stock.

Importantly, others, notably FDA and other regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate, and our company in general. If the interim, topline, or preliminary data that we report differs from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, any of our potential product candidates may be harmed, which could harm our business, operating results, prospects, or financial condition.

NMBs and our other product candidates may cause adverse events or undesirable side effects that could delay or prevent its regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Any adverse events or undesirable side effects caused by, or other unexpected properties of, our NMBs or our other product candidates could cause us, any future collaborators, an IRB, or ethics committee or regulatory authorities to interrupt, delay, or halt clinical trials of our product candidates and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. It is possible that as we progress NMBs or our other product candidates through preclinical and clinical development, or as the use of NMBs or our other product candidates become more widespread if they receive regulatory approval, illnesses, injuries, discomforts, and other adverse events that were not observed in preclinical studies or clinical trials, as well

as conditions that did not occur or went undetected, will be reported by patients. If such side effects become known later in development or after approval, such findings may harm our business, financial condition, and prospects significantly. Further, if a serious safety issue is identified in connection with the use of NMBs or our other product candidates commercially or in third-party clinical trials elsewhere, such issues may adversely affect the development potential of NMBs or our other product candidates or result in regulatory authorities restricting our ability to develop or commercialize NMBs or our other product candidates. In addition, since our NMBs are utilized in patients undergoing potentially dangerous surgical operations, patients may experience adverse events or side effects that are unrelated to the use of our NMBs.

Further, if NMBs or any of our other product candidates were to receive regulatory approval and we or others identify undesirable side effects caused by the product (or any other product) after the approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may request that we recall or withdraw the product from the market or may limit the approval of the product through labeling or other means;
- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication or a precaution;
- we may be required to change the way the product is distributed or administered, including through a REMS program, conduct additional clinical trials, or change the labeling of the product;
- we may decide to recall or remove the product from the marketplace;
- we could be sued and/or held liable for injury caused to individuals exposed to or taking our product candidates;
- damage to the public perception of the safety of NMBs or our other product candidates; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved, and could substantially increase the costs of commercializing our product candidates and significantly impact our ability to successfully commercialize our product candidates, if approved, and generate revenues, all of which would materially adversely affect our business, financial condition, and results of operations.

Our business, financial condition, and results of operations are subject to risks arising from the international scope of our manufacturing and supply relationships.

Some of the contract manufacturers we use for our NMBs manufacture and source raw materials outside the United States and we may, in the future, use manufacturers outside the United States for our product candidates. As such, we are subject to risks associated with such international manufacturing relationships, including:

- unexpected changes in regulatory requirements;
- problems related to markets with different cultural biases or political systems;
- political unrest, terrorism and war;
- possible difficulties in enforcing agreements in multiple jurisdictions;
- longer payment cycles and shipping lead-times;
- increased risk relating to the transport of products internationally, including damage to our product, shipment delays relating to the import or export of our products or the delivery of our products by means of additional third-party vendors;
- difficulties obtaining export or import licenses for our products;
- compliance with the U.S. Foreign Corrupt Practices Act and other laws and regulations governing international trade;
- fluctuations in foreign currency exchange rates;
- changes to U.S. and foreign trade policies, including the enactment of tariffs on goods imported into the United States.; and
- imposition of domestic and international customs and tariffs, withholding or other taxes, including any value added taxes.

Additionally, we are subject to periodic reviews and audits by governmental authorities responsible for administering import/export regulations. To the extent that we are unable to successfully defend against an audit or review, we may be required to pay assessments, penalties, and increased duties on products imported into the United States.

If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our product candidates, if approved, may be delayed.

From time to time, we estimate the timing of the accomplishment of various scientific, clinical, regulatory, manufacturing and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of preclinical studies and clinical trials and the submission of regulatory filings, including IND submissions. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are, and will be, based on a variety of assumptions. The actual timing of these milestones can vary significantly compared to our estimates, in some cases for reasons beyond our control. We may experience numerous unforeseen events during, or as a result of, any future clinical trials that we conduct that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, if approved.

Changes in regulatory requirements, guidance from the FDA and other regulatory authorities, or unanticipated events during our clinical trials of NMBs or our other product candidates may result in changes to preclinical studies or clinical trials or additional preclinical or clinical trial requirements, which could result in increased costs to us and could delay our development timeline.

It is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for NMBs or our other product candidates. Changes in regulatory requirements, FDA guidance or guidance from other regulatory agencies, or unanticipated events during our preclinical studies or clinical trials may force us to terminate or adjust our development program.

In addition, the clinical trial requirements of the FDA and foreign regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty, intended use, and market of such product candidates. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or more extensively studied product candidates. The FDA, or the applicable regulatory authorities, may impose additional preclinical or clinical trial requirements. Amendments to clinical trial protocols would require resubmission to the FDA, or the applicable regulatory authorities as well as IRBs and ethics committees for review and approval, which may adversely impact the cost, timing, or successful completion of a clinical trial. If we experience delays completing, or if we terminate, any of our clinical trials, or if we are required to conduct additional preclinical or clinical trials, the commercial prospects for NMBs or our other product candidates may be harmed and our ability to generate product revenue will be delayed, and it would materially adversely affect our business, financial condition, and results of operations.

In order to market any product outside of the United States, we must comply with numerous and varying regulatory requirements of other countries regarding development and commercialization. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain, or deploy key leadership and other personnel, or otherwise prevent new or modified products from being advanced, developed, cleared or approved, or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and approve new products or regulatory submissions can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events, such as the ongoing COVID-19 pandemic, and the efforts to mitigate it, that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the United States government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Since March 2020, when FDA largely placed foreign and domestic inspections of facilities on hold in response to the COVID-19 pandemic, the FDA has been working to resume pre-pandemic levels of inspection activities, including routine surveillance, bioresearch monitoring and pre-approval inspections. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive

evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a CRL or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of companies announced receipt of CRLs due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the ongoing COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We rely on third-party manufacturers and suppliers to produce preclinical and clinical supplies, and, if approved, intend to rely on third-party manufacturers for commercial supplies, of our product candidates.

We do not own facilities for clinical-scale or commercial manufacturing of our product candidates. We rely on third parties to supply the materials for, and manufacture, our research and development, and preclinical and clinical trial APIs. There can be no assurance that our supply of research and development, preclinical and clinical development drugs and other materials will not be limited, interrupted, restricted in certain geographic regions or of satisfactory quality or continue to be available at acceptable prices. In particular, any replacement of our active pharmaceutical ingredient, or API, manufacturer could require significant effort and expertise because there may be a limited number of qualified manufacturers.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party's failure to execute on our manufacturing requirements could adversely affect our business in a number of ways, including:

- an inability to initiate or continue preclinical studies or clinical trials of product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of a collaborator
- subjecting our product candidates to additional inspections by regulatory authorities; and
- in the event of approval to market and commercialize a product candidate, the withdrawal of such approval and/or an inability to meet commercial demand.

In addition, our ability to obtain materials from these suppliers could be disrupted if the operations of these manufacturers are affected by earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, including the ongoing COVID-19 pandemic, and other natural or man-made disasters or business interruptions. If their facilities are unable to operate because of an accident or incident, even for a short period of time, some or all of our research and development programs may be harmed or delayed, and our operations and financial condition could suffer. Our third-party manufacturers also may use hazardous materials, including chemicals and compounds that could be dangerous to human health and safety or the environment, and their operations may also produce hazardous waste products. In the event of contamination or injury, our third-party manufacturers could be held liable for damages or be penalized with fines in an amount exceeding their resources, which could result in our clinical trials or regulatory approvals being delayed or suspended. If we encounter any issues with our contract manufacturers or choose to engage a new supplier or contract manufacturer for any of our product candidates for which we seek regulatory approval, we would need to qualify and obtain FDA approval for another contract manufacturer or supplier as an alternative source for these products and services, which could be costly and cause significant delays.

We use third parties to assist with conducting, supervising and monitoring portions of our nonclinical and clinical studies, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We use third parties to provide certain manufacturing and operational support and for assistance with clinical trials, data management and statistical support. While we have agreements governing their activities, we have limited influence over certain of these third parties' actual performance. We have previously relied upon such third parties and plan to continue to use third parties to assist with monitoring and managing clinical trials and data for our NMBs and our other product candidates, as well as the execution of nonclinical studies. We control only certain aspects of our third parties' activities.

We and our contractors are required to comply with Good Laboratory Practices, or GLPs, and Good Clinical Practices, or GCPs, which are regulations and guidelines enforced by the FDA and equivalent regulatory authorities in other countries for all of our product candidates in development. The FDA and the equivalent regulatory authorities in other countries enforce these GLPs and GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our contractors fail to comply with

applicable GLPs and GCPs, the data generated in our nonclinical studies and clinical trials may be deemed unreliable and the FDA may require us to perform additional studies or clinical trials before approving our marketing applications. In addition, our clinical trials for our product candidates will require a sufficiently large number of test subjects to evaluate the safety and effectiveness of each product candidate. Accordingly, if our contractors fail to comply with these regulations or fail to recruit a sufficient number of patients, we may be required to repeat the clinical trials, which would delay the regulatory approval process.

These contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities that could harm our competitive position. While we take steps to protect our intellectual property, we face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by our contractors, which may allow our potential competitors to access our proprietary technology. If our contractors do not successfully carry out their contractual duties or obligations or fail to meet expected deadlines for items within their purview, or if the quality or accuracy of the clinical data they oversee is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for our product candidates, or successfully commercialize our NMBs or our other product candidates, if approved. As a result, our financial results and the commercial prospects for our NMBs or any other future product candidates that we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative providers or to do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and requires management's time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines.

We are highly dependent upon Curia Global, or Curia, formerly AMRI, as the current single supplier of the active pharmaceutical ingredient, or API, for our NMB clinical program.

In 2017, we entered into a master services agreement, or MSA, with Curia, as our single source supplier of our NMB API, or the Curia MSA. Under the MSA, Curia provides all of the API for our NMBs. If Curia is unable to supply the API for the NMBs at the levels we anticipate or that are needed to conduct our preclinical and clinical testing, we may be unable to acquire a substitute supply of raw materials and components on a timely basis, if at all. Our ability to advance our development candidates depends, in part, on our ability to obtain these materials and components in sufficient quantities. While Curia has historically met our demand for raw materials and components for our NMBs on a timely basis in the past, we cannot guarantee that it will always be able to meet our demand, especially if our product candidates become approved for commercialization and we need to meet the market demand for such products. As such, we are highly dependent upon Curia's continued ability to supply the API at the levels we require and any production shortfall that impairs the supply of raw materials and components could have a material adverse effect on our business, financial condition and results of operations.

If our license agreement with Cornell University is terminated, we could lose our rights to develop our NMB product candidates.

Our success will depend in part on the maintenance of our current and future license agreements. We are party to a License Agreement with Cornell University, as represented by its Center for Technology Licensing at Cornell University, or Cornell, effective June 30, 2017, as amended, or the Cornell License. Pursuant to the Cornell License, we have the exclusive global rights to our NMBs and proprietary reversal agent. The Cornell License imposes, and future license agreements may impose, various diligence, milestone payment, royalty, and other obligations on us. If we fail to comply with our obligations under the Cornell License, or any future license agreements with any party, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to develop products covered by such license.

If, for any reason, the Cornell License is terminated or we otherwise lose the rights under the Cornell License, it would adversely affect our business. If we breach any material obligations under the Cornell License, Cornell may have the right to terminate the agreement, which could result in us being unable to develop, manufacture, or sell our product candidates that incorporate the intellectual property subject to such license. If this in-license is terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. In addition, we may seek to obtain additional licenses, and, in connection with obtaining such licenses, we may agree to amend the Cornell License in a manner that may be more favorable to Cornell, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing license. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects, and we may be required to identify and license replacement technology from third parties, which may not be available on reasonable terms or at all.

We may explore strategic collaborations that may never materialize or we may be required to relinquish important rights to and control over the development and commercialization of our product candidates to any future collaborators.

We may in the future determine to collaborate with companies for development and potential commercialization of one or more therapeutic products. At the current time however, we cannot predict what form such a strategic collaboration might take. We are likely to face significant competition in seeking appropriate strategic collaborators, and strategic collaborations can be complicated and time-consuming to negotiate and document.

We may not be able to negotiate strategic collaborations on acceptable terms, if at all. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market, if approved, or continue to develop our technology platforms and our business may be materially and adversely affected.

If and when we collaborate with a third party for development and commercialization of a product candidate, if approved, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. We are unable to predict when, if ever, we will enter into any strategic partnerships because of the numerous risks and uncertainties associated with establishing them, including:

- expenditure of substantial operational, financial and management resources;
- dilutive issuances of our securities;
- substantial actual or contingent liabilities; and
- termination or expiration of the arrangement, which would delay the development and may increase the cost of developing our product candidates.

Strategic partners may also delay clinical trials, experience financial difficulties, provide insufficient funding, terminate a clinical trial, or abandon a product candidate, which could negatively impact our development efforts. Additionally, strategic partners may not properly maintain, enforce, or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation, any of which could adversely affect our business, financial position, and operations.

If our collaborations do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. All of the risks relating to product development, regulatory approval, and commercialization described in this Annual Report on Form 10-K also apply to the activities of our program collaborators. Additionally, subject to its contractual obligations to us, if one of our collaborators is involved in a business combination, the collaborator may deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If our collaborator terminates its agreement with us, it may find it more difficult to attract new collaborators.

Risks Related to Commercialization of Our Product Candidates

If we are unable to successfully commercialize NMBs or any of our other product candidates for which we receive regulatory approval, or experience significant delays in doing so, our business will be materially harmed.

If we are successful in obtaining marketing approval from applicable regulatory authorities for NMBs or any of our other product candidates, our ability to generate revenues from such product candidates will depend on our success in:

- launching commercial sales of our product candidates, whether alone or in collaboration with others;
- receiving an approved label with claims that are necessary or desirable for successful marketing, and that does not contain safety or other limitations that would impede our ability to market our product candidates;
- creating market demand for our product candidates through marketing, sales, and promotion activities;
- hiring, training, and deploying a sales force or contracting with third parties to commercialize our product candidates;
- manufacturing, either on our own or through third parties, product candidates in sufficient quantities and at acceptable quality and cost to meet commercial demand at launch and thereafter;

•establishing and maintaining agreements with wholesalers, distributors, and group purchasing organizations on commercially reasonable terms;

•creating partnerships with, or offering licenses to, third parties to promote and sell product candidates in foreign markets where we receive marketing approval;

•obtaining, maintaining, protecting, and enforcing patent and trade secret protection and regulatory exclusivity for our product candidates;

•achieving market acceptance of our product candidates by patients, the medical community, and third-party payors;

•achieving appropriate reimbursement for our product candidates, if approved;

•effectively competing with other product candidates; and

•maintaining an acceptable tolerability profile of our product candidates following launch.

To the extent we are not able to do any of the foregoing, our business, financial condition, results of operations, and prospects will be materially harmed.

We face significant competition, and if our competitors develop product candidates more rapidly than we do or their product candidates are more effective, our ability to develop and successfully commercialize products may be adversely affected.

The biopharmaceutical and pharmaceutical industries are characterized by rapid innovation, intense and dynamic competition and a strong emphasis on proprietary and novel products and product candidates. We face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biopharmaceutical companies, academic institutions, governmental agencies, and public and private research institutions, as well as standard-of-care treatments, and new products undergoing development and combinations of existing and new therapies. Any product candidates that we successfully develop and commercialize, if approved, will compete with existing therapies and new therapies, including combinations thereof, that may become available in the future. We compete with these organizations to recruit management, scientists, and clinical development personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling subjects for clinical trials that are willing to be temporarily paralyzed prior to receiving our product candidate, and in identifying and in-licensing new product candidates. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Companies that compete with us directly on the level of the development of NMBs and our other product candidates include Merck and other NMB multisource companies. Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales, and supply resources or experience than we do. If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage, and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, more convenient, less expensive, or marketed and sold more effectively than any products we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates, if approved. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new products could limit our product revenues.

Our ability to successfully commercialize any of our product candidates, for which we receive approval will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers, and other organizations. In the United States, the principal decisions about reimbursement for new therapies are typically made by Centers for Medicare and Medicaid Services, or CMS, an agency within the United States Department of Health and Human Services. CMS decides whether and to what extent a new drug that assists in surgery will be covered and reimbursed under Medicare, and private payors tend to follow CMS determinations to a substantial degree. The availability and extent of reimbursement by governmental and private payors is essential for most patients. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products by government and third-party payors. Our products may not qualify for coverage or direct reimbursement, or may be subject to limited reimbursement. If reimbursement or insurance coverage is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates, if approved.

Even if coverage is provided, the approved reimbursement amount may not be sufficient to allow us to establish or maintain pricing to generate income.

In addition, reimbursement agencies in foreign jurisdictions may be more conservative than those in the United States. Accordingly, in markets outside the United States, the reimbursement for our product candidates, if approved, may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits. Moreover, increasing efforts by governmental and third-party payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved, and as a result, they may not cover or provide adequate payment for our product candidates, if approved. Failure to obtain or maintain adequate reimbursement for any products for which we receive marketing approval will adversely affect our ability to achieve commercial success and could have a material adverse effect on our financial condition, results of operations, growth prospects and our ability to raise capital needed to commercialize products.

Even if we obtain regulatory and marketing approval for a product candidate, our product candidates will remain subject to regulatory oversight.

Even if we receive marketing and regulatory approval for NMBs or any of our other product candidates, regulatory authorities may still impose significant restrictions on the indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. NMBs and our other product candidates will also be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, and submission of safety and other post-market information. The FDA has significant post-market authority, including, for example, the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate serious safety risks related to the use of a new product. Any regulatory approvals that we receive for NMBs or our other product candidates may also be subject to a risk evaluation and mitigation strategy, or REMS, limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including post-approval clinical trials, and surveillance to monitor the quality, safety, and efficacy of the product, all of which could lead to lower sales volume and revenue.

In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the U.S. or foreign marketing application. Manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. If we, or a regulatory authority, discover(s) previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured or disagrees with the promotion, marketing or labeling of that product, a regulatory authority may impose restrictions relative to that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. Additionally, under the Food and Drug Omnibus Reform Act of 2022, or FDORA, sponsors of approved drugs must provide 6 months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed.

If we or our contractors fail to comply with applicable regulatory requirements following approval of NMBs or our other product candidates, a regulatory authority may:

- issue a warning letter, untitled letter, or Form 483, asserting that we are in violation of the law;
- request voluntary product recalls;
- seek an injunction or impose administrative, civil, or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending U.S. or comparable foreign marketing application (or any supplements thereto);
- restrict the marketing or manufacturing of the product;
- seize or detain the product or otherwise require the withdrawal of the product from the market;
- refuse to permit the import or export of product candidates; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize NMBs.

Even if we receive marketing approval for NMBs or our other product candidates, we may not achieve broad market acceptance.

The commercial success of NMBs or our other product candidates, if developed and approved for marketing by the FDA or comparable foreign regulatory authority, will depend upon the awareness and acceptance of NMBs or such other product candidate among the medical community, including physicians, patients, advocacy groups, and healthcare payors. Market acceptance of our product candidates, if approved, will depend on a number of factors, including, among others:

- the prevalence and severity of any adverse side effects associated with our product candidates;
- limitations or warnings contained in the labeling approved for our product candidates by the FDA or comparable foreign regulatory authority, such as a "black box" warning;
- availability of alternative treatments, including any competitive product candidates in development that could be approved or commercially launched prior to approval of our product candidates;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- pricing;
- payor acceptance;
- the impact of any future changes to the United States healthcare system;
- the effectiveness of our sales and marketing strategies; and
- the likelihood that the FDA may require development of a REMS, as a condition of approval or post-approval or may not agree with our proposed REMS or may impose additional requirements that limit the promotion, advertising, distribution, or sales of our product candidates.

If NMBs or any of our other product candidates are approved but do not achieve an adequate level of acceptance by patients, advocacy groups, physicians and payors, we may not generate sufficient revenue to become or remain profitable and our business, financial condition, and results of operations could be materially adversely affected. For example, we have not generated significant revenue from sales of ANJESO, and in December 2022, we announced the discontinuation of the sale of ANJESO and are evaluating commercial partnering options for the product, including divestiture.

Our efforts to educate the medical community and third-party payors about the benefits of NMBs and our other product candidates may require significant resources and may never be successful.

Even if we receive marketing approval for NMBs or our other product candidates in the United States, we may never receive regulatory approval to market NMBs or our other product candidates outside of the United States.

In order to market any product outside of the United States, we must establish and comply with the numerous and varying safety, efficacy, and other regulatory requirements of other jurisdictions, including potential additional clinical trials and/or preclinical studies. Approval procedures vary among jurisdictions and can involve additional testing and additional administrative review periods. The time required to obtain approvals in other jurisdictions might differ from that required to obtain FDA approval. The marketing approval processes in other jurisdictions may implicate all of the risks detailed above regarding FDA approval in the United States as well as other risks. In particular, in many jurisdictions outside of the United States, products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such jurisdictions. Marketing approval in one jurisdiction does not necessarily ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process or commercial activities in others. Failure to obtain marketing approval in other jurisdictions or any delay or other setback in obtaining such approval would impair our ability to market a product candidate in such foreign markets. Any such impairment would reduce the size of our potential market, which could have a material adverse impact on our business, financial condition, results of operations, and prospects.

We may be unable to establish effective marketing, sales and distribution capabilities or enter into agreements with third parties to market and sell NMBs or our other product candidates, if approved.

We currently do not have a commercial infrastructure for the marketing, sale, and distribution of NMBs, or our other product candidates. If NMBs or our other product candidates receive marketing approval, we intend to commercialize such product candidates in the United States and potentially in other geographies. In order to commercialize our products, we must build our marketing, sales, and distribution capabilities or make arrangements with third parties to perform these services. We may not be successful in doing so. Should we decide to move forward in developing our own marketing capabilities, we may incur expenses prior to product launch or even approval in order to recruit a sales force and develop a marketing and sales infrastructure. If a commercial launch is delayed as a result of the FDA's or comparable foreign regulatory authority's requirements or for other reasons, we would incur these expenses prior to being able to realize any revenue from sales of NMBs and our other product candidates. Even if we are able to effectively hire a sales

force and develop a marketing and sales infrastructure, our sales force and marketing teams may not be successful in commercializing NMBs or our other product candidates, if approved. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We may also or alternatively decide to collaborate with third-party marketing and sales organizations to commercialize any approved product candidates, if approved, in the United States, in which event, our ability to generate product revenues may be limited. To the extent we rely on third parties to commercialize any products for which we obtain regulatory approval, we may receive less revenues than if we commercialized these products ourselves, which could materially harm our prospects. In addition, we would have less control over the sales efforts of any other third parties involved in our commercialization efforts, and could be held liable if they failed to comply with applicable legal or regulatory requirements.

There are significant risks involved in building and managing a commercial infrastructure. The establishment and development of commercial capabilities, including compliance plans, to market any product candidates we may develop and for which we receive approval will be expensive and time-consuming and could delay any product launch, and we may not be able to successfully develop this capability. We will have to compete with other biopharmaceutical and pharmaceutical companies to recruit, hire, train, manage, and retain marketing and sales personnel, which is expensive and time-consuming and could delay any product launch. Developing our sales capabilities may also divert resources and management attention away from product development.

In the event we are unable to develop a marketing and sales infrastructure, we may not be able to commercialize NMBs or our other product candidates, if approved, in the United States or elsewhere, which could limit our ability to generate product revenues and materially harm our business, financial condition, results of operations, and prospects.

We have limited sales and marketing experience and may be unable to successfully commercialize our product candidates for which we receive approval or generate product revenue.

We have limited experience in the marketing and sale of pharmaceutical products, and there are significant risks involved in managing a sales and marketing organization, including our ability to hire, retain, adequately compensate and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. If we decide not to promote our product candidates, if approved, ourselves, we may consider promotional partnership arrangements. For instance, we are exploring commercial partnering options for ANJESO, including divestiture. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our product candidates for which we receive approval. Any failure or delay in entering promotional partnerships or developing our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our product candidates, if approved. If we are not successful in commercializing our products for which we obtain approval, either on our own or through partnering with one or more third parties, our future product revenue will suffer and we would incur significant additional losses.

Risks Related to Our Business Operations and Industry

Our future success depends on our ability to retain and have the full attention of our key executives as well as to attract, retain and motivate other qualified personnel.

Our success depends in part on our continued ability to attract, retain, and motivate highly qualified management, clinical, and scientific personnel. As we continue developing our product candidates in our pipeline, we will require personnel with medical, scientific, or technical qualifications specific to NMBs. We are highly dependent on the principal members of our executive team and, in particular, the services of Gerri A. Henwood, our President and Chief Executive Officer, the loss of whose services would adversely impact the achievement of our objectives. Recruiting and retaining qualified employees for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. In addition, failure to succeed in clinical studies may make it more challenging to recruit and retain qualified personnel. The inability to recruit or loss of the services of any executive or key employee could impede the progress of our research, development and commercialization objectives.

We will need to grow the size of our organization, and we may experience difficulties in managing our growth.

Once we received FDA approval of ANJESO, we increased the size of our managerial, operational, sales, marketing, financial and other resources as we prepared for the commercialization of ANJESO. Our efforts to commercialize ANJESO were severely impacted by the COVID-19 pandemic. Hospitals reduced elective surgeries, and many have still not yet returned to their prior number of surgeries before the COVID-19 outbreak, which caused, and likely will continue to result in a decreased demand for ANJESO. COVID-19 also impacted revenue for hospitals, reduced staffing, diverted resources from other normal activities to patients suffering from COVID-19 and limited hospital access for nonpatients, including our sales professionals, which we believe has impacted our

marketing and commercialization efforts. As a result of the negative impacts of the COVID-19 pandemic on our commercialization efforts, in November 2020 we implemented a restructuring initiative, which included a reduction of workforce of approximately 40 positions and in March 2022, implemented plans to reduce expenses including an approximately 80% reduction in our workforce. As of December 31, 2022, we had 9 full-time employees.

As we advance our product candidates through the development process and commercialize our product candidates, if approved, we may need to expand our development, regulatory, quality, managerial, sales and marketing, operational, finance and other resources to manage our operations and clinical trials, continue our development activities and commercialize our product candidates, if approved. If our operations expand, we expect that we will need to manage additional relationships with various manufacturers and collaborative partners, suppliers and other organizations. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

We may acquire other assets or businesses, or form collaborations or make investments in other companies or technologies, that could have a material adverse effect on our operating results, dilute our shareholders' ownership, increase our debt or cause us to incur significant expense.

A key aspect of our business strategy is seeking in-license or acquisition opportunities to add commercial or near-commercial products to our portfolio. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any such transaction, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. We may not be able to find suitable acquisition candidates, and if we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business and we may incur additional debt or assume unknown or contingent liabilities in connection therewith. Integration of an acquired company or assets may also disrupt ongoing operations, require the hiring of additional personnel and the implementation of additional internal systems and infrastructure, especially the acquisition of commercial assets, and require management resources that would otherwise focus on developing our existing business.

To finance any acquisitions or collaborations, we may choose to issue debt or shares of our common or preferred stock as consideration. Any such issuance of shares would dilute the ownership of our shareholders. If the price of our common stock is low or volatile, we may not be able to acquire other assets or companies or fund a transaction using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

Our employees, partners, independent contractors, principal investigators, consultants, vendors and contract research organizations may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, partners, independent contractors, principal investigators, consultants, vendors and CROs may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these employees could include intentional, reckless and/or negligent conduct or unauthorized activity that violates: (1) FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA; (2) manufacturing standards; (3) federal and state healthcare fraud and abuse laws and regulations; or (4) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. Any incidents or any other conduct that leads to an employee receiving an FDA debarment could result in a loss of business from our partners and severe reputational harm. We adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business, operating results, financial condition and growth prospects.

We are subject to various foreign, federal, and state healthcare and privacy laws and regulations, and our failure to comply with these laws and regulations could harm our results of operations and financial condition.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, and customers expose us to broadly applicable foreign, federal and state fraud and abuse, and other healthcare and privacy laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our

operations, including how we research, market, sell, and distribute any products for which we obtain marketing approval. Such laws include:

•the federal Anti-Kickback Statute, which prohibits, among other things, persons, or entities from knowingly and willfully soliciting, offering, receiving, or providing any remuneration (including any kickback, bribe, or certain rebates), directly or indirectly, overtly or covertly, in cash or in-kind, in return for, either the referral of an individual or the purchase, lease, or order, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

•the federal false claims and civil monetary penalties laws, including the civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government;

•the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal liability and amends provisions on the reporting, investigation, enforcement, and penalizing of civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items, or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

•HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, also impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses, and certain healthcare providers as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;

•the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report annually to the CMS information related to payments and other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members, and beginning in 2022, applicable manufacturers are required to report such information regarding payments and transfers of value provided, as well as ownership and investment interests held, during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives;

•the Foreign Corrupt Practices Act, or FCPA, which prohibits companies and their intermediaries from making, or offering or promising to make improper payments to non-United States officials for the purpose of obtaining or retaining business or otherwise seeking favorable treatment; and

•analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third-party payors, including private insurers, or by the patients themselves; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug and biologic manufacturers to file reports relating to pricing and marketing information or which require tracking gifts and other remuneration and items of value provided to physicians, other healthcare providers and entities; state and local laws that require the registration of pharmaceutical sales representatives; state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA; state and foreign governments that have enacted or proposed requirements regarding the collection, retention, distribution, use, security, sharing, transfer, storage, and other processing of personally identifiable information and other data relating to individuals (including the EU General Data Protection Regulation 2016/679, or GDPR, and the California Consumer Protection Act, or CCPA), and federal and state

consumer protection laws are being applied to enforce regulations related to the online collection, use, and dissemination of data, thus complicating compliance efforts.

Ensuring that our internal operations and business arrangements with third parties comply with applicable healthcare laws and regulations involves substantial costs. It is possible that governmental authorities will conclude that our business practices, including any consulting and advisory board arrangements with physicians and other healthcare providers, do not comply with current or future statutes, regulations, agency guidance, or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal, and administrative penalties, damages, fines, exclusion from United States government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, individual imprisonment, contractual damages, reputational harm, additional reporting requirements, and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, diminished profits, and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly, time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusion from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

Healthcare legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates.

The commercial potential for our approved products, if any, could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry. New laws, regulations, or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products, and services could adversely affect our business, operations, and financial condition. The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system, including implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs and biologics. These efforts may affect our ability to profitably sell our product candidates, if approved.

The ACA was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry, and impose additional health policy reforms. There have been significant ongoing administrative, executive, and legislative efforts to modify or eliminate the ACA. For example, the Tax Cuts and Jobs Act, enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Code, commonly referred to as the individual mandate. Other legislative changes have been proposed and adopted since passage of the ACA. The ACA has also been subject to challenges in the courts. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by the United States Congress, or Congress. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional and remanded the case to the Texas District Court to reconsider its earlier invalidation of the entire ACA. An appeal was taken to the U.S. Supreme Court and on June 17, 2021, the Supreme Court ruled that the plaintiffs lacked standing to challenge the law as they had not alleged personal injury traceable to the allegedly unlawful conduct. As a result, the Supreme Court did not rule on the constitutionality of the ACA or any of its provisions.

Further changes to and under the ACA remain possible but it is unknown what form any such changes or any law proposed to replace or revise the ACA would take, and how or whether it may affect our business in the future. We expect that changes to the ACA, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug prices, and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing, or other legislation in individual states, could have a material adverse effect on the healthcare industry.

The Budget Control Act of 2011 has resulted in reductions in spending on certain government programs, including aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year. These reductions have been extended until 2030 although adjustments have been made as a result of the ongoing COVID-19 pandemic. The 2% reduction is suspended through March 31, 2022. From April through June 2022, a 1% reduction was in effect, with the full 2% cut resuming thereafter.

The Inflation Reduction Act of 2022 (the "IRA") contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the IRA. The IRA could have the effect of reducing the prices we can charge and reimbursement we receive for

our products, if approved, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results of operations, and growth prospects. The effects of the IRA on our business and the pharmaceutical industry in general is not yet known.

Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain and maintain profitability of our product and product candidates, if approved.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our product candidates may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would materially adversely affect our business, financial condition, and results of operations.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our products.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. While we currently have no product candidates that have commenced clinical trials or been approved for commercial sale, the future use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. For example, we may be sued if our product candidates allegedly cause injury or are found to be otherwise unsuitable during product testing, manufacturing, marketing. or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product candidate, negligence, strict liability, and a breach of warranties. Claims may be brought against us by clinical trial participants, patients, or others using, administering or selling products that may be approved in the future. Claims could also be asserted under state consumer protection acts.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease the commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing, or promotional restrictions;
- significant negative financial impact;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize our product candidates, if approved; and
- a decline in our stock price.

We currently hold product liability coverage in an amount we consider reasonable. We may need to increase our insurance coverage as we expand our preclinical and clinical trials for our product candidates. Insurance coverage is increasingly expensive. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our NMBs or any other future product candidates. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

The JOBS Act allows us to postpone the date by which we must comply with certain laws and regulations and reduce the amount of information provided in reports filed with the SEC. We cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or JOBS Act. In addition, we qualify as a "smaller reporting company." For so long as we remain an emerging growth company, we will be exempt from Section 404(b) of the Sarbanes-Oxley Act, which requires auditor attestation to the effectiveness of internal control over financial reporting. We will cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total gross annual revenues of $1.235 billion or more; (ii) December 31, 2024; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. Even after we no longer qualify as an emerging growth company, we may still qualify as a smaller reporting company, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in this Annual Report on Form 10-K and our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on the exemptions available to us as an emerging growth company and/or smaller reporting company. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

As of the expiration of our emerging growth company status, we will be broadly subject to enhanced reporting and other requirements under the Exchange Act and Sarbanes-Oxley Act. This will require, among other things, annual management assessments of the effectiveness of our internal control over financial reporting and a report by our independent registered public accounting firm addressing these assessments. These and other obligations could place significant demands on our management, administrative and operational resources, including accounting and information technology resources and our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Under the Exchange Act, a material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis by the company's internal controls. If material weaknesses or deficiencies in our internal controls exist and go undetected or unremediated, our financial statements could contain material misstatements that, when discovered in the future, could cause us to fail to meet our future reporting obligations and cause the price of our common stock to decline. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity, which could negatively affect our operating results and business.

We are subject to laws and regulations that address privacy and data security of patients who use our product candidates in the United States and in other jurisdictions in which we conduct our business. Numerous federal, state and international laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Health Insurance Portability and Accountability Act of 1996 (HIPAA), and Section 5 of the Federal Trade Commission Act) govern the collection, use, disclosure, and protection of health-related and other personal information in the United States. These laws impose certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of personal information, including individually identifiable health information, and impose notification obligations in the event of a breach

of the privacy or security of personal information. Failure to comply with applicable data protection laws and regulations could result in government enforcement actions and create liability for us, which could include civil and/or criminal penalties, as well as private litigation and/or adverse publicity that could negatively affect our operating results and business.

In addition to regulations in the United States, to the extent we choose to clinically evaluate or sell any products outside of the United States, we will be subject to a variety of foreign data protection laws and compliance requirements. For example, in the European Union, the EU General Data Protection Regulation imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. Switzerland and the United Kingdom have adopted similar restrictions. Data protection authorities from different European countries may interpret the applicable laws differently, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data in Europe. Any failure, or perceived failure, by us to comply with privacy and data protection laws, rules and regulations could result in proceedings or actions against us by governmental entities or others. These proceedings or actions may subject us to significant penalties and negative publicity, require us to change our business practices, increase our costs and severely disrupt our business.

We may be subject to litigation or government investigations for a variety of claims, which could adversely affect our operating results, harm our reputation or otherwise negatively impact our business.

We may be subject to litigation or government investigations. These may include claims, lawsuits, and proceedings involving securities laws, fraud and abuse, healthcare compliance, product liability, labor and employment, wage and hour, commercial and other matters. For example, in May 2018, a securities class action lawsuit, or the Securities Litigation, was filed against Societal CDMO, Inc., or Societal CDMO, and certain of Societal CDMO's officers and directors 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. In connection with our November 2019 separation from Societal CDMO, 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. Although the Securities Litigation settled in December 2022, we could face securities litigation in the future that could result in the payment of substantial damages or settlement costs in excess of our insurance coverage. Any adverse outcome could harm our business. Even if we were to be meritorious in any such litigation, we could incur substantial legal costs and management's attention and resources could be diverted from our business that could cause our business to suffer.

Risks Related to Our Intellectual Property

We own or license numerous pending patent applications and issued patents in the United States. If our pending patent applications fail to issue or if our issued patents are not sufficiently broad, expire or are successfully opposed, invalidated, or rendered unenforceable, our business will be adversely affected.

Our commercial success will depend in part on obtaining and maintaining patent protection for our product candidates, as well as successfully defending our current and future patents against third-party challenges. To protect our proprietary technology, we intend to rely on patents, and we may also rely on other intellectual property protections, including trade secrets, nondisclosure agreements and confidentiality provisions.

There can be no assurance that our pending patent applications will result in issued patents. The patent applications that we have filed and have not yet been granted may fail to result in issued patents in the United States or foreign countries. Even if the patents do successfully issue, third parties may challenge the patents or the inventorship thereof, which can lead to an issued patent being found invalid, unenforceable or can otherwise alter the ownership of the patents.

The issuance of any patent is not a certainty. Unless and until our pending applications issue, their protective scope is impossible to determine. It is impossible to predict whether or how many of these applications will result in issued patents and patents that issue may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of patent exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which may limit our ability to prevent others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, upon expiration of a patent, we may be limited in our ability to prevent others from using or commercializing subject matter covered by the expired patents. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. The patent position of biotechnology and pharmaceutical companies, including us, generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after the first filing, or in some cases at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions

claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. In addition, we may not be aware of particular prior art publications that may have an impact on patentability or enforceability. Further, the examination process may require us or our licensors to narrow the claims for our pending patent applications due to, for example, such prior art publications, which may limit the scope of patent protection that may be obtained if these applications issue. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Furthermore, our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or have licensed from third parties may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents, and/or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical technology and products or limit the duration of the patent protection for our technology and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of patents or narrow the scope of patent protection.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. The Leahy Smith America Invents Act, or the Leahy Smith Act, enacted in September 2011, brought significant changes to the U.S. patent system. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent Office continues to develop and implement new regulations and procedures to govern administration of the Leahy Smith Act, and many of the substantive changes to patent law associated with the Leahy Smith Act became effective on March 16, 2013. The Leahy Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patent, all of which could have a material adverse effect on our business and financial condition.

We exclusively license from Cornell University issued patents in the U.S. and other major foreign markets directed to BX1000 that expire in 2027, subject to any applicable extension, along with a pending PCT application directed to certain methods of using BX1000 that, if issued, would expire in 2041, subject to any applicable disclaimer or extension. We also exclusively license from Cornell University issued patents in the U.S. and other major foreign markets directed to BX2000 that expire in 2033, subject to any applicable extension, along with a pending PCT application directed to certain methods of using BX2000 that, if issued, would expire in 2041, subject to any applicable disclaimer or extension. With respect to intranasal Dex, we own issued patents in the U.S. and certain major foreign markets that expire in 2032, subject to any disclaimers or extensions. Finally, we own and exclusively license patents and patent applications in the U.S. and certain major foreign markets relating to pharmaceutical compositions containing meloxicam and methods of use for IV, intramuscular or parenteral administration, that expire between 2024 and 2039.

Generic competitors can challenge the U.S. patents protecting our product candidates by filing an ANDA or 505(b)(2) NDA for a generic or a modified version of our product candidates and negatively affect our competitive position.

Separate and apart from the protection provided under the U.S. patent laws, drug candidates may be subject to the provisions of the Hatch-Waxman Act, which may provide drug candidates with either a three- or five-year period of marketing exclusivity following receipt of FDA approval. The Hatch-Waxman Act prohibits the FDA from accepting the filing of an abbreviated new drug application, or ANDA, (for a generic product) or a 505(b)(2) NDA (for a modified version of the product) for three years for active drug ingredients previously approved by the FDA or for five years for active drug ingredients not previously approved by the FDA.

There is an exception, however, for newly approved molecules that allows competitors to challenge a patent beginning four years into the five-year exclusivity period by alleging that one or more of the patents listed in the FDA's list of approved drug products are invalid, unenforceable and/or not infringed and submitting an ANDA for a generic version of a drug candidate. This patent challenge is commonly known as a Paragraph IV certification. If we have an Orange Book listed patent and a third party submits a Paragraph IV certification to the FDA, a notice of the Paragraph IV certification must also be sent to us once the third party's ANDA is accepted for filing by the FDA. We may then initiate a patent infringement lawsuit within 45 days of receipt of the notice and we will be entitled to a 30 month stay running from the end of the 5-year new chemical entity, or NCE, exclusivity period. If we do not file a patent infringement lawsuit within the required 45-day period, the third party's ANDA or 505(b)(2) NDA will not be subject to the 30-month stay and the FDA could approve the ANDA or 505(b)(2) application after expiration of any applicable marketing exclusivity, such as the 5-year NCE exclusivity period or 3-year clinical investigation exclusivity. Within the past several years, the generic industry has aggressively pursued approvals of generic versions of innovator drugs at the earliest possible point in time.

If a generic company is able to successfully challenge the patents covering drug candidates or design around our patents and obtain FDA approval for an ANDA or 505(b)(2) application, the generic company may choose to launch a generic or modified version of our drug candidate. Any launch of a generic or modified version of our drug candidates prior to the expiration of patent protection will have a material adverse effect on our revenues and our results of operations.

If we do not obtain protection under the Hatch-Waxman Act by extending the patent term and obtaining data exclusivity for our product and product candidates, our business may be materially harmed.

Our success will largely depend on our ability to obtain and maintain patent and other intellectual property in the United States and other countries with respect to our proprietary technology, drug candidates and our target indications. Our issued patents directed to our various product and product candidates expire between 2024 to 2041. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting our drug candidates might expire before or shortly after such candidates begin to be commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents.

Depending upon the timing, duration and specifics of FDA marketing approval of our drug candidates, one or more of our U.S. patents may be eligible for limited patent term extension under The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, for a drug candidate. The Hatch-Waxman Act permits a patent extension term of up to five years beyond the normal expiration of the patent as compensation for patent term lost during development and the FDA regulatory review process, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the total patent term including the period of extension cannot exceed 14 years from the product's approval date. Furthermore, this extension is limited to only one patent per regulatory review period that covers the approved product. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. Similar provisions are available in certain foreign countries, such as the European Union and Japan.

If we are unable to extend the expiration date of our existing patents or obtain new patents with longer expiry dates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to obtain approval of competing products following our patent expiration and launch their product earlier than might otherwise be the case.

Outside of the United States we cannot be certain that any country's patent or trademark office will not implement new rules that could seriously affect how we draft, file, prosecute and maintain patents, trademarks and patent and trademark applications.

We cannot be certain that the patent or trademark offices of countries outside the United States will not implement new rules that increase costs for drafting, filing, prosecuting and maintaining patents, trademarks and patent and trademark applications or that any such new rules will not restrict our ability to file for patent or trademark protection. For example, we may elect not to seek patent protection in some jurisdictions or for some drug candidates in order to save costs. We may be forced to abandon or return the rights to specific patents due to a lack of financial resources.

For example, following the result of a referendum in 2016, the U.K. left the EU on January 31, 2020, commonly referred to as Brexit. The impact of the withdrawal of the U.K. from the EU will not be known for some time, which could lead to a period of uncertainty relating to our ability to obtain and maintain patents and trademarks in the U.K. In 2012, the European Patent Package, or EU Patent Package, regulations were passed with the goal of providing for a single pan-European Unitary Patent, and a new European Unified Patent Court, or UPC, for litigation of European patents. It is possible that implementation of the EU Patent Package will occur in the first half of 2023. If the EU Patent Package is ratified and in effect, all European patents, including those issued prior to ratification, would by default automatically fall under the jurisdiction of the UPC and allow for the possibility of obtaining pan-European injunctions. Under the EU Patent Package as currently proposed, once the UPC is established, patent holders are permitted to "opt out" of the UPC on a patent-by-patent basis during an initial seven year period after the EU Patent Package is ratified. Owners of traditional European patent applications who receive notice of grant after the EU Patent Package is ratified could either accept a Unitary Patent or validate the patent nationally and file an opt-out demand. The EU Patent Package may increase the uncertainties and costs surrounding the enforcement or defense of our issued European patents and pending applications. The full impact on future European patent filing strategy and the enforcement or defense of our issued European patents in member states and/or the UPC is not known.

Risks Related to Our Securities

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 stockholders' equity of at least $2,500,000, or the Stockholders' Equity Requirement pursuant to Nasdaq Listing Rule 5550(b)(1), or Rule 5550(b)(1). On November 15, 2022, we received notice from Nasdaq, or the Notice, advising us that we are not in

compliance with the Stockholders' Equity Requirement. Pursuant to the Notice, Nasdaq gave us until December 30, 2022, to submit to Nasdaq a plan to regain compliance. On January 17, 2023, Nasdaq informed us that our plan has been accepted and we have until May 15, 2023 to comply with such plan.

There can be no assurance that we will be able to maintain compliance with 5550(b)(1) or the other Nasdaq listing requirements. If we do not 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.

The market price for our common stock has been volatile and may continue to fluctuate or may decline significantly in the future.

An active, liquid and orderly market for our common stock may not be sustained, which could depress the trading price of our common stock or cause it to continue to be highly volatile or subject to wide fluctuations. Some of the factors that could negatively affect our share price or result in fluctuations in the price or trading volume of our common stock include, among other things:

- the commencement, enrollment, or results of our current and future preclinical studies and clinical trials, and the results of trials of our competitors or those of other companies in our market sector;
- regulatory approval of our product candidates, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- manufacturing, supply or distribution delays or shortages;
- our ability to identify and successfully acquire or in-license new product candidates on acceptable terms;
- our ability to achieve commercial partnering or divestiture of ANJESO;
- FDA, state or international regulatory actions, including actions on regulatory applications any of our product candidates;
- legislative or regulatory changes;
- judicial pronouncements interpreting laws and regulations;
- changes in government programs;
- announcements of new products, services or technologies, commercial relationships, acquisitions or other events by us or our competitors;
- market conditions in the pharmaceutical and biotechnology sectors;
- fluctuations in stock market prices and trading volumes of similar companies;
- changes in accounting principles;
- litigation or public concern about the safety of our product candidates or similar product candidates;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant shareholders;
- our ability to obtain additional financing to advance our development operations;
- our announcement of financing transactions, including debt, convertible notes, warrant exchanges, etc.;
- our ability to regain and maintain compliance with the listing standard of Nasdaq;
- the continued negative effects of the COVID-19 pandemic on the global economy; and
- actions by institutional shareholders.

These broad market and industry factors may decrease the market price of our common stock, regardless of our actual operating performance. The stock market in general has from time-to-time experienced extreme price and volume fluctuations, including recently. In addition, in the past, following periods of volatility in the overall market and decreases in the market price of a company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

We do not expect to pay any cash dividends for the foreseeable future.

We do not anticipate that we will pay any cash dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our operations. Our ability to pay cash dividends is currently restricted by the terms of our credit facility with MAM Eagle Lender. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

Some provisions of our charter documents and Pennsylvania law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our shareholders and may prevent attempts by our shareholders to replace or remove our current management.

Provisions in our amended and restated articles of incorporation, as amended, or our Articles, and amended and restated bylaws, or Bylaws, could make it more difficult for a third-party to acquire us or increase the cost of acquiring us, even if doing so would benefit our shareholders, or remove our current management. These include provisions that:

- divide our board of directors into three classes with staggered three-year terms;
- provide that a special meeting of shareholders may be called only by a majority of our board of directors, the chairman of our board of directors or our chief executive officer or president;
- establish advance notice procedures with respect to shareholder proposals to be brought before a shareholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of director;
- provide that certain provisions of the Articles may only be amended with the affirmative vote of 662/3% of the holders of the outstanding shares of capital stock;
- provide that shareholders may only act at a duly organized meeting; and
- provide that members of our board of directors may be removed from office by our shareholders only for cause by the affirmative vote of 75% of the total voting power of all shares entitled to vote generally in the election of directors.

These provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it more difficult for shareholders to replace members of our board of directors, who are responsible for appointing the members of our management. Because we are incorporated in Pennsylvania, we are governed by the provisions of the Pennsylvania Business Corporation Law of 1988, or PBCL, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our shareholders. Under Pennsylvania law, a corporation may not, in general, engage in a business combination with any holder of 20% or more of its capital stock unless the holder has held the stock for five years or, among other things, the board of directors has approved the transaction. Any provision of our Articles or Bylaws or Pennsylvania law that has the effect of delaying or deterring a change in control could limit the opportunity for our shareholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

Our Articles designate the state and federal courts located within the County of Philadelphia in the Commonwealth of Pennsylvania as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our shareholders, which could discourage lawsuits against us and our directors and officers.

Our Articles provide that, unless we consent in writing to the selection of an alternative forum, a state or federal court located within the County of Philadelphia in the Commonwealth of Pennsylvania will be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of our company, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees or our shareholders, (iii) any action asserting a claim arising pursuant to any provision of PBCL, or (iv) any action asserting a claim peculiar to the relationships among or between our company and our officers, directors and shareholders. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our Articles described above. This choice of forum provision may limit a shareholder's ability to bring a claim in a judicial forum that it finds favorable for the types of claims listed above, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provision contained in our Bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results and financial condition.

General Risk Factors

The security of our information technology systems may be compromised in the event of system failures, unauthorized access, cyberattacks or a deficiency in our cybersecurity, and confidential information, including non-public personal information that we maintain, could be improperly disclosed.

We rely extensively on information technology and systems including internet sites, data hosting, physical security, and software applications and platforms. Despite our security measures, our information technology systems, some of which are managed by third parties, may be susceptible to damage, disruptions or shutdowns due to computer viruses, attacks by computer hackers, failures during the process of upgrading or replacing software, power outages, user errors or catastrophic events. A significant breakdown, invasion, corruption, destruction or interruption of critical information technology systems, by our employees, others with authorized access to our systems or unauthorized persons could negatively impact or interrupt operations. For example, the loss of data from completed or ongoing clinical trials for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. The use of technology, including cloud-based computing, creates opportunities for the unintentional dissemination or intentional destruction of confidential information stored in our systems or our third-party systems. We could also experience a business interruption, theft of confidential information or reputational damage from malware or other cyberattacks, which may compromise our systems or lead to data leakage, either internally or at our third-party providers.

As part of our business, we maintain large amounts of confidential information, including non-public personal information on patients and our employees. Breaches in security, either internally or at our third-party providers, could result in the loss or misuse of this information, which could, in turn, result in potential regulatory actions or litigation, including material claims for damages, interruption to our operations, damage to our reputation or otherwise have a material adverse effect on our business, financial condition and operating results. Although we maintain information security policies and systems designed to prevent unauthorized use or disclosure of confidential information, including non-public personal information, there can be no assurance that such use or disclosure will not occur.

Any such business interruption, theft of confidential information or reputational damage from malware or other cyberattacks, or violation of personal information laws, could have a material adverse effect on our business, financial condition, and results of operations.

Litigation involving patents, patent applications and other proprietary rights is expensive and time-consuming. If we are involved in such litigation, it could cause delays in bringing our product candidates to market and interfere with our business.

Our success depends in part on not infringing patents and proprietary rights of third parties. Although we are not currently aware of litigation or other proceedings or third-party claims of intellectual property infringement related to our product candidates, the pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights.

In a patent infringement claim against us, we may assert, as a defense, that we do not infringe the relevant patent claims, that the patent is invalid or both. The strength of our defenses will depend on the patents asserted, the interpretation of these patents and/or our ability to invalidate the asserted patents. However, we could be unsuccessful in advancing non-infringement and/or invalidity arguments in our defense. In the United States, issued patents enjoy a presumption of validity, and the party challenging the validity of a patent claim must present clear and convincing evidence of invalidity, which is a high burden of proof. Conversely, the patent owner need only prove infringement by a preponderance of the evidence, which is a low burden of proof.

If we were found by a court to have infringed a valid third-party patent claim, we could be prevented from using the patented technology or be required to pay the owner of the patent for the right to license the patented technology or other compensatory damages. If we decide to pursue a license to one or more of these patents, we may not be able to obtain a license on commercially reasonable terms, if at all, or the license we obtain may require us to pay substantial royalties or grant cross licenses to our patent rights. For example, if the relevant patent is owned by a competitor, that competitor may choose not to license patent rights to us. If we decide to develop alternative technology, we may not be able to do so in a timely or cost-effective manner, if at all.

In addition, because patent applications can take years to issue and are often afforded confidentiality for some period of time, there may currently be pending applications, unknown to us, that later result in issued patents that could cover one or more of our products.

It is possible that we may in the future receive, particularly as a public company, communications from competitors and other companies alleging that we may be infringing their patents, trade secrets or other intellectual property rights, offering licenses to such intellectual property or threatening litigation. In addition to patent infringement claims, third parties may assert copyright, trademark or other proprietary rights against us. We may need to expend considerable resources to counter such claims and may not be able to be successful in our defense. Our business may suffer if a finding of infringement is established.

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.

The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged in the United States to date. The pharmaceutical patent situation outside of the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents that may

be issued from the applications we currently or may in the future own or license from third parties. Further, if any patent license we obtain is deemed invalid and/or unenforceable, it could impact our ability to commercialize or partner our technology.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- we were the first to make the inventions covered by each of our pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- an individual or party will not challenge inventorship, that if successful, could have an adverse effect on our business;
- any patents issued to us or our collaborators will provide a basis for commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties; or
- the patents of others will not have an adverse effect on our business.

If we do not adequately protect our proprietary rights, competitors may be able to use our technologies and erode or negate any competitive advantage we may possess, which could materially harm our business, negatively affect our position in the marketplace, limit our ability to commercialize our product candidates and delay or render impossible our achievement of profitability.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

In the future, we may rely on trade secrets to protect our proprietary know-how and technological advances, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection could enable competitors to use our proprietary information to develop products that compete with our products or cause additional, material adverse effects on our competitive business position.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the United States Patent and Trademark Office and various foreign governmental patent agencies in several stages over the lifetime of the patents and/or applications.

We have systems in place to remind us to pay periodic maintenance fees, renewal fees, annuity fees and various other patent and application fees, and we employ an outside law firm to pay these fees. The U.S. Patent and Trademark Office and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ an outside law firm and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If this occurs, our competitors may be able to enter the market, which would have a material adverse effect on our business.

We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property. If we are unable to adequately enforce our intellectual property rights throughout the world, our business, financial condition, and results of operations could be adversely impacted.

If securities or industry analysts fail to initiate or maintain coverage of our stock, publish a negative report or change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us, our business, our market or our competitors. If securities or industry analysts fail to initiate coverage of our stock, the lack of exposure to the market could cause our stock price or trading volume to decline. If any of the analysts who cover us or may cover us in the future publish a negative report or change their recommendation regarding our stock adversely, or provide more favorable relative recommendations about our competitors, our stock price would likely decline. If any analyst who covers us or may cover us in the future were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Our shareholders may experience dilution in the future.

In the future, our shareholders' percentage ownership in the company may be diluted because of equity issuances for acquisitions, capital market transactions or otherwise, including equity awards that we plan to grant to our directors, officers and employees. Such awards will have a dilutive effect on our earnings per share, which could adversely affect the market price of our common stock. From time to time, we expect to issue stock options or other share-based awards to employees under our employee benefits plans.

In addition, our Articles will authorize us to issue, without the approval of our shareholders, one or more classes or series of preferred stock having such designation, powers, preferences and relative, participating, optional and other special rights, including preferences over our common stock with respect to dividends and distributions, as our board of directors may determine. The terms of one or more classes or series of preferred stock could dilute the voting power or reduce the value of our common stock. For example, we could grant the holders of preferred stock the right to elect some number of directors in all events or on the happening of specified events or the right to veto specified transactions. Similarly, the repurchase or redemption rights or liquidation preferences we could assign to holders of preferred stock could affect the residual value of the common stock.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal executive offices are located at 490 Lapp Road, Malvern, PA 19355, where we occupy approximately 17,369 square feet of leased laboratory and office space pursuant to an eleven-year lease, which expires on December 31, 2027. We also lease a 4,145 square foot office space in Dublin, Ireland pursuant to a short-term lease.

Item 3. Legal Proceedings

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. 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, 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 was held on October 26, 2022, and the settlement was approved in December 2022. 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.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock is traded on The Nasdaq Capital Market under the symbol "BXRX."

Holders of Common Stock

As of February 21, 2023, there were 9 holders of record of our common stock. We believe that the number of beneficial owners of our common stock at that date was substantially greater.

Dividend Policy

We have never declared or paid any cash dividends on our common stock and our ability to pay cash dividends is currently restricted by the terms of our credit facility with MAM Eagle Lender. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends on our common stock will be made at the discretion of our board of directors and will depend on various factors, including applicable laws, our results of operations, financial condition, future prospects, anticipated cash needs, plans for expansion and any other factors deemed relevant by our board of directors.

Issuer Repurchases of Equity Securities

None.

Securities Authorized for Issuance Under Equity Compensation Plans

Other information about our equity compensation plans is incorporated herein by reference to Part III, Item 12 of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions and other factors that could cause actual results to differ materially from those made, projected or implied in the forward-looking statements. Our actual results may differ materially from those discussed below. Please see "Forward-Looking Statements" and "Risk Factors" included in Part I, Item 1A of this Annual Report on Form 10-K for factors that could cause or contribute to such differences.

Overview

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

We hold exclusive global rights to two new molecular entities, which are centrally acting Neuromuscular Blocking Agents (NMBs), BX1000, an intermediate duration of action NMB currently undergoing a Phase II clinical trial, and BX2000, an ultra-short acting NMB currently undergoing a Phase I clinical trial, as well as a proprietary blockade reversal agent, BX3000, currently being evaluated in preclinical studies intended to support an IND filing in 2023. BX3000 is an agent that is expected to rapidly reverse BX1000 and BX2000 blockade. All three agents are licensed from Cornell University. We believe these agents, when administered in succession, allow for a rapid onset of centrally acting neuromuscular blockade, followed by a rapid reversal of the neuromuscular blockade with BX3000. These novel agents have the potential to meaningfully reduce time to onset of blocking and of reversal of blockade, reducing time in operating rooms or post operative suites (PACU), resulting in potential clinical and cost advantages, as well as valuable cost savings for hospitals and ambulatory surgical centers.

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 could be administered alone or in combination with other non-NSAID analgesics. We 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 positive health economic impacts in specific surgical settings. As many sources have documented, many hospitals have suffered great economic impact associated with the Covid-19 pandemic and with its continuing impact on surgery rates, as well as the impacts of the "Great Resignation" of 2021 and beyond, impacting nursing and other professional staff available to support surgery and post operative care. These market conditions and the ensuing economic hardship that threatens the functioning of numerous well known and highly regarded institutions have impacted the willingness and ability of acute care facilities to use agents that may cost slightly more than available opioid treatments to manage post operative pain, even when these less expensive treatments prolong hospital stay. These factors influenced the uptake of ANJESO and a number of other non-opioid treatments. The expense of maintaining a commercial presence in an acute care setting that is distressed, as well as maintaining milestone payments due to our licensor during the present and upcoming years caused us to discontinue commercial sales of ANJESO in December of 2022.

Our 2022 costs have consisted primarily of expenses incurred in conducting our manufacturing and commercialization of ANJESO, public company and personnel costs, as well as clinical trials and manufacturing costs for our NMB blocking and reversal agents. 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 development programs, including our clinical, preclinical and manufacturing related activities. Our expenses over the next several years are expected to primarily relate to developing our product candidates. In addition, we may incur costs associated with the acquisition or in-license of products and successful commercialization of the acquired or in-licensed products.

COVID-19 Impact

Our efforts to commercialize ANJESO were impacted in 2020, 2021, and continued 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. Intermittent impacts in the reduction of elective surgeries have occurred and this has had an impact in the recent quarter. Overall, many centers have not 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 and the financial condition of many hospitals, caused a reduction in hospital staffing, leading, in some cases, to continued 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 retirement and resignation of a higher percentage of staff than normal as well as 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 demand for ANJESO, and was a contributing factor in our decision to discontinue 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, changes in COVID-19, Medicare and other reimbursements, and this impact may result in ongoing decreased revenue. 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 financial results may be adversely impacted in the future.

Financial Overview

Revenue

We sold 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. In December 2022, we discontinued the commercialization of ANJESO and expect that the majority of expenses associated with the discontinuation will be incurred by the end of the first quarter of 2023.

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 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 used in the commercialization as research and development expense prior to the regulatory approval of ANJESO. We discontinued commercialization of ANJESO in December 2022. We believe there is modest inventory held at the wholesaler level and have notified wholesalers through our 3PL that we will accept product returns until June 30, 2023.

Research and Development Expenses

Research and development expenses have consisted primarily of costs incurred in connection with the NMB portfolio and the pediatric development of ANJESO 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;
- costs related to facilities, depreciation and other allocated expenses;
- 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 section titled “Risk Factors” of this Annual Report on Form 10-K.

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 the development and commercialization scale-up of our NMB product candidate portfolio. 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 supported 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 for the year ended December 31, 2022 as a result of a reduction in personnel and marketing costs and further as a result of the discontinuation of commercial efforts for ANJESO. We expect our future selling and commercial costs to be minimal. We expect general and administrative expenses will remain relatively constant in the near term. Our quarterly selling, general and administrative expenses for the year ended December 31, 2022 were:

3/31/2022	6/30/2022	9/30/2022	12/31/2022
$ 14,190	$ 4,029	$ 3,808	$ 2,092

2022 Reduction in Force

Due to our current cash position and assessment of market conditions in the hospital pain space, in March 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, of which $0.6 million remains accrued and unpaid as of December 31, 2022. The reduction in force was designed to substantially reduce our operational expenses and conserve cash resources. Further, in September 2022, we terminated the remaining dedicated commercial team of 7 employees and incurred a third quarter charge of $0.2 million for severance and other related costs.

Change in Fair Value of Contingent Consideration

In connection with the Separation, we entered into an Assignment and a Partial Assignment, Assumption and Bifurcation Agreement, or the Alkermes Agreements, relating to the Purchase and Sale Agreement for the acquisition of certain assets, including the worldwide rights to injectable meloxicam and 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 $1.2 million, which was due in the first quarter of 2022, 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 December 31, 2022 recorded a $19.9 million payment obligation, representing the present 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 December 31, 2022, we have paid $22.6 million in milestone payments to Alkermes. We are in discussions with Alkermes regarding the discontinuation of commercial efforts for ANJESO and the associated obligations.

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, or PPP, of the CARES Act administered by the Small Business Administration (the "SBA"), which has been fully forgiven as of December 31, 2021.

Income Taxation

We maintained a valuation allowance against our deferred tax assets as of December 31, 2022 and 2021.

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021

	Year ended December 31,	
	2022	2021
	(amounts in thousands)	
Revenue, net	$ 1,269	$ 1,080
Operating expenses:		
Cost of sales	7,009	2,445
Research and development	3,887	3,125
Selling, general and administrative	24,119	45,310
Amortization of intangible assets	1,997	2,576
Change in warrant valuation	(7)	(58)
Change in contingent consideration valuation	(2,761)	(33,312)
Loss on impairment of property and equipment	4,157	—
Loss on impairment of intangible asset	19,681	—
Total operating expenses	58,082	20,086
Operating loss	(56,813)	(19,006)
Other expense, net	(1,982)	(763)
Net loss	$ (58,795)	$ (19,769)

Revenue, net. For the year ended December 31, 2022, net product revenue related to sales of ANJESO in the U.S. was $1.3 million. This compares to $1.1 million for the year ended December 31, 2021. While utilizing the title model of distribution, product revenue is recognized as shipments are made to our 3PL provider. The increase of $0.2 million was attributable to increased demand at existing accounts.

Cost of sales. Our cost of sales was $7.0 million and $2.4 million for the years ended December 31, 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 years ended December 31, 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. The increase of $4.6 million is primarily a result of the increase in the inventory reserve of $5.2 million, partially offset by the reduction in personnel related costs of $0.4 million and the reduction in production and storage costs of $0.2 million.

Research and Development. Our research and development expenses were $3.9 million and $3.1 million for the years ended December 31, 2022 and 2021, respectively. The increase of $0.8 million was primarily due to the increase in the NMB portfolio clinical trial costs of $1.0 million and an increase of $0.2 million related to the pediatric trial costs for ANJESO. These costs were partially offset by a decrease in personnel related costs of $0.4 million.

Selling, General and Administrative. Our selling, general and administrative expenses were $24.1 million and $45.3 for the years ended December 31, 2022 and 2021. The decrease of $21.2 million was as a result of a reduction in personnel costs of $12.6 million, a decrease in marketing costs of $4.7 million, a decrease in public company costs of $2.3 million, a decrease in consulting costs of $0.9 million, a decrease in travel expenses of $0.4 million, and a decrease in other costs of $0.3 million.

Amortization of Intangible Assets. Amortization expense was $2.0 million and $2.6 million for the years ended December 31, 2022 and 2021, respectively, which was related to the amortization of our intangible asset resulting from research and development activities over its estimated useful life beginning in the first quarter of fiscal year 2020.

Change in Warrant Valuation. There was not a material change in warrant valuation for the year ended December 31, 2022. The change in warrant valuation decrease in value of $0.1 million for the year ended December 31, 2021 related to the warrants sold as part of our March 26, 2020 underwritten public offering, including the impact of our warrant exchange transaction in October 2020.

Change in Contingent Consideration valuation. Our change in contingent consideration valuation consisted of a decrease of value of $2.8 million for the year ended December 31, 2022 as compared to an decrease in value of $33.3 million for the year ended December 31, 2021. The non-cash charge for contingent consideration in each period relates to the revaluation of the probability-adjusted fair value of the Alkermes Transaction payment obligation. The decrease in the fair value of the liability of $2.8 million in 2022 was primarily due to the discontinuation of commercialization of ANJESO and as a result the updated forecasts of ANJESO as well as an increase in the discount rate used to calculate the fair value. The decrease in the fair value of the liability of $33.3 million in 2021 was primarily due to updated forecasts for ANJESO as well as an increase in the discount rate used to calculate the fair value.

Loss on impairment of property and equipment. Loss on impairment of property and equipment was $4.2 million for the year ended December 31, 2022, which relates to the impairment associated with the second manufacturing suite in the Alkermes facility that will no longer be needed for manufacturing ANJESO due to current business conditions and discontinuation of commercialization. There was no loss on impairment of property and equipment for the year ended December 31, 2021.

Loss on impairment of intangible asset. Loss on impairment of intangible asset was $19.7 million for the year ended December 31, 2022, which was recorded to eliminate the carrying value of the intangible asset as a result of our quantitative impairment test and discontinuation of commercialization of ANJESO. There was no loss on impairment of intangible asset for the year ended December 31, 2021.

Other Expense, net. Other expense for the years ended December 31, 2022 and 2021 was $2.0 million and $0.8 million, respectively. The change in other 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 and the decrease of $0.1 million in the interest expense incurred on our Credit Agreement with MAM Eagle Lender due to the reduction in principal balance.

Liquidity and Capital Resources

As of December 31, 2022, we had $5.3 million in cash and cash equivalents.

On December 6, 2022, we closed a best efforts public offering of: (i) 54,787 shares of its common stock, par value $0.01 per share and accompanying Series A-3 warrants to purchase 54,787 shares of common stock and Series A-4 warrants to purchase 54,787 shares of common stock, at a combined public offering price of $4.795 per share and accompanying Series A Warrants and (ii) Series C pre-funded warrants to purchase 988,000 shares of common stock and accompanying Series A-3 Warrants to purchase 988,000 shares of common stock and Series A-4 Warrants to purchase 988,000 shares of common stock at a combined public offering price of $4.785 per Series C pre-funded warrant and accompanying Series A warrants, which was equal to the public offering price per share of common stock and accompanying Series A warrants less the $0.01 per share exercise price of each such Series C pre-funded warrant. The Series A warrants have an exercise price of $4.50 per share of common stock. The Series A-3 warrants are exercisable upon issuance and will expire on December 6, 2027. The Series A-4 warrants are exercisable upon issuance and will expire on January 8, 2024. The exercise price of the Series A Warrants and the Series A-4 Warrants is subject to adjustment for stock splits, reverse splits, and similar capital transactions as described in the Series A Warrants. The Series C Warrants have been exercised in full. As compensation to H.C. Wainwright & Co., LLC, as the exclusive placement agent in connection with the offering, the Company paid 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 reimbursement of certain expenses and legal fees. The Company also issued to designees of the placement agent warrants to purchase up to 62,567 shares of common stock. The placement agent warrants have substantially the same terms as the Series A warrants, except that the placement agent warrants have an exercise price equal to $5.99375 per share and expire on December 2, 2027. Net proceeds, after deducting underwriting discounts and commissions and offering expenses, was $4.0 million

On September 1, 2022, we closed a best efforts public offering of: (i) 188,872 shares of its common stock, par value $0.01 per share and accompanying Series A-1 warrants to purchase 188,872 shares of Common stock and Series A-2 warrants, and together with the Series A-1 warrants to purchase 188,872 shares of Common Stock, at a combined public offering price of $21.00 per share and Series A warrants and (ii) Series B pre-funded warrants to purchase 106,607 shares of Common Stock and accompanying Series A-1 warrants to purchase 106,607 shares of Common Stock and Series A-2 warrants to purchase 106,607 shares of Common stock at a combined public offering price of $20.60 per Series B pre-funded warrant and Series A warrants, which is equal to the public offering price per share of Common Stock and accompanying Series A warrants less the $0.01 per share exercise price of each such Series B pre-funded warrant. The Series A warrants have an exercise price of $21.00 per share of Common Stock. The Series A-1 warrants are exercisable upon issuance and will expire five years from the date of issuance. The Series A-2 warrants are exercisable upon issuance and will expire thirteen months from the date of issuance. The exercise price of the Series A warrants is subject to adjustment for stock splits, reverse splits, and similar capital transactions as described in the Series A warrants. Subject to certain ownership limitations, the Series B pre-funded warrants were immediately exercisable and were exercised at a nominal consideration of $0.01 per share of Common Stock upon the closing of the transaction. As compensation to H.C. Wainwright & Co., LLC, as the exclusive placement agent in connection with the Offering, we paid 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 reimbursement of certain expenses and legal fees. We also issued to designees of the placement agent warrants to purchase up to 17,728 shares of common stock. The placement agent warrants have substantially the same terms as the Series A warrants, except that the placement agent warrants have an exercise price equal to $26.25 per share and expire on August 29, 2027. Net proceeds, after deducting underwriting discounts and commissions and offering expenses, was $5.0 million.

On May 17, 2022, we closed a registered direct offering of 41,152 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 41,152 shares of common stock at a combined offering price of $48.60 per share and associated warrant. The warrants have an exercise price of $43.60 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 2,469 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 $60.75 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 45,791 shares of common stock, pre-funded warrants to purchase 41,929 shares of common stock at an exercise price of $0.01 per share and warrants to purchase 87,719 shares of common stock at an exercise price of $130.00 per share, as well as up to 13,158 additional shares of common stock and/or additional warrants to purchase up to 13,158 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 $114.00, and the public offering price for each pre-funded warrant and accompanying warrant was $113.60. 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 5,263 shares of common stock at an exercise price of $142.50 per share. On February 28, 2022, the Underwriter partially exercised its option to purchase an additional 2,847 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 9,062 shares of common stock, or the December 2021 Warrants, for net proceeds of $3,656. 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 12,083 shares of common stock at a conversion price of $350.00 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 724 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 $448.00 per share and became exercisable upon the six-month anniversary of their issuance.

On May 31, 2021, we closed a registered direct offering of 10,021 shares of common stock, or the May Offering, at an offering price of $1,190.00 per share and warrants to purchase 10,021 shares of common stock, or the May Warrants, at an exercise price of $1,260.00 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 601 shares of common stock at an exercise price of $1,487.50 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 7,857 shares of common stock, or the February Offering, at an offering price of $2,240.00 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 471 shares of common stock, or the February Placement Agent Warrants. The February Placement Agent Warrants have an exercise price of $2,800.00 per share.

On January 21, 2021, we entered into an agreement to issue and sell warrants exercisable for an aggregate of 7,358 shares of common stock, or the January Warrants, at an offering price of $175.00 per warrant in exchange for the exercise of the institutional investor's existing December Series A warrants that were issued to them on December 21, 2020, at an exercise price of $1,652 per warrant. The January Warrants have an exercise price of $2,240.00 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 441 shares of common stock, or the January Placement Agent Warrants. The January Placement Agent Warrants have substantially the same terms as the January Warrants, except that the January Placement Agent Warrants have an exercise price equal to $2,800.00 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 Annual 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 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, 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 October 24, 2022, we entered into Amendment No. 2 and Waiver to Credit Agreement with MAM Eagle Lender. Pursuant to the terms of the amendment, the Credit Agreement is amended such that we must repay the principal thereunder (i) on the first business day of each month until the Interest Payment Date on December 1, 2022, in equal monthly installments of principal based on an amortization schedule of 36 months, (ii) an additional payment of principal in the amount of $0.3 million prior to December 31, 2022 and (iii) commencing on the Interest Payment Date on January 2, 2023 and on each Interest Payment Date thereafter until the obligations have been repaid in full, the principal amount of $0.5 million. In addition, the amendment decreases the minimum cash covenant we are required to maintain under the Credit Agreement to (i) $3.0 million for the period beginning on October 1, 2022, and ending on November 30, 2022, (ii) $4.5 million for the period beginning on December 1, 2022, and ending on February 28, 2023, and (iii) $4.0 million from and after March 1, 2023. Further, we have agreed that prior to December 31, 2022, we shall not, without the prior written consent of the Lenders, make or permit any payment under its agreements with Alkermes. In consideration for the amendment, we paid the Agent an amendment fee of $0.01 million and the Lender an amendment fee of $0.2 million.

On December 1, 2022, we entered into Amendment No. 3 to Credit Agreement with MAM Eagle Lender. Pursuant to the terms of the amendment, the amendment decreases the minimum cash covenant we are required to maintain under the credit agreement to (a) from October 1, 2022 to December 6, 2022 to not be less than $3.0 million at any time, (b) from December 7, 2022 to February 28, 2023 to not be less than $4.5 million, and (c) from and after March 1, 2023 to not be less than $4.0 million.

In January 2023, we entered into Amendment No. 4 to Credit Agreement with MAM Eagle Lender. Pursuant to the terms of the amendment, the credit agreement was amended such that we must make (i) a payment of principal in the amount of $0.5 million on January 3, 2023, (ii) a payment of principal in the amount of $0.3 million on February 1, 2023 and March 1, 2023, and (iii) on the interest payment date on April 3, 2023 and on each interest payment date thereafter until the obligations are repaid in full, a payment in the principal amount of $0.5 million. In addition, the amendment decreases the minimum cash covenant we are required to maintain under the credit agreement, or the Minimum Liquidity Covenant, to (i) $3.0 million for the period beginning on October 1, 2022, and ending on December 6, 2022, (ii) $4.5 million for the period beginning on December 7, 2022, and ending on January 10, 2023, (iii) $2.225 million for the period beginning on January 11, 2023, and ending on February 28, 2023, and (iv) $3.0 million from and after March 1, 2023. Further, we have agreed that prior to April 30, 2023, we will not, without the prior written consent of MAM Eagle Lender, make or permit any payment under our agreements with Alkermes.

On May 8, 2020, we entered into a promissory note for $1.5 million under the PPP of the CARES Act administered by the SBA. We have used the loan proceeds for covered payroll costs in accordance with the relevant terms and conditions of the CARES Act. This Loan may be partially or fully forgiven if we comply with the provisions of the CARES Act including the use of Loan proceeds for payroll costs, rent, utilities and other expenses, and at least 60% of the loan proceeds must be used for payroll costs as defined by the CARES Act. 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, 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 December 31, 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 $27.8 million and $49.3 million for the years ended December 31, 2022 and 2021, respectively, which represents our operating losses less our non-cash items including: stock-based compensation, non-cash interest expense, gain on extinguishment of debt in the prior year, depreciation, amortization, changes in warrant valuations, changes in fair value of contingent consideration, and impairment losses on property and equipment and intangible asset, as well as changes in operating assets and liabilities.

There was no significant cash used in investing activities for the year ended December 31, 2022. Cash used in investing activities for the year ended December 31, 2021 was $0.2 million, which was primarily due to purchases of property and equipment of $0.2 million.

There was $17.2 million of cash provided by financing activities in the year ended December 31, 2022 consisting of net proceeds of $18.6 million from public offerings 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, and $0.4 million in proceeds from warrant exercises. This was partially offset by a payment of contingent consideration of $1.2 million, payments on long-term debt of $2.2 million and payment of $0.2 million in deferred financing costs. There was $35.0 million of cash provided by financing activities in the year ended December 31, 2021 consisting of net proceeds of $30.8 million from registered direct offerings and net proceeds of $12.2 million from warrant exercises, partially offset by a payment of contingent consideration of $7.9 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 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 sale of certain assets;
- our ability to maintain listing on the Nasdaq Capital Market;
- 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 any 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 December 31, 2022:

	Payments Due by Period (in 000s)				
Contractual Obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Debt Obligations (1):					
Debt	$ 7,756	$ 5,600	$ 2,156	$ —	$ —
Interest on Debt	1,056	727	329	—	—
Purchase Obligations (2):	338	204	106	28	—
Operating Leases (3)	1,468	330	556	582	—
Other Long-Term Liabilities:					
Other License Commitments and Milestone payments (4)	16,395	80	190	125	—
Alkermes Payments (5)	117,371	9,829	21,113	6,429	—
Employment Agreements (6)	927	618	309	—	—
Total Contractual Obligations	$ 145,311	$ 17,388	$ 24,759	$ 7,164	$ —

(1)Debt obligations consist of principal, an exit fee of 2.5% of that principal and interest on the $7.8 million outstanding term loan under our Credit Agreement. See Note 11 to the Consolidated Financial Statements included in this Annual Report on Form 10-K.
(2)These obligations consist of cancelable and non-cancelable purchase commitments related to goods or services. In accordance with U.S. GAAP, these obligations are not recorded on our Consolidated Balance Sheets. See Note 12 to the Consolidated Financial Statements included in this Annual Report on Form 10-K.
(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 Annual Report on Form 10-K.
(4)We license the 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 that may arise based on meeting certain milestones. 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 timing for has not been established. In accordance with U.S. GAAP, certain of these obligations are not recorded on our Consolidated Balance Sheets. See 12(a) to the Consolidated Financial Statements included in this Annual Report on Form 10-K.
(5)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 $80,000 because they are in some instances, events that are not in our control and dependent on the commercial success of the product. In accordance with U.S. GAAP, the fair value of these obligations is recorded as contingent consideration on our Consolidated Balance Sheets. See Note 12(b) to the Consolidated Financial Statements included in this Annual Report on Form 10-K.
(6)We have entered into an employment agreement with one of our named executive officers. As of December 31, 2022, this employment agreement provided for, among other things, annual base salary in an aggregate amount of not less than this amount, from that date through June 2024. 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 Annual Report on Form 10-K.

Critical Accounting Policies and Estimates

This management's discussion and analysis of our financial condition and results of operations is based on our consolidated and combined financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, expenses and the disclosure of contingent assets and liabilities in our combined financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Revenue Recognition – Subsequent to regulatory approval for ANJESO from the FDA in 2020, we began selling ANJESO in the U.S. through a single 3PL which takes title to and control of the goods. We recognized 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 payment terms are generally between thirty to ninety days.

Impairment of Long-lived Assets – We are required to review the carrying value of long-lived assets, including property and equipment and amortizable intangible assets, for recoverability whenever events occur or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. The impairment test is a two-step test. Under step one we assess the recoverability of an asset (or asset group). The carrying amount of an asset (or asset group) is not recoverable if it exceeds the sum of the undiscounted cash flows expected from the use and eventual disposition of the asset (or asset group). The impairment loss is measured in step two as the difference between the carrying value of the asset (or asset group) and its fair value. Assumptions and estimates used in the evaluation of impairment are subjective and changes in these assumptions may negatively impact projected undiscounted cash flows, which could result in impairment charges in future periods. The Company performed an impairment test as of December 31, 2022 after identifying indicators of impairment, including a decline in share price, the termination of the dedicated commercial team, sustained impacts of COVID-19 on the market and the discontinuation of commercialization. Based on the quantitative analysis, an impairment loss of $19.7 million was recorded as of December 31, 2022 eliminating the carrying value of the intangible asset. Further, an impairment loss on property and equipment of $4.2 million was recorded for the year ended December 31, 2022, which relates to the impairment associated with the second manufacturing suite in the Alkermes facility that will no longer be needed for manufacturing ANJESO, due to discontinuation of commercialization.

Contingent Consideration – We revalue our contingent consideration on a quarterly basis using a discounted cash flow valuation model. The model uses significant unobservable inputs, including the discount rate and projected future revenue.

New Accounting Pronouncements

For a discussion of new accounting pronouncements see Note 3 to the Consolidated Financial Statements included in this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business. These market risks are principally limited to interest rate fluctuations. At December 31, 2022, we had approximately $2.2 million invested in money market instruments. We believe our policy of investing in highly-rated securities, whose maturities are, at December 31, 2022, all less than one month, minimizes such risks. Due to the short-term duration of our investment portfolio and the low-risk profile of our investments, an immediate 10.0% change in interest rates would not have a material effect on the fair market value of our portfolio. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our investment portfolio. We do not enter into investments for trading or speculative purposes.

We have license agreements with Orion for certain product pipeline candidates which require the payment of milestones in Euros upon the achievement of certain regulatory and commercialization events and royalties on product sales. As of December 31, 2022, no milestones or royalties were due under these agreements, and we do not anticipate incurring milestone or royalty costs under these agreements until we advance our development of certain product pipeline candidates. We do not believe foreign currency exchange rate risk is a material risk at this time; however, these agreements could, in the future, give rise to foreign currency transaction gains or losses. As a result, our results of operations and financial position could be exposed to changing currency exchange rates. In the future, we may periodically use forward contracts to hedge certain transactions or to neutralize exposures.

Item 8. Financial Statements and Supplementary Data

Our consolidated financial statements and the reports of our independent registered public accounting firms are included in this Annual Report on Form 10-K on the pages indicated in Part IV, Item 15.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures

None.

Item 9A. 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 December 31, 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 December 31, 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.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance of the reliability of financial reporting and of the preparation of financial statements for external reporting purposes, in accordance with U.S. generally accepted accounting principles.

Internal control over financial reporting includes policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and disposition of assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with the authorization of its management and directors; and (3) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on its financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of the effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies and procedures included in such controls may deteriorate.

Our management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2022. In making this assessment, management used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control – Integrated Framework (2013). These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and monitoring. Management's assessment included extensive documentation, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

Based on management's processes and assessment, as described above, management has concluded that, as of December 31, 2022, our internal control over financial reporting was effective.

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.

Item 9B. Other Information

On February 22, 2023, the board of directors of the Company, or the Board, approved an increase in the base salary for our principal financial officer, Jillian Dilmore, for the fiscal year 2023. The Board approved an increase in Ms. Dilmore's base salary from $235,000 to $280,000. The increase is effective as of November 1, 2022, with salary payments at the new rate beginning March 1, 2023, with retroactive payments to cover the increase in salary from November 1, 2022 to March 1, 2023 to be paid pro rata from June 2023 until December 2023.

This disclosure is provided in this Part II, Item 9B in lieu of disclosure under Item 5.02(e) of Form 8-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information with respect to this item will be set forth in the Proxy Statement for the 2023 Annual Meeting of Shareholders, or the Proxy Statement, under the headings "Board of Directors," "Executive Officers," "Section 16(a) Beneficial Ownership Reporting Compliance," and "Corporate Governance and Risk Management" and is incorporated herein by reference. The Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

Item 11. Executive Compensation

Information with respect to this item will be set forth in the Proxy Statement under the headings "Director Compensation," "Executive Compensation," and "Corporate Governance and Risk Management" is incorporated herein by reference. The Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Information with respect to this item will be set forth in the Proxy Statement under the headings "Security Ownership of Directors, Certain Beneficial Owners and Management," "Executive Compensation," and "Director Compensation," and is incorporated herein by reference. The Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Information with respect to this item will be set forth in the Proxy Statement under the headings "Certain Relationships and Related Party Transactions" and "Corporate Governance and Risk Management" and is incorporated herein by reference. The Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

Item 14. Principal Accounting Fees and Services

Our independent registered public accounting firm is EisnerAmper LLP, Philadelphia, PA, Auditor Firm ID: 274.

Information with respect to this item will be set forth in the Proxy Statement under the heading "Independent Registered Public Accounting Firms," and is incorporated herein by reference. The Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

PART IV

Item 15. Exhibits and Consolidated Financial Statement Schedules

(a)(1) Consolidated Financial Statements.

The following consolidated financial statements are filed as a part of this Annual Report on Form 10-K:

Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm (PCAOB ID: 274)

Report of Independent Registered Public Accounting Firm (PCAOB ID: 185)

Consolidated Balance Sheets as of December 31, 2022 and 2021

Consolidated Statements of Operations for the years ended December 31, 2022 and 2021

Consolidated Statements of Shareholders' (Deficit) Equity for the years ended December 31, 2022 and 2021

Consolidated Statements of Cash Flows for the years ended December 31, 2022 and 2021

(a)(2) Consolidated Financial Statement Schedules.

Not applicable.

(a)(3); (b) Exhibits:

Exhibit No.	Description	Method of Filing
2.1	Separation Agreement, dated November 20, 2019, by and between Recro Pharma, Inc. and Baudax Bio, Inc.	Incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on November 26, 2019 (File No. 001-39101).
3.1	Amended and Restated Articles of Incorporation of Baudax Bio, Inc.	Incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on November 26, 2019 (File No. 001-39101).
3.2	Articles of Amendment to the Amended and Restated Articles of Incorporation of Baudax Bio, Inc.	Incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on August 11, 2021 (File No. 001-39101).
3.3	Articles of Amendment to the Amended and Restated Articles of Incorporation of Baudax Bio, Inc.	Incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed February 15, 2022 (File No. 001-39101).
3.4	Articles of Amendment to the Amended and Restated Articles of Incorporation, as amended of Baudax Bio, Inc.	Incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on November 30, 2022 (File No. 001-39101).
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock.	Incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on December 28, 2021 (File No. 001-39101).
3.6	Certificate of Designation of Preferences, Rights and Limitations of Series B Preferred Stock.	Incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on September 20, 2022 (File No. 001-39101).
3.7	Amended and Restated Bylaws of Baudax Bio, Inc.	Incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on November 26, 2019 (File No. 001-39101).

4.1	Form of Series A Warrant, issued March 26, 2020.	Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on March 24, 2020 (File No. 001-39101).
4.2	Form of Series B Warrant, issued March 26, 2020.	Incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on March 24, 2020 (File No. 001-39101).
4.3	Common Stock Purchase Warrant, dated May 29, 2020, in favor of MAM Eagle Lender, LLC.	Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on June 2, 2020 (File No. 001-39101).
4.4	Form of Series A Warrant, issued November 25, 2020.	Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on November 24, 2020 (File No. 001-39101).
4.5	Form of Placement Agent Warrant, issued November 25, 2020.	Incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed on November 24, 2020 (File No. 001-39101).
4.6	Form of Series A Warrant, issued December 21, 2020.	Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on December 18, 2020 (File No. 001-39101).
4.7	Form of Placement Agent Warrant, issued December 21, 2020.	Incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed on December 18, 2020 (File No. 001-39101).
4.8	Form of Warrant, issued January 25, 2021.	Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on January 22, 2021 (File No. 001-39101).
4.9	Form of Placement Agent Warrant, issued January 25, 2021.	Incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on January 22, 2021 (File No. 001-39101).
4.10	Form of Placement Agent Warrant, issued February 10, 2021.	Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on February 9, 2021 (File No. 001-39101).
4.11	Form of Warrant, issued June 1, 2021.	Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on June 1, 2021 (File No. 001-39101).
4.12	Form of Placement Agent Warrant, issued June 1, 2021.	Incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on June 1, 2021 (File No. 001-39101).
4.13	Form of Warrant, issued December 28, 2021.	Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on December 28, 2021 (File No. 001-39101).
4.14	Form of Placement Agent Warrant, issued December 28, 2021.	Incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on December 28, 2021 (File No. 001-39101).
4.15	Form of Investor Warrant, issued March 1, 2022.	Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on March 1, 2022 (File No. 001-39101).
4.16	Form of Pre-Funded Warrant, issued March 1, 2022.	Incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on March 1, 2022 (File No. 001-39101).

4.17	Form of Underwriter Warrant, issued March 1, 2022.	Incorporated herein by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed on March 1, 2022 (File No. 001-39101).
4.18	Form of Warrant, issued May 17, 2022.	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).
4.19	Form of Placement Agent Warrant, issued May 17, 2022.	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).
4.20	Form of Series A-1 Warrant, issued August 29, 2022.	Incorporated herein by reference to Exhibit 4.20 to the Company's Registration Statement on Form S-1/A filed on August 17, 2022 (File No. 333-266499).
4.21	Form of Series A-2 Warrant, issued August 29, 2022.	Incorporated herein by reference to Exhibit 4.21 to the Company's Registration Statement on Form S-1/A filed on August 17, 2022 (File No. 333-266499).
4.22	Form of Series B Pre-funded Warrant, issued August 29, 2022.	Incorporated herein by reference to Exhibit 4.22 to the Company's Registration Statement on Form S-1/A filed on August 17, 2022 (File No. 333-266499).
4.23	Form of Placement Agent Warrant, issued August 29, 2022.	Incorporated herein by reference to Exhibit 4.23 to the Company's Registration Statement on Form S-1/A filed on August 17, 2022 (File No. 333-266499).
4.24	Form of Warrant Amendment Agreement, entered into on December 2, 2022.	Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on December 5, 2022 (File No. 001-39101).
4.25	Form of Series A-3 Warrant, issued on December 2, 2022.	Incorporated herein by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1/A filed on November 28, 2022 (File No. 333-268251).
4.26	Form of Series A-4 Warrant, issued on December 2, 2022.	Incorporated herein by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-1/A filed on November 28, 2022 (File No. 333-268251).
4.27	Form of Series C Pre-funded Warrant, issued on December 2, 2022.	Incorporated herein by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-1/A filed on November 28, 2022 (File No. 333-268251).
4.28	Form of Placement Agent Warrant, issued on December 2, 2022.	Incorporated herein by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-1/A filed on November 28, 2022 (File No. 333-268251).
4.29	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.	Incorporated herein by reference to Exhibit 4.18 to the Company's Annual Report on Form 10-K filed on March 16, 2022 (File No. 001-39101).
10.1•	Form of Indemnification Agreement between Baudax Bio, Inc. and individual directors and officers.	Incorporated herein by reference to Exhibit 10.4 to the Company's Registration Statement on Form 10 filed on November 5, 2019 (File No. 001-39101).
10.2†	Purchase and Sale Agreement, dated March 7, 2015, by and among Recro Pharma, Inc., Recro Pharma LLC, Daravita Limited, Alkermes Pharma Ireland Limited and Eagle Holdings USA, Inc.	Incorporated herein by reference to Exhibit 10.5 to the Company's Registration Statement on Form 10 filed on October 22, 2019 (File No. 001-39101).
10.3	First Amendment, dated December 8, 2016 to Purchase and Sale Agreement, dated March 7, 2015, by and among Recro Pharma, Inc., Recro Pharma LLC, Daravita Limited, Alkermes Pharma Ireland Limited and Eagle Holdings USA, Inc.	Incorporated herein by reference to Exhibit 10.6 to the Company's Registration Statement on Form 10 filed on October 22, 2019 (File No. 001-39101).

10.4	Second Amendment, dated December 20, 2018 to Purchase and Sale Agreement, dated March 7, 2015, by and among Recro Pharma, Inc., Recro Pharma LLC, Daravita Limited, Alkermes Pharma Ireland Limited and Eagle Holdings USA, Inc.	Incorporated herein by reference to Exhibit 10.7 to the Company's Registration Statement on Form 10 filed on October 22, 2019 (File No. 001-39101).
10.5	Third Amendment to the Purchase and Sale Agreement, dated August 17, 2020 by and among Alkermes Pharma Ireland Limited, Daravita Limited, Alkermes US Holdings, Inc. and Baudax Bio, Inc.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 21, 2020 (File No. 001-39101).
10.6†	Dexmedetomidine License Agreement, dated August 22, 2008, by and between Recro Pharma, Inc. and Orion Corporation.	Incorporated herein by reference to Exhibit 10.8 to the Company's Registration Statement on Form 10 filed on October 22, 2019 (File No. 001-39101).
10.7†	First Amendment to Dexmedetomidine License Agreement, dated January 17, 2009, by and between Recro Pharma, Inc., and Orion Corporation.	Incorporated herein by reference to Exhibit 10.9 to the Company's Registration Statement on Form 10 filed on October 22, 2019 (File No. 001-39101).
10.8†	Dexmedetomidine API Supply Agreement, dated August 22, 2008, by and between Recro Pharma, Inc., and Orion Corporation.	Incorporated herein by reference to Exhibit 10.10 to the Company's Registration Statement on Form 10 filed on October 22, 2019 (File No. 001-39101).
10.9•	Baudax Bio, Inc. 2019 Equity Incentive Plan.	Incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on November 26, 2019 (File No. 001-39101).
10.10†	Asset Transfer and License Agreement, dated as of April 10, 2015, by and between Alkermes Pharma Ireland Limited and DV Technology LLC.	Incorporated herein by reference to Exhibit 10.12 to the Company's Registration Statement on Form 10 filed on October 22, 2019 (File No. 001-39101).
10.11	Amendment to Asset Transfer and License Agreement, dated December 23, 2015, by and between Alkermes Pharma Ireland Limited and Recro Gainesville LLC.	Incorporated herein by reference to Exhibit 10.13 to the Company's Registration Statement on Form 10 filed on October 22, 2019 (File No. 001-39101).
10.12	Second Amendment to Asset Transfer and License Agreement, dated December 20, 2018, by and between Alkermes Pharma Ireland Limited and Recro Gainesville LLC.	Incorporated herein by reference to Exhibit 10.14 to the Company's Registration Statement on Form 10 filed on October 22, 2019 (File No. 001-39101).
10.13	Third Amendment to Asset Transfer and License Agreement, dated August 17, 2020, by and among Alkermes Pharma Ireland Limited, Recro Gainesville LLC and Baudax Bio, Inc.	Incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on August 21, 2020 (File No. 001-39101).
10.14†	Development, Manufacturing and Supply Agreement, dated July 10, 2015, by and between Alkermes Pharma Ireland Limited and Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 10.15 to the Company's Registration Statement on Form 10 filed on October 22, 2019 (File No. 001-39101).
10.15†	First Amendment to the Development, Manufacturing and Supply Agreement, dated October 19, 2016, by and between Alkermes Pharma Ireland Limited and Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 10.16 to the Company's Registration Statement on Form 10 filed on October 22, 2019 (File No. 001-39101).
10.16†	Second Amendment to the Development, Manufacturing and Supply Agreement, dated February 1, 2017, by and between Alkermes Pharma Ireland Limited and Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 10.17 to the Company's Registration Statement on Form 10 filed on October 22, 2019 (File No. 001-39101).
10.17†	Third Amendment to the Development, Manufacturing and Supply Agreement, dated June 15, 2017, by and between Alkermes Pharma Ireland Limited and Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 10.18 to the Company's Registration Statement on Form 10 filed on October 22, 2019 (File No. 001-39101).
10.18	Assignment, Assumption and Bifurcation Agreement, dated November 20, 2019, by and among Alkermes Pharma Ireland	Incorporated herein by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed on November 26, 2019 (File No. 001-39101).

	Limited, Recro Gainesville LLC, Recro Pharma, Inc. and Baudax Bio, Inc.	
10.19†	License Agreement, dated June 30, 2017, by and between Cornell University and Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 10.19 to the Company's Registration Statement on Form 10 filed on October 22, 2019 (File No. 001-39101).
10.20†	Amendment to License Agreement, dated October 31, 2018, by and between Cornell University and Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 10.20 to the Company's Registration Statement on Form 10 filed on October 22, 2019 (File No. 001-39101).
10.21†	Amendment to License Agreement, dated October 21, 2019, by and between Cornell University and Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K filed on February 13, 2020 (File No. 001-39101).
10.22†	Master Manufacturing Services Agreement, dated July 14, 2017, by and between Patheon UK Limited and Recro Ireland Limited.	Incorporated herein by reference to Exhibit 10.21 to the Company's Registration Statement on Form 10 filed on October 22, 2019 (File No. 001-39101).
10.23†	Product Agreement, dated July 14, 2017, by and between Patheon UK Limited and Recro Ireland Limited.	Incorporated herein by reference to Exhibit 10.22 to the Company's Registration Statement on Form 10 filed on October 22, 2019 (File No. 001-39101).
10.24•	Form of Employment Agreement to be entered into between Baudax Bio, Inc. and its executive officers.	Incorporated herein by reference to Exhibit 10.23 to the Company's Registration Statement on Form 10 filed on November 5, 2019 (File No. 001-39101).
10.25†	Credit Agreement, dated as of May 29, 2020, among the Company, the lenders party thereto and Wilmington Trust, National Association.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 2, 2020 (File No. 001-39101).
10.26	Security Agreement, dated as of May 29, 2020, by and among the Company, Baudax Bio N.A. LLC, Baudax Bio Limited and Wilmington Trust, National Association.	Incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on June 2, 2020 (File No. 001-39101).
10.27	Intellectual Property Security Agreement, dated as of May 29, 2020, by and among the Company, Baudax Bio N.A. LLC, Baudax Bio Limited and Wilmington Trust, National Association.	Incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on June 2, 2020 (File No. 001-39101).
10.28•	Employment Agreement, dated February 12, 2020, between Baudax Bio, Inc. and Gerri Henwood.	Incorporated herein by reference to Exhibit 10.26 to the Company's Annual Report on Form 10-K filed on February 13, 2020 (File No. 001-39101).
10.30•	Form of Stock Option Award Agreement.	Incorporated herein by reference to Exhibit 10.34 to the Company's Annual Report on Form 10-K filed on February 16, 2021(File No. 001-39101).
10.31•	Form of Restricted Stock Unit Award Agreement.	Incorporated herein by reference to Exhibit 10.35 to the Company's Annual Report on Form 10-K filed on February 16, 2021(File No. 001-39101).
10.32•	Form of Performance-Based Restricted Stock Unit Award Agreement.	Incorporated herein by reference to Exhibit 10.36 to the Company's Annual Report on Form 10-K filed on February 16, 2021(File No. 001-39101).
10.33•	Form of Award Agreement for Option Inducement Award.	Incorporated herein by reference to Exhibit 10.37 to the Company's Annual Report on Form 10-K filed on February 16, 2021(File No. 001-39101).
10.34•	Form of Award Agreement for Restricted Stock Unit Inducement Award.	Incorporated herein by reference to Exhibit 10.38 to the Company's Annual Report on Form 10-K filed on February 16, 2021(File No. 001-39101).

10.35	Amendment No. 1 and Waiver to Credit Agreement, dated August 1, 2022, by and Baudax Bio, Inc., Baudax Bio N.A. LLC, Baudax Bio Limited, Wilmington Trust, National Association, and the Lenders party thereto.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 3, 2022 (File No. 001-39101).
10.36	Amendment No. 2 to Credit Agreement, dated October 24, 2022, by and among Baudax Bio, Inc., Baudax Bio N.A. LLC, Baudax Bio Limited, Wilmington Trust, National Association, and the Lenders party thereto.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 28, 2022 (File No. 001-39101).
10.37	Amendment No. 3 to Credit Agreement, dated December 1, 2022, by and among Baudax Bio, Inc., Baudax Bio N.A. LLC, Baudax Bio Limited, Wilmington Trust, National Association, and the Lenders party thereto.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 1, 2022 (File No. 001-39101).
10.38	Amendment No. 4 to Credit Agreement, dated January 5, 2023, by and among Baudax Bio Inc., Baudax Bio N.A. LLC, Baudax Bio Limited, Wilmington Trust, National Association, and the Lenders party thereto.	Filed herewith.
16.1	Notification of Change in Certifying Accountant.	Incorporated herein by reference to Exhibit 16.1 to the Company's Current Report on Form 8-K filed on June 27, 2022 (File No. 001-39101).
21.1	Subsidiaries of Baudax Bio, Inc.	Incorporated herein by reference to Exhibit 21.1 to the Company's Annual Report on Form 10-K filed on February 16, 2021(File No. 001-39101).
23.1	Consent of KPMG LLP, Independent Registered Public Accounting Firm.	Filed herewith.
23.2	Consent of EisnerAmper LLP, Independent Registered Public Accounting Firm.	Filed herewith.
31.1	Rule 13a-14(a)/15d-14(a) certification of Principal Executive Officer.	Filed herewith.
31.2	Rule 13a-14(a)/15d-14(a) certification of Principal Financial Officer.	Filed herewith.
32.1	Section 1350 certification, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
101.INS	Inline XBRL Instance Document.	Filed herewith.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	Filed herewith.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	Filed herewith.
101.DEF	Inline XBRL Taxonomy Extension Definition 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.
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).	Filed herewith.

• Management contract or compensatory plan or arrangement.

† Certain identified information in the exhibit has been omitted because it is both (i) not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

(c) Not applicable

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: February 23, 2023

BAUDAX BIO, INC.

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

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, Annual Report on Form 10-K has been signed by the following persons in the capacities held on the dates indicated.

Signature	Title	Date
/s/ Gerri A. Henwood Gerri A. Henwood	President, Chief Executive Officer and Director (Principal Executive Officer)	February 23, 2023
/s/ Jillian Dilmore Jillian Dilmore	Corporate Controller (Principal Financial Officer and Principal Accounting Officer)	February 23, 2023
/s/ Wayne B. Weisman Wayne B. Weisman	Director and Chairman of the Board	February 23, 2023
/s/ William L. Ashton William L. Ashton	Director	February 23, 2023
/s/ Arnold Baskies, M.D. Arnold Baskies, M.D.	Director	February 23, 2023
/s/ Winston J. Churchill Winston J. Churchill	Director	February 23, 2023
/s/ Andrew Drechsler Andrew Drechsler	Director	February 23, 2023

BAUDAX BIO, INC. AND SUBSIDIARIES

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of
Baudax Bio, Inc:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Baudax Bio, Inc. and Subsidiaries (the "Company") as of December 31, 2022, and the related consolidated statements of operations, shareholders' equity (deficit), and cash flows for the year then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022, and the results of their operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

The consolidated financial statements of the Company as of and for the year ended December 31, 2021 (the "2021 financial statements"), before the effects of both the reverse stock split discussed in Note 1 to the financial statements, and the retrospective adjustments upon adoption of ASU No. 2020-06 discussed in Note 3(l) to the financial statements (collectively, the "retrospective adjustments"), were audited by other auditors whose report, dated March 16, 2022, expressed an unqualified opinion on those statements. We have also audited the adjustments to the 2021 financial statements to retrospectively give effect to the retrospective adjustments discussed in Notes 1 and 3(l) to the financial statements. In our opinion, such retrospective adjustments are appropriate and have been properly applied. However, we were not engaged to audit, review, or apply any procedures to the 2021 financial statements of the Company other than with respect to the retrospective adjustments, and accordingly, we do not express an opinion or any other form of assurance on the 2021 financial statements taken as a whole.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred recurring losses and negative cash flows from operations and has an accumulated deficit of $190.9 million as of December 31, 2022 that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ EisnerAmper LLP

We have served as the Company's auditor since 2022.

EISNERAMPER LLP
Philadelphia, Pennsylvania
February 23, 2023

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors
Baudax Bio, Inc.:

Opinion on the Consolidated Financial Statements

We have audited, before the effects of the adjustments to retrospectively apply the changes in accounting described in Notes 1 and 3(l), the consolidated balance sheet of Baudax Bio, Inc. and subsidiaries (the Company) as of December 31, 2021, the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for the year then ended, and the related notes (collectively, the consolidated financial statements). The 2021 consolidated financial statements before the effects of the adjustments described in Notes 1 and 3(l) are not presented herein. In our opinion, the consolidated financial statements, before the effects of the adjustments to retrospectively apply the changes in accounting described in Notes 1 and 3(l), present fairly, in all material respects, the financial position of the Company as of December 31, 2021, and the results of its operations and its cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles

We were not engaged to audit, review, or apply any procedures to the adjustments to retrospectively apply the changes in accounting described in Notes 1 and 3(l) and, accordingly, we do not express an opinion or any other form of assurance about whether such adjustments are appropriate and have been properly applied. Those adjustments were audited by other auditors.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has incurred recurring losses and negative cash flows from operations and has an accumulated deficit of $132.1 million as of December 31, 2021 that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provides a reasonable basis for our opinion.

We served as the Company's auditor from 2019 to 2022.

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 16, 2022

BAUDAX BIO, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

(amounts in thousands, except share and per share data)	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 5,259	$ 15,891
Accounts receivable, net	335	542
Inventory	—	5,002
Prepaid expenses and other current assets	753	2,059
Total current assets	6,347	23,494
Property, plant and equipment, net	704	5,015
Intangible assets, net	—	21,678
Goodwill	2,127	2,127
Other long-term assets	854	963
Total assets	$ 10,032	$ 53,277
Liabilities and Shareholders' (Deficit) Equity		
Current liabilities:		
Accounts payable	$ 3,927	$ 1,468
Accrued expenses and other current liabilities	2,729	5,540
Current portion of long-term debt, net	5,600	2,222
Current portion of contingent consideration	9,204	6,416
Total current liabilities	21,460	15,646
Long-term debt, net	1,519	6,309
Long-term portion of contingent consideration	10,697	17,446
Other long-term liabilities	598	650
Total liabilities	34,274	40,051
Commitments and contingencies (Note 12)		
Shareholders' (deficit) equity:		
Preferred stock, $0.01 par value. Authorized, 10,000,000 shares; issued and outstanding, 0 shares at December 31, 2022 and 8,289 shares at December 31, 2021	—	—
Common stock, $0.01 par value. Authorized, 190,000,000 shares; issued and outstanding, 1,623,913 shares at December 31, 2022 and 70,181 shares at December 31, 2021	16	1
Additional paid-in capital	166,646	145,314
Accumulated deficit	(190,904)	(132,089)
Total shareholders' (deficit) equity	(24,242)	13,226
Total liabilities and shareholders' (deficit) equity	$ 10,032	$ 53,277

See accompanying notes to consolidated financial statements.

BAUDAX BIO, INC. AND SUBSIDIARIES

Consolidated Statements of Operations

(amounts in thousands, except share and per share data)	For the Year ended December 31, 2022	2021
Revenue, net	$ 1,269	$ 1,080
Operating expenses:		
Cost of sales	7,009	2,445
Research and development	3,887	3,125
Selling, general and administrative	24,119	45,310
Amortization of intangible assets	1,997	2,576
Change in warrant valuation	(7)	(58)
Change in contingent consideration valuation	(2,761)	(33,312)
Loss on impairment of property and equipment	4,157	—
Loss on impairment of intangible asset	19,681	—
Total operating expenses	58,082	20,086
Operating loss	(56,813)	(19,006)
Other expense:		
Other expense, net	(1,982)	(763)
Net loss	(58,795)	(19,769)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (177.30)	$ (361.16)
Weighted average common shares outstanding, basic and diluted	331,615	54,738

See accompanying notes to consolidated financial statements.

BAUDAX BIO, INC. AND SUBSIDIARIES

Consolidated Statements of Shareholders' (Deficit) Equity

(amounts in thousands, except share data)	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional paid-in capital	Accumulated deficit	Total
Balance, December 31, 2020	—	$ —	34,777	$ 1	$ 97,521	$ (112,320)	$ (14,798)
Societal CDMO allocation - stock-based compensation	—	—	—	—	1,201	—	1,201
Stock-based compensation expense	—	—	—	—	3,588	—	3,588
Issuance of common and preferred stock and warrants for registered direct offerings, net	42,289	—	17,878	—	30,946	—	30,946
Conversion of preferred stock	(34,000)	—	9,714	—	—	—	—
Issuance of shares pursuant to vesting of restricted stock units, net of shares withheld for income taxes	—	—	375	—	(97)	—	(97)
Exercise of warrants	—	—	7,437	—	12,155	—	12,155
Net loss	—	—	—	—	—	(19,769)	(19,769)
Balance, December 31, 2021	8,289	—	70,181	1	145,314	(132,089)	13,226
Stock-based compensation expense	—	—	—	—	1,386	—	1,386
Issuance of common stock and warrants for public offerings, net	—	—	1,425,986	14	17,788	—	17,802
Issuance of common and preferred stock and warrants for registered direct offerings, net	—	—	41,152	—	1,707	—	1,707
Issuance of shares pursuant to vesting of restricted stock units, net of shares withheld for income taxes	—	—	351	—	(2)	—	(2)
Conversion of preferred stock	(8,289)	—	2,368	—		—	—
Exercise of warrants	—	—	83,875	1	433	—	434
Stock dividend	20,004	—	—	—	—	(20)	(20)
Redemption of preferred stock	(20,004)	—	—	—	20	—	20
Net loss	—	—	—	—	—	(58,795)	(58,795)
Balance, December 31, 2022	—	$ —	1,623,913	$ 16	$ 166,646	$ (190,904)	$ (24,242)

See accompanying notes to consolidated financial statements.

BAUDAX BIO, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

(amounts in thousands)	For the Year ended December 31, 2022	2021
Cash flows from operating activities:		
Net loss	$ (58,795)	$ (19,769)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	1,401	4,789
Non-cash-interest expense	1,017	897
Gain on extinguishment of debt	—	(1,553)
Depreciation expense	165	240
Amortization	1,997	2,576
Non-cash loss on retirement of fixed assets	8	—
Change in warrant valuation	(7)	(58)
Change in contingent consideration valuation	(2,761)	(33,312)
Loss on impairment of property and equipment	4,157	—
Loss on impairment of intangible asset	19,681	—
Write off of inventory	5,282	—
Changes in operating assets and liabilities:		
Inventory	(280)	(2,024)
Prepaid expenses and other assets	1,435	921
Accounts receivable	207	(491)
Accounts payable, accrued expenses and other liabilities	(1,300)	(1,486)
Net cash used in operating activities	(27,793)	(49,270)
Cash flows from investing activities:		
Purchases of property and equipment	(20)	(203)
Purchase of short-term investments	—	(19,641)
Proceeds from maturity of short-term investments	—	19,650
Net cash used in investing activities	(20)	(194)
Cash flows from financing activities:		
Proceeds from public offering, net of transaction costs	18,637	—
Payments on long-term debt	(2,244)	—
Payment of deferred financing costs	(205)	—
Proceeds from registered direct offerings, net of transaction costs	1,762	30,824
Proceeds from warrant exercises	434	12,155
Payments of contingent consideration	(1,200)	(7,869)
Payments of withholdings on shares withheld for income taxes	(3)	(97)
Net cash provided by financing activities	17,181	35,013
Net (decrease) increase in cash and cash equivalents	(10,632)	(14,451)
Cash and cash equivalents, beginning of year	15,891	30,342
Cash and cash equivalents, end of year	$ 5,259	$ 15,891
Supplemental disclosure of cash flow information:		
Offering costs included in accounts payable and accrued expenses	$ 915	$ 108
Right-of-use assets acquired	$ —	$ 575
Retirement of fully depreciated property, plant and equipment	$ 225	$ 16

See accompanying notes to consolidated financial statements.

(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 to the hospital and acute care markets.

The Company launched ANJESO, which is indicated for the management of moderate to severe pain in 2020. Due to the hospital and acute care pain market conditions, in the fourth quarter of 2022, the Company notified the U.S. Food and Drug Administration ("FDA") of its request to discontinue commercialization of ANJESO and the FDA acknowledged this request by publishing the discontinuation in the FDA's Orange Book in late December 2022.

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.

Basis of Presentation

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

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

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"). On December 1, 2022, the Company effected a second reverse split of shares of the Company's common stock on a 1-for-40 basis (the "December 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 these reverse stock splits for all periods presented. The par value and authorized shares of common stock were not adjusted as a result of the reverse stock splits. 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 splits.

(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 $190,904 as of December 31, 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, and, if approved, commercialization of the Company's 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, future 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.

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 as of December 31, 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) 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.

(b) 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.

(c) 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 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.

(d) Property and Equipment

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

(e) Goodwill and Intangible Assets

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

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

The Company performs its annual goodwill impairment test as of November 30th, or whenever an event or change in circumstances occurs that would require reassessment of the recoverability of goodwill. In performing the evaluation, the Company assesses qualitative factors such as overall financial performance of its reporting unit, anticipated changes in industry and market conditions, including recent tax reform, intellectual property protection, and competitive environments. The Company performed its annual test as of November 30, 2022 and 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 was 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. Recoverability of intangible assets is measured by comparing the carrying value of an asset to future net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment recognized is measured by the amount the carrying value of the assets exceeds the fair value of the assets. The Company performed an impairment test as of September 30, 2022 after identifying indicators of impairment, including a decline in share price, the termination of the dedicated commercial team, and sustained impacts of COVID-19 on the market and based on the analysis recorded an impairment loss of $17,746. The Company performed another impairment test as of December 31, 2022 after further identifying other indicators of impairment, such as the discontinuation of commercialization, and based on the quantitative analysis an impairment loss of $1,935 was recorded as of December 31, 2022 eliminating the remaining carrying value of the intangible asset.

(f) Revenue Recognition

The Company sold 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 recognized 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.

(g) Concentration of Credit Risk

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

(h) Research and Development

Research and development costs for the Company's proprietary products/product candidates are charged to expense as incurred. Research and development expenses consist of internal costs and funds paid to third parties for the provision of services for pre-commercialization and manufacturing scale-up activities, drug development, pre-clinical activities, clinical trials, statistical analysis, 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.

(i) Stock-Based Awards

Baudax 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 cash dividends and has no plans to do so in the foreseeable future, therefore the dividend yield is zero.

(j) Income Taxes

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

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

(k) Net Loss Per Common Share

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 December 31, 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

(amounts in thousands, except share and per share data)

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:

	Year ended December 31,	
	2022	2021
Basic and Diluted Loss Per Share		
Net loss	$ (58,795)	$ (19,769)
Weighted average common shares outstanding, basic and diluted	331,615	54,738
Net loss per share of common stock, basic and diluted	$ (177.30)	$ (361.16)

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as of December 31, 2022 and 2021 as they would be anti-dilutive:

	December 31,	
	2022	2021
Options and restricted stock units outstanding	12,550	3,996
Warrants	2,849,559	37,176

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

(l) 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

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.

(amounts in thousands, except share and per share data)

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

	Fair value measurements at reporting date using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
At December 31, 2022:			
Assets:			
Cash equivalents			
Money market mutual funds (See Note 5)	$ 2,241	$ —	$ —
Total cash equivalents	$ 2,241	$ —	$ —
Liabilities:			
Contingent consideration (See Note 12)	$ —	$ —	$ 19,901
	$ —	$ —	$ 19,901
At December 31, 2021:			
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)	$ —	$ —	$ 23,862
	$ —	$ —	$ 23,869

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	—	(1,200)
Remeasurement	(7)	(2,761)
Balance at December 31, 2022	$ —	$ 19,901

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

(amounts in thousands, except share and per share data)

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. The first of these payments was made in February 2021, the first anniversary of such approval, and a partial payment of $1,200 was made in installments during 2022. 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 does not have a fair value assigned as of December 31, 2022 due to the discontinuation of commercialization of ANJESO. 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 December 31, 2022 and 2021, the calculations used a discount rate of 50% and 35%, respectively.

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 December 31, 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 December 31, 2022, the financial assets and liabilities recorded on the Consolidated Balance Sheets that are not measured at fair value on a recurring basis include those recorded in 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 December 31, 2022 due to the fact that the debt arrangements reflect market terms from recent transactions.

(5) Cash Equivalents

The following is a summary of cash equivalents:

	December 31, 2022			
Description	**Amortized Cost**	**Gross Unrealized Gain**	**Gross Unrealized Loss**	**Estimated Fair Value**
Money market mutual funds	$ 2,241	$ —	$ —	$ 2,241
Total cash equivalents	$ 2,241	$ —	$ —	$ 2,241

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

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

(amounts in thousands, except share and per share data)

(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:

	December 31, 2022	December 31, 2021
Raw materials	$ 26	$ 53
Sub-assemblies	4,028	4,656
Finished goods	1,580	645
	5,634	5,354
Reserve for inventory impairment and obsolescence	(5,634)	(352)
Inventory	$ —	$ 5,002

(7) Property, Plant and Equipment

Property, plant and equipment consists of the following:

	December 31, 2022	December 31, 2021
Building and improvements	$ 166	$ 196
Furniture, office and computer equipment	748	952
Manufacturing and laboratory equipment	717	717
Equipment not placed in service	485	4,622
	2,116	6,487
Less: accumulated depreciation	1,412	1,472
Property, plant and equipment, net	$ 704	$ 5,015

Depreciation expense for the years ended December 31, 2022 and 2021 was $165 and $240, respectively.

The Company recorded an impairment loss on property and equipment of $4,157 during the year ended December 31, 2022, which represents the non-cash impairment charge recorded for assets that were previously capitalized in connection with the construction of a second manufacturing suite at the Alkermes manufacturing facility. The suite is no longer planned to be used for production. There were no such impairment charges reported during the year ended December 31, 2021.

(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 5 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

(amounts in thousands, except share and per share data)

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 December 31, 2022, undiscounted future lease payments for non-cancellable operating leases are as follows:

	December 31, 2022
2023	$ 330
2024	278
2025	278
2026	287
2027	295
Total lease payments	1,468
Less imputed interest	(652)
Total operating lease liability	$ 816

For the year ended December 31, 2022, the weighted average remaining lease term was 5 years and the weighted average discount rate was 23%.

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

	December 31, 2022	December 31, 2021
Operating lease cost	$ 285	$ 330
Short-term lease cost	139	192
Total lease cost	$ 424	$ 522

Cash paid for amounts included in the measurement of lease liabilities, which is included in operating cash flows, was $326 and $348 for the years ended December 31, 2022 and 2021, respectively.

(9) Intangible Assets

The following represents the balances of the intangible assets:

	December 31, 2022	December 31, 2021
Asset resulting from R&D activities	$ 26,400	$ 26,400
Accumulated amortization	(6,719)	(4,722)
Impairment loss	(19,681)	—
Intangible assets, net	$ —	$ 21,678

Amortization expense for the years ended December 31, 2022 and 2021 was $1,997 and $2,576, respectively.

During the year ended December 31, 2022, the Company recorded an impairment loss of $19,681 to eliminate the carrying value of the intangible asset as a result of its impairment tests after identifying indicators of impairment, including a decline in share price, the termination of the dedicated commercial team, sustained impacts of COVID-19 on the market and the discontinuation of commercialization of ANJESO, of which $17,746 was recorded as of September 30, 2022 and $1,935 was recorded as of December 31, 2022.

(amounts in thousands, except share and per share data)

(10) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	December 31, 2022	December 31, 2021
Payroll and related costs	$ 747	$ 3,516
Professional and consulting fees	961	1,071
Other research and development costs	593	157
Interest payable	94	116
Other	334	680
Accrued expenses and other current liabilities	$ 2,729	$ 5,540

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 $597 remains accrued and unpaid as of December 31, 2022. Further, in September 2022, the Company eliminated the remaining dedicated commercial team of approximately 7 employees, which resulted in a third quarter charge of $241 and was fully paid as of December 31, 2022.

(11) Debt

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

	December 31, 2022	December 31, 2021
Credit Agreement	$ 10,000	$ 10,000
Payment of principal	(2,244)	—
Unamortized deferred issuance costs	(828)	(1,583)
Exit fee accretion	191	114
Total debt	$ 7,119	$ 8,531
Current portion	$ 5,600	$ 2,222
Long-term portion, net	1,519	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 December 31, 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 Company does not expect to draw additional loan tranches from the Credit Agreement as of December 31, 2022.

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"), which the Company did not achieve. Beginning on the Amortization Date, the Company will be obligated to pay amortization payments (in addition to the interest stated above) on such date and each month thereafter in equal month installments of principal based on an amortization schedule of thirty-six months. Any unpaid principal amount of the Term Loans is due and payable on the Maturity Date.

Subject to certain exceptions, the Company is required to make mandatory prepayments of the Term Loans, with the proceeds of asset sales, extraordinary receipts, debt issuances and specified other events. The Company may make voluntary prepayments in whole or in part, subject to a prepayment premium equal to (i) with respect to any prepayment paid on or prior to the third anniversary of the Tranche One Loan (or, in the case of each of the Tranche Two Loans, Tranche Three Loans, Tranche Four Loans or Tranche Five Loans, the third anniversary of the date each such loan is funded), the remaining scheduled payments of interest that would have accrued on the Term Loans being prepaid, repaid or accelerated, but that remained unpaid, in no event to be less than 5.0% of the principal amount of the Term Loan being prepaid, and (ii) with respect to any prepayment paid after the third but prior to the fourth anniversary of the Tranche One Loan (or, in the case of each of the Tranche Two Loans, Tranche Three Loans, Tranche Four Loans or Tranche Five Loans, the fourth anniversary of the date each such loan is funded), 3.0% of the principal amount of the Term Loan being prepaid. In addition, an exit fee will be due and payable upon prepayment or repayment of the Term Loans (including, without limitation, on the Maturity Date) equal to the lesser of 2.5% of the sum of the aggregate principal amount of the Term Loans advanced or approved to be advanced by the Lenders and $700; provided that such exit fee will be equal to $700 if fee is paid in conjunction with a change of control that occurs in connection with the payoff or within 6 months thereof. As of December 31, 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 December 31, 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 December 31, 2022, borrowings under the Credit Agreement are classified based on their scheduled maturities.

In connection with the Credit Agreement, the Company issued a warrant to MAM Eagle Lender, LLC to purchase 376 shares of the Company's common stock, at an exercise price equal to $6,426.00 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 December 31, 2022, the effective interest rate was 31.77%, 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 $960 and $844 for the years ended December 31, 2022 and 2021, respectively.

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.

On October 24, 2022, the Company entered into Amendment No. 2 and Waiver to Credit Agreement, or the Amendment, with MAM Eagle Lender. Pursuant to the terms of the Amendment, the Credit Agreement was amended such that the Company must repay the principal thereunder (i) on the first business day of each month until the Interest Payment Date on December 1, 2022, in equal monthly installments of principal based on an amortization schedule of 36 months, (ii) an additional payment of principal in the amount of $300 prior to December 31, 2022 and (iii) commencing on the Interest Payment Date on January 2, 2023 and on each Interest Payment Date thereafter until the obligations have been repaid in full, the principal amount of $500. In addition, the Amendment decreases the minimum cash covenant the Company is required to maintain under the Credit Agreement to (i) $3,000 for the period beginning on October 1, 2022, and ending on November 30, 2022, (ii) $4,500 for the period beginning on December 1, 2022, and ending on February 28, 2023, and (iii) $4,000 from and after March 1, 2023. Further, the Company has agreed that prior to December 31, 2022, it shall not, without the prior written consent of the Lenders, make or permit any payment under its agreements with Alkermes. In consideration for the Amendment, the Company agreed to pay the Agent an amendment fee of $5 and the Lender an amendment fee of $200.

On December 1, 2022, the Company entered into Amendment No. 3 to Credit Agreement with MAM Eagle Lender. Pursuant to the terms of the amendment, the amendment decreases the minimum cash covenant the Company is required to maintain under the credit agreement to (a) from October 1, 2022 to December 6, 2022 to not be less than $3,000 at any time, (b) from December 7, 2022 to February 28, 2023 to not be less than $4,500, and (c) from and after March 1, 2023 to not be less than $4,000.

In January 2023, the Company entered into Amendment No. 4 to Credit Agreement with MAM Eagle Lender. Pursuant to the terms of the amendment, the credit agreement was amended such that the Company must make (i) a payment of principal in the amount of $500 on January 3, 2023, (ii) a payment of principal in the amount of $300 on February 1, 2023 and March 1, 2023, and (iii) on the interest payment date on April 3, 2023 and on each interest payment date thereafter until the obligations are repaid in full, a payment in the principal amount of $500. In addition, the amendment decreases the minimum cash covenant the Company is required to maintain under the credit agreement, or the Minimum Liquidity Covenant, to (i) $3,000 for the period beginning on October 1, 2022, and ending on December 6, 2022, (ii) $4,500 for the period beginning on December 7, 2022, and ending on January 10, 2023, (iii) $2,225 for the period beginning on January 11, 2023, and ending on February 28, 2023, and (iv) $3,000 from and after March 1, 2023. Further, the Company agreed that prior to April 30, 2023, it will not, without the prior written consent of MAM Eagle Lender, make or permit any payment under its agreements with Alkermes.

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.

(12) Commitments and Contingencies

(a) Licenses and Supply Agreements

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 December 31, 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.

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 $1,200 of the second payment, which was due in the first quarter of 2022. 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. In January 2023, the Company entered into the Amendment with MAM Eagle lender and has agreed that prior to April 30, 2023, it shall not, without the prior written consent of the Lenders, make or permit any payment under its agreements with Alkermes.

As of December 31, 2022, the Company has paid $22,629 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 was held on October 26, 2022, and the settlement was approved in December 2022. The decision had no impact to the financial statements.

(d) Purchase Commitments

As of December 31, 2022, the Company had outstanding non-cancelable and cancelable purchase commitments in the aggregate amount of $338 related to goods and services, predominately related to development activities.

(e) Certain Compensation and Employment Agreements

The Company entered into an employment agreement with one of its named executive officers in February 2020. As of December 31, 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 June 2024.

(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, 6,712 shares of common stock were issued.

The Company is authorized to issue 190,000,000 shares of common stock, with a par value of $0.01 per share.

On February 8, 2021, the Company closed a registered direct offering of 7,857 shares of common stock (the "February Offering") at an offering price of $2,240.00 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 471 shares of common stock (the "February Placement Agent Warrants") at an exercise price of $2,800.00 per share.

On May 31, 2021, the Company closed a registered direct offering of 10,021 shares of common stock (the "May Offering") at an offering price of $1,190.00 per share and warrants to purchase 10,021 shares of common stock (the "May Warrants") at an exercise price of $1,260.00 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 601 shares of common stock (the "May Placement Agent Warrants") at an exercise price of $1,487.50 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 9,062 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 12,083 shares of common stock at a conversion price of $350.00 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 125,000 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 724 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 $448.00 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 45,791 shares of its common stock, pre-funded warrants to purchase 41,929 shares of common stock at an exercise price of $0.40 per share and warrants to purchase 87,719 shares of common stock at an exercise price of $130.00 per share, as well as up to 13,158 additional shares of common stock and/or additional warrants to purchase up to 13,158 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 $114.00, and the public offering price for each pre-funded warrant and accompanying warrant was $113.60. 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 5,263 shares of common stock at an exercise price of $142.50 per share. On February 28, 2022, the Underwriter partially exercised its option to purchase an additional 2,847 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"), 41,152 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 41,152 shares of Common Stock at a combined offering price of $48.60 per share and associated warrant. The warrants have an exercise price of $43.60 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 2,469 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 $60.75 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.

On September 1, 2022, the Company closed a best efforts public offering of: (i) 188,872 shares of its common stock, par value $0.01 per share and accompanying Series A-1 warrants ("Series A-1 warrants") to purchase 188,872 shares of Common stock and Series A-2 warrants ("Series A-2 warrants", and together with the Series A-1 warrants, "Series A warrants") to purchase 188,872 shares of Common Stock, at a combined public offering price of $21.00 per share and Series A warrants and (ii) Series B pre-funded warrants ("Series B pre-funded warrants") to purchase 106,607 shares of Common Stock and accompanying Series A-1 warrants to purchase 106,607 shares of Common Stock and Series A-2 warrants to purchase 106,607 shares of Common stock at a combined public offering price of $20.60 per Series B pre-funded warrant and Series A warrants, which is equal to the public offering price per share of Common Stock and accompanying Series A warrants less the $0.01 per share exercise price of each such Series B pre-funded warrant. The Series A warrants have an exercise price of $21.00 per share of Common Stock. The Series A-1 warrants are exercisable upon issuance and will expire five years from the date of issuance. The Series A-2 warrants are exercisable upon issuance and will expire thirteen months from the date of issuance. The exercise price of the Series A warrants is subject to adjustment for stock splits, reverse splits, and similar capital transactions as described in the Series A warrants. Subject to certain ownership limitations, the Series B pre-funded warrants are immediately exercisable and were exercised at a nominal consideration of $0.40 per share of Common Stock upon the closing of the transaction. As compensation to H.C. Wainwright & Co., LLC, as the exclusive placement agent in connection with the Offering, the Company paid 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 reimbursement of certain expenses and legal fees. The Company also issued to designees of the placement agent warrants to purchase up to 17,728 shares of common stock. The placement agent warrants have substantially the same terms as the Series A warrants, except that the placement agent warrants have an exercise price equal to $26.25 per share and expire on August 29, 2027. Net proceeds to the Company, after deducting underwriting discounts and commissions and offering expenses, was $5,065.

On December 6, 2022 the Company closed a best efforts public offering of: (i) 54,787 shares of its common stock, par value $0.01 per share and accompanying Series A-3 warrants to purchase 54,787 shares of common stock and Series A-4 warrants to purchase 54,787 shares of common stock, at a combined public offering price of $4.795 per share and accompanying series A warrants and (ii) series C pre-funded warrants to purchase 988,000 shares of common stock and accompanying series A-3 warrants to purchase 988,000 shares of common stock and series A-4 warrants to purchase 988,000 shares of common stock at a combined public offering price of $4.785 per series C pre-funded warrant and accompanying series A warrants, which was equal to the public offering price per share of common stock and accompanying series A warrants less the $0.01 per share exercise price of each such series C pre-funded warrant. The series A warrants have an exercise price of $4.50 per share of common stock. The series A-3 warrants are exercisable upon issuance and will expire on December 6, 2027. The series A-4 warrants are exercisable upon issuance and will expire on January 8, 2024. The exercise price of the series A warrants is subject to adjustment for stock splits, reverse splits, and similar capital transactions as described in the Series A Warrants. The Series C prefunded warrants have been exercised in full as of December 31, 2022. As compensation to H.C. Wainwright & Co., LLC as the exclusive placement agent in connection with the offering, the Company paid 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 reimbursement of certain expenses and legal fees. The Company also issued to designees of the placement agent warrants to purchase up to 62,567 shares of common stock. The Placement Agent Warrants have substantially the same terms as the series A warrants, except that the placement agent warrants have an exercise price equal to $5.99375 per share and expire on December 2, 2027. Net proceeds to the Company, after deducting underwriting discounts and commissions and offering expenses, was $3,966.

(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.

On September 19, 2022, the board of directors of the Company declared a dividend of one one-thousandth (1/1,000th) of a share of Series B Preferred Stock, par value $0.01 per share ("Series B Preferred Stock"), for each outstanding share of the Company's common stock, par value $0.01 per share to shareholders of record on September 29, 2022 (the "Record Date"). The shares of Series B Preferred Stock were distributed to such recipients on October 3, 2022. Each share of Series B Preferred Stock entitles the holder thereof to 1,000,000 votes per share. The outstanding shares of Series B Preferred Stock vote together with the outstanding shares of Common Stock of the Company as a single class exclusively with respect to (1) any proposal to adopt an amendment to the Company's Amended and Restated Articles of Incorporation, as amended, to reclassify the outstanding shares of common stock into a smaller number of shares of common stock at a ratio specified in or determined in accordance with the terms of such amendment (the "Reverse Stock Split") and (2) any proposal to adjourn any meeting of shareholders called for the purpose of voting on the Reverse Stock Split. The Series B Preferred Stock will not be entitled to vote on any other matter, except to the extent required under the Pennsylvania Business Corporation Law.

In September 2022, 20,003.745 shares of Series B Preferred Stock were declared as a stock dividend and issued on October 3, 2022. On November 3, 2022, all of our outstanding shares of Series B Preferred Stock were redeemed for nominal consideration pursuant to the terms of the Series B Preferred Stock.

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

As of December 31, 2022, there were no shares of Preferred Stock issued and outstanding.

(c) Warrants

On May 29, 2020, in connection with the Credit Agreement, the Company issued a warrant to MAM Eagle Lender, LLC to purchase 376 shares of common stock, at an exercise price equal to $6,426.00 per share (see Note 11).

On October 19, 2020, the Company entered into Warrant Exchange Agreements (each, an "Exchange Agreement") with certain holders (each, a "Holder") of the Company's outstanding March Series A Warrants and March Series B Warrants. Pursuant to the Exchange Agreements, the Holders, at their election, agreed to a cashless exchange of either all of their March Series A Warrants or March Series B Warrants, in each case for 0.2 shares of the Company's common stock per warrant (rounded up to the nearest whole share) (the "Exchange"). The Company issued 848 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 $14.00, 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 7,358 shares of common stock of the Company (the "January Warrants") at an offering price of $175.00 per warrant in exchange for the exercise of the institutional investor's existing December Series A warrants that were issued to them on December 21, 2020, at an exercise price of $1,652.00 per warrant. The January Warrants have an exercise price of $2,240.00 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 441 shares of common stock (the "January Placement Agent Warrants") at an exercise price of $2,800.00 per share.

On August 24, 2022, the Company entered into warrant amendment agreements (the "Warrant Amendment Agreements") with certain holders of the Company's (i) Series A Warrants to purchase 7,234 shares of common stock with an exercise price of $1,680.00 per share, (ii) Warrants to purchase 7,358 shares of common stock with an exercise price of $2,240.00 per share, (iii) Warrants to purchase 10,021 shares of common stock with an exercise price of $1,260.00 per share, (iv) Warrants to purchase 9,062 shares of common stock with an exercise price of $448.00 per share, and (v) Warrants to purchase 88,615 shares of common stock with an exercise price of $130.00 per share (the "Existing Warrants"). Under the Warrant Amendment Agreements, the Company agreed to amend the Existing Warrants by lowering the exercise price of the Existing Warrants to $23.92 per share. The warrant modification resulted in an increase in the fair value of warrants of $1,151. Subsequent to the warrant amendment, the Company issued 2,875 shares of common stock upon exercise of a portion of the amended warrants for net proceeds of $69.

On December 2, 2022, the Company entered into a warrant amendment agreement (the "December Warrant Amendment Agreement") with a certain holder of the Company's (i) warrants to purchase 7,234 shares of common stock with an exercise price of $23.92 per share, (ii) warrants to purchase 7,358 shares of common stock with an exercise price of $23.92 per share, (iii) warrants to purchase 6,013 shares of common stock with an exercise price of $23.92 per share, (iv) Warrants to purchase 5,143 shares of common stock with an exercise price of $23.92 per share, (v) warrants to purchase 48,246 shares of common stock with an exercise price of $23.92 per share, (vi) Series A-1 warrants to purchase 14,404 shares of common stock with an exercise price of $43.60 per share, (vii) Series A-2 warrants to purchase 142,858 shares of common stock with an exercise price of $21.00 per share and (viii) warrants to purchase 142,858 shares of common stock with an exercise price of $21.00 per share (collectively, the "December Existing Warrants"). Under the December Warrant Amendment Agreement, the Company (i) agreed to amend the December Existing Warrants by lowering the exercise price of the December Existing Warrants to $4.50 per share and (ii) amend the expiration date of the December Existing Warrants to December 6, 2027, in each case effective on December 6, 2022. The warrant modification resulted in an increase in the fair value of warrants of $746.

During the year ended December 31, 2021, the Company issued 80 shares of common stock upon exercise of the March Series B Warrants for net proceeds of $1 and 7,357 shares of common stock upon exercise of the December Series A Warrants for proceeds of $12,155.

(amounts in thousands, except share and per share data)

As of December 31, 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)	15	$	14.00	March 26, 2025
MAM Eagle Lender Warrant	376	$	6,426.00	May 29, 2027
November Series A Warrants	7,234	$	4.50	December 6, 2027
November Placement Warrants	433	$	2,073.75	November 24, 2025
December Placement Warrants	441	$	2,038.75	December 18, 2025
January Warrants	7,358	$	4.50	December 6, 2027
January Placement Warrants	441	$	2,800.00	January 21, 2026
February Placement Warrants	471	$	2,800.00	February 8, 2026
May Warrants	4,008	$	23.924	June 1, 2027
May Warrants, repriced	6,013	$	4.50	December 6, 2027
May Placement Warrants	601	$	1,487.50	May 31, 2026
December 2021 Warrants	3,918	$	23.924	June 27, 2027
December 2021 Warrants, repriced	5,143	$	4.50	December 6, 2027
December 2021 Placement Agent Warrants	724	$	448.00	December 27, 2026
March 2022 Warrants	1,952	$	130.00	March 1, 2027
March 2022 Warrants, repriced	37,492	$	23.924	March 1, 2027
March 2022A Warrants, repriced	48,246	$	4.50	December 6, 2027
March 2022 Underwriter Warrants	5,263	$	142.50	February 24, 2027
May 2022 Warrants	26,748	$	43.60	May 19, 2027
May 2022 Warrants, repriced	14,404	$	4.50	December 6, 2027
May 2022 Placement Agent Warrants	2,469	$	60.752	May 17, 2027
August 2022 Series A-1 Warrants	152,612	$	21.00	September 1, 2027
August 2022 Series A-1 Warrants, repriced	142,858	$	4.50	December 6, 2027
August 2022 Series A-2 Warrants	152,612	$	21.00	October 2, 2023
August 2022 Series A-2 Warrants, repriced	142,858	$	4.50	December 6, 2027
August 2022 Placement Agent Warrants	17,728	$	26.25	August 29, 2027
December 2022 Series A-3 Warrants	1,042,787	$	4.50	December 6, 2027
December 2022 Series A-4 Warrants	961,787	$	4.50	January 8, 2024
December 2022 Placement Agent Warrants	62,567	$	5.99375	December 2, 2027

With the exception of the March Series A Warrants to purchase 15 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.

	December 31, 2022 Series A Warrants
Fair value	$ —
Expected dividend yield	— %
Expected volatility	76.92 %
Risk-free interest rates	4.41 %
Remaining contractual term	2.24 years

(amounts in thousands, except share and per share data)

(14) Stock-Based Compensation

The Company has adopted the 2019 Plan that allows for the grant of stock options, stock appreciation rights and stock awards for a total of 85,714 shares of common stock. On December 1st of each year, pursuant to the "Evergreen" provision of the 2019 Plan, the number of shares available under the plan shall be increased by an amount equal to 5% of the outstanding common stock on December 1st of that year or such lower amount as determined by the Board of Directors. In December 2022, the number of shares available for issuance under the 2019 Plan was increased by 25,004. The total number of shares authorized for issuance under the 2019 plan as of December 31, 2022 is 31,581. As of December 31, 2022, 27,997 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 year ended December 31, 2022. The weighted average grant-date fair value of options awarded to employees during the year ended December 31, 2021 was $735.69. Under the 2019 Plan, the fair value of the options was estimated on the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions:

	December 31, 2021
Expected option life	5.6 years
Expected volatility	74.47%
Risk-free interest rate	1.0%
Expected dividend yield	—

The following table summarizes stock option activity during the years ended December 31, 2022 and 2021:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life
Balance, December 31, 2020	1,577	$ 4,353.98	9.1 years
Granted	1,855	1,815.58	
Exercised	—	—	
Expired/forfeited/cancelled	(388)	2,497.63	
Balance, December 31, 2021	3,044	3,043.71	8.6 years
Granted	—	—	
Exercised	—	—	
Expired/forfeited/cancelled	(1,105)	2,197.62	
Balance, December 31, 2022	1,939	$ 3,525.88	6.5 years
Vested	1,466	$ 3,537.21	6.0 years
Vested and expected to vest	1,939	$ 3,525.88	6.5 years

Included in the table above are 47 stock options outstanding as of December 31, 2022 that were granted outside of the 2019 Plan. The grants were made pursuant to the Nasdaq inducement grant exception in accordance with Nasdaq Listing Rule 5635(c)(4).

(amounts in thousands, except share and per share data)

Restricted Stock Units (RSUs):

The following table summarizes Baudax Bio RSUs activity during the year ended December 31, 2022 and 2021:

	Number of shares	Weighted average grant date fair value
Balance, December 31, 2020	647	$ 5,418.52
Granted	886	1,439.81
Vested and settled	(501)	4,254.54
Expired/forfeited/cancelled	(80)	2,747.06
Balance, December 31, 2021	952	2,552.69
Granted	12,519	30.43
Vested and settled	(887)	1,314.11
Expired/forfeited/cancelled	(1,973)	205.75
Balance, December 31, 2022	10,611	$ 116.81
Expected to vest	10,233	

In June 2022, the Company granted 12,519 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 4 time-based RSUs outstanding as of December 31, 2022 that were granted outside of the 2019 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 years ended December 31, 2022 and 2021 was $1,401 and $4,789, respectively. For the prior year, this represents stock-based compensation from the Baudax Bio awards as well as stock-based compensation from the Societal CDMO Equity Plan for the acceleration of vesting for Baudax Bio employees in their Societal CDMO awards.

As of December 31, 2022, there was $1,052 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 1.1 years. As of December 31, 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 December 31, 2022, there was no aggregate intrinsic value of the vested and unvested options.

(15) Income Taxes

The components of loss before income tax are as follows:

	December 31,	
	2022	2021
Domestic	$ (53,887)	$ (18,347)
Foreign	(4,908)	(1,422)
Loss before income taxes	$ (58,795)	$ (19,769)

(amounts in thousands, except share and per share data)

The components of income tax provision (benefit) are as follows:

	December 31, 2022	2021
Current:		
Federal	$ —	$ —
State and local	—	—
Foreign	—	—
	—	—
Deferred:		
Federal	(12,037)	(4,116)
State and local	(5,557)	636
Foreign	—	228
	(17,594)	(3,252)
Change in valuation allowance	17,594	3,252
	$ —	$ —

A reconciliation of the statutory U.S. federal income tax rate to the Company's effective tax rate is as follows:

	Year ended December 31, 2022	2021
U.S. federal statutory income tax rate	21.0 %	21.0 %
Foreign tax rate differential	—	—
State taxes, net of federal benefit	9.4 %	(3.2)%
Nondeductible expenses	(0.4)%	(0.2)%
Change in valuation allowance	(29.9)%	(16.5)%
Other	(0.1)%	(1.1)%
Effective income tax rate	(0.0)%	(0.0)%

The tax effects of temporary differences that gave rise to significant portions of the deferred tax assets were as follows:

	December 31, 2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 35,677	$ 26,679
Intangibles	2,691	2,559
Contingent consideration	998	1,709
Stock-based compensation	1,747	1,587
Inventory reserve	1,595	—
Right-of-use asset	241	63
Asset impairment	6,747	—
Fixed assets	122	44
Capitalized research	996	—
Other temporary differences	293	890
Gross deferred tax asset	51,107	33,531
Valuation allowance	(50,681)	(33,087)
Net deferred tax asset	426	444
Deferred tax liabilities:		
Prepaid expenses	(195)	(389)
Operating lease liability	(231)	(55)
Deferred tax liabilities	(426)	(444)
Net deferred taxes	$ —	$ —

(amounts in thousands, except share and per share data)

In assessing the realizability of the net deferred tax asset, the Company considers all relevant positive and negative evidence in determining whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The realization of the gross deferred tax assets is dependent on several factors, including the generation of sufficient taxable income prior to the expiration of the net operating loss carryforwards.

In 2022 and 2021, the Company evaluated the need for a valuation allowance against its U.S. and state deferred tax assets based on the available positive and negative evidence available. An important aspect of objective negative evidence evaluated was the Company's historical operating results over its life to date. The Company is in a three-year cumulative loss position through December 31, 2022. Thus, it is more likely than not that the Company's U.S. and state deferred tax assets will not be realized, and a full valuation allowance has been recognized against the Company's U.S. and state deferred tax assets.

The following table summarizes carryforwards of Federal net operating losses and tax credits as of December 31, 2022:

		Amount	Expiration
Federal net operating losses	$	123,675	No expiration
State net operating losses	$	122,286	2025 – 2042
Foreign net operating losses	$	673	No expiration

Under the Tax Reform Act of 1986, as amended (the "Act"), the utilization of a corporation's net operating loss and research and development tax credit carryforwards is limited following a greater than 50% change in ownership during a three-year period. Any unused annual limitation may be carried forward to future years for the balance of the carryforward period. The Company has done an analysis to determine whether or not ownership changes, as defined by the Act, have occurred since inception in 2019. The Company determined that it has experienced ownership changes, as defined by the Act, during the current and previous tax years as a result of financings; accordingly, the Company's ability to utilize the aforementioned carryforwards will be limited. Subsequent ownership changes may affect the limitation in future years. In addition, state net operating loss carryforwards may be further limited, including in Pennsylvania, which has a limitation of 40% of taxable income after modifications and apportionment on state net operating losses utilized in any one year during tax years beginning 2019 going forward. The Company has not conducted an IRS Section 382 study for the year ended December 31, 2022.

The Company will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2022, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in the Company's statements of operations.

(16) 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 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 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.

(17) 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 year ended December 31, 2022 and 2021 were $405 and $773, respectively.

Exhibit 10.38

AMENDMENT NO. 4 TO CREDIT AGREEMENT

This Amendment No. 4 to Credit Agreement (this "Amendment") dated as of January 5, 2023, is among Baudax Bio, Inc., a Pennsylvania corporation ("Borrower"), Baudax Bio N.A. LLC, a Delaware limited liability company ("Baudax LLC"), Baudax Bio Limited, a private company incorporated under the laws of Ireland limited by shares having company number 562027 (together with Baudax LLC, collectively, the "Guarantors" and together with the Borrower, the "Loan Parties"), Wilmington Trust, National Association, not individually, but solely in its capacity as administrative and collateral agent for the Lenders (the "Agent") and the Lenders party hereto.

WHEREAS, the Borrower, the Lenders and the Agent are party to that certain Credit Agreement, dated as of May 29, 2020, as amended by that certain Amendment No. 1 and Waiver to Credit Agreement, dated as of August 1, 2022, that certain Amendment No. 2 to Credit Agreement, dated as of October 24, 2022 and that certain Amendment No. 3 to Credit Agreement, dated as of November 30, 2022 (collectively, the "Credit Agreement"), pursuant to which the Lenders agreed to make loans to the Borrower on the terms set forth therein;

WHEREAS, the Borrower has requested that the Agent and the Lenders make certain amendments to the Credit Agreement, and the Agent and the Lenders are willing to make such amendments to the Credit Agreement on the terms and subject to the conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual agreements herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Definitions: Loan Document. Capitalized terms used herein without definition shall have the meanings assigned to such terms in the Credit Agreement. This Amendment shall constitute a Loan Document for all purposes of the Credit Agreement and the other Loan Documents.

2. Amendment. Upon the effectiveness of this Amendment, the Credit Agreement is hereby amended as follows:

(a) Section 2.4.1 is amended and restated in its entirety as follows:

"(a) Subject to earlier Payment In Full following the occurrence of an Event of Default or termination of this Agreement, the Borrower shall repay the Loans as follows: (i) commencing on the Amortization Date, and on each Interest Payment Date thereafter until the Interest Payment Date on December 1, 2022, in equal monthly installments of principal based on an amortization schedule of 36 months, (ii) an additional payment of principal in the amount of $300,000 by December 31, 2022, (iii) a payment of principal in the amount of $500,000 on January 2, 2023, (iv) on each of the Interest Payment Dates on February 1, 2023 and March 1, 2023, the principal amount of $300,000, and (v) on the Interest Payment Date on April 3, 2023 and on each Interest Payment Date thereafter until the Obligations are repaid in full, the principal amount of $500,000."

(b) Section 7.17.1 is amended and restated in its entirety as follows:

"7.17.1 Liquidity Accounts. Not suffer or permit the aggregate amount of cash in the Liquidity Accounts (a) from October 1, 2022 to December 6, 2022 to be less than $3,000,000 at any time, (b) from December 7, 2022 to January 10, 2023 to be less than $4,500,000, (c) from January 11, 2023 to February 28, 2023 to be less than $2,225,000, and (d) from and after March 1, 2023 to be less than $3,000,000."

(c) Section 7.5(d) is amended and restated in its entirety as follows:

"(d) Without the prior written consent of the Lenders, prior to April 30, 2023, make or permit any payment under or in connection with the Meloxicam Acquisition Agreement or the Meloxicam Transfer Agreement."

3. Expenses. The Loan Parties agree to pay all out-of-pocket and documented costs and expenses of the Agent and the Lenders (including diligence costs, consulting fees and Costs) in connection with the transactions contemplated by this Agreement invoiced to the Borrower (including, without limitation, the reasonable and documented fees and out-of-pocket expenses of counsel to the Agent and the Lenders incurred in connection with the negotiation, preparation, execution and delivery of this Amendment and the other Loan Documents).

4. Conditions to Effectiveness. This Amendment shall become effective on the date on which (a) the Agent and the Lenders receive counterpart signatures to this Amendment duly executed and delivered by the Loan Parties, the Agent and the Lenders, and (b) the representations and warranties in Section 5 shall be true and correct.

5. Representations and Warranties. The Loan Parties represent and warrant to the Lenders and the Agent that, after giving effect to this Amendment:

(a) The representations and warranties of the Loan Parties contained in the Credit Agreement or any other Loan Document are true, accurate and correct in all material respects (without duplication of any materiality qualifiers); provided, however, that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects (without duplication of any materiality qualifiers) as of such date.

(b) No Default or Event of Default under the Loan Documents has occurred and is continuing or would result from the effectiveness of this Amendment.

6. No Implied Amendment or Waiver. Except as expressly set forth in this Amendment, this Amendment is limited to the matters specifically set forth herein and shall not, by implication or otherwise, limit, impair, constitute a waiver of or otherwise affect any rights or remedies of the Agent or any Lender under the Loan Documents, or alter, modify, amend or in any way affect any of the terms, obligations or covenants contained in the Loan Documents, all of which shall continue in full force and effect. Nothing in this Amendment shall be construed to imply any willingness on the part of the Agent or any Lender to agree to or grant any similar or future amendment, consent or waiver of any of the terms and conditions of the Loan Document.

7. Waiver and Release. TO INDUCE THE AGENT AND THE LENDERS TO AGREE TO THE TERMS OF THIS AMENDMENT, EACH LOAN PARTY AND ITS AFFILIATES (COLLECTIVELY, THE "RELEASING PARTIES") REPRESENT AND WARRANT THAT, AS OF THE DATE HEREOF, THERE ARE NO CLAIMS OR OFFSETS AGAINST, OR RIGHTS OF RECOUPMENT WITH RESPECT TO, OR DISPUTES OF, OR DEFENSES OR COUNTERCLAIMS TO, THEIR OBLIGATIONS UNDER THE LOAN DOCUMENTS, AND IN ACCORDANCE THEREWITH THEY:

(a) WAIVE ANY AND ALL SUCH CLAIMS, OFFSETS, RIGHTS OF RECOUPMENT, DISPUTES, DEFENSES AND COUNTERCLAIMS, WHETHER KNOWN OR UNKNOWN, ARISING PRIOR TO THE DATE HEREOF.

(b) FOREVER RELEASE, RELIEVE AND DISCHARGE THE AGENT, EACH LENDER AND THEIR RESPECTIVE OFFICERS, DIRECTORS, SHAREHOLDERS, MEMBERS, PARTNERS, PREDECESSORS, SUCCESSORS, ASSIGNS, ATTORNEYS, ACCOUNTANTS, AGENTS, EMPLOYEES AND REPRESENTATIVES (COLLECTIVELY, THE "RELEASED PARTIES"), AND EACH OF THEM, FROM ANY AND ALL CLAIMS, LIABILITIES, DEMANDS, CAUSES OF ACTION, DEBTS, OBLIGATIONS, PROMISES, ACTS, AGREEMENTS AND DAMAGES, OF WHATEVER KIND OR NATURE, WHETHER KNOWN OR UNKNOWN, SUSPECTED OR UNSUSPECTED, CONTINGENT OR FIXED, LIQUIDATED OR UNLIQUIDATED, MATURED OR UNMATURED, WHETHER AT LAW OR IN EQUITY, WHICH THE RELEASING PARTIES EVER HAD, NOW HAVE, OR MAY, SHALL OR CAN HEREAFTER HAVE, DIRECTLY OR INDIRECTLY ARISING OUT OF OR IN ANY WAY BASED UPON, CONNECTED WITH, OR

RELATED TO MATTERS, THINGS, ACTS, CONDUCT AND/OR OMISSIONS AT ANY TIME FROM THE BEGINNING OF THE WORLD THROUGH AND INCLUDING THE DATE HEREOF, INCLUDING WITHOUT LIMITATION ANY AND ALL CLAIMS AGAINST THE RELEASED PARTIES ARISING UNDER OR RELATED TO ANY OF THE LOAN DOCUMENTS OR ANY OF THE TRANSACTIONS CONTEMPLATED THEREBY.

(c)IN CONNECTION WITH THE RELEASE CONTAINED HEREIN, ACKNOWLEDGE THAT THEY ARE AWARE THAT THEY MAY HEREAFTER DISCOVER CLAIMS PRESENTLY UNKNOWN OR UNSUSPECTED, OR FACTS IN ADDITION TO OR DIFFERENT FROM THOSE WHICH THEY KNOW OR BELIEVE TO BE TRUE, WITH RESPECT TO THE MATTERS RELEASED HEREIN. NEVERTHELESS, IT IS THE INTENTION OF THE RELEASING PARTIES, THROUGH THIS AMENDMENT AND WITH ADVICE OF COUNSEL, FULLY, FINALLY AND FOREVER TO RELEASE ALL SUCH MATTERS, AND ALL CLAIMS RELATED THERETO, WHICH DO NOW EXIST, OR HERETOFORE HAVE EXISTED. IN FURTHERANCE OF SUCH INTENTION, THE RELEASES HEREIN GIVEN SHALL BE AND REMAIN IN EFFECT AS A FULL AND COMPLETE RELEASE OF SUCH MATTERS NOTWITHSTANDING THE DISCOVERY OR EXISTENCE OF ANY SUCH ADDITIONAL OR DIFFERENT CLAIMS OR FACTS RELATED THERETO.

(d)COVENANT AND AGREE NOT TO BRING ANY CLAIM, ACTION, SUIT OR PROCEEDING AGAINST THE RELEASED PARTIES, DIRECTLY OR INDIRECTLY, REGARDING OR RELATED IN ANY MANNER TO THE MATTERS RELEASED HEREBY, AND FURTHER COVENANT AND AGREE THAT THIS AGREEMENT IS A BAR TO ANY SUCH CLAIM, ACTION, SUIT OR PROCEEDING.

(e)REPRESENT AND WARRANT TO THE RELEASED PARTIES THAT THEY HAVE NOT HERETOFORE ASSIGNED OR TRANSFERRED, OR PURPORTED TO ASSIGN OR TRANSFER, TO ANY PERSON OR ENTITY ANY CLAIMS OR OTHER MATTERS HEREIN RELEASED.

(f)ACKNOWLEDGE THAT THEY HAVE HAD THE BENEFIT OF INDEPENDENT LEGAL ADVICE WITH RESPECT TO THE ADVISABILITY OF ENTERING INTO THIS RELEASE AND HEREBY KNOWINGLY, AND UPON SUCH ADVICE OF COUNSEL, WAIVE ANY AND ALL APPLICABLE RIGHTS AND BENEFITS UNDER, AND PROTECTIONS OF, CALIFORNIA CIVIL CODE SECTION 1542, AND ANY AND ALL STATUTES AND DOCTRINES OF SIMILAR EFFECT. CALIFORNIA CIVIL CODE SECTION 1542 PROVIDES AS FOLLOWS:

> *A general release does not extend to claims that the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release, and that if known by him or her, would have materially affected his or her settlement with the debtor or released party.*

8.Guarantor Reaffirmation. Each Guarantor hereby ratifies and reaffirms as of the date hereof the guarantee granted by it to the Agent for the benefit of the Lenders under the Loan Documents and agrees and acknowledges that such guarantee shall continue and shall remain in full force and effect from and after the date hereof after giving effect from and after the date hereof, and the obligations guaranteed thereby shall include the Loan Parties' obligations under the Loan Documents from and after the date hereof. Except as expressly provided herein, this Amendment shall not release, reduce or diminish any Loan Party's obligations to the Agent and the Lenders under the Loan Documents, or prejudice, alter or in any regard adversely affect the rights and remedies of the Agent or any Lender in respect thereof.

9.Reaffirmation of Security Interest. Each Loan Party hereby (i) affirms that each of the security interests and liens granted in or pursuant to the Loan Documents are valid and subsisting and shall continue and shall remain in full force and effect from and after the date hereof and (ii) agree that this Agreement shall in no manner impair or otherwise adversely affect any of the security interests and liens granted in or pursuant to the Loan Documents.

10.Counterparts. This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one agreement. Executed copies of the signature pages of this Amendment sent by facsimile or transmitted

electronically shall be treated as originals, fully binding and with full legal force and effect, and the parties waive any rights they may have to object to such treatment.

11. Governing Law. THIS AMENDMENT SHALL BE A CONTRACT MADE UNDER AND GOVERNED BY THE INTERNAL LAWS OF THE STATE OF NEW YORK APPLICABLE TO CONTRACTS MADE AND TO BE PERFORMED ENTIRELY WITHIN SUCH STATE, WITHOUT REGARD TO CONFLICT OF LAWS PRINCIPLES (OTHER THAN SECTION 5-1401 OF THE NEW YORK GENERAL OBLIGATIONS LAW).

12. Agent Authorization. Each of the undersigned Lenders, who collectively constitute all of the Lenders under the Credit Agreement, hereby (i) authorizes and directs the Agent to execute and deliver this Amendment and any documents related thereto (ii) acknowledges and agrees that the undersigned Lenders constitute all of the Lenders necessary to direct the Agent to execute such documents; and (iii) acknowledges and agrees that the direction set forth in this Amendment constitutes an instruction, consent and request of the Lenders under the Loan Documents, including Section 9.3 of the Credit Agreement.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be duly executed as of the date first above written.

BORROWER:

BAUDAX BIO, INC.

By: /s/ Gerri Henwood
Name: Gerri Henwood
Title: Chief Executive Officer and President

GUARANTORS:

BAUDAX BIO N.A. LLC

By: /s/ Gerri Henwood
Name: Gerri Henwood
Title: Director

BAUDAX BIO LIMITED

By: /s/ Gerri Henwood
Name: Gerri Henwood
Title: Director

AGENT:

WILMINGTON TRUST, NATIONAL ASSOCIATION

By: /s/ Andrew Lennon
Name: Andrew Lennon
Title: Assistant Vice President

LENDERS:

MAM EAGLE LENDER, LLC

By: /s/ Lou Hanover
Name: Lou Hanover
Title: Authorized Signatory

[Signature Page to Amendment No. 4 to Credit Agreement]

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (Nos. 333-235408, 333-243488 and 333-253117) on Form S-3, in the registration statements (Nos. 333-235377, 333-253118, 333-253120, 333-263606 and 333-263608) on Form S-8 and in the registration statements (Nos. 333-266499 and 333-268251) on Form S-1 of our report dated March 16, 2022, with respect to the consolidated financial statements of Baudax Bio, Inc.

/s/ KPMG LLP

Philadelphia, Pennsylvania
February 23, 2023

Exhibit 23.2

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements of Baudax Bio, Inc. on Form S-3 (No(s). 333-235408, 333-243488 and 333-253117) and Form S-8 (No(s). 333-235377, 333-253118, 333-253120, 333-263606 and 333-263608) of our report dated February 23, 2023, on our audit of the financial statements as of December 31, 2022 and for the year then ended, which report is included in this Annual Report on Form 10-K to be filed on or about February 23, 2023. Our report includes an explanatory paragraph about the existence of substantial doubt concerning the Company's ability to continue as a going concern.

/s/ EisnerAmper LLP

Philadelphia, Pennsylvania
February 23, 2023

Exhibit 31.1

CERTIFICATION

I, Gerri A. Henwood, certify that:

1. I have reviewed this Annual Report on Form 10-K 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 fourth fiscal quarter 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: February 23, 2023

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

Exhibit 31.2

CERTIFICATION

I, Jillian Dilmore, certify that:

1. I have reviewed this Annual Report on Form 10-K 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 fourth fiscal quarter 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: February 23, 2023

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

Exhibit 32.1

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

In connection with the Annual Report of Baudax Bio, Inc. (the "Company") on Form 10-K for the year ended December 31, 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: February 23, 2023

/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)