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, 2020

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

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

Indicate by check mark whether the registrant 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. ☐

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, 2020 was $70.8 million.

The number of shares of Registrant's Common Stock outstanding as of February 10, 2021, was 70,142,608.

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 2021 annual meeting of shareholders to be filed no later than 120 days after the end of the Registrant's fiscal year ended December 31, 2020.

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

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

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

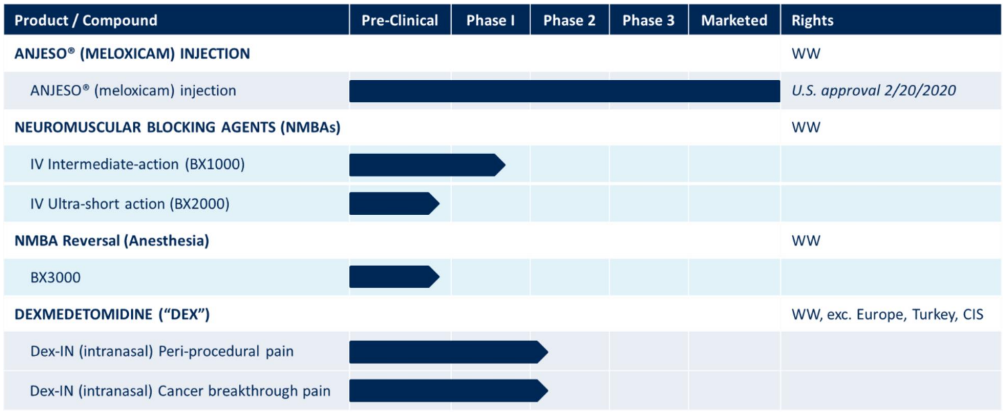
We are a pharmaceutical company primarily focused on developing and commercializing innovative products for hospital and related acute care settings. We believe that we can bring valuable therapeutic options for patients, prescribers and payers to the hospital and related acute care markets.

Our first commercial product, ANJESO, had its New Drug Application, or NDA, approved by the United States Food and Drug Administration, or FDA, on February 20, 2020 for the management of moderate to severe pain, alone or in combination with other non-NSAID analgesics. Because of delayed onset of analgesia, ANJESO alone is not recommended for use when rapid onset of analgesia is required. ANJESO is a once daily intravenous, or IV, NSAID with preferential Cox-2 activity, which has successfully completed three Phase III studies, including two pivotal efficacy trials, a large double-blind Phase III safety trial and other safety studies for the management of moderate to severe pain. Overall, the total NDA program included over 1,400 patients. We have established sales management, marketing and reimbursement functions in connection with the commercialization of ANJESO in the United States.

We commenced our commercial launch of ANJESO in June of 2020. We utilize an internal sales team and collaborate with third parties who market ANJESO to health care professionals at called-on institutions for the commercialization of ANJESO in the United States. We continue to evaluate strategic partnerships to commercialize ANJESO outside of the United States. In August 2020, the Centers for Medicare and Medicaid Services, or CMS, established a new permanent J-code for ANJESO, which became effective on October 1, 2020, facilitating reimbursement of ANJESO in the hospital outpatient, ambulatory surgery center and physician office settings of care. We have also entered into agreements with leading group purchasing organizations in the U.S., including Vizient Inc., and Premier Inc., as well as one of the top 3 integrated delivery networks for terms for availability of ANJESO to their member institutions. Over 65 institutions added ANJESO to their formulary. The number of vials sold to end-customers has increased 58% in the fourth quarter of 2020 versus the third quarter of 2020. The number of vials sold to hospitals and ambulatory surgical centers increased over 80% during the same time period. The average quarterly orders per account increased over 60% in the fourth quarter of 2020 versus the third quarter of 2020 and the re-order rate is approximately 55% with a deepening usage pattern.

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

Products and Pipeline



Separation from Recro

We separated from Recro on November 21, 2019 as a result of a special dividend distribution of all the outstanding shares of our common stock to Recro shareholders, which we refer to as the Separation. On November 21, 2019, the distribution date, each Recro shareholder received one share of Baudax Bio's common stock for every two and one-half shares of Recro common stock, or the Distribution, held of record at the close of business on November 15, 2019, the record date for the Distribution. As a result of the Distribution, we are an

independent public company whose shares of common stock are trading under the symbol “BXRX” on The Nasdaq Capital Market, or Nasdaq.

Our Strategy

We believe that we can bring valuable therapeutic options for patients, prescribers and payers, such as ANJESO, to the hospital and acute care markets. We believe we can create value for our shareholders through the commercialization of ANJESO and the development, registration and commercialization of our other pipeline product candidates. 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:

- *Successful commercialization of ANJESO.*
- *Pursuing the license or acquisition of additional products.* We are seeking in-license or acquisition opportunities to add commercial or near-commercial products to our portfolio. We have established sales management, marketing and reimbursement functions for the commercialization of ANJESO in the United States and we believe we can utilize this infrastructure for the successful commercialization of an acquired or licensed product.
- *Leveraging our development experience to progress our other pipeline product candidates.* Our early-stage product pipeline includes proprietary product candidates for use in anesthesia (neuromuscular blockade and reversal). Our goal is to leverage our drug development expertise to develop these product candidates for use in hospital and acute care settings.

Our Lead Product - ANJESO

ANJESO is a once a day, preferential COX-2 inhibitor that possesses analgesic, anti-inflammatory, and antipyretic activities. This proprietary injectable form of IV meloxicam, which utilizes NanoCrystal® technology, increases overall drug solubility that provides a faster onset of action of meloxicam and provides a rapid treatment of acute pain, which lasts for approximately 24 hours.

Post-Operative Pain Market

Based upon information from the National Center for Health Statistics, it is estimated that there are over 100 million surgeries performed in the United States each year. Of these surgeries, we believe at least 50 million procedures require post-operative pain medication. Additionally, despite efforts to improve the provision of perioperative analgesia, the proportion of patients reporting moderate to severe pain after surgery has remained constant over the past decade.

While opioids provide effective analgesia for post-operative pain, their use is increasingly limited due to the known side effects of nausea, vomiting, constipation, respiratory depression, the development of tolerance and the potential for impact on addiction, misuse and abuse. Due to the potential for abuse, opioids are regulated as controlled substances and are listed on Schedule II and III by the U.S. Drug Enforcement Agency, or DEA. According to a January 2016 article in the New England Journal of Medicine, overdose deaths from prescription painkillers (defined to mean opioid or narcotic pain relievers) increased significantly over the past 14 years and emergency department visits involved with misusing or abusing prescription opioid painkillers increased 153% between 2004 and 2011. In the acute care setting, and according to the Joint Commission Sentinel Event Alert on the Safe Use of Opioids in Hospitals, opioid analgesics rank among the drugs most frequently associated with adverse drug events. As a result of the addictive potential and side effects, pain sufferers tend to limit their use of opioids, resulting in as many as 40% of post-operative patients reporting inadequate pain relief. This can reduce the quality of life for individuals and, according to an August 2012 article in the Journal of Pain, creates an economic burden estimated to be at least $560 to $635 billion a year in medical costs and lost productivity.

Efforts to improve pain control with multimodal analgesia are being recommended by many medical societies as a way to decrease opioid-related morbidity and mortality. Multimodal analgesia, or MMA, refers to the use of two or more drugs or nonpharmacologic interventions with differing mechanisms. Its use has been demonstrated to limit the amount of opioids consumed and provide more effective pain control than opioids alone. Effective MMA may further lessen the cost burden and personal toll of opioid-centric regimens. According to an April 2013 article in Pharmacotherapy, opioid-related adverse events negatively impact patients and the healthcare system and cause a 55% longer length of hospital stay, 47% higher cost of care, 36% higher 30-day readmission rates and a 3.4% higher risk of inpatient mortality.

We believe that ANJESO offers an attractive alternative for relief of moderate to severe pain without the risks associated with opioids. We also believe it can be an important part of an MMA approach for patients in the post-operative setting. Accordingly, we believe that physicians, hospitals and third-party payers, including Integrated Delivery Systems (IDNs), Medicare and Medicaid, are interested in new non-opioid pain therapies that provide effective post-operative pain relief without the adverse issues associated with opioids.

ANJESO (meloxicam) Injection Advantages

We believe ANJESO has a number of advantages over existing analgesics, including the following:

Does not cause respiratory depression. Meloxicam does not cause respiratory depression. Besides the addictive nature of opioids, we believe that medical practitioners are highly concerned with respiratory depression, which is a well-documented side effect of opioid use (all opioids, including morphine, fentanyl and oxycodone). Respiratory depression, which is defined by inadequate ventilation leading to increased carbon dioxide levels and respiratory acidosis, is an established outcome of opioid use and requires significant patient monitoring in the acute care setting. One of the more concerning adverse effects of chronic opioid use, for which tolerance does not develop, is respiratory depression during sleep, which can be life-threatening. ANJESO has demonstrated through multiple clinical trials and patient use that it does not cause respiratory depression.

Not a controlled substance. Meloxicam is not an opioid and not a controlled substance. Opioid therapeutics are currently controlled by the DEA under the Controlled Substances Act. Under this act, opioids have been scheduled based on their potential for abuse and/or addiction. For those opioids placed in Schedule II, federal law prohibits the refilling of prescriptions, thus requiring patients to request, and physicians to write, additional prescriptions for each refill. Examples of Schedule II opioids include morphine, fentanyl, sufentanil, hydrocodone and oxycodone.

Duration of pain relief. ANJESO has demonstrated the potential to be an effective analgesic for up to 24 hours after a single dose in clinical trials. Injectable forms of ketorolac, ibuprofen and acetaminophen provide effective pain relief up to four to six hours, resulting in the need for four to six doses per day.

Administration. We believe that ANJESO has an administration advantage in terms of being administered by bolus injection, whereas ibuprofen and acetaminophen can take up to 15 to 30 minutes to be infused.

GI Tolerability. Unlike opioids, the mechanism of action of meloxicam provides analgesic activity with limited impact on gastrointestinal motility thus limiting the common unwanted side effects of opioids, referred to as Opioid Induced Bowel Dysfunction, or OIBD. OIBD comprises several symptoms including constipation, anorexia, nausea and vomiting, gastroesophageal reflux, delayed digestion, abdominal pain, flatulence, bloating, hard stool, straining during bowel movement and incomplete evacuation.

Reduction of Opioid Consumption. Reducing opioid use inside and outside the hospital is becoming more of a priority for physicians and hospital administrators. ANJESO has demonstrated the potential to relieve serious pain while reducing overall opioid consumption. ANJESO also demonstrated a potential greater reduction in opioid use in patients over 65 years old with mild renal impairment in clinical trials.

Commercial Strategy

On February 20, 2020, we announced the FDA approved the NDA for ANJESO, which is indicated for the management of moderate to severe pain, alone or in combination with other non-NSAID analgesics. Limitation of Use: Because of delayed onset of analgesia, ANJESO alone is not recommended for use when rapid onset of analgesia is required.

We believe that ANJESO may have a positive value proposition based on our current clinical data. Based on our market research, a new analgesic would be perceived to have a strong value proposition if it can: (1) reduce opioid consumption, (2) allow ambulatory surgical centers to perform more complex procedures and discharge patients on the same day, and (3) allow hospitals to safely speed up patient discharge, reduce inpatient admission and/or length of stay.

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

In spite of the COVID-19 challenges on our commercialization efforts, we have generated some early commercial experience with ANJESO at settings that have lower barriers to new product adoption and/or have an appetite to use newer therapies. We initially targeted approximately 1,500 hospitals and associated hospital outpatient departments, or HOPDs, and 600 ambulatory surgical centers, or ASCs, which together represented approximately 12.6 million patients across all settings of care. We refocused our efforts in November 2020 due to the challenges further presented by the COVID-19 pandemic and our current customer facing commercial team, which includes approximately 30 individuals in roles ranging from sales, sales management, account management and reimbursement. We have deployed a contracted telesales team who expands our customer outreach to target hospitals and ASCs. We also have a medical affairs team.

We believe this focused approach will help educate health care professionals, support formulary review processes and continue to generate early adoption. We believe it is important to continue to educate surgeons (e.g., orthopedic, colorectal and general) and anesthesiologists that practice at multiple settings of care within the acute care market, including ASCs, hospital outpatient departments,

and hospitals (often referred to as the “hospital inpatient setting”). We have found that some ASCs and small to mid-sized hospitals have lower barriers to adoption and have incorporated ANJESO into some of their post-operative pain management protocols. We believe early success in commercializing ANJESO with ASC’s could lead to increased adoption of ANJESO in hospital outpatient settings, and ultimately hospital inpatient settings.

Clinical Development

Multiple clinical trials have been conducted to evaluate the safety, pharmacokinetics and analgesic effect of injectable meloxicam. Based on the results of these trials, we believe injectable meloxicam has the potential to be a potent analgesic used in the management of moderate to severe pain. injectable meloxicam has successfully completed two pivotal Phase III clinical trials, a large double-blind Phase III safety trial as well as four Phase II trials and additional pharmacokinetics/safety studies. Overall, we enrolled a total of approximately 1,400 patients in our Phase II/III programs. In addition, we have evaluated the results of injectable meloxicam in Phase IIIb clinical trials in colorectal surgery patients and orthopedic surgery patients that were completed in 2019. Per the Pediatric Study Plan Agreement with FDA, two clinical trials will be conducted in the pediatric population. These trials will be initiated following NDA approval of injectable meloxicam and after appropriate regulatory and institutional review board, or IRB, review.

Phase IIIb Clinical Trials

We have evaluated the results of injectable meloxicam from a Phase IIIb program that included clinical trials in colorectal surgery patients and orthopedic surgery patients to assess opioid consumption, pain intensity and length of hospital stay with associated pharmacoeconomic parameters.

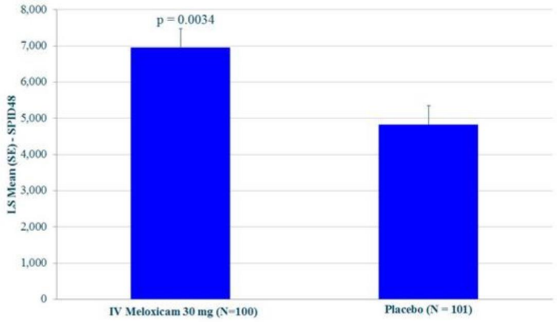
Phase III Clinical Trials

Study REC-15-016

In this pivotal clinical trial, evaluating pain relief over a 48-hour period in a hard tissue, post-operative pain model (bunionectomy), injectable meloxicam achieved the primary endpoint of a statistically significant difference in Summed Pain Intensity Difference, or SPID, over the first 48 hours, or SPID48, compared to placebo. This was a Phase III, randomized, multicenter, multi-dose, double-blind, placebo-controlled study evaluating injectable meloxicam in the management of post-operative pain following bunionectomy surgery. Two hundred and one patients who met the eligibility criteria were randomized to receive either injectable meloxicam (30 mg) or placebo once daily for up to three days. Following the beginning of treatment, patients remained under observation for 48 hours at study centers. Patients were followed for 28 days after the initial dose of study medication. There was an oral opioid rescue treatment available to all patients, if required. The primary objective of the trial was to evaluate pain relief over a 48-hour period of injectable meloxicam when administered as a bolus injection.

The primary efficacy endpoint of the trial was SPID48, utilizing a windowed 2-hour last observation carried forward, or W2LOCF, analysis method. Secondary efficacy endpoints included use of opioid rescue medication, SPIDs over various time intervals, and patient global assessment, or PGA, of pain control. The injectable meloxicam treatment arm demonstrated a statistically significant reduction in SPID48 (p=0.0034) compared to the placebo arm (Figure 1).

Figure 1: SPID48



The study also achieved the majority of secondary endpoints, including statistically significant differences in SPID6 (p=0.0153), SPID12 (p=0.0053), SPID24 (p=0.0084), SPID24-48 (p=0.0050), time to first use of rescue medication (p=0.0076), and several other rescue use and pain relief metrics during the first 48 hours, compared to placebo. Times to Perceptible and Meaningful Pain Relief, % Subjects with >50% Improvement within 6 Hours, and PGA of Pain Control at 24 hours were not significantly different between treatment groups.

The safety results demonstrated that injectable meloxicam was well tolerated with no serious adverse events, or SAEs, or bleeding events in the injectable meloxicam-treated patients. The most common adverse events, or AEs, occurring in at least 3% of injectable meloxicam-treated patients, were nausea, headache, pruritus, constipation, vomiting, dizziness, flushing and somnolence, and the incidence of these

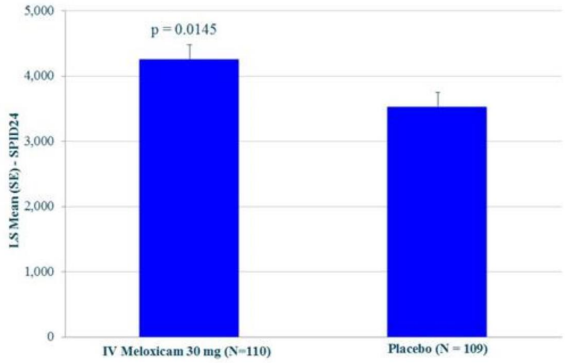
AEs was generally comparable to the placebo group. Theinjectable meloxicam-treated patients experienced injection site pain and injection site erythema at a rate comparable to placebo. The majority of treatment emergent AEs, or TEAEs, were mild in nature and there were no discontinuations due to AEs. There were no meaningful differences between treatment groups in vital signs, electrocardiogram, or ECGs, or clinical lab assessments.

Study REC-15-015

In the second of our two Phase III pivotal clinical trials, evaluating pain relief over a 24-hour period in a soft tissue, post-operative pain model (abdominoplasty), injectable meloxicam achieved the primary endpoint of a statistically significant difference in SPID over the first 24 hours, or SPID24, compared to placebo. This was a Phase III, randomized, multicenter, multi-dose, double-blind, placebo-controlled study evaluating injectable meloxicam in the management of post-operative pain following abdominoplasty surgery. Two hundred nineteen patients who met the eligibility criteria were randomized to receive either injectable meloxicam (30 mg) or placebo once daily for up to three days. Following the beginning of treatment, patients remained under observation for 48 hours at study centers. Patients were followed for 28 days after the initial dose of study medication. There was an oral opioid rescue treatment available to all patients, if required. The primary objective of the trial was to evaluate pain relief over a 24-hour period of injectable meloxicam when administered as a bolus injection (over 15-30 seconds).

The primary efficacy endpoint of the trial was SPID24 (0-24), utilizing a W2LOCF analysis method. Secondary efficacy endpoints included use of opioid rescue medication, SPIDs over various time intervals, time to pain relief and PGA of pain control. The injectable meloxicam treatment arm demonstrated a statistically significant reduction in SPID24 (p=0.0145) compared to the placebo arm (Figure 2).

Figure 2: SPID24



The study also achieved statistical significance for 10 of the secondary endpoints, including statistically significant differences in SPID12 (p=0.0434), time to perceptible pain relief (p=0.0050), subjects with ≥30% improvement at 24 hours (p=0.0178), number of times patients required rescue in the first 24 hours after randomization (p=0.0275), as well as number of times rescued from 24 to 48 hours (p=0.0009), and several other pain relief metrics, compared to placebo.

SPID6, Times to Meaningful Pain Relief and First Rescue, Number of Subjects rescued 0-24 and 0-48 hours, % Subjects with≥30 and ≥50% Improvement within 6 Hours and ≥50% within 24 hours, and PGA of Pain Control at 24 hours were not significantly different between treatment groups.

The safety results demonstrated that injectable meloxicam was well tolerated with no difference in SAEs related to bleeding for injectable meloxicam treated patients versus placebo (1 each). There were two additional SAEs observed in the placebo group. The most common (at least 3% in the injectable meloxicam group) AEs were nausea, headache, vomiting, and dizziness. The incidence of these events was lower than those observed in the placebo group. The majority of AEs were mild in nature and one patient in the placebo group discontinued treatment due to an adverse event of post-procedural bleeding. There were no meaningful differences between treatment groups in vital signs, ECGs or clinical lab assessments.

Safety Study

Injectable meloxicam has also successfully completed a double-blind, randomized Phase III safety study evaluating injectable meloxicam (30mg bolus injection) or placebo following major surgery. The primary objective of the study was to evaluate the safety and tolerability of injectable meloxicam 30mg vs. placebo through Day 28 following treatment. The clinical trial demonstrated that the adverse event profile of injectable meloxicam 30mg was consistent with previously completed clinical trials and was similar to placebo reported events.

This was a multicenter, randomized, double-blind, placebo-controlled Phase III clinical trial and included patients who had undergone major elective surgical procedures which were expected to result in hospitalization for at least 24-48 hours. Major surgical procedures included total hip and knee replacements, spinal, GI, hernia repair, and gynecologic surgeries, as well as a range of other surgeries. Patient demographics were balanced across treatment groups and included 40% male patients and about 23% of patients who were over age 65. Unlike the pivotal efficacy trials, minimum pain scores were not required for treatment. Sites were permitted to use opioids and other pain management modes according to their "standard of care" and meloxicam or placebo was added to this regimen in a randomized, double-blind manner. Patients were randomized in a 3:1 ratio to receive either injectable meloxicam 30mg or injectable placebo daily for up to 7 doses. A total of 721 patients received at least one dose of study medication.

The most common (≥3%) AEs observed in the injectable meloxicam 30mg treatment group (n=538) are listed in the table below:

	Injectable Meloxicam			
Preferred Term	**30 mg N = 538**		**Placebo N = 183**	
Subjects with ≥1 AE	339	(63.0)	119	(65.0)
Nausea	123	(22.9)	51	(27.9)
Constipation	51	(9.5)	17	(9.3)
Vomiting	27	(5.0)	14	(7.7)
Pruritis	21	(3.9)	10	(5.5)
Gamma-glutamyl transferase (GGT) increased	21	(3.9)	5	(2.7)
Headache	20	(3.7)	12	(6.6)
Anemia	18	(3.3)	4	(2.2)

In patients age 65 and over, the percentage of patients reporting at least one AE was approximately 7% less in the injectable meloxicam 30mg treatment arm compared to the placebo arm. The total occurrence of patients with at least one SAE was observed to be lower in the injectable meloxicam 30mg group, 2.6%, than in the placebo group, 5.5%. In this safety study only two SAE events were listed as possibly related to study treatment. Both of these SAEs occurred in one placebo treated patient. No deaths were reported in either treatment group. Approximately 3% of patients in each study group discontinued.

There were no meaningful clinical differences between treatment groups in vital signs, ECGs, clinical lab assessments and surgeon satisfaction with wound healing. Overall, there was low incidence of clinically significant wound healing abnormalities, as scored by the primary investigator, in both treatment groups (~2%). The meloxicam group had 4/538 patients with more than one attribute scored "clinically significant", while in placebo, 1/183 patients were scored "clinically significant" for only one attribute.

In addition, mean opioid consumption for the total population was lower in the injectable meloxicam 30mg group compared with placebo at all evaluated intervals; Hour 0-24, Hour 24-48, Hour 48-72 and Hour 0-72 intervals, or the full treatment period. There was also a significant increase in time to first use of opioids in the injectable meloxicam 30mg treatment arm, compared to placebo. Mean opioid consumption in the injectable meloxicam group was lower than the placebo group at all evaluated intervals in the subgroups of Orthopedic Surgeries, Total Knee Replacements, and subjects >65 years with Mild Renal Impairment, as depicted in the table below.

	% reduction in Opioid Use			
Population	**Hour 0-24**	**Hour 24-48**	**Hour 48-72**	**Treatment Period**
Total Population	23.2%*	23.0%	33.9%	23.6%
Orthopedic Surgeries	28.9%*	25.5%*	38.4%	26.8%*
Total Knee Replacement Surgeries	41.0%**	35.2%**	58.9%	40.8%**
>65 years & Mild Renal Impairment Population	42.8%*	41.9%*	56.9%	40.7%*

*reaching statistical significance ($p<0.05$)
**reaching statistical significance ($p<0.01$)

Our Other Pipeline Candidates

While our current priority is the commercialization of ANJESO, our pipeline also includes other earlier stage product candidates including intermediate and short-acting NMBAs, and accompanying reversal agents, DEX-IN, along with other product candidates that we may choose to develop for use in hospital or related settings.

NMBAs

Neuromuscular blocking agents are used as muscle paralyzing agents to facilitate intubation and surgery. We are developing an intermediate-acting NMBA, BX1000, an ultrashort-acting NMBA, BX2000, and a reversal agent specific to our NMBAs. The table

below summarizes the predicted onset and duration of activity for each NMBA based on currently available data, as well as the development status of each NMBA:

Compound	Onset Time	Duration of Activity	Status
BX1000	Rapid	Intermediate acting	Phase I
BX2000	Rapid	Ultra-short acting	Pre-clinical

In animal models, the proprietary reversal agent acts quickly by chemical reaction to reverse the neuromuscular blockade. We believe that the NMBAs can reduce the time required for induction of anesthesia and the reversal agent can reduce the time needed to recover from NMBA dosing post-procedure, while potentially enhancing patient safety and resulting in cost savings for the hospital or other provider. BX1000, the intermediate-acting NMBA, and the reversal agent were subject to a clinical hold imposed by the FDA due to need for additional toxicity data at higher dose exposures. We have met with the FDA and the clinical hold has been lifted with respect to BX1000. We continue to work with the FDA regarding a path forward for the reversal agent. We submitted a new IND for BX1000 in 2019.

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

We are conducting a Phase I study with BX1000 which began in 2020 to evaluate the safety profile when administered with Total Intravenous Anesthesia, as well as to evaluate the dose response of neuromuscular blockade. We filed an IND, or equivalent application, for BX2000 in order to conduct a First-in-Human study and are working on responding to the FDA review.

Dex-IN

Dex (dexmedetomidine) is a selective alpha-2 adrenergic agonist that has demonstrated sedative, analgesic and anxiolytic properties. Dex has an extensive commercial history of safe injectable use. We have formulated Dex-IN, a proprietary intranasal formulation of Dex, at a significantly lower dose (approximately as low as 1/10th) than the currently recommended injectable dosage levels used for clinical sedation. Based upon our lower dose, we have seen minimal sedation to date in our clinical trials while still demonstrating an analgesic effect.

We continue to explore possible uses of Dex-IN in other indications in the acute care space as well as pursue possible partnering opportunities. Once an indication is identified, clinical studies will be required to evaluate the safety of Dex-IN as well as the doses required to establish efficacy with respect to such indication.

Intellectual Property

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 2022 and 2030 in the United States, and the pending applications, if issued, would expire between 2024 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 license the patents and other intellectual property covering the NMBAs and the related reversal agent under a worldwide, exclusive, sublicensable, royalty-bearing license from Cornell. The issued patents and pending patent applications, if issued, expire between 2027 and 2033, subject to any applicable disclaimers 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 NMBA, 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 NMBAs 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 and transmucosal methods of use ofDex, 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 are party to an exclusive license with Orion for the development and commercialization of Dex for use in the treatment of pain in humans in any dosage form for transdermal, transmucosal (including sublingual and intranasal), topical, enteral or pulmonary (inhalational) delivery, but specifically excluding delivery vehicles for administration by injection or infusion, worldwide, except for Europe, Turkey, and the CIS (currently includes Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine and Uzbekistan), referred to herein as the Territory. We have the right to sublicense the rights under such license at any time. We are required to pay Orion lump sum payments in an aggregate amount of €20.5 million on the achievement of certain developmental milestones and upon the achievement of certain commercial milestones, as well as a royalty on net sales during the term, which varies from 10% to 20% depending on annual sales levels.

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.

Sales and Marketing

We believe the initial target audience for ANJESO and our product candidates will be specialty physicians, including surgeons, anesthesiologists and pain specialists. Our management team has experience building and launching therapeutics to specialty physicians, including hospital and related settings. As this target audience is only a portion of all physicians, we believe we have the capabilities to maintain and develop the sales and marketing infrastructure established and effectively market ANJESO and our product candidates. We are also seeking in-license or acquisition opportunities to add commercial or near-commercial products to our portfolio. We have established sales management, marketing and reimbursement functions for the commercialization of ANJESO in the United States and we believe we can utilize this infrastructure for the successful commercialization of an acquired or licensed product.

Competition

The pharmaceutical and biotechnology industries are intensely competitive and subject to rapid and significant technological change. Our current and future competitors include pharmaceutical, biotechnology and specialty pharmaceutical companies. Many of our competitors have greater financial and other resources than we have, such as more commercial resources, larger research and development staffs and more extensive marketing and manufacturing organizations. As a result, these companies may obtain marketing approval more rapidly than we are able to obtain and may be more effective in selling and marketing their products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective or less costly than our product candidates or any other products that we may develop which could render our products obsolete and noncompetitive.

We expect any products that we develop and commercialize, either alone or through a strategic partnership, to competeon the basis of, among other things, efficacy, safety, convenience of administration and delivery, price and the availability of reimbursement from government and other third-party payers. We also expect to face competition in our efforts to identify appropriate collaborators or partners to help commercialize our product candidates in our target commercial markets.

In the post-operative pain relief setting, we believe patients are prescribed injectable acetaminophen, NSAIDs, sodium channel blockers and opioids, depending on the severity of pain. Specifically, acetaminophen, NSAIDs and sodium channel blockers, we believe, are prescribed for mild to moderate pain relief, whereas we believe opioids are prescribed for moderate to severe pain relief. While we compete with all of these compounds in the post-operative pain setting, ANJESO is prescribed for moderate to severe pain, also competing with opioids and other non-opioid pain treatments. There are a number of pharmaceutical companies that currently market and or manufacture therapeutics in the pain relief area, including Johnson & Johnson, Mallinckrodt plc, Pacira Pharmaceuticals, Inc., AcelRx Pharmaceuticals, Inc., Trevena, Inc., and Innocoll Holdings plc. Mallinckrodt commercializes an injectable formulation of acetaminophen which is now available generically by many manufacturers, including Sandoz. Pacira commercializes an intraoperative formulation of bupivacaine, a sodium channel blocker, that is injected or instilled at the surgical site. Additionally, companies such as Adynxx, Inc., Durect Corporation, Heron Therapeutics, Inc., Sandoz AG, Avenue Therapeutics, Inc., Neumentum Inc. and Cara Therapeutics, Inc. are currently developing post-operative pain therapeutics that could compete with ANJESO in the future.

Manufacturing

We currently rely on contract manufacturers to produce commercial supplies of ANJESO drug product as well as for our clinical studies with respect to our product candidates under current Good Manufacturing Practices, or cGMP, with oversight by our internal managers. We currently rely on a single manufacturer for commercial supply of ANJESO and for the clinical supplies of our drug product for each of our product candidates and do not currently have agreements in place for redundant supply or a second source for any of our product candidates. 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. Additionally, should a supplier or a manufacturer on whom we rely on to produce ANJESO or a product candidate provide us with a faulty product or a product that is later recalled, we would likely experience significant delays and additional costs.

ANJESO

Alkermes is currently our exclusive supplier of bulk injectable meloxicam. Pursuant to a Development, Manufacturing and Supply Agreement, or Supply Agreement with our subsidiary, Baudax Bio Limited, Alkermes (through a subsidiary), provides clinical and commercial bulk supplies of injectable meloxicam formulation. During the term of the Supply Agreement, we will purchase our clinical and commercial supplies of bulk injectable meloxicam formulation exclusively from Alkermes. The Supply Agreement has an initial term expiring on March 31, 2030. The Supply Agreement will then automatically renew for successive one-year terms unless terminated by either party upon written notice at least 180 days prior to the expiration of the applicable term.

Patheon provides sterile fill-finish of injectable meloxicam drug product pursuant to a Master Manufacturing Services Agreement and Product Agreement, collectively the Patheon Agreements, at its Monza, Italy manufacturing site. We have agreed to purchase a certain percentage of our annual requirements of finished injectable meloxicam from Patheon during the term of the Patheon Agreements. The Patheon Agreements expire on December 31, 2020 and will automatically renew thereafter for successive two-year periods unless terminated by either party upon prior written notice. The Patheon Agreement was renewed for a two-year term beginning on January 1, 2021.

NMBAs

We have successfully sourced the manufacturing of the NMBAs and reversing agent at contract manufacturers for use in pre-clinical studies and early clinical trials for these product candidates.

Dex-IN

We are party to an API supply agreement with Orion, whereby Orion provides us with API for the development and, if approved, commercialization of Dex-IN. Prior to obtaining regulatory approval, subject to advance notice to Orion, Orion will provide API without charge for agreed upon amounts. Any amounts ordered by us that are greater than the planned supply will be charged at 50% of the supply price for commercial product. The single unit dose intranasal sprayer for Dex-IN is manufactured by a supplier of proprietary components and devices. Suppliers of components, subassemblies and other materials are located in Europe, Asia and the United States.

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 cGCPs 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 cGCP 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. A waiver of such fee may be obtained under certain limited circumstances. For example, an applicant is eligible for waiver of the application fee if the applicant is a small business submitting its first human drug application and does not have another product approved under a human drug application and introduced and delivered for introduction into interstate commerce. However, we did not qualify due to prior NDA approvals received by Recro's contract development and manufacturing, or CDMO, business.

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 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 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 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. For example, in December 2016, the 21st Century Cures Act, or the Cures Act, became law. The Cures Act contains numerous provisions, including provisions designed to speed development of innovative therapies and encourage greater use of real-world evidence to support regulatory decision making for drugs.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our product candidates to the extent we choose to clinically evaluate or sell any products 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 (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 commercialize our product candidates successfully, 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 for our product candidates 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.

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 for which we receive regulatory approval.

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.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. Moreover, the requirements governing drug pricing and reimbursement vary widely from country to country. For example, in the European Union the sole legal instrument at the European Union level governing the pricing and reimbursement of medicinal products is Council Directive 89/105/EEC, or the Price Transparency Directive. The aim of the Price Transparency Directive is to ensure that pricing and reimbursement mechanisms established in European Union member states are transparent and objective, do not hinder the free movement and trade of medicinal products in the European Union and do not hinder, prevent or distort competition on the market. The Price Transparency Directive does not, however, provide any guidance concerning the specific criteria on the basis of which pricing and reimbursement decisions are to be made in individual European Union member states. Neither does it have any direct consequence for pricing or levels of reimbursement in individual European Union member states. The national authorities of the individual European Union member states are free to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices and/or reimbursement of medicinal products for human use. Some individual European Union member states adopt policies according to which a specific price or level of reimbursement is approved for the medicinal product. Other European Union member states adopt a system of reference pricing, basing the price or reimbursement level in their territory either, on the pricing and reimbursement levels in other countries, or on the pricing and reimbursement levels of medicinal products intended for the same therapeutic indication. Furthermore, some European Union member states impose direct or indirect controls on the profitability of the company placing the medicinal product on the market.

Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some European Union member states. These countries include the United Kingdom, France, Germany and

Sweden. The HTA process in the European Union member states is governed by the national laws of these countries. HTA is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of the use of a given medicinal product in the national healthcare systems of the individual country is conducted. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost, and cost-effectiveness of individual medicinal products as well as their potential implications for the national healthcare system. Those elements of medicinal products are compared with other treatment options available on the market.

The outcome of HTA may influence the pricing and reimbursement status for specific medicinal products within individual European Union member states. The extent to which pricing and reimbursement decisions are influenced by the HTA of a specific medicinal product vary between the European Union member states.

In 2011, Directive 2011/24/EU was adopted at European Union level. This Directive concerns the application of patients' rights in cross-border healthcare. The Directive is intended to establish rules for facilitating access to safe and high-quality cross-border healthcare in the European Union. Pursuant to Directive 2011/24/EU, a voluntary network of national authorities or bodies responsible for HTA in the individual European Union member states was established. The purpose of the network is to facilitate and support the exchange of scientific information concerning HTAs. This could lead to harmonization between European Union member states of the criteria taken into account in the conduct of HTA in pricing and reimbursement decisions and negatively impact price in at least some European Union member states.

United States Healthcare Reform

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system. The United States government, state legislatures and foreign governments also have shown significant interest in 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 recent years, Congress has considered reductions in Medicare reimbursement levels for drugs administered by physicians. CMS, the agency that administers the Medicare and Medicaid programs, also has authority to revise reimbursement rates and to implement coverage restrictions for some drugs. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products. While Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payers.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the Affordable Care Act, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Affordable Care Act is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms. Among other things, the Affordable Care Act expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum Medicaid rebate for both branded and generic drugs, expanded the 340B program, and revised the definition of AMP, which could increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The legislation also extended Medicaid drug rebates, previously due only on fee-for-service Medicaid utilization, to include the utilization of Medicaid managed care organizations as well and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the amount of rebates due on those drugs. On February 1, 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate program under the Affordable Care Act. These regulations became effective on April 1, 2016. Since that time, there have been significant ongoing efforts to modify or eliminate the Affordable Care Act.

On January 20, 2017, President Trump signed an executive order directing federal agencies to exercise existing authorities to reduce burdens associated with the Affordable Care Act pending further action by Congress. In October 2017, he signed an Executive Order which directed federal agencies to modify how the Affordable Care Act is implemented. 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 of 1986, as amended, or the 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. However, pursuant to the Coronavirus Aid, Relief and Economic Security Act, or CARES Act, the 2% Medicare sequester reductions have been suspended from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. 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.

Further legislative changes to and regulatory changes under the Affordable Care Act remain possible, although the new Administration under President-elect Joseph Biden has signaled that it plans to build on the Affordable Care Act and expand the number of people who are eligible for subsidies under it. President-elect Biden indicated that he may use executive orders to undo changes to the Affordable Care Act made by the Trump administration and would advocate for legislation to build on the Affordable Care Act. It is unknown what form any such changes or any law proposed to replace 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.

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 which heard oral arguments in the case on November 10, 2020. A ruling is expected in 2021.

The Affordable Care Act requires pharmaceutical manufacturers of branded prescription drugs to pay a branded prescription drug fee to the federal government. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. Furthermore, the law requires manufacturers to provide a 50% discount off the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the "donut hole." The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole," by increasing from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D.

The Affordable Care Act also expanded the Public Health Service's 340B drug pricing program. As noted above, 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. The Affordable Care Act expanded the 340B program to include additional types of covered entities: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the Affordable Care Act. Because the 340B ceiling price is determined based on AMP and Medicaid drug rebate data, revisions to the Medicaid rebate formula and AMP definition could cause the required 340B discounts to increase.

Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives as well. For example, CMS may develop new payment and delivery models, such as bundled payment models. Recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Such scrutiny has resulted in several recent U.S. Congressional inquiries and proposed, and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare, and reform government program reimbursement methodologies for pharmaceutical products.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that additional foreign, federal and state healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

Other Healthcare Laws and Compliance Requirements

For ANJESO and if we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our activities are 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 and 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.

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 22,313 square feet of leased laboratory and office space pursuant to a six-year lease, which expires on December 31, 2022. 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. In response to the COVID-19 pandemic, we implemented significant changes that we determined were in the best interest of our employees, and which comply with local and federal government regulations. This includes having some of our employees work from home, while implementing additional safety measures for employees continuing critical on-site work.

As of December 31, 2020, we had 57 full-time employees. 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 may 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 and we may not be entitled to forgiveness of our Paycheck Protection Program Loan, which could adversely affect our business.
- The COVID-19 pandemic has and may continue to materially and adversely affect our financial results.
- We have no history of commercializing drugs prior to ANJESO and our success depends heavily on the successful commercialization of ANJESO. To the extent ANJESO is not commercially successful, our business, financial condition and results of operations will be materially harmed.
- ANJESO may cause adverse events or other safety concerns or have other properties that could limit the scope of market acceptance.
- Even with regulatory approval for ANJESO, we will still face extensive regulatory requirements and ANJESO may face future regulatory difficulties.
- If third-party service providers, including carriers, logistics providers and distributors fail to devote sufficient time and resources to ANJESO or their performance is substandard, our successful commercialization 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 may never obtain approval for or commercialize ANJESO outside of the United States, which would limit our ability to realize its full market potential, and if we receive such approval outside the United States, a variety of risks associated with international operations could materially adversely affect our business.
- We are subject to intense competition and, if we are unable to compete effectively, ANJESO may not reach its commercial potential.
- If third-party payers do not reimburse physicians or patients for ANJESO or if reimbursement levels are, or pricing pressures cause the sales price to be, set too low for us to sell ANJESO at a profit, our ability to successfully commercialize ANJESO and our results of operations will be harmed.
- If we participate in but fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program, or other governmental pricing programs, we could be subject to additional pricing pressures and controls, reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.
- 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.
- 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.

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. Please see pages 3 and 4 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. All references and risks related to the launch, commercialization or sale of ANJESO or any of our product candidates are predicated on such product candidates receiving the requisite marketing and regulatory approval in the United States and applicable foreign jurisdictions.

Risks Related to Our Finances and Capital Requirements

Our business has incurred significant losses 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, 2020 and 2019 were $76.1 million and $32.6 million, respectively.

We expect to continue to incur substantial and increased expenses as we continue to pursue full commercialization of ANJESO, expand our research and development activities and advance our clinical programs for our product candidates. The size of our future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenues. Our ability to generate future revenues depends heavily on our success in:

- commercializing ANJESO;
- maintaining a sufficient commercial organization capable of sales, marketing and distribution for ANJESO or an acquired or in-licensed new product
- maintaining a commercially viable price for ANJESO;
- manufacturing commercial quantities of ANJESO at acceptable cost levels;
- effectively managing the levels of production, distribution and delivery of ANJESO through our supply chain and adequately adjusting such production and delivery to correspond to market demand;
- obtaining coverage and adequate reimbursement from third-parties, including government payers;
- identifying and completing the acquisition or in-licensing of other commercial or near-commercial products;
- obtaining and maintaining patent protection for our product candidates; and
- completing the clinical development of our product candidates.

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 achieve or maintain profitability.

If ANJESO is not successfully commercialized, if any of our product candidates are not successfully developed or commercialized, or if revenues are insufficient following commercialization of ANJESO or any of our product candidates, we will not achieve profitability and our business may fail. Our revenues from ANJESO are also dependent upon the size of the markets outside of the United States, as well as our ability to obtain market approval for ANJESO and achieve commercial success outside of the United States on our own or with a collaboration partner. As a result of the foregoing, we expect to continue to incur significant and increasing losses from operations for the foreseeable future. Even though we have generated revenues from sales of ANJESO, we may not become profitable and may need to obtain additional funding to continue operations.

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 12 months from the date of the financial statements included in this Annual Report on Form 10-K. As of December 31, 2020, we had an accumulated deficit of $112.3 million, cash and cash equivalents of $30.3 million and current liabilities of $18.1 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, 2020 are sufficient to fund our currently anticipated operating and capital requirements through the first half of 2021, however, our current capital resources are not sufficient to support our planned operations for the next 12 months from the date of the financial statements included in this report.

We did not become a revenue-generating company until the second quarter of 2020, following the commercial launch of ANJESO. We expect our expenses relating to the commercialization of ANJESO, including those related to personnel, marketing and selling, to increase. We expect to continue to incur losses for the foreseeable future as we continue our efforts to commercialize ANJESO and develop our other current and future product candidates. We have also incurred significant indebtedness. As of December 31, 2020, we had an outstanding balance under our PPP Loan of approximately $1.5 million, of which we cannot assure forgiveness in whole or in part, and an outstanding balance of $10 million under our credit facility with MAM Eagle Lender. These factors, individually and collectively, raise substantial doubt about our ability to continue as a going concern, and therefore, could materially limit our ability to raise additional funds through an issuance of debt or equity securities or otherwise.

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

The report of our independent registered accounting firm on our audited financial statements for the fiscal year ended December 31, 2020 contain 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, 2020 includes an explanatory paragraph stating that we have incurred recurring losses and negative cash flows and have an accumulated deficit of $112.3 million as of December 31, 2020 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 our commercialization efforts for ANJESO. 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 have used almost all of our unreserved, authorized shares of common stock.

We have used almost all of our unreserved authorized shares of common stock and will need shareholder approval to implement an increase in our authorized shares of common stock or a reverse stock split if we intend to issue unreserved shares of common stock in the future. Our amended and restated articles of incorporation and the Pennsylvania Business Corporation Law currently require the affirmative vote of the holders of a majority in voting power of the outstanding shares of capital stock to approve an increase in our authorized shares of common stock or a reverse stock split. There are no assurances that shareholder approval will be obtained, in which event we will be unable to raise additional capital through the issuance of shares of common stock to fund our future operations.

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.

As of December 31, 2020, our cash and cash equivalents were approximately $30.3 million.

Developing and commercializing pharmaceutical products, including conducting preclinical studies and clinical trials and ramping up commercialization and manufacturing activities, is expensive. We anticipate incurring significant costs of sales and general and commercialization expenses in connection with the continued commercialization of ANJESO. In addition, we will need to raise additional funds to support our future product development operations. Such financing may not be available to us on acceptable terms, or at all.

We will need to raise additional funding to continue our commercialization of ANJESO and to satisfy the milestone payments due to Alkermes related to the FDA approval and commercialization of ANJESO. We may also require additional funding to finance the acquisition or in-license of new product candidates. In addition, changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. For example, our commercialization activities for ANJESO may lead to additional, unexpected costs related to the commercial manufacture of ANJESO or the build-out of our commercial sales organization. We may also encounter technical, enrollment or other difficulties that could increase our development costs more than we expect for our product candidates. Additional funding will also be needed 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, scale back or cease any commercialization efforts or wind down our business. In addition, such additional fundraising efforts may divert our management from their day-to-day activities, which may impede our ability to commercialize ANJESO or our product candidates and could have a material adverse effect on our business, operating results and prospects.

We have incurred significant indebtedness, which could adversely affect our business.

As of December 31, 2020, we had an outstanding balance under our PPP Loan of approximately $1.5 million and an outstanding balance of $10 million under our credit agreement with MAM Eagle Lender. Our indebtedness could have important consequences to our shareholders. For example, it:

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

Any of the above-listed factors could materially adversely affect our business, financial condition, results of operations and cash flows. Our credit agreement with MAM Eagle Lender also contains certain financial and other covenants, including a minimum liquidity requirement of $5 million at all times, 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. Any failure to comply with the terms, covenants and conditions of the credit agreement may limit our ability to draw upon additional tranches of term loans and 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.

We may not be entitled to forgiveness of our recently received Paycheck Protection Program Loan, and our application for the Paycheck Protection Program Loan could in the future be determined to have been impermissible or could result in damage to our reputation.

On May 8, 2020, we received loan proceeds of approximately $1.5 million pursuant to the PPP under the CARES Act, administered by the Small Business Administration, or SBA. We used the PPP money on permitted purposes under the CARES Act and related regulations, including but not limited to retaining current employees, maintaining payroll and making lease and utility payments. The PPP Loan is evidenced by a promissory note, dated as of May 8, 2020, issued by PNC Bank, National Association, which contains customary events of default relating to, among other things, payment defaults and breaches of representations and warranties. The PPP Loan is scheduled to mature on May 8, 2022, or the Maturity Date, bears interest at a rate of 1.00% per annum, and is subject to the standard terms and conditions applicable to loans administered by the SBA under the CARES Act.

Commencing December 15, 2020, we were required to pay regular monthly payments in an amount equal to one month's accrued interest under the PPP Loan. All interest which accrues during the initial six months of the loan period will be deferred and payable on the Maturity Date. The amounts outstanding under the PPP Loan may be prepaid by us at any time prior to maturity without penalty. Under the CARES Act, as amended in June 2020, loan forgiveness is generally available for the sum of documented payroll costs, covered rent payments, covered mortgage interest and covered utilities during the 8-week period beginning on the date of the first disbursement of the PPP Loan. The amount of the PPP Loan eligible to be forgiven may be reduced in certain circumstances, including as a result of certain headcount or salary reductions. We will be required to repay any portion of the outstanding principal that is not forgiven, along with accrued interest, and we cannot provide any assurance that we will be eligible for loan forgiveness, that we will apply for forgiveness, or that any amount of the PPP Loan will ultimately be forgiven by the SBA.

In order to apply for the PPP Loan, we were required to certify, among other things, that the current economic uncertainty made the PPP Loan request necessary to support our ongoing operations. We made this certification in good faith after analyzing, among other things, the maintenance of our workforce, our need for additional funding to continue operations, and our ability to access alternative forms of capital in the current market environment in light of the uncertainty resulting from the COVID-19 pandemic. Following this analysis, we believe that we satisfied all eligibility criteria for the PPP Loan, and that our receipt of the PPP Loan is consistent with the broad objectives of the CARES Act. The certification described above did not contain any objective criteria and is subject to interpretation.

On April 23, 2020, the SBA issued new guidance that raised the possibility that certain public companies with substantial market value and access to capital markets would not be able to make this certification in good faith. That SBA guidance further indicated that borrowers "must make this certification in good faith, taking into account their current business activity and their ability to access other sources of liquidity sufficient to support their ongoing operations in a manner that is not significantly detrimental to the business." After being made aware of this new guidance, we conducted additional analysis and determined that we still satisfied the eligibility criteria and had made the certification in good faith. Once again, though, this guidance did not contain any objective criteria and is subject to interpretation.

Under PPP, all or a portion of the PPP Loan is eligible for forgiveness if we were eligible for the PPP Loan, use the loan proceeds for eligible expenses and otherwise satisfy PPP requirements. While we believe we are eligible for the PPP Loan, in the event it was determined that we were not eligible for the PPP Loan, it is possible we would be required to repay the PPP Loan on an accelerated basis, rather than over two years provided under the PPP Loan, and at a higher interest rate than 1.000% per annum. If we were to be audited and receive an adverse finding in such audit, some or all of the PPP Loan might not be forgiven and we could be required to return or repay some or all of the PPP Loan, together with interest on the loan, which could reduce our liquidity, and potentially subject us to fines and penalties.

The COVID-19 pandemic has and may continue to materially and adversely affect our financial results.

Our business, results of operations, financial condition, cash flows and stock price have and may continue to be adversely affected by pandemics, epidemics or other public health emergencies, such as the international outbreak of COVID-19. In December 2019, COVID-19, was identified in China and has since spread to multiple countries, including the United States. In March 2020, the World Health Organization characterized COVID-19 as a pandemic. COVID-19 has had a broad adverse impact on the global economy across many industries and has resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, travel restrictions and business shutdowns, as well as significant volatility in global financial markets. Our business performance was significantly impacted by COVID-19 during the second, third and fourth quarters of 2020, and we continue to expect to see challenges while the pandemic persists and potentially thereafter. The economic impact of the COVID-19 virus, which has caused a broad impact globally, has materially and adversely impacted our business and may continue to adversely affect us. In particular, hospitals in certain geographical regions have reduced and diverted staffing, diverted resources to patients suffering from the infectious disease and limited hospital access for non-patients, including our sales professionals. In addition, travel restrictions due to COVID-19 have impacted our sales professionals' ability to travel to hospitals. These circumstances have negatively impacted the ability of our sales professionals to effectively market to hospital pharmacists and formulary committees, which has impacted our commercial launch of ANJESO. In addition, the spread of COVID-19 has had, and may continue to have, an impact on the number or patients suffering from post-surgical pain, as hospitals cancel elective surgeries and patients postpone these procedures due to COVID-19 concerns, which may reduce demand for ANJESO and negatively impact our ability to successfully commercialize ANJESO. 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.

COVID-19 has and will continue to have an impact on ports and trade globally. We currently rely on Alkermes and Patheon UK Limited, or Patheon, for supply of ANJESO from locations in Ireland and Italy. There is a risk that supplies of ANJESO may be significantly delayed or may become unavailable as a result of COVID-19 and the resulting impact on Alkermes' and Patheon's labor force and operations, including as a result of governmental restrictions on business operations and the movement of people and goods in an effort to curtail the spread of the virus. There can be no assurance that we would be able to timely implement any mitigation plans. Disruptions in our supply chain, whether as a result of restricted travel, quarantine requirements or otherwise, could negatively impact our ability to supply and sell ANJESO.

While the potential long-term economic impact of the COVID-19 virus may be difficult to assess or predict, COVID-19 pandemic has resulted in significant disruption of global financial markets, which could reduce our ability to access capital, thereby negatively affecting our liquidity. The extent to which the COVID-19 pandemic impacts our results will depend on future developments that are highly uncertain and cannot be predicted. Given the rapid and evolving nature of the COVID-19 virus, the full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be predicted.

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

We may seek to raise such capital through public or private equity or debt financings. 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. 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 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.

Risks Related to Commercialization of ANJESO

Our success depends heavily on the successful commercialization of ANJESO. To the extent ANJESO is not commercially successful, our business, financial condition and results of operations will be materially harmed, and the price of our common stock may decline.

We have invested and continue to invest a significant portion of our efforts and financial resources in the development, approval and now commercialization of ANJESO. Our ability to successfully commercialize ANJESO will depend on many factors, including but not limited to:

- our ability to create sufficient capital (through debt, equity or both) to fund commercial operations;
- our ability to consistently manufacture commercial quantities of ANJESO at a reasonable cost and with sufficient speed to meet commercial demand, which may be higher or lower than expected demand on which our manufacturing forecasts have been based;
- our ability to build and maintain a sales and marketing organization to market ANJESO;
- our ability to identify a strategic partner with appropriate sales and marketing capabilities and to enter into a strategic partnership on commercially acceptable terms with such partner to commercialize ANJESO outside the United States;
- our success in educating physicians, patients and caregivers about the benefits, administration and use of ANJESO;
- our ability to effectively compete with other medications for the treatment of moderate-to-severe pain in medically supervised settings, including IV-opioids and any subsequently approved products;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of competing products;
- our ability to successfully defend any challenges to our intellectual property relating to our product candidates;
- our ability to set an acceptable price for ANJESO and to obtain adequate coverage and adequate reimbursement for ANJESO;
- our ability to obtain acceptance of ANJESO by physicians, patients and the healthcare community;
- our ability to contract with pharmaceutical wholesalers and specialty distributors on acceptable terms;
- the effectiveness of our marketing campaigns;
- our effective use of promotional resources;
- our success in obtaining formulary approvals; and
- a continued acceptable safety profile for ANJESO.

Many of these matters are beyond our control and are subject to other risks described elsewhere in this "Risk Factors" section. Accordingly, we cannot assure that we will be able to successfully commercialize ANJESO. If we cannot do so or are significantly delayed in doing so, our business, financial condition and results of operations may be materially adversely affected, and the price of our common stock may decline.

The commercial success of ANJESO will depend upon the acceptance of ANJESO by the medical community, including physicians, patients, pharmacy and therapeutics committees, health care payers and hospital formularies.

Physicians may not prescribe a sufficient amount of ANJESO, in which case we would not generate the revenues we anticipate. The degree of market acceptance of ANJESO will depend on a number of factors, including:

- the relative convenience, ease of administration and acceptance by physicians, patients and health care payers;
- the use of ANJESO for the management of moderate-to-severe pain in the hospital setting for patient types that were not specifically studied in our clinical trials;
- demonstration of clinical safety and efficacy and the prevalence and severity of any AEs or SAEs;
- limitations or warnings contained in the FDA-approved label for ANJESO;
- availability of alternative treatments and perceived advantages of ANJESO over such alternative treatments;
- pricing and cost-effectiveness;
- the availability of adequate third-party coverage and reimbursement;
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- our ability to obtain formulary approvals; and
- consolidation among healthcare providers, which increases the impact of the loss of any relationship;

If ANJESO does not achieve an adequate level of acceptance by physicians, patients, pharmacy and therapeutics committees, health care payers and hospital formularies, we may not generate sufficient revenue and we may not become profitable.

ANJESO may cause adverse events or other safety concerns or have other properties that could limit the scope of market acceptance.

AEs caused by ANJESO could cause us, other reviewing entities, clinical study sites or regulatory authorities to interrupt, delay or halt clinical studies. Clinical studies conducted with ANJESO have generated some AEs, and in some cases SAEs, as those terms are defined by the FDA in its regulations. During the Study REC-15-015 trial for ANJESO, four treatment-related SAEs were observed in one ANJESO-treated patient and three placebo-treated patients. During the Safety Study, two SAEs occurred in a single placebo-treated patient. It was subsequently determined that none of the SAEs from the Study REC-15-015 trial or the Safety Study were attributable to ANJESO. Additional AEs or SAEs could be generated during future clinical trials. Our commercialization of ANJESO could be adversely impacted by these AEs, SAEs or other safety concerns.

Further, even though ANJESO has already received regulatory approval in the United States, if it is shown to cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of ANJESO or impose restrictions on its distribution;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way ANJESO is administered or conduct additional clinical studies;
- we could be sued and held liable for harm caused to patients; and/or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of ANJESO and could substantially increase the costs of commercializing ANJESO, which could have a material adverse effect on our business, financial condition and results of operations.

Even with regulatory approval for ANJESO, we will still face extensive regulatory requirements and ANJESO may face future regulatory difficulties.

Even with regulatory approval in the United States or if approved in other countries, the FDA and the equivalent regulatory authorities in other countries may still impose significant restrictions on the indicated uses or marketing of ANJESO or impose ongoing requirements for potentially costly post-approval studies or post-marketing surveillance. ANJESO is subject to ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping and reporting of safety and other post-marketing information. The holder of an approved NDA is obligated to monitor and report AEs and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

The applicable regulations in countries outside the United States grant similar powers to the competent authorities and impose similar obligations on companies. In addition, manufacturers of drug products and their facilities are subject to payment of substantial user fees and continual review and periodic inspections by the FDA and other regulatory authorities, including equivalent regulatory authorities in other countries, for compliance with cGMP regulations and adherence to commitments made in the NDA or the application for marketing authorization. If we, or a regulatory authority, discover previously unknown problems with ANJESO, such as AEs of unanticipated severity or frequency, or problems with a facility where the product is manufactured, a regulatory authority may impose restrictions relative to ANJESO or the manufacturing facility, including requiring recall or withdrawal of the product from the market, suspension of manufacturing, or other FDA action or other action by the equivalent regulatory authorities in other countries. If we fail to comply with applicable regulatory requirements following approval of ANJESO, a regulatory authority may:

- issue a warning letter, untitled letter or Form 483 asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend, modify or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending supplements to an NDA submitted by us;
- seize our product candidate; and/or
- refuse to allow us to enter into supply contracts, including government contracts.

If any of the above were to occur, our ability to successfully commercialize ANJESO and achieve profitability could be negatively impacted, which could have a material adverse effect on our business, financial condition and results of operations.

Manufacturing issues may arise that could increase product costs or delay commercialization of ANJESO.

As ANJESO is manufactured and we conduct required stability testing, issues may arise involving product-packaging and third-party equipment malfunctions. These issues may require refinement or resolution in order to proceed with commercial scale manufacturing of ANJESO. In addition, quality issues may arise during scale-up and validation of commercial manufacturing processes. Any issues in ANJESO manufacturing could result in increased scrutiny by regulatory authorities, increases in our operating expenses, or failure to maintain approval for ANJESO.

If we fail to supply ANJESO in sufficient quantities and at acceptable quality and pricing levels, we may face delays in the continued commercialization of ANJESO, or be unable to meet market demand, and may lose potential revenues.

Our ability to supply sufficient quantities of ANJESO is substantially dependent on the performance of third-party manufacturers. We do not own facilities with capabilities for clinical-scale or commercial manufacturing of injectable meloxicam and we rely, and expect to continue to rely, on third-party suppliers and contract manufacturers to manufacture injectable meloxicam. Alkermes is currently our sole supplier of bulk injectable meloxicam formulation and is the only established supplier of bulk injectable meloxicam formulation. We have committed to purchase our current requirements of injectable meloxicam formulation from Alkermes, and we have commissioned dedicated space in Alkermes' manufacturing facility for the production of bulk injectable meloxicam. Patheon provides sterile fill and finish services, and we have committed to purchase a certain percentage of our annual requirements of sterile fill and finish services from Patheon. Our agreement with Patheon also obligates us to a minimum annual order quantity, which, if higher than the commercial demand for ANJESO, could expose us to increased costs.

Although our supply agreement and manufacturing agreements for ANJESO allow us to qualify and purchase from an alternative supplier or manufacturer in certain circumstances, it would be time-consuming and expensive for us to do so, and there can be no assurance that an alternative supplier could be found on terms that are acceptable to us or at all. The number of potential manufacturers that have the necessary equipment, expertise and governmental licenses to produce ANJESO is limited. If we encounter any issues with our contract manufacturers or choose to engage a new supplier or contract manufacturer for ANJESO, we would need to qualify and obtain FDA approval for another contract manufacturer or supplier as an alternative source, which could be costly and cause significant delays. Such delay could in turn delay the marketing and continued commercialization of ANJESO, which would materially and adversely affect our business.

Our reliance on a limited number of vendors to manufacture ANJESO exposes us to risks, any of which could delay commercialization of our products, result in higher costs, or deprive us of potential revenues. Our contract manufacturers may encounter difficulties in achieving the volume of production needed to satisfy our demand for ongoing commercial demand (even after accounting for the increased capacity to be provided by the dedicated space at the Alkermes facility), may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, may be affected by natural disasters that interrupt or prevent manufacturing of our products, may experience shortages of qualified personnel to adequately staff production operations, may experience shortages of raw materials and may have difficulties finding replacement parts or equipment. In addition, our contract manufacturers could default on their agreement with us to meet our requirements for commercial supplies of ANJESO and/or Alkermes could fail to deliver the dedicated space according to the currently agreed timeline.

We and our contract manufacturers must comply with federal, state and foreign regulations, including FDA's regulations governing cGMP, enforced by the FDA through its facilities inspection program and by similar regulatory authorities in other jurisdictions where we do business. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The FDA or similar foreign regulatory authorities at any time may implement new standards or change their interpretation and enforcement of existing standards for manufacture, packaging or testing of our products. Our contract manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the DEA, and corresponding state agencies to ensure strict compliance with these regulations. We do not have control over third-party manufacturers' compliance with these regulations and standards and our manufacturers may be found to be in noncompliance with certain regulations, which may impact our ability to manufacture our drug product candidates and may impact the regulatory status of our product candidate. Any failure to comply with applicable regulations may result in fines and civil penalties, suspension of production, product seizure or recall, imposition of a consent decree, or withdrawal of product approval, and would limit the availability of ANJESO. Any manufacturing defect or error discovered after ANJESO has been produced and distributed also could result in significant consequences, including costly recall procedures, re-stocking costs, damage to our reputation and potential for product liability claims. In addition, our contract manufacturers could default on their agreement with us to meet our requirements for commercial supplies of ANJESO and/or Alkermes could fail to deliver the dedicated space according to the currently agreed timeline.

While we have scaled up our manufacturing of ANJESO for commercialization, due to the delay in our commercial launch of ANJESO as a result of the two Complete Response Letters, or CRLs, we have launch stock of ANJESO that could be unable to be sold or could be sold but returned by our wholesalers if expired prior to final sale. A significant amount of expired product or returned product could impact the success of our commercialization of ANJESO, and result in additional costs to manufacture additional product.

If, as a result of any of these issues, we are unable to supply the required commercial quantities of ANJESO to meet market demand for ANJESO, on a timely basis or at all, we may suffer damage to our reputation and commercial prospects and we will lose potential revenues.

If third-party service providers, including carriers, logistics providers and distributors, fail to devote sufficient time and resources to ANJESO or their performance is substandard, our successful commercialization may be delayed, and our costs may be higher than expected.

Our reliance on third-party service providers, including carriers, logistics providers and distributors, exposes us to risks that could delay or impair the successful commercialization of ANJESO, result in higher costs, or deprive us of potential product revenues. Our carriers may experience technical issues relating to the timing and shipment of ANJESO, may encounter issues in connection with transporting our products internationally, or may become subject to other transit difficulties that could cause loss or damage to ANJESO, some of which may not be adequately covered under our insurance policies. Our third-party logistic providers may experience difficulty in providing key services relating to customer service, warehousing, inventory management, distribution services, contract management, chargeback processing, accounts receivable management, cash application and financial management. Our distributors could become unable to sell and deliver ANJESO for regulatory, compliance and other reasons. Our carriers, logistics providers, distributors and other third-party service providers may not perform as agreed or may not remain in business for the time required to successfully ship, store, deliver, sell and distribute ANJESO and we may incur additional cost. Any of our vendors could also default on or terminate their agreements with us, which could delay or impair the successful commercialization of ANJESO, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. All of these risks are further exacerbated by COVID-19 and its potential impact on the third-parties on which we rely.

Even with FDA approval for ANJESO in the United States, we may never obtain approval for or commercialize ANJESO outside of the United States, which would limit our ability to realize its full market potential.

In order to market ANJESO outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding quality, safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional non- clinical studies or clinical trials, which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of ANJESO in those countries. While our management has experience in obtaining foreign regulatory approvals, we do not have any product candidates approved for sale in any jurisdiction, including international markets, and we, as a company, do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, our target market will be reduced, and our ability to realize the full market potential of ANJESO will be adversely affected.

For example, in the European Union, similar to the United States regulation scheme, both marketing authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA and the competent authorities of the individual European Union member states both before and after grant of the manufacturing and Marketing Authorizations. This includes control of compliance with cGMP rules, which govern quality control of the manufacturing process and require documentation policies and procedures. We and our third-party manufacturers are required to ensure that all of our processes, methods, and equipment are compliant with cGMP. Failure by us or by any of our third-party partners, including suppliers, manufacturers, and distributors to comply with European Union laws and the related national laws of individual European Union member states governing the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products, both before and after grant of marketing authorization, and marketing of such products following grant of authorization may result in administrative, civil, or criminal penalties. These penalties could include delays in or refusal to authorize the conduct of clinical trials or to grant Marketing Authorization, product withdrawals and recalls, product seizures, suspension, or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing, or clinical trials, operating restrictions, injunctions, suspension of licenses, fines, and criminal penalties, which could have a material adverse effect on our business, financial condition and results of operations.

We have no history of commercializing drugs prior to ANJESO, which may make it difficult to predict our ability to successfully commercialize ANJESO and our future performance or evaluate our business and prospects.

Our operations have been primarily limited to developing our technology and undertaking non-clinical studies and clinical trials for our product candidates and we have only obtained regulatory approval for one product, ANJESO. To date, we have a limited time period in demonstrating our ability to successfully manufacture at commercial scale or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Because our success is dependent on our ability to successfully commercialize ANJESO, any predictions about our ability to do so and our future success or viability may not be as accurate as they could be if we had a longer history of successfully developing and commercializing drugs.

If we are unable to identify a strategic partner with appropriate sales and marketing capabilities to sell ANJESO in markets outside of the United States and enter into a strategic partnership on commercially acceptable terms with such partner, we may be unable to generate sufficient revenue from ANJESO to achieve profitability.

To date, we have not entered into any strategic partnerships for ANJESO; however, we may enter into a strategic partnership to commercialize ANJESO outside of the United States. We face significant competition in seeking appropriate strategic partners, and these strategic partnerships can be intricate and time-consuming to negotiate and document. We may not be able to negotiate strategic partnerships on acceptable terms, or at all. 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 strategic partnerships. In addition, our future collaboration partners, if any, may not dedicate sufficient resources to the commercialization of ANJESO or may otherwise fail in their commercialization due to factors beyond our control. If we are unable to establish effective collaborations to enable the sale of ANJESO to healthcare professionals in geographic regions that are not be covered by our own marketing and sales force, or if our potential future collaboration partners do not successfully commercialize ANJESO, our ability to generate revenues from ANJESO will be adversely affected.

We are subject to intense competition and, if we are unable to compete effectively, ANJESO may not reach its commercial potential.

The market for ANJESO is characterized by intense competition and rapid technological advances. ANJESO competes with a number of existing and future pharmaceuticals and drug delivery devices developed, manufactured and marketed by others. We compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations.

In the post-operative pain relief setting, we believe patients are prescribed injectable acetaminophen, nonsteroidal anti-inflammatory drugs, or NSAIDs, sodium channel blockers and opioids, depending on the severity of pain. Specifically, acetaminophen, NSAIDs and sodium channel blockers, we believe, are prescribed for mild to moderate pain relief, whereas we believe opioids are prescribed for moderate to severe pain relief. While we compete with all of these compounds in the post-operative pain setting, ANJESO is prescribed for moderate to severe pain, also competing with opioids and other non-opioid pain treatments. There are a number of pharmaceutical companies that currently market and/or manufacture therapeutics in the pain relief area, including Johnson & Johnson, Mallinckrodt plc, Pacira Pharmaceuticals, Inc. AcelRx Pharmaceuticals, Inc., Trevena, Inc. and Innocoll Holdings plc. Mallinckrodt commercializes an injectable formulation of acetaminophen. Pacira commercializes an intraoperative formulation of bupivacaine, a sodium channel blocker. Trevena commercializes an intravenous opioid analgesic. Additionally, companies such as Adynxx, Inc., Durect Corporation, Heron Therapeutics, Inc., Sandoz AG, Avenue Therapeutics, Inc., Neumentum Inc. and Cara Therapeutics, Inc. are currently developing post-operative pain therapeutics that could compete with ANJESO in the future.

More established companies may have a competitive advantage over us due to their greater size, cash flows and institutional experience. Compared to us, many of our competitors may have significantly greater financial, technical and human resources. As a result of these factors, our competitors may have an advantage in marketing their approved products, which may limit our ability to successfully commercialize ANJESO. Our competitors may also develop drugs that are safer, more effective, more widely used and less expensive than ours, and our competitors may also be more successful than we are in manufacturing and marketing their products. These advantages could materially impact our ability to develop and commercialize ANJESO successfully.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We anticipate that we will face intense and increasing competition as new drugs enter the market and additional technologies become available in the pain management and relief space. Finally, the development of different methods for the treatment of acute pain following surgery could render ANJESO non-competitive or obsolete or decrease its market share for the treatment of acute pain following surgery. These and other risks may materially adversely affect our ability to attain or sustain profitable operations.

If we are unable to establish additional relationships with group purchasing organizations any future revenues or future profitability could be materially affected.

Many end-users of pharmaceutical products have relationships with group purchasing organizations, or GPOs, whereby such GPOs provide such end-users access to a broad range of pharmaceutical products from multiple suppliers at competitive prices and, in certain cases, exercise considerable influence over the drug purchasing decisions of such end-users. Hospitals and other end-users contract with the GPO of their choice for their purchasing needs. We have contracted with GPOs such as Vizient, Inc. and Premier Inc. We expect to derive revenue for sales of ANJESO from end-user customers that are members of GPOs, for ANJESO. Establishing and maintaining strong relationships with these GPOs will require us to be a reliable supplier, remain price competitive and comply with FDA regulations. The GPOs with whom we have relationships may have relationships with manufacturers that sell competing products, and such GPOs may earn higher margins from these products or combinations of competing products or may prefer products other than

ours for other reasons. If we are unable to establish or maintain our GPO relationships,or establish additional GPO relationships, sales of ANJESO related revenues could be negatively impacted.

If we are unable to achieve and maintain adequate levels of coverage or reimbursement for ANJESO or pricing pressures cause the sales price to be set too low for us to sell ANJESO at a profit, our ability to successfully commercialize ANJESO and our results of operations will be harmed.

Our ability to commercialize ANJESO successfully will depend in part on the extent to which coverage and adequate reimbursement for ANJESO will be available in a timely manner from third-party payers, including governmental healthcare programs such as Medicare and Medicaid, commercial health insurers and managed care organizations and other pricing limitations such as mandatory rebates or discounts. Reimbursement and pricing limitations may hinder our ability to recoup our investment in ANJESO. Although the CMS established a permanent J-code reimbursement code for ANJESO, which provides hospital outpatient departments, ambulatory surgery centers and physician offices in the United States one consistent Healthcare Common Procedure Coding System code to standardize the submission and payment of ANJESO insurance claims, this does not guarantee reimbursement across such plans.

Government authorities and other third-party payers, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. Reimbursement decisions by particular third-party payers depend upon a number of factors, including each third-party payer's determination that use of a product is:

- a covered benefit under its health plan;
- appropriate and medically necessary for the specific condition or disease;
- cost-effective; and
- neither experimental nor investigational.

Obtaining and maintaining coverage and reimbursement approval for ANJESO from government authorities or other third-party payers is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data, including expensive pharmacoeconomic studies beyond the data required to obtain marketing approval, for the use of ANJESO to each government authority or other third-party payer. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. In addition, acceptance by third-party payers could be negatively impacted by any negative perception third-party payers may have of ANJESO as a result of our receipt of two CRLs received from the FDA for ANJESO, and the resulting labeling, despite subsequent FDA approval.

Third-party payers may deny reimbursement for covered products if they determine that a medical product was used for an unapproved indication. Third-party payers may also limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. Failure to obtain timely hospital formulary approval will limit our commercial success, and obtaining and maintaining such approval can be an expensive and time-consuming process. We cannot be certain if and when we will obtain the formulary approvals to allow us to sell ANJESO into our target markets, nor, if formulary approval is obtained, at what price ANJESO will be accepted for sale and reimbursement.

Increasingly, third-party payers are also requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. These third-party payers could also impose price controls restricting the prices at which the products will be reimbursed and other conditions that must be met by patients prior to providing coverage for the use of ANJESO.

Third-party payers are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for medical products and services, which can impact the demand for, or the price of, such products and services. The process for determining whether a payer will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payer will pay for the product once coverage is approved. Levels of reimbursement may also decrease in the future, due to the availability of numerous generic pain medications available at lower costs or future legislation, regulation or reimbursement policies of third-party payers which may adversely affect the demand for and reimbursement available for ANJESO, which in turn, could negatively impact pricing. If patients are not adequately reimbursed for ANJESO, they may reduce or discontinue purchases of it, which could result in a significant shortfall in achieving revenue expectations, prevent us from achieving profitability and negatively impact our business, prospects and financial condition.

Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payers and by any future relaxation of laws that presently restrict imports of drugs from policy and payment limitations in setting their own reimbursement policies. Our inability to obtain and maintain coverage and profitable reimbursement rates from both government-funded and private payers for ANJESO could result in a significant shortfall

in achieving revenue expectations, prevent us from achieving profitability and negatively impact our business, prospects and financial condition.

If we obtain approval to commercialize ANJESO outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

We may enter into agreements with third parties to seek approval for and market ANJESO outside the United States. We expect that we will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- lower pricing of products in our market segment or in general; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

The realization of any of these risks would negatively affect our ability to attain or sustain profitability.

Our relationships with physicians, patients and payers in the U.S. are subject to applicable anti-kickback, fraud and abuse laws and regulations. Our failure to comply with these laws could expose us to criminal, civil and administrative sanctions, reputational harm, and could harm our results of operations and financial conditions.

Our current and future operations with respect to the commercialization of ANJESO are subject to various U.S. federal and state healthcare laws and regulations. These laws impact, among other things, our proposed sales, marketing, support and education programs and constrain our business and financial arrangements and relationships with third-party payers, healthcare professionals and others who may prescribe, recommend, purchase or provide ANJESO, and other parties through which we will market, sell and distribute ANJESO. Finally, our current and future operations are subject to additional healthcare-related statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws are described in greater detail in the section below under "Business Government Regulation — Other Healthcare Laws and Compliance Requirements," and include, but are not limited to:

- 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;
- HIPAA which imposes criminal and 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, biologicals 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.

The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance or reporting requirements in multiple jurisdictions increases the possibility that a healthcare or pharmaceutical company may fail to comply fully with one or more of these requirements. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with applicable fraud and abuse or other healthcare laws and regulations or guidance. In addition, the complex framework of laws and regulations at the federal and state law are subject to change, which could lead to non-compliance or additional costs in updating our compliance mechanism to reflect these changes. For example, several states have enacted laws or regulations affecting or restricting payments that pharmaceutical manufacturers or distributors can make to physicians and other drug prescribers. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional oversight and reporting requirements if we become subject to a corporate integrity agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to the same criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our financial condition and divert resources and the attention of our management from operating our business.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity in addition to the aforementioned potential regulatory actions. The occurrence of any event or penalty described above may inhibit our ability to commercialize ANJESO and generate revenues which would have a material adverse effect on our business, financial condition and results of operations.

If we are able to successfully commercialize ANJESO and if we participate in but fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program, or other governmental pricing programs, we could be subject to additional pricing pressures and controls, reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

If we participate in the Medicaid Drug Rebate Program, and other governmental pricing programs, we will be obligated to pay certain specified rebates and report pricing information with respect to ANJESO. Pricing and rebate calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies and the courts. We cannot assure you that our submissions will not be found by the CMS to be incomplete or incorrect. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. The Medicaid rebate amount is computed each quarter based on our submission to CMS of our current average manufacturer price, or AMP, and best price for the quarter. If we become aware that our reporting for a prior quarter was incorrect or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for a period not to exceed twelve quarters from the quarter in which the data originally were due, and CMS may request or require restatements for earlier periods as well. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate Program. Any corrections to our rebate calculations could result in an overage or underage in our rebate liability for past quarters, depending on the nature of the correction. Price recalculations also may affect the ceiling price at which we are required to offer our products to certain covered entities, such as safety-net providers, under the 340B program, and other similar government pricing programs. These programs are described in greater detail in the section titled "Business — Government Regulation — Formulary Approvals and Third-Party Payer Coverage and Reimbursement."

We will also be liable for errors associated with our submission of pricing data. In addition to retroactive rebates and the potential for 340B program refunds, if we are found to have knowingly submitted false AMP, or best price information to the government, we may be liable for civil monetary penalties in the amount of $181,071 per item of false information. If we are found to have made a misrepresentation in the reporting of our average sales price, we may be liable for civil monetary penalties of up to $13,066

for each misrepresentation for each day in which the misrepresentation was applied. Our failure to submit monthly/quarterly AMP and best price data on a timely basis could result in a civil monetary penalty of $18,107 per day for each day the information is late beyond the due date. Such failure also could be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, federal payments may not be available under Medicaid for ANJESO. A final regulation imposes a civil monetary penalty of up to $5,000 for each instance of knowingly and intentionally charging a 340B covered entity more than the 340B ceiling price.

Federal law requires that a company must participate in the FSS pricing program to be eligible to have its products paid for with federal funds. As part of this program, we would be obligated to make ANJESO available for procurement on an FSS contract, under which we must comply with standard government terms and conditions and charge a price that is no higher than the statutory Federal Ceiling Price to four federal agencies (VA, DoD, Public Health Service, and U.S. Coast Guard). The Federal Ceiling Price is based on the Non-Federal Average Manufacturer Price, which we calculate and report to the VA on a quarterly and annual basis. If we overcharge the government in connection with our FSS contract or Section 703 Agreement, whether due to a misstated Federal Ceiling Price or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the U.S. civil False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The Affordable Care Act and any changes in healthcare law may increase the difficulty and cost for us to commercialize ANJESO and affect the prices we may obtain.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could restrict or regulate post-approval activities relating to ANJESO and affect our ability to profitably sell ANJESO. The United States government, state legislatures and foreign governments also have shown significant interest in 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.

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. These intended reforms are described in greater detail in the section below under "Business — Government Regulation — United States Healthcare Reform."

Among the provisions of the Affordable Care Act that have been implemented since enactment and are of importance to the commercialization of ANJESO 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. During his Administration, President Trump issued executive orders which sought to reduce burdens associated with the Affordable Care Act and modified how it was implemented. 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. However, pursuant to the CARES Act, the 2% Medicare sequester reductions have been suspended from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. 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 which heard oral arguments in the case on November 10, 2020. A ruling is expected in 2021.

Further changes to and under the Affordable Care Act remain possible, although the new Administration under President Biden has signaled that it plans to build on the Affordable Care Act and expand the number of people who are eligible for subsidies under it. President Biden indicated that he may use executive orders to undo changes to the Affordable Care Act made by the Trump administration and would advocate for legislation to build on the Affordable Care Act. It is unknown what form any such changes or any law proposed to replace 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 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 ANJESO and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or successfully commercialize ANJESO.

Legislative or regulatory programs that may influence prices of prescription drugs could have a material adverse effect on our ability to successfully commercialize ANJESO.

Current or future federal or state laws and regulations may influence the prices of drugs and, therefore, could adversely affect the prices that we receive for ANJESO. Programs in existence in certain states seek to set prices of all drugs sold within those states through the regulation and administration of the sale of prescription drugs. Expansion of these programs, in particular, state Medicaid programs, or changes required in the way in which Medicaid rebates are calculated under such programs, could adversely affect the price we receive for ANJESO and could have a material adverse effect on our business, results of operations and financial condition.

Further, the pharmaceutical industry has in recent years been the subject of significant publicity regarding the pricing of pharmaceutical products, including publicity and pressure resulting from prices charged by pharmaceutical companies for new products as well as price increases by pharmaceutical companies on older products that the public has deemed excessive. Any downward pricing pressure on the price of ANJESO arising from social or political pressure to lower the cost of pharmaceutical products could have a material adverse impact on our business, results of operations and financial condition. As a result, pharmaceutical product prices have been the focus of increased scrutiny by the government, including certain state attorneys general, members of Congress and the United States Department of Justice. Decreases in health care reimbursements or prices of ANJESO could limit our ability to sell ANJESO or decrease our revenues, which could have a material adverse effect on our business, results of operations and financial condition.

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 of ANJESO 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, including ANJESO. 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;
- 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.

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

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 other than ANJESO will receive regulatory approval. Our revenue is dependent, to a significant extent, upon the size of the markets in the territories for which we have gained regulatory approval of ANJESO and will be dependent on the size of the market in the territories for which we require regulatory approval of our product candidates. 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.

Our product candidates may cause adverse events or other safety concerns or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

AEs caused by our product candidates could cause us, reviewing entities, clinical study sites or regulatory authorities to interrupt, delay or halt clinical studies and could result in the denial of regulatory approval. Clinical studies conducted with our product candidates have generated some AEs, and in some cases SAEs, as those terms are defined by the FDA in its regulations, and AEs or SAEs could be generated during our on-going and future clinical trials. Our ability to obtain regulatory approval for our product candidates may be adversely impacted by these AEs, SAEs or other safety concerns.

Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Clinical failure can occur at any stage of clinical development.

Clinical trials are expensive, can take many years to complete and have highly uncertain outcomes. Failure can occur at any time during the clinical trial process as a result of inadequate study design, inadequate performance of a drug, inadequate adherence by patients or investigators to clinical trial protocols, or other factors. New drugs in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through earlier clinical trials. Some of our pipeline product candidates are in early stages of development, and positive preclinical and Phase I clinical trials for those product candidates may not necessarily be predictive of the results of later stage clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials as a result of a lack of efficacy or adverse safety profiles, despite promising results in earlier trials. Our clinical trials may not be successful or may be more expensive or time-consuming than we currently expect. If clinical trials for any of our product candidates fail to demonstrate safety or efficacy to the satisfaction of the FDA or the equivalent regulatory authorities in other countries, the FDA or the equivalent regulatory authorities in other countries will not approve that drug and we would not be able to commercialize it, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.

We may experience delays in clinical trials of our product candidates, or the time required to complete clinical trials for our product candidates may be longer than anticipated. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients, or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including, but not limited to:

- inability to raise funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching an agreement with the FDA or the equivalent regulatory authorities in other countries on final trial design or the scope of the development program;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or the equivalent regulatory authorities in other countries;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- delays in obtaining required IRB approval at each site;
- delays in recruiting suitable patients to participate in a trial;
- delays in having subjects complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new clinical sites; or
- delays by our contract manufacturers to produce and deliver a sufficient supply of clinical trial materials.

If clinical trials for any of our product candidates are delayed for any of the above reasons or other reasons, our development costs may increase, our approval process could be delayed and our ability to commercialize our product candidates could be materially harmed, which could have a material adverse effect on our business, financial condition or results of operations.

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 data for our ongoing clinical programs for ANJESO and our 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 cGCPs, 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 cGCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our contractors fail to comply with applicable GLPs and cGCPs, 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 ANJESO or our product candidates. As a result, our financial results and the commercial prospects for ANJESO and any future product candidates that we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

Risks Related to Our Business Operations and Industry

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, on May 31, 2018, the Securities Litigation was filed against Recro and certain of its officers and directors in the U.S. District Court for the Eastern District of Pennsylvania (Case No. 2:18-cv-02279-MMB) and purported to state a claim for alleged violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder, based on statements made by Recro concerning the NDA for ANJESO. The second amended complaint seeks unspecified damages, interest, attorneys' fees, and other costs. Recro filed a motion to dismiss the second amended complaint on June 18, 2020. The plaintiff filed an opposition to Recro's motion to

dismiss on August 17, 2020. On September 16, 2020, Recro filed a reply in support of the motion to dismiss.See *"Legal Proceedings"* included in Part I, Item 3 of this Annual Report on Form 10-K.

In connection with our November 2019 separation from Recro, we accepted assignment by Recro of all of Recro's obligations in connection with the Securities Litigation and agreed to indemnify Recro for all liabilities related to the Securities Litigation. Recro and we believe that the lawsuit is without merit and intend to vigorously defend against it. At this time, no assessment can be made as to its likely outcome or whether the outcome will be material to us. This litigation could result in substantial costs and a diversion of management's resources and attention. In addition, any adverse determination could expose us to significant liabilities, which could have a material adverse effect on our business, financial condition, and results of operations.

Issues with product quality could have a material adverse effect upon our business, subject us to regulatory actions and cause a loss of customer confidence in us or our products.

Our success depends upon the quality of our products. Quality management plays an essential role in meeting customer requirements, preventing defects, improving our product candidates and services and assuring the safety and efficacy of our product candidates. Our future success depends on our ability to maintain and continuously improve our quality management program. A quality or safety issue may result in adverse inspection reports, warning letters, product recalls or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, costly litigation, refusal of a government to grant approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses. An inability to address a quality or safety issue in an effective and timely manner may also cause negative publicity, a loss of customer confidence in us or our future products, which may result in difficulty in successfully launching product candidates and the loss of sales, which could have a material adverse effect on our business, financial condition, and results of operations.

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 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 continue to grow the size of our organization. We may experience difficulties in managing this growth and factors outside our control, including the COVID-19 pandemic, may make it more difficult to operate and maintain a larger organization.

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 and development of our other product candidates. 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 has 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 impacting 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.

If ANJESO is successfully commercialized, we intend to expand our employee base to fully support our evolution as a commercial stage pharmaceutical company. We will need to increase and maintain a specialty sales force to promote ANJESO to healthcare professionals and third-party payers. As we continue to expand, we may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Additional future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. Future growth would impose significant added responsibilities on members of management, including:

- managing the commercialization of any FDA approved product candidates;
- overseeing our ongoing clinical trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees, including any additional sales and marketing personnel engaged in connection with the commercialization of any approved product, on terms that are favorable to us if at all;

- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- improving our managerial, development, operational and financial systems and procedures; and
- expanding our facilities.

As our operations expand, we will need to manage additional relationships with various collaboration partners, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. At this time, we cannot guarantee that we will be able to manage such growth amid the ongoing effects of the COVID-19 pandemic. 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 or DEA 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 have adopted adopt 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 and financial condition.

We face potential product liability claims, and, if successful claims are brought against us, we may incur substantial liability.

Commercial sales of ANJESO expose us to the risk of product liability claims. Additionally, the use of any of our product candidates in clinical studies and the sale of any future products for which we obtain marketing approval exposes us to the risk of these claims. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and negative media attention;
- inability to commercialize ANJESO or any future product candidates subject to product liability claims;
- withdrawal of clinical study participants or termination of clinical trials;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- decreased demand for our manufacturing services or loss of any of our commercial partners;
- substantial monetary awards to patients or other claimants;
- decreased demand for ANJESO or any future approved products subject to product liability claims;
- increased scrutiny and potential investigation by, among others, the FDA, the Department of Justice, the Office of Inspector General of the U.S. Department of Health and Human Services, State Attorneys General, members of Congress and the public.

Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments are excluded from our insurance coverage or exceed our insurance coverage, could adversely affect our results of operations and business. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability.

We incur increased costs and demands upon our management as a result of complying with the laws and regulations affecting public companies. Failure to comply with such laws and regulations could result in sanctions or other penalties that would harm our business.

We are a public company and, as such, we incur significant legal, accounting and other expenses, including costs associated with public company reporting requirements. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act and we incur costs associated with current corporate governance requirements, including certain of the requirements under Section 404 and other provisions of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, as well as other rules implemented by the SEC and the Nasdaq, the stock exchange on which our common stock is listed. If we fail to comply with current corporate governance requirements, our business may be negatively affected, including by having our common stock delisted from Nasdaq.

The expenses incurred by public companies for reporting and corporate governance purposes have increased dramatically in recent years. We expect these rules and regulations to continue to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. We are unable to currently estimate these costs with any degree of certainty. We also expect that these rules and regulations may make it difficult and expensive for us to continue to maintain director and officer liability insurance, and if we are able to maintain such insurance, we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage available to privately-held companies. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors, or the board, or as our executive officers.

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 $1.07 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.

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. We own patents and patent applications for injectable meloxicam that cover pharmaceutical compositions, including compositions produced using NanoCrystal® technology, methods of making ANJESO and methods of treating pain with ANJESO. These issued patents expire between 2022 and 2030 in the United States. We also exclusively in-license from Alkermes to manufacture and commercialize IV, intramuscular and parenteral meloxicam, on a perpetual royalty-free basis, patents and applications that are directed to methods of reducing flake-like aggregates in injectable nanoparticulate active agent compositions, and directed to injectable nanoparticulate active agent compositions produced by methods for reducing flake-like aggregates, which begin to expire in 2030, and an application directed to injectable, nanoparticulate meloxicam compositions containing flake-like aggregation reducing agents, which, if issued, would expire in 2030 in the field of manufacturing and commercializing IV, intramuscular and parenteral meloxicam. As of February 1, 2021, we own nine issued U.S. patents and four U.S. pending patent applications, and 58 issued foreign patents (including European validation countries) and fifteen pending PCT or foreign applications related to meloxicam, ANJESO, formulations of meloxicam, and methods of using meloxicam, which expire or would expire (if issued) between 2022 and 2039. As of February 1, 2021, we exclusively license eight issued U.S. patents and one U.S. pending patent application, and 40 issued foreign patents (including European validation countries) and two pending foreign applications relating to ANJESO, formulations of meloxicam and methods of manufacturing meloxicam to manufacture and commercialize ANJESO, intramuscular meloxicam and parenteral meloxicam. February 1, 2021, we own four issued U.S. patents, 20 issued foreign patents, including European validation countries, and one pending foreign application to Dex. In addition, we have licensed four patent families containing several U.S. and foreign issued patents and one pending application related to neuromuscular blocking agents from Cornell University. 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.

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.

Risks Related to Our Securities

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:

- our ability to successfully commercialize ANJESO;
- our ability to identify a strategic partner with appropriate sales and marketing capabilities and to enter into a strategic partnership on commercially acceptable terms with such partner to commercialize ANJESO outside the United States;
- our ability to effectively manage the levels of production, distribution and delivery of ANJESO through our supply chain;
- our ability to leverage our development experience to progress our other pipeline product candidates;
- our ability to identify and successfully acquire or in-license new product candidates on acceptable terms;
- FDA, state or international regulatory actions, including actions on regulatory applications for ANJESO or 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 products or product candidates or similar products or product candidates;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant shareholders;
- our announcement of financing transactions, including debt, convertible notes, warrant exchanges, etc.;
- our ability to have sufficient authorized shares of our common stock available;
- the ability to effectuate a reverse stock split or other similar change to our capital structure;
- the 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 and amended and restated 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 amended and restated articles of incorporation may only be amended with the affirmative vote of 66⅔% 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 amended and restated articles of incorporation or amended and restated 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 amended and restated articles of incorporation will 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 amended and restated articles of incorporation 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 amended and restated articles of incorporation 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 amended and restated 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 commercial 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 amended and restated articles of incorporation 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 22,313 square feet of leased laboratory and office space pursuant to a six-year lease, which expires on December 31, 2022. 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 Recro and certain of Recro's officers and directors in the U.S. District Court for the Eastern District of Pennsylvania (Case No. 2:18-cv-02279-MMB) that purported to state a claim for alleged violations of Section 10(b) and 20(a) of the Exchange Act and Rule 10(b)(5) promulgated thereunder, based on statements made by Recro concerning the NDA for 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, Recro filed a motion to dismiss the amended complaint in its entirety, which the lead plaintiff opposed on April 9, 2019. On May 9, 2019, 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. Recro filed a motion to dismiss the second amended complaint on June 18, 2020. The plaintiff filed an opposition to Recro's motion to dismiss on August 17, 2020. On September 16, 2020, Recro filed a reply in support of the motion to dismiss. In connection with the Separation, we accepted assignment by Recro of all of Recro's obligations in connection with the Securities Litigation and agreed to indemnify Recro for all liabilities related to the Securities Litigation. Recro and we believe that the lawsuit is without merit and intend to vigorously defend against it. At this time, no assessment can be made as to its likely outcome or whether the outcome will be material to us.

Item 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 10, 2021, there were 8 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. Selected Financial Data

Not applicable.

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 and combined 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 developing and commercializing innovative products for hospital and related acute care settings. We believe that we can bring valuable therapeutic options for patients, prescribers and payers to the hospital and related acute care markets.

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

We commenced our commercial launch of ANJESO in June of 2020. We utilize an internal sales team and collaborate with third parties who market ANJESO to health care professionals at our called-on institutions. We continue to evaluate strategic partnerships to commercialize ANJESO outside of the United States. In August 2020, the CMS established a new permanent J-code for ANJESO, which became effective on October 1, 2020, facilitating reimbursement of ANJESO in the hospital outpatient, ambulatory surgery center and physician office settings of care. We have also entered into agreements with leading group purchasing organizations in the U.S., including Vizient Inc., and Premier Inc., as well as one of the top 3 integrated delivery networks for terms for availability of ANJESO to their member institutions. Over 65 institutions added ANJESO to their formulary. The number of vials sold to end-customers has increased 58% in the fourth quarter of 2020 versus the third quarter of 2020. The number of vials sold to hospitals and ambulatory surgical centers increased over 80% during the same time period. The average quarterly orders per account increased over 60% in the fourth quarter of 2020 versus the third quarter of 2020 and the re-order rate is approximately 55% with a deepening usage pattern.

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

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

COVID-19 Impact

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

We anticipate that many hospitals and health care providers will continue to suffer negative financial consequences due to an increase in unexpected costs, personal protective equipment and ventilators, along with a dramatic reduction in revenue due to fewer elective procedures being performed, which may result in a decreased demand for ANJESO. While access restrictions have eased in some locations, cycling spikes of COVID-19 cases in certain states or regions may further impact our sales force as access to hospitals may be restricted and elective surgeries may be limited in those areas. In addition, the absence of hospital formulary meetings where new drugs can be adopted has impacted our efforts to commercialize ANJESO. Many hospital formularies recently resumed meetings after a 6-month absence. Despite the existence of a backlog of agents scheduled to be reviewed, we believe we will make progress getting

ANJESO added to additional hospital formularies in the near term. Due to the rapidly evolving environment, continued uncertainties from the impact of the COVID-19 global pandemic, and the recent regional outbreaks that are impacting the recovery, we cannot estimate the full extent to which our commercialization of ANJESO and financial results may be adversely impacted.

Separation from Recro Pharma, Inc.

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

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

Financial Overview

Revenue

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

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

Cost of Sales

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

Research and Development Expenses

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

- expenses incurred under agreements with CROs, investigative sites and consultants that conduct our clinical trials and a substantial portion of our preclinical studies;
- the cost of acquiring and manufacturing clinical trial drug supply and related manufacturing services and pre-commercial product validation and inventory manufacturing expenses;
- costs related to facilities, depreciation and other allocated expenses;

- acquired in-process research and development;
- costs associated with non-clinical and regulatory activities; and
- salaries and related costs for personnel in research and development and pre-commercial regulatory functions.

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

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

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

Selling, General and Administrative Expenses

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

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

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

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

2020 Reduction in Force

Due to the impacts of COVID-19 and the resultant slower than expected commercial ramp of ANJESO, in November of 2020, we implemented a reduction in workforce by approximately 40 employees. We expect that the reorganization will result in annualized

savings of an estimated $10.6 million in personnel and other related costs. There were also significant cost reductions made for 2021 manufacturing and launch related activities. The reorganization was completed in November 2020 and we incurred approximately $1.7 million of charges for severance and other costs relating to such reorganization activities, primarily during the fourth quarter of 2020.

2019 Reduction in Force

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

Change in Fair Value of Contingent Consideration

In connection with the Separation, we entered into an Assignment and a Partial Assignment, Assumption and Bifurcation Agreement, or the Alkermes Agreements, relating to the Purchase and Sale Agreement for the acquisition of certain assets, including the worldwide rights to injectable meloxicam and Recro's development, formulation and manufacturing business from Alkermes, or the Alkermes Transaction, as amended in December 2018 and August 2020. Pursuant to the Alkermes Agreements, we are required to pay up to $140.0 million in milestone payments, including $10.0 million that was paid during 2019, another $3.6 million paid in 2020, $1.4 million which becomes due June 20, 2021, and $45.0 million over seven years beginning one year after approval, as well as net sales milestones and a royalty percentage of future product net sales related to injectable meloxicam between 10% and 12% (subject to a 30% reduction when no longer covered by patent). The estimated fair value of the initial $54.6 million payment obligation was recorded as part of the purchase price for the Alkermes Transaction. We have continued to reevaluate the fair value each subsequent period and as of December 31, 2020 recorded a $65.0 million payment obligation, representing the estimated probability-adjusted fair value of the liability. Each reporting period, we revalue this estimated obligation with changes in fair value recognized as a non-cash operating expense or gain. As of December 31, 2020, we have paid $13.6 million in milestone payments to Alkermes.

Interest Expense

Interest expense for the periods presented primarily includes interest expense incurred on our Credit Agreement with MAM Eagle Lender, the amortization of related financing costs, and interest expense on a promissory note with PNC Bank under the PPP of the CARES Act administered by the SBA.

Income Taxation

We maintained a valuation allowance against our deferred tax assets as of December 31, 2020 and 2019.

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019

	Year ended December 31,	
	2020	**2019**
	(amounts in thousands)	
Revenue, net	$ 493	$ —
Operating expenses:		
Cost of sales	1,732	—
Research and development	9,087	20,061
Selling, general and administrative	43,335	27,012
Amortization of intangible assets	2,146	—
Change in warrant valuation	16,734	—
Change in contingent consideration valuation	2,245	(14,554)
Total operating expenses	75,279	32,519
Operating loss	(74,786)	(32,519)
Other expense, net	(1,314)	(38)
Net loss	$ (76,100)	$ (32,557)

Revenue, net. For the year ended December 31, 2020, net product revenue was $0.5 million, related to sales of ANJESO in the U.S. While utilizing the title model of distribution, product revenue represents shipments to our 3PL provider. For the year ended December 31, 2019, we did not recognize any product revenue.

Cost of sales. Our cost of sales was $1.7 million for the year ended December 31, 2020 and consisted 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 year ended December 31, 2020 were incurred prior to FDA approval of ANJESO in February 2020, and therefore are not included in cost of sales during the period. We expect that over time, our cost of sales will increase as sales increase and as inventory values change to include all direct and indirect costs and expenses post FDA approval. No cost of sales was recorded for the year ended December 31, 2019.

Research and Development. Our research and development expenses were $9.1 million and $20.1 million for the years ended December 31, 2020 and 2019, respectively. Excluding $0.9 million and $2.8 million of costs associated with restructuring initiatives recorded for the years ended December 31, 2020 and 2019, respectively, research and development expenses decreased $9.1 million. The decrease was primarily due to a decrease in pre-commercial manufacturing and clinical costs of $5.9 million, a decrease of $1.3 million as a result of re-allocating costs related to supply chain, regulatory, quality and medical affairs associated with support of the commercial launch of ANJESO to cost of sales and selling, general and administrative expense, a decrease of $1.2 million in preclinical costs and a decrease of $0.7 million in other general expenses.

Selling, General and Administrative. Our selling, general and administrative expenses were $43.3 million and $27.0 million for the years ended December 31, 2020 and 2019, respectively. Excluding $0.8 million and $4.4 million of costs associated with the restructuring initiatives recorded for the years ended December 31, 2020 and 2019, respectively, selling, general and administrative expenses increased $19.9 million. This increase was primarily due to the commercial launch of ANJESO, specifically, an increase in personnel related costs of $11.6 million, an increase in marketing and consulting costs of $6.4 million and an increase of $3.9 million attributable to medical affairs and regulatory support. Other general costs increased $0.9 million. These increases were partially offset by the decrease in costs associated with the separation from Recro of $2.9 million in 2019.

Amortization of Intangible Assets. Amortization expense was $2.1 million for the year ended December 31, 2020, which was related to the amortization of our intangible asset over its estimated useful life that commenced when ANJESO was approved in February 2020. There was no amortization expense for the year ended December 31, 2019.

Change in Warrant Valuation. The change in warrant valuation was an increase in value of $16.7 million for the year ended December 31, 2020related to the warrants sold as part of the March 26, 2020 underwritten public offering, including the impact of the warrant exchange transaction in October 2020.

Change in Contingent Consideration valuation. Our change in contingent consideration valuation consisted of an increase of value of $2.2 million for the year ended December 31, 2020 as compared to a reduction in value of $14.6 million for the year ended December 31, 2019. 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 increase in the fair value of the liability of $2.2 million in 2020 was primarily due to the increase in probability of success of milestones tied to the FDA approval of ANJESO, partially offset by the adjusted timing of estimated milestone and royalty payments due to updated forecasts reflecting an estimate of the launch trajectory of ANJESO. The decrease in the fair value of the liability of $14.6 million in 2019 was due to the adjusted timing of estimated milestone and royalty payments after the receipt of the CRL from the FDA in March 2019.

Liquidity and Capital Resources

As of December 31, 2020, we had $30.3 million in cash and cash equivalents. Historically, prior to the Separation, the primary source of liquidity for our business was cash flow provided to us from Recro. Prior to the Separation, transfers of cash to and from Recro were reflected in Net Parent Investment in the historical combined balance sheets, statements of cash flows and statements of changes in Net Parent Investment.

On January 21, 2021, we entered into an agreement to issue and sell warrants exercisable for an aggregate of 10,300,430 shares of common stock (the “January Warrants”) at an offering price of $0.125 per warrant in exchange for the exercise of the institutional investor’s existing December Series A warrants that were issued to them on December 21, 2020, at an exercise price of $1.18 per warrant. The January Warrants have an exercise price of $1.60 per share. The January Warrants are immediately exercisable and will expire five years from the issuance date. As compensation to H.C. Wainwright & Co., LLC, or the Placement Agent, as placement agent, we agreed to pay a cash fee of 6.0% of the aggregate gross proceeds raised in the January Offering (including the proceeds relating to the exercise of the December Series A Warrants), plus a management fee equal to 1.0% of the gross proceeds raised in the January

Offering (including the proceeds relating to the exercise of the December Series A Warrants) and reimbursement of certain expenses and legal fees. We also issued to designees of the Placement Agent warrants to purchase up to 618,026 shares of common stock (the "January Placement Agent Warrants"). The January Placement Agent Warrants have substantially the same terms as the January Warrants, except that the January Placement Agent Warrants have an exercise price equal to $2.00 per share.

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

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. We may not be able to continue as a going concern. The report of our independent registered public accounting firm regarding our financial statements for the year ended December 31, 2020 contained an explanatory paragraph regarding our ability to continue as a going concern based upon our history of net losses and dependence on future financing in order to meet our planned operating activities. See "Item 1A – Risk Factors" for more information.

On December 18, 2020, we closed a registered direct offering of 4,250,000 shares of common stock, warrants to purchase 10,300,430 shares of common stock, or the December Series A Warrants, at an exercise price of $1.18 per share, pre-funded warrants to purchase 6,050,430 shares of common stock, or the December Series B Warrants, at an exercise price of $0.01 per share, for net proceeds of $10.9 million. As compensation to the Placement Agent, we agreed to pay to the Placement Agent a cash fee of 6.0% of the aggregate gross proceeds, plus a management fee equal to 1.0% of the gross proceeds and reimbursement of certain expenses and legal fees. We also issued warrants to purchase 618,026 shares of common stock, or the December Placement Agent Warrants, at an exercise price of $1.45625 per share.

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

On May 29, 2020, we entered in a $50.0 million Credit Agreement with MAM Eagle Lender, pursuant to which we have drawn $10.0 million as of the date of this 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 May 8, 2020, we entered into a promissory note for $1.5 million under the PPP of the CARES Act administered by the SBA. We have used the loan proceeds for covered payroll costs in accordance with the relevant terms and conditions of the CARES Act. This Loan may be partially or fully forgiven if we comply with the provisions of the CARES Act including the use of Loan proceeds for payroll costs, rent, utilities and other expenses, and at least 60% of the loan proceeds must be used for payroll costs as defined by the CARES Act. Any forgiveness of the Loan will be subject to approval by the SBA and the Lender will require us to apply for such treatment in the future. Should we meet the requirements for forgiveness, we would extinguish the note upon receiving legal release from PNC Bank and record a gain on extinguishment in the period. We expect that the full $1.5 million balance of the PPP Loan will be forgiven, however, no assurance can be given that we will obtain forgiveness of the PPP Loan in whole or in part.

On March 26, 2020, we closed an underwritten public offering of 7,692,308 shares of our common stock, Series A Warrants to purchase 7,692,308 shares of our common stock, or the March Series A Warrants, at an exercise price of $4.59 per share and Series B Warrants to purchase 7,692,308 shares of our common stock, or the March Series B Warrants, at an exercise price of $3.25 per share, resulting in $23.1 million of net proceeds, after deducting underwriting discounts and commissions and estimated offering expenses. Subsequent to the closing of the underwritten public offering, the exercise of warrants related to the transaction has provided net proceeds of an additional $2.5 million. In October 2020, we executed Warrant Exchange Agreements with certain holders of our March Series A Warrants and March Series B Warrants. We issued 1,186,774 shares of common stock to the participating Holders as a result of the Exchange. See Note 13(c) to the Consolidated and Combined Financial Statements included in this Annual Report for additional information.

On February 13, 2020, we entered into a Sales Agreement with JMP Securities LLC, as sales agent, or the Agent, pursuant to which we may, from time to time, issue and sell shares of our common stock, in an aggregate offering price of up to $25.0 million through the Agent, or the ATM Program. As of December 31, 2020, 441,967 shares have been sold under the ATM Program for net proceeds of $3.6 million. The Agent was paid a sales commission of 3% for such sales under the Sales Agreement.

Under the terms of the Separation Agreement, Recro made a cash capital contribution of $19.0 million to us to fund our initial operations. Subsequent to the Separation, we no longer participate in Recro's centralized cash management or benefit from direct funding from Recro. Our ability to fund our operations and capital needs will depend on our ability to raise additional funds through debt financings, bank or other loans, licensing, including out-licensing activities, sale of assets and/or marketing arrangements or through public or private sales of equity or debt securities from time to time. Financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could materially adversely impact our growth plans and our financial condition or results of operations. Additional debt or equity financing, if available, may be dilutive to the holders of our common stock and may involve significant cash payment obligations and covenants that restrict our ability to operate our business or access to capital.

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

Sources and Uses of Cash

Cash used in operations was $44.1 million and $50.0 million for the years ended December 31, 2020 and 2019, respectively, which represents our operating losses less our non-cash items including: stock-based compensation, non-cash interest expense, depreciation, amortization, changes in warrant valuations, and changes in fair value of contingent consideration, as well as changes in operating assets and liabilities.

Cash used in investing activities was $0.6 million and $1.5 million for the years ended December 31, 2020 and 2019, respectively. During the years ended December 31, 2020 and 2019, our capital expenditures were $0.6 million and $1.3 million, respectively.

There was $57.3 million of cash provided by financing activities in the year ended December 31, 2020 consisting of net proceeds of $23.1 million from the public offering of common stock and warrants, net proceeds of $21.9 million from registered direct offerings of common stock and warrants, net proceeds of $1.5 million from the issuance of the PPP Loan, net proceeds of $8.5 million from the incurrence of long-term debt under the Credit Agreement with MAM Eagle Lender, net proceeds of $3.6 million from our ATM Program, and net proceeds of $2.7 million from warrant exercises, partially offset by a payment of contingent consideration of $3.6 million. There was $69.3 million of cash provided by financing activities in the year ended December 31, 2019 from net proceeds from parent company investment of $60.3 million in addition to the $19.0 million contributed by Recro upon the Distribution, which was partially offset by $10.0 million of contingent consideration payments.

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

- our relationships with Recro, third parties, licensors, collaborators and our employees;
- our ability to continue to operate as a standalone company and execute our strategic priorities;
- potential indemnification liabilities we may owe to Recro;
- the timing of the Alkermes Transaction regulatory milestone payments and other contingent consideration;
- the costs of continued manufacturing scale-up and commercialization activities, for ANJESO;
- the level of market acceptance of ANJESO;
- the scope, progress, results and costs of development for our other product candidates;
- the cost, timing and outcome of regulatory review of our other product candidates;
- the cost of manufacturing scale-up, acquiring drug product and other capital equipment for our other product candidates;
- the extent to which we in-license, acquire or invest in products, businesses and technologies;

- our ability to raise additional funds through equity or debt financings or sale of certain assets;
- the extent to which any holders of our warrants exercise their warrants resulting in the payment of cash proceeds to us;
- our ability to have sufficient authorized shares of our common stock available;
- the ability to effectuate a reverse stock split or other similar change to our capital structure;
- the costs of preparing, submitting and prosecuting patent applications and maintaining, enforcing and defending intellectual property claims; and
- the effect of any changes in our effective tax rate due to changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities, tax impacts and net operating loss utilization related to the Separation and changes in tax laws.

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

Contractual Commitments

The table below reflects our contractual commitments as of December 31, 2020:

	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	$ 11,537	$ 683	$ 6,410	$ 4,444	$ —
Interest on Debt	4,211	1,394	2,275	542	—
Purchase Obligations (2):	6,620	3,109	484	—	—
Operating Leases (3)	807	434	373	—	—
Other Long-Term Liabilities:					
Other License Commitments and Milestone payments (4), (5)	56,625	60	150	190	125
Alkermes Payments (6)	126,440	7,869	19,286	12,857	6,429
Employment Agreements (7)	927	618	309	—	—
Total Contractual Obligations	$ 207,167	$ 14,167	$ 29,287	$ 18,033	$ 6,554

(1) Debt obligations consist of principal, an exit fee of 2.5% of that principal and interest on the $10.0 million outstanding term loan under our Credit Agreement in addition to principal and interest on a $1.5 million promissory note under the SBA Paycheck Protection Program of the CARES Act. See Note 11 to the Consolidated and Combined Financial Statements included in this Annual Report on Form 10-K.

(2) These obligations consist of cancelable and non-cancelable purchase commitments related to capital expenditures and other goods or services. The timing of certain purchase commitments cannot be estimated as it is dependent on the outcome of strategic evaluations and agreements. In accordance with U.S. GAAP, these obligations are not recorded on our Consolidated Balance Sheets. See Note 12 to the Consolidated and Combined 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 and Combined Financial Statements included in this Annual Report on Form 10-K.

(4) We are party to exclusive licenses with Orion for the development and commercialization of certain pipeline product candidates, under which we may be required to make certain milestone and royalty payments to Orion. See Note 12(a) to the Consolidated and Combined Financial Statements included in this Annual Report on Form 10-K. The amount reflects only payment obligations that are fixed and determinable. We are unable to reliably estimate the timing of these payments

because they are dependent on the type and complexity of the clinical studies and intended uses of the products, which have not been establishedIn accordance with U.S. GAAP, these obligations are not recorded on our Consolidated Balance Sheets.

(5) We license the NMBAs from Cornell University pursuant to a license agreement under which we are obligated to make annual license maintenance fee payments, milestone payments and patent cost payments and to pay royalties on net sales of the NMBAs. The amount reflects only payment obligations that are fixed and determinable. We are unable to reliably estimate the timing of certain of these payments because they are dependent on the type and complexity of the clinical studies and intended uses of the products, which have not been established. In accordance with U.S. GAAP, certain of these obligations are not recorded on our Consolidated Balance Sheets. See 12(a) to the Consolidated and Combined Financial Statements included in this Annual Report on Form 10-K.

(6) Pursuant to the purchase and sale agreement governing the Alkermes Transaction, we agreed to pay to Alkermes milestone and royalty payments. The amount reflects only payment obligations that are fixed and determinable. We are unable to reliably estimate the timing of these payments 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 and Combined Financial Statements included in this Annual Report on Form 10-K.

(7) We have entered into an employment agreement with our named executive officer. As of December 31, 2020, 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 2022. In accordance with U.S. GAAP, these obligations are not recorded on our Consolidated Balance Sheets. See Note 12 (e) to the Consolidated and Combined Financial Statements included in this Annual Report on Form 10-K.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Estimates

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. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, stock-based compensation and contingent consideration. 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, we began selling ANJESO in the U.S. through a single 3PL which takes title to and control of the goods. We recognize revenue from ANJESO product sales at the point the title to the product is transferred to the customer and the customer obtains control of the product. The transaction price that is recognized as revenue for products includes an estimate of variable consideration for reserves which result from discounts, returns, chargebacks, rebates and other allowances that are offered within contracts between us and our end-customers, wholesalers, group purchasing organizations and other indirect customers. Our payment terms are generally between thirty to ninety days.

Impairment of Goodwill – We are required to review, on an annual basis, the carrying value of goodwill, to determine whether impairment may exist. For goodwill, 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. Based on accounting standards, it is required that these assets be assessed at least annually for impairment unless a triggering event occurs between annual assessments which would then require an assessment in the period which a triggering event occurred.

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, and 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. On an ongoing periodic basis, we evaluate the useful life of our long-lived assets and determine if any economic, governmental or regulatory event has modified their estimated useful lives.

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 projected future revenue. We estimate injectable meloxicam net revenues based on estimated market share, pricing and customary trade discounts, taking into consideration variables such as, market acceptance of the product and the expected number of product competitors in the market.

On a periodic basis, we evaluate the realizability of our deferred tax assets and adjust such amounts in light of changing facts and circumstances, including but not limited to projections of future taxable income, the reversal of deferred tax liabilities, tax legislation, rulings by relevant tax authorities, tax planning strategies and the progress of ongoing tax examinations. As part of this evaluation, we consider whether it is more likely than not that all or some portion of the deferred tax asset will not be realized. The ultimate realization of a deferred tax asset is dependent upon the generation of future taxable income during the period in which the related temporary difference becomes deductible or the net operating loss, or NOL, and credit carryforwards can be utilized.

We maintain a full valuation allowance against our deferred tax assets where realizability is not certain. We periodically evaluate the likelihood of the realization of deferred tax assets and adjust the carrying amount of these deferred tax assets by a valuation allowance based on the anticipated realizability. The valuation allowance can be reversed if objective negative evidence in the form of cumulative losses is no longer present and additional weight is given to subjective evidence, such as our projection of future growth. This determination depends on a variety of factors, some of which are subjective, including our current year taxable income in the United States, expectations of future taxable income, impact of tax reform, achievement of milestones, carryforward periods available to us for tax reporting purposes, various income tax strategies and other relevant factors. If we determine that the deferred tax assets realizability is impacted, we would record material changes to income tax expense in that period.

New Accounting Pronouncements

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

Transition from Recro and Costs to Operate as an Independent Company

The combined financial statements for periods prior to the Separation reflect our operating results and financial position as it was operated by Recro, rather than as an independent company. We are now incurring additional ongoing operating expenses to operate as an independent company. These costs will include the cost of various corporate headquarters functions, incremental insurance, audit and information technology-related costs and incremental costs to operate stand-alone accounting, legal and other administrative functions. We are now incurring non-recurring expenses and non-recurring capital expenditures.

As an independent company, our operating costs may be higher than the costs allocated in the historical combined financial statements prior to the Separation.

It is not practicable to estimate the costs that would have been incurred in each of the periods presented in the historical financial statements for the functions described above. Actual costs that would have been incurred if we operated as a stand-alone company during these periods would have depended on various factors, including organizational design, capital financing needs, status of threatened or pending lawsuits, regulatory outcomes, outsourcing and other strategic decisions related to corporate functions, information technology and back office infrastructure.

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, 2020, we had approximately $28.7 million invested in money market instruments and commercial paper. We believe our policy of investing in highly-rated securities, whose liquidities are, at December 31, 2020, 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 upon the achievement of certain regulatory and commercialization events and royalties on product sales, which are required to be made in Euros. As of December 31, 2020, 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 and combined financial statements and the report of our independent registered public accounting firm 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, 2020. We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure.

A control system, no matter how well conceived and operated, can provide only reasonable, and not absolute, assurance that the objectives of the control system will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. However, our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives. Based on the evaluation of our disclosure controls and procedures as of December 31, 2020, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

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, 2020. 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, 2020, 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

None.

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 2020 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

Information with respect to this item will be set forth in the Proxy Statement under the heading "Independent Registered Public Accounting Firm," 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, Consolidated and Combined Financial Statement Schedules

(a)(1) Consolidated and Combined Financial Statements.

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

Consolidated and Combined Financial Statements

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2020 and 2019

Consolidated and Combined Statements of Operations for the years ended December 31, 2020 and 2019

Consolidated and Combined Statements of Shareholders' Equity for the years ended December 31, 2020 and 2019

Consolidated and Combined Statements of Cash Flows for the years ended December 31, 2020 and 2019

(a)(2) Consolidated and Combined 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 Organization 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	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).

Exhibit No.	Description	Method of Filing
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	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.	Filed herewith.
10.1	Tax Matters Agreement, dated November 20, 2019, by and between Recro Pharma, Inc. and Baudax Bio, Inc.	Incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on November 26, 2019 (File No. 001-39101).
10.2	Employee Matters Agreement, dated November 20, 2019, by and between Recro Pharma, Inc. and Baudax Bio, Inc.	Incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on November 26, 2019 (File No. 001-39101).
10.3•	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).
10.4†	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).
10.5	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).
10.6	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).
10.7	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).
10.8†	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).
10.9†	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).
10.10†	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).
10.11•	Baudax Bio, Inc. 2019 Equity Incentive Plan.	Incorporated herein by reference to Exhibit 10.4 tothe Company's Current Report on Form 8-K filed on November 26, 2019 (File No. 001-39101).

Exhibit No.	Description	Method of Filing
10.12†	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).
10.13	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).
10.14	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).
10.15	Third Amendment to 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).
10.16†	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).
10.17†	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).
10.18†	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).
10.19†	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).
10.20	Assignment, Assumption and Bifurcation Agreement, dated November 20, 2019, by and among Alkermes Pharma Ireland Limited, Recro Gainesville LLC, Recro Pharma, Inc. and Baudax Bio, Inc.	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).
10.21†	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).
10.22†	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).
10.23†	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).
10.24†	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).
10.25•	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).
10.26†	Amendment to License Agreement, dated October 21, 2019, by and between Cornell University and Recro Pharma, Inc.	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).

Exhibit No.	Description	Method of Filing
10.27	Note dated May 8, 2020, between Baudax Bio, Inc. and PNC Bank, National Association.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 13, 2020 (File No. 001-39101).
10.28†	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).
10.29	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).
10.30	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).
10.31•	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).
10.32•	Employment Agreement, dated February 12, 2020, between Baudax Bio, Inc. and Ryan D. Lake.	Incorporated herein by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-K filed on February 13, 2020 (File No. 001-39101).
10.33	Amendment to Employee Matters Agreement, dated February 12, 2020, by and between Recro Pharma, Inc. and Baudax Bio, Inc.	Incorporated herein by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K filed on February 13, 2020 (File No. 001-39101).
10.34•	Form of Stock Option Award Agreement.	Filed herewith.
10.35•	Form of Restricted Stock Unit Award Agreement.	Filed herewith.
10.36•	Form of Performance-Based Restricted Stock Unit Award Agreement.	Filed herewith.
10.37•	Form of Award Agreement for Option Inducement Award.	Filed herewith.
10.38•	Form of Award Agreement for Restricted Stock Unit Inducement Award.	Filed herewith.
10.39	Sales Agreement, dated February 13, 2020, by and between Baudax Bio, Inc. and JMP Securities LLC.	Incorporated herein by reference to Exhibit 10.29 to the Company's Annual Report on Form 10-K filed on February 13, 2020 (File No. 001-39101).
21.1	Subsidiaries of Baudax Bio, Inc.	Filed herewith.
23.1	Consent of KPMG 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.

Exhibit No.	Description	Method of Filing
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 16, 2021

BAUDAX BIO, INC.

By: /s/ Gerri A. Henwood
Gerri A. Henwood
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 16, 2021
/s/ Ryan D. Lake Ryan D. Lake	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 16, 2021
/s/ Alfred F. Altomari Alfred F. Altomari	Director and Chairman of the Board	February 16, 2021
/s/ William L. Ashton William L. Ashton	Director	February 16, 2021
/s/ Arnold Baskies, M.D. Arnold Baskies, M.D.	Director	February 16, 2021
/s/ Winston J. Churchill Winston J. Churchill	Director	February 16, 2021
/s/ Andrew Drechsler Andrew Drechsler	Director	February 16, 2021
/s/ Wayne B. Weisman Wayne B. Weisman	Director	February 16, 2021

BAUDAX BIO, INC. AND SUBSIDIARIES

Index to Consolidated and Combined Financial Statements

Report of Independent Registered Public Accounting Firm

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

Opinion on the Consolidated and Combined Financial Statements

We have audited the accompanying consolidated balance sheets of Baudax Bio, Inc. and subsidiaries (the Company) as of December 31, 2020 and 2019, the related consolidated and combined statements of operations, shareholders' equity, and cash flows for each of the years then ended, and the related notes (collectively, the consolidated and combined financial statements). In our opinion, the consolidated and combined financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the years then ended, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated and combined financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated and combined financial statements, the Company has incurred recurring losses and negative cash flows from operations and has an accumulated deficit of $112.3 million as of December 31, 2020 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 and combined financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated and combined financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated and combined 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. 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 audits, 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 audits included performing procedures to assess the risks of material misstatement of the consolidated and combined 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 and combined 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 and combined financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2019.

Philadelphia, Pennsylvania
February 16, 2021

BAUDAX BIO, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

(amounts in thousands, except share and per share data)	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 30,342	$ 17,740
Accounts receivable, net	51	—
Inventory	2,978	—
Prepaid expenses and other current assets	3,346	2,395
Total current assets	36,717	20,135
Property, plant and equipment, net	5,052	4,821
Right-of-use asset	583	730
Intangible assets, net	24,254	26,400
Goodwill	2,127	2,127
Total assets	$ 68,733	$ 54,213
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 3,653	$ 271
Accrued expenses and other current liabilities	4,993	3,532
Current portion of long-term debt, net	683	—
Current portion of operating lease liability	333	318
Current portion of contingent consideration	8,467	3,592
Total current liabilities	18,129	7,713
Long-term debt, net	8,469	—
Long-term operating lease liability	293	455
Warrant liability	65	—
Long-term portion of contingent consideration	56,576	62,766
Total liabilities	83,532	70,934
Commitments and contingencies (Note 12)		
Shareholders' equity:		
Preferred stock, $0.01 par value. Authorized, 10,000,000 shares; none issued and outstanding at December 31, 2020	—	—
Common stock, $0.01 par value. Authorized, 100,000,000 shares; issued and outstanding, 48,688,480 shares at December 31, 2020 and 9,350,709 shares at December 31, 2019	487	94
Additional paid-in capital	97,034	19,405
Accumulated deficit	(112,320)	(36,220)
Total shareholders' equity (deficit)	(14,799)	(16,721)
Total liabilities and shareholders' equity	$ 68,733	$ 54,213

See accompanying notes to consolidated and combined financial statements.

BAUDAX BIO, INC. AND SUBSIDIARIES

Consolidated and Combined Statements of Operations

(amounts in thousands, except share and per share data)	For the Year ended December 31, 2020	2019
Revenue, net	$ 493	$ —
Operating expenses:		
Cost of sales	1,732	—
Research and development	9,087	20,061
Selling, general and administrative	43,335	27,012
Amortization of intangible assets	2,146	—
Change in warrant valuation	16,734	—
Change in contingent consideration valuation	2,245	(14,554)
Total operating expenses	75,279	32,519
Operating loss	(74,786)	(32,519)
Other income (expense):		
Other income (expense)	45	(38)
Interest expense	(1,359)	—
Net loss	$ (76,100)	$ (32,557)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (3.93)	$ (3.48)
Weighted average common shares outstanding, basic and diluted	19,355,944	9,350,709

See accompanying notes to consolidated and combined financial statements.

BAUDAX BIO, INC. AND SUBSIDIARIES

Consolidated and Combined Statements of Shareholders' Equity

For the Years Ended December 31, 2020 and 2019

(amounts in thousands, except share data)	Common Stock Shares	Common Stock Amount	Parent Company Net Investment	Additional paid-in capital	Accumulated Deficit	Total
Balance, December 31, 2018	—	$ —	$ (68,347)	$ —	$ —	$ (68,347)
Recro Pharma allocation - stock-based compensation	—	—	4,964	—	—	4,964
Issuance of common stock upon separation	9,350,709	94	—	(94)	—	—
Stock-based compensation expense	—	—	—	499	—	499
Reclassification of parent company net investment	—	—	33,480	—	(33,480)	—
Net transfer from parent company	—	—	60,268	—	—	60,268
Contribution of cash by Recro Pharma, Inc. upon separation	—	—	—	19,000	—	19,000
Separation related adjustments	—	—	—	—	(548)	(548)
Net loss	—	—	(30,365)	—	(2,192)	(32,557)
Balance, December 31, 2019	9,350,709	94	—	19,405	(36,220)	(16,721)
Recro Pharma allocation - stock-based compensation	—	—	—	1,773	—	1,773
Stock-based compensation expense	—	—	—	7,568	—	7,568
Issuance of common stock upon separation	45,874	1	—	—	—	1
Issuance of common stock and warrants for public offering, net	7,692,308	77	—	14,896	—	14,973
Issuance of common stock and warrants for registered direct offerings, net	7,100,000	71	—	21,625	—	21,696
Sale of common stock under equity facility, net of transaction costs	441,967	4	—	3,608	—	3,612
Issuance of shares pursuant to vesting of restricted stock units, net of shares withheld for income taxes	707,172	7	—	(482)	—	(475)
Warrants issued in connection with financing facility	—	—	—	1,423	—	1,423
Exercise of warrants	22,163,676	221	—	5,372	—	5,593
Warrant exchange	1,186,774	12	—	21,846	—	21,858
Net loss	—	—	—	—	(76,100)	(76,100)
Balance, December 31, 2020	48,688,480	$ 487	$ -	$ 97,034	$ (112,320)	$ (14,799)

See accompanying notes to consolidated and combined financial statements.

BAUDAX BIO, INC. AND SUBSIDIARIES

Consolidated and Combined Statements of Cash Flows

(amounts in thousands)	For the Year ended December 31, 2020	2019
Cash flows from operating activities:		
Net loss	$ (76,100)	$ (32,557)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	9,341	5,463
Non-cash-interest expense	535	—
Depreciation expense	408	480
Amortization	2,146	—
Change in warrant valuation	16,734	—
Change in contingent consideration valuation	2,245	(14,554)
Changes in operating assets and liabilities:		
Inventory	(2,978)	—
Prepaid expenses and other current assets	(951)	119
Right-of-use asset	147	444
Accounts receivable	(51)	—
Accounts payable, accrued expenses and other liabilities	4,613	(8,993)
Operating lease liability	(147)	(446)
Net cash used in operating activities	(44,058)	(50,044)
Cash flows from investing activities:		
Purchases of property and equipment	(639)	(1,319)
Acquisition of license agreement	—	(165)
Net cash used in investing activities	(639)	(1,484)
Cash flows from financing activities:		
Proceeds from issuance of long-term debt, net of transaction costs	10,041	—
Proceeds from equity facility, net of transaction costs	3,612	—
Proceeds from public offering, net of transaction costs	23,085	—
Proceeds from registered direct offerings, net of transaction costs	21,925	—
Proceeds from warrant exercises	2,671	—
Payments of contingent consideration	(3,560)	(10,000)
Contribution upon separation	—	19,000
Investment from parent company	—	60,268
Payments of withholdings on shares withheld for income taxes	(475)	—
Payment of deferred equity costs	—	—
Proceeds from option exercise	—	—
Net cash provided by financing activities	57,299	69,268
Net increase in cash and cash equivalents	12,602	17,740
Cash and cash equivalents, beginning of year	17,740	—
Cash and cash equivalents, end of year	$ 30,342	$ 17,740
Supplemental disclosure of cash flow information:		
Deferred financing costs included in accounts payable and accrued expenses	$ 1	$ —
Offering costs included in accounts payable and accrued expenses	$ 229	$ —
Fair value of warrants issued in connection with public offering	$ 8,111	$ —
Fair value of warrants issued in connection with financing facility	$ 1,423	$ —

See accompanying notes to consolidated and combined financial statements.

(1) Background

Business

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

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

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

The Separation

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

Basis of Presentation

For all periods prior to the Separation, the accompanying combined financial statements represent the Acute Care Business of Recro and are derived from Recro's consolidated financial statements. The Acute Care Business of Recro did not consist of a separate, standalone group of legal entities for public company reporting and certain other corporate functions in the periods prior to the Separation and, accordingly, allocations were required through the Distribution date. These combined financial statements, prior to the Separation, reflect the Company's historical financial position, results of operations and cash flows as the business was operated as part of Recro prior to the Separation, in conformity with U.S. generally accepted accounting principles ("U.S. GAAP"). See Note 16 for a description of the agreements entered into between Recro and Baudax Bio following the Separation.

Prior to the Separation, all intercompany transactions between the Company and Recro were considered to be effectively settled in the combined financial statements at the time the transaction was recorded. The total net effect of the settlement of these intercompany transactions is reflected in the combined statements of cash flows as a financing activity. The Company did not record interest expense on amounts funded by Recro. Long-term debt held at the Recro corporate level was retained by Recro and was not assumed by the Company.

Historically, certain corporate level activity costs have been incurred and reported within the legal entity that included the Recro Acute Care Business. The Company's combined financial statements, prior to the Separation, include an allocation of these expenses related to these certain Recro corporate functions, including senior management, legal, human resources, finance, and information technology through the distribution date. These expenses are included in general and administrative expense and have been allocated based on direct usage or benefit where identifiable, with the remainder allocated on a pro rata basis of expenses, headcount, or other measures. The Company considers the expense allocation methodology and results to be reasonable for all periods presented, however, the allocations may not be indicative of the actual expense that would have been incurred had the Company operated as an independent, publicly-traded company for the periods presented prior to the Separation. For the year ended December 31, 2019 (prior to the Separation), a total of $7,278 of costs have been allocated to Recro's contract manufacturing and development segment (the "CDMO business").

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

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

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

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

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

(2) Development-Stage Risks, Liquidity and Going Concern

The Company has incurred operating losses and negative cash flows since inception and has an accumulated deficit of $112,320 as of December 31, 2020.

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

The Company follows the provisions of Financial Accounting Standards Board ("FASB"), Accounting Standards Codification ("ASC"), Topic 205-40, *"Presentation of Financial Statements — Going Concern"*, or ASC 205-40, which requires management to assess the Company's ability to continue as a going concern for one year after the date the consolidated financial statements are issued. The Company expects to seek additional funding to sustain its future operations and while the Company has successfully raised capital in the past, the ability to raise capital in future periods is not assured. Based on the Company's available cash as of December 31, 2020, management has concluded that substantial doubt exists about the Company's ability to continue as a going concern for one year from the date these financial statements are issued. The consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates continuity of operations, the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

(3) Summary of Significant Accounting Principles

(a) 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 their maturity that they present insignificant risk of changes in value because of the changes in interest rates.

(c) Property and Equipment

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

(d) Business Combinations

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

(e) Goodwill and Intangible Assets

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

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

As of December 31, 2020, the Company's intangible asset is classified as an asset resulting from R&D activities. Historically, prior to receiving FDA approval, the intangible asset was classified as an IPR&D asset. Intangible assets related to IPR&D are considered indefinite-lived intangible assets and are assessed for impairment annually or more frequently if impairment indicators exist. If the associated research and development effort is abandoned, the related assets would be written-off, and the Company would record a noncash impairment loss in its Consolidated and Combined Statements of Operations. For those compounds that reach commercialization, the IPR&D assets will be amortized over their estimated useful lives. The Company determined the useful life of its asset resulting from R&D activities to be approximately 10 years, which is based on the remaining patent life, and is being amortized on a straight-line basis. The Company is required to review the carrying value of assets resulting from R&D activities for recoverability whenever events occur or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable.

The Company performs its annual goodwill impairment test as of November 30th, or whenever an event or change in circumstances occurs that would require reassessment of the recoverability of goodwill. In performing the evaluation, the Company assesses qualitative factors such as overall financial performance of its reporting unit, anticipated changes in industry and market conditions, including recent tax reform, intellectual property protection, and competitive environments. Due to the global market disruption from COVID-19 in March 2020, an indicator of potential impairment, the Company performed an impairment test as of March 31, 2020, which indicated that there was no impairment to goodwill or intangible assets. The Company also performed its annual test as of November 30, 2020 and there was no impairment to goodwill or intangible assets based on the analysis.

(f) Revenue Recognition

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

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

(g) Concentration of Credit Risk

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

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

(h) Research and Development

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

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

(i) Stock-Based Awards

Baudax Awards

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

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

The expected life of stock options was estimated using the "simplified method," as the Company has limited historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock options grants. The simplified method is based on the average of the vesting tranches and the contractual life of each grant. For stock price volatility, the Company uses an average of its peer group's volatility in order to estimate future stock price trends. The risk-free interest rate is based on U.S. Treasury notes with a term approximating the expected life of the option.

Recro Awards

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

Recro measures employee stock-based awards at grant-date fair value and recognizes employee compensation expense on a straight-line basis over the vesting period of the award. Forfeitures are accounted for as they occur.

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

The expected life of stock options was estimated using the "simplified method," as Recro has limited historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for its stock options grants. The simplified method is based on the average of the vesting tranches and the contractual life of each grant. For stock price volatility, Recro uses the historical volatility of its publicly traded stock in order to estimate future stock price trends. The risk-free interest rate is based on U.S. Treasury notes with a term approximating the expected life of the option.

(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 combined financial statements. The Company recognizes the benefit of an income tax position only if it is more likely

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

than not (greater than 50%) that the tax position will be sustained upon tax examination, based solely on the technical merits of the tax position. Otherwise, no benefit is recognized. The tax benefits recognized are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. The Company does not anticipate significant changes in the amount of unrecognized income tax benefits over the next year.

(k) Net Loss Per Common Share

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

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

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

	Year ended December 31,	
	2020	**2019**
Basic and Diluted Loss Per Share		
Net loss	$ (76,100)	$ (32,557)
Weighted average common shares outstanding, basic and diluted	19,355,944	9,350,709
Net loss per share of common stock, basic and diluted	$ (3.93)	$ (3.48)

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as of December 31, 2020 and 2019 as they would be anti-dilutive:

	December 31,	
	2020	**2019**
Options and restricted stock units outstanding	3,275,310	2,023,909
Warrants	22,244,610	—

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

(l) Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

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

In August 2018, the FASB issued ASU 2018-13, "*Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement,*" or ASU 2018-13. ASU 2018-13 removes, modifies and adds certain disclosure requirements in Topic 820 "*Fair Value Measurement*". ASU 2018-13 eliminates certain disclosures related to transfers and the valuations process, clarifies the measurement uncertainty disclosure, and requires additional disclosures for Level 3 fair value measurements, including the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. ASU 2018-13 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019 with early adoption permitted. The Company adopted this guidance as of January 1, 2020. The adoption did not have a material impact to the Company or its disclosures.

Accounting Pronouncements Not Yet Adopted

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

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

(4) Fair Value of Financial Instruments

The Company follows the provisions of FASB ASC Topic 820, "*Fair Value Measurements and Disclosures*," for fair value measurement recognition and disclosure purposes for its financial assets and financial liabilities that are remeasured and reported at fair value each reporting period. The Company measures certain financial assets and liabilities at fair value on a recurring basis, including cash equivalents and the 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, 2020:			
Assets:			
Cash equivalents			
Money market mutual funds (See Note 5)	$ 24,210	$ —	$ —
Commercial paper (See Note 5)	-	4,500	
Total cash equivalents	$ 24,210	$ 4,500	$ —
Liabilities:			
Warrants (See Note 13(c))	$ —	$ —	$ 65
Contingent consideration (See Note 12)	$ —	$ —	$ 65,043
	$ —	$ —	$ 65,108
At December 31, 2019:			
Assets:			
Cash equivalents			
Money market mutual funds (See Note 5)	$ 16,514	$ —	$ —
Total cash equivalents	$ 16,514	$ —	$ —
Liabilities:			
Contingent consideration (See Note 12)	$ —	$ —	$ 66,358
	$ —	$ —	$ 66,358

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, 2018	$ —	$ 90,912
Payment of contingent consideration	—	(10,000)
Remeasurement	—	(14,554)
Balance at December 31, 2019	—	66,358
Additions	8,111	—
Reclassification to equity upon exercise of warrants	(2,922)	—
Payment of contingent consideration	—	(3,560)
Remeasurement	16,734	2,245
Reclassification to equity upon warrant exchange	(21,858)	—
Total at December 31, 2020	$ 65	$ 65,043
Current portion as of December 31, 2020	$ —	$ 8,467
Long-term portion as of December 31, 2020	65	56,576

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

Based on the amended terms of the Alkermes agreement (see Note 12(b)), the remaining contingent consideration payments include the second components, which became payable upon regulatory approval, and includes remaining payments of $1,440 due on or prior to June 20, 2021 and $45,000 payable in seven equal annual payments of approximately $6,400 beginning in February 2021, the first anniversary of such approval. The third component consists of three potential payments, based on the achievement of specified annual revenue targets, the last of which represents over 60% of these milestone payments and currently does not have a fair value assigned

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

to its achievement. The fourth component consists of a royalty payment between10% and 12% (subject to a 30% reduction when no longer covered by patent) for a defined term on future injectable meloxicam net sales. The fair value of the remaining second consideration component is estimated by applying a risk-adjusted discount rate to the scheduled remaining payments. The fair value of the third contingent consideration component is estimated using the Monte Carlo simulation method and applying a risk-adjusted discount rate to the potential payments resulting from probability-weighted revenue projections based upon the expected revenue target attainment dates. The fair value of the fourth contingent consideration component is estimated by applying a risk-adjusted discount rate to the potential payments resulting from probability-weighted revenue projections and the defined royalty percentage. As of December 31, 2020, the fair value calculations used discount rates in the range of 19.41% to 36.03%, with a weighted average of 27.39%.

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, 2020. 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, 2020, the financial assets and liabilities recorded on the Consolidated Balance Sheets that are not measured at fair value on a recurring basis include accounts receivable, accounts payable and accrued expenses, 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, 2020 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, 2020			
	Amortized	Gross Unrealized		Estimated
Description	Cost	Gain	Loss	Fair Value
Money market mutual funds	$ 24,210	$ —	$ —	$ 24,210
Commercial paper	4,500	—	—	4,500
Total cash equivalents	$ 28,710	$ —	$ —	$ 28,710

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

As of December 31, 2020 and 2019, the Company's cash equivalents had maturities ofone month. To derive the fair value of its commercial paper, the Company uses benchmark inputs and industry standard analytical models.

(6) Inventory

Inventory is stated at the lower of cost and net realizable value. Cost is determined using the first-in, first-out method. The Company expensed costs related to inventory within the Research and development line in the Consolidated and Combined Statements of Operations until it received approval from the FDA to market a product, at which time the Company commenced

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

capitalization of costs relating to that product. Adjustments to inventory are determined at the raw material, sub-assemblies and finished goods levels to reflect obsolescence or impaired balances.

Inventory was as follows:

	December 31, 2020	December 31, 2019
Raw materials	$ 130	$ —
Sub-assemblies	2,476	—
Finished goods	928	—
	3,534	—
Provision for inventory obsolescence	(556)	—
	$ 2,978	$ —

(7) Property, Plant and Equipment

Property, plant and equipment consists of the following:

	December 31, 2020	December 31, 2019
Building and improvements	$ 196	$ 196
Furniture, office and computer equipment	934	902
Manufacturing equipment	717	717
Construction in progress	4,453	3,846
	6,300	5,661
Less: accumulated depreciation	1,248	840
Property, plant and equipment, net	$ 5,052	$ 4,821

Depreciation expense for the years ended December 31, 2020 and 2019 was $408 and $480, respectively.

(8) Leases

The Company is a party to various operating leases in Malvern, Pennsylvania and Dublin, Ireland for office space and office equipment.

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

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

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

Undiscounted future lease payments for non-cancellable operating leases are as follows:

	December 31, 2020
2021	$ 434
2022	373
Total lease payments	807
Less imputed interest	(181)
Total operating liabilities	$ 626

For the year ended December 31, 2020, the weighted average remaining lease term was 2 years and the weighted average discount rate was 16%.

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

	December 31, 2020	December 31, 2019
Operating lease cost	$ 393	$ 484
Short-term lease cost	100	12
Total lease cost	$ 493	$ 496

(9) Intangible Assets

The following represents the balances of the intangible assets at December 31, 2020:

	Cost	Accumulated Amortization	Net Intangible Assets
Asset resulting from R&D activities	$ 26,400	$ 2,146	$ 24,254
Total	$ 26,400	$ 2,146	$ 24,254

The following represents the balance of the intangible assets at December 31, 2019:

	Cost
In-process research and development	$ 26,400
Total	$ 26,400

Amortization expense for the year ended December 31, 2020 was $2,146. There was no amortization expense for the year ended December 31, 2019.

As of December 31, 2020, future amortization expense is as follows:

	Amortization
2021	$ 2,576
2022	2,576
2023	2,576
2024	2,576
2025 and thereafter	13,950
Total	$ 24,254

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

(10) Accrued Expenses

Accrued expenses consist of the following:

	December 31, 2020	December 31, 2019
Payroll and related costs	$ 3,177	$ 2,181
Professional and consulting fees	802	209
Guarantee liability	422	548
Other research and development costs	243	538
Interest payable	126	—
Other	223	56
	$ 4,993	$ 3,532

In November 2020, the Company implemented a reduction in force impacting approximately 40 employees and resulted in a charge of $1,753, primarily related to severance, of which $829 is accrued at December 31, 2020.

(11) Debt

The following table summarizes the components of the carrying value of debt as of December 31, 2020:

Paycheck Protection Program Loan	$ 1,537
Credit Agreement	10,000
Unamortized deferred issuance costs	(2,427)
Exit fee accretion	42
Total debt	$ 9,152
Current portion as of December 31, 2020	$ 683
Long-term portion, net as of December 31, 2020	8,469

(a) Paycheck Protection Program Loan

On April 13, 2020, the Company applied to PNC Bank, National Association (the "Lender") under the Small Business Administration (the "SBA") Paycheck Protection Program ("PPP") of the Coronavirus Aid, Relief and Economic Security Act of 2020 (the "CARES Act") for a loan of $ 1,537 (the "Loan"). On May 8, 2020, the Company entered into a promissory note with respect to the Loan in favor of the Lender (the "PPP Loan").

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

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

(b) Credit Agreement

On May 29, 2020 (the "Credit Agreement Closing Date"), the Company entered into a $50,000 Credit Agreement (the "Credit Agreement") by and among the Company, Wilmington Trust, National Association, in its capacity as the agent ("Agent"), and MAM Eagle Lender, LLC, as the lender (together with any other lenders under the Credit Agreement from

time to time, collectively, the "Lenders"). The Credit Agreement provides for a term loan in the original principal amount of $10,000 (the "Tranche One Loans") funded on the Credit Agreement Closing Date. Pursuant to the terms of the Credit Agreement, there are four additional tranches of term loans, in an aggregate original principal amount of $40,000 (the "Tranche Two Loans", "Tranche Three Loans", "Tranche Four Loans" and the "Tranche Five Loans", and collectively with the Tranche One Loans, the "Term Loans" and each a "Term Loan").

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

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

Subject to certain exceptions, the Company is required to make mandatory prepayments of the Term Loans, with the proceeds of asset sales, extraordinary receipts, debt issuances and specified other events. The Company may make voluntary prepayments in whole or in part, subject to a prepayment premium equal to (i) with respect to any prepayment paid on or prior to the third anniversary of the Tranche One Loan (or, in the case of each of the Tranche Two Loans, Tranche Three Loans, Tranche Four Loans or Tranche Five Loans, the third anniversary of the date each such loan is funded), the remaining scheduled payments of interest that would have accrued on the Term Loans being prepaid, repaid or accelerated, but that remained unpaid, in no event to be less than 5.0% of the principal amount of the Term Loan being prepaid, and (ii) with respect to any prepayment paid after the third but prior to the fourth anniversary of the Tranche One Loan (or, in the case of each of the Tranche Two Loans, Tranche Three Loans, Tranche Four Loans or Tranche Five Loans, the fourth anniversary of the date each such loan is funded), 3.0% of the principal amount of the Term Loan being prepaid. In addition, an exit fee will be due and payable upon prepayment or repayment of the Term Loans (including, without limitation, on the Maturity Date) equal to the lesser of 2.5% of the sum of the aggregate principal amount of the Term Loans advanced or approved to be advanced by the Lenders and $700; provided that such exit fee will be equal to $700 if fee is paid in conjunction with a change of control that occurs in connection with the payoff or within 6 months thereof. As of December 31, 2020, the Company will have to pay a 2.5% exit fee, which is $250 at the current outstanding loan balance and is being accreted to the carrying amount of the debt using the effective interest method over the term of the loan.

The Credit Agreement contains certain usual and customary affirmative and negative covenants, as well as financial covenants including a minimum liquidity requirement of $5,000 at all times and minimum EBITDA levels that the Company may need to satisfy on a quarterly basis beginning in September 2021, subject to borrowing levels. As of December 31, 2020, the Company was in compliance with the required covenants. As of December 31, 2020, borrowings under the Credit Agreement are classified based on their schedule maturities. As a result of the liquidity conditions discussed in Note 2, the Company is not expected to be able to maintain its minimum liquidity covenant over the next twelve months without additional capital financing. If the Company is unable to maintain its minimum liquidity covenant, it is reasonably possible that the Lenders could demand repayment of the borrowings under the Credit Agreement during the next twelve months.

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

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 and Combined Statements of Operations. As of December 31, 2020, the effective interest rate was 23.12%%, which takes into consideration the non-cash amortization of the debt issuance costs and accretion of the exit fee. The Company recorded debt issuance cost amortization related to the Credit Agreement of $492 for the year ended December 31, 2020.

(12) Commitments and Contingencies

(a) License and Supply Agreements

The Company is party to an exclusive license with Orion for the development and commercialization of Dexmedetomidine for use in the treatment of pain in humans in any dosage form for transdermal, transmucosal (including sublingual and intranasal), topical, enteral or pulmonary (inhalational) delivery, but specifically excluding delivery vehicles for administration by injection or infusion, worldwide, except for Europe, Turkey and the CIS (currently includes Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine and Uzbekistan), referred to herein as the Territory. The Company is required to pay Orion lump sum payments of up to €20,500 ($25,141 as of December 31, 2020) on the achievement of certain developmental and commercial milestones, as well as a royalty on net sales during the term, which varies from 10% to 20% depending on annual sales levels. Through December 31, 2020, no such milestones have been achieved.

The Company is also party to an exclusive license agreement with Orion for the development and commercialization of Fadolmidine for use as a human therapeutic, in any dosage form in the Territory. The Company is required to pay Orion lump sum payments of up to €12,200 ($14,962 as of December 31, 2020) on achievement of certain developmental and commercial milestones, as well as a royalty on net sales during the term, which varies from 10% to 15% depending on annual sales levels. Through December 31, 2020, no such milestones have been achieved.

In June 2017, the Company acquired the exclusive global rights to two novel neuromuscular blocking agents ("NMBAs") and a proprietary reversal agent from Cornell University ("Cornell"). The NMBAs and reversal agent are referred to herein as the NMBA Related Compounds. The NMBA Related Compounds include one novel intermediate-acting NMBA that has initiated Phase I clinical trials and two other agents, a novel short-acting NMBA, and a rapid-acting reversal agent specific to these NMBAs. The Company is obligated to make: (i) an annual license maintenance fee payment to Cornell until the first commercial sale of the NMBA Related Compounds; and (ii) milestone payments to Cornell upon the achievement of certain milestones, up to a maximum, for each NMBA Related Compound, of $5,000 for U.S. regulatory approval and commercialization milestones and $3,000 for European regulatory approval and commercialization milestones. The Company is obligated to pay Cornell royalties on net sales of the NMBA Related Compound at a rate ranging from low to mid-single digits, depending on the applicable NMBA Related Compounds and whether there is a valid patent claim in the applicable country, subject to an annual minimum royalty amount. Further, the Company will reimburse Cornell ongoing patent costs related to prosecution and maintenance of the patents related to the Cornell patents for the NMBA Related Compounds.

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

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

(b) Contingent Consideration for the Alkermes Transaction

On April 10, 2015, Recro completed the acquisition of a manufacturing facility in Gainesville, Georgia and the licensing and commercialization rights to injectable meloxicam (the "Alkermes Transaction"). Pursuant to the purchase and sale agreement and subsequent amendment with Alkermes, as amended, governing the Alkermes Transaction, the Company agreed to pay to Alkermes up to an additional $140,000 in milestone payments including $60,000 upon regulatory approval payable over a seven-year period, as well as net sales milestones related to injectable meloxicam and royalties on future product sales of injectable meloxicam.

Based on the amended terms of the Alkermes agreement, the contingent consideration consists of four separate components. The first component is (i) a $5,000 payment made in the first quarter of 2019 and (ii) a $5,000 payment made in the second quarter of 2019. The second components became payable upon regulatory approval in February 2020 and include (i) a $5,000 payment due within 180 days following regulatory approval for ANJESO, of which timing of payment was amended as noted below, and (ii) $45,000 payable in seven equal annual payments of approximately $6,400 beginning on the first anniversary of such approval. The third component consists of three potential payments, based on the achievement of specified annual revenue targets, the last of which represents over 60% of these milestone payments and currently does not have a fair value assigned to its achievement. The fourth component consists of a royalty payment between 10% and 12% (subject to a 30% reduction when no longer covered by patent) for a defined term on future injectable meloxicam net sales.

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

As of December 31, 2020, the Company has paid $13,560 in milestone payments to Alkermes.

(c) Litigation

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

On May 31, 2018, a securities class action lawsuit (the "Securities Litigation") was filed against Recro and certain of Recro's officers and directors in the U.S. District Court for the Eastern District of Pennsylvania (Case No. 2:18-cv-02279-MMB) that purported to state a claim for alleged violations of Section 10(b) and 20(a) of the Exchange Act and Rule 10(b)(5) promulgated thereunder, based on statements made by Recro concerning the NDA for 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, the Company 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. Recro filed a motion to dismiss the second amended complaint on June 18, 2020. The plaintiff filed an opposition to the motion to dismiss on August 17, 2020. On September 16, 2020, Recro filed a reply in support of the motion to dismiss. In connection with the Separation, the Company accepted assignment by Recro of all of Recro's obligations in connection with the Securities Litigation and agreed to indemnify Recro for all liabilities related to the Securities Litigation. The Company has recorded a liability equal to the estimated fair value of the indemnification to Recro related to this Securities Litigation. The Company believes that the lawsuit is without merit and intends to vigorously defend against it. At this time, no assessment can be made as to its likely outcome or whether the outcome will be material to the Company.

(d) Purchase Commitments

As of December 31, 2020, the Company had outstanding non-cancelable and cancelable purchase commitments of $6,620 related to inventory and other goods and services, including manufacturing and clinical activities. The timing of certain purchase commitments cannot be estimated as it is dependent on the outcome of strategic evaluations and agreements.

(e) Certain Compensation and Employment Agreements

The Company has entered into employment agreements with certain of its named executive officers. As of December 31, 2020, these employment agreements provided for, among other things, annual base salaries in an aggregate amount of not less than $927 from that date through June 2022.

(13) Capital Structure

(a) Common Stock

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

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

On February 13, 2020, the Company entered into a Sales Agreement (the "Agreement") with JMP Securities LLC, as sales agent (the "Agent"), pursuant to which the Company may, from time to time, issue and sell shares of its common stock, par value $0.01 per share, in an aggregate offering price of up to $25,000 (the "Shares") through the Agent. As of December 31, 2020, 441,967 shares of common stock have been sold under the Sales Agreement for net proceeds of $3,612. The Agent was paid a sales commission of 3% for such sales under the Sales Agreement.

On March 26, 2020, the Company closed an underwritten public offering of7,692,308 shares of its common stock, Series A Warrants to purchase 7,692,308 shares of common stock (the "March Series A Warrants") and Series B Warrants to purchase 7,692,308 shares of common stock (the "March Series B Warrants"), at an exercise price of $4.59 per share for the March Series A Warrants and at an exercise price of $3.25 per share for the March Series B Warrants, for net proceeds to the Company of $23,085, after deducting underwriting discounts and commissions and offering expenses.

On November 24, 2020, the Company closed a registered direct offering of2,850,000 shares of its common stock, warrants to purchase10,126,583 shares of common stock (the "November Series A Warrants") at an exercise price of $ 1.20 per share, pre-funded warrants to purchase 7,276,583 shares of common stock (the "November Series B Warrants") at an exercise price of $0.01 per share, for net proceeds to the Company of $10,763. As compensation to H.C. Wainwright & Co., LLC (the "Placement Agent") as placement agent, the Company agreed to pay to the Placement Agent a cash fee of 6.0% of the aggregate gross proceeds, plus a management fee equal to 1.0% of the gross proceeds and reimbursement of certain expenses and legal fees. The Company also issued warrants to purchase 607,595 shares of common stock (the "November Placement Agent Warrants") at an exercise price of $1.48125 per share.

On December 18, 2020, the Company closed a registered direct offering of4,250,000 shares of its common stock, warrants to purchase10,300,430 shares of common stock (the "December Series A Warrants") at an exercise price of $ 1.18 per share, pre-funded warrants to purchase 6,050,430 shares of common stock (the "December Series B Warrants") at an exercise price of $0.01 per share, for net proceeds to the Company of $10,933. As compensation to the Placement Agent, the Company agreed to pay to the Placement Agent a cash fee of 6.0% of the aggregate gross proceeds, plus a management fee equal to1.0% of the gross proceeds and reimbursement of certain expenses and legal fees. The Company also issued warrants to purchase 618,026 shares of common stock (the "December Placement Agent Warrants") at an exercise price of $1.45625 per share.

(b) Preferred Stock

The Company is authorized to issue 10,000,000 shares of preferred stock, with a par value of $0.01 per share. As of December 31, 2020, no preferred stock was issued or outstanding.

(c) Warrants

On May 29, 2020, in connection with the Credit Agreement, the Company issued a warrant to MAM Eagle Lender, LLC to purchase527,100 shares of common stock, at an exercise price equal to $4.59 per share (see Note 11(b)).

On October 19, 2020, the Company entered into Warrant Exchange Agreements (each, an "Exchange Agreement") with certain holders (each, a "Holder") of the Company's outstanding March Series A Warrants and March Series B Warrants. Pursuant to the Exchange Agreements, the Holders, at their election, agreed to a cashless exchange of either all of their

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

March Series A Warrants or March Series B Warrants, in each case for 0.2 shares of the Company's common stock per warrant (rounded up to the nearest whole share) (the "Exchange"). The Company issued 1,186,774 shares of its common stock to the participating Holders as a result of the Exchange.

As a result of the Exchange, pursuant to certain price adjustment provisions in the warrants, the exercise price of each of the March Series A Warrants or March Series B Warrants (including warrants held by holders not participating in the Exchange) that were not exchanged were adjusted to par value, or $0.01, for each share of common stock underlying such warrant. Pursuant to the Exchange Agreements, any outstanding warrant held by a Holder participating in the Exchange (i) was amended to remove certain anti-dilution and variable pricing protections and (ii) in the case of March Series A Warrants not exchanged by a participating Holder, was amended to adjust the expiration date of such March Series A Warrants to April 26, 2021 (which is the expiration date of the March Series B Warrants). The March Series A and Series B warrants were liability classified prior to the Exchange because they contained anti-dilution provisions that did not meet the standard definition of anti-dilution provisions. The Company recorded a mark-to-market adjustment to record the March Series A and Series B warrant at their fair values immediately prior to the Exchange and then reclassified the remaining balance of $21,858 to equity as a result of the issuance of shares and the removal of the anti-dilution and variable pricing protections in the Exchange.

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

During the year ended December 31, 2020, the Company issued 7,276,583 shares of common stock upon exercise of the November Series B Warrants for proceeds of $73 and 6,050,430 shares of common stock upon exercise of the December Series B Warrants for proceeds of $60.

As of December 31, 2020, the Company had the following warrants outstanding to purchase shares of the Company's common stock:

	Number of Shares	Exercise Price per Share	Expiration Date
March Series A Warrants, (non-participating holders)	32,438	$ 0.01	March 26, 2025
March Series B Warrants, (non-participating holders)	32,438	$ 0.01	April 26, 2021
March Series A and Series B Warrants (participating holders)	549,231	$ 0.01	April 26, 2021
MAM Eagle Lender Warrant	527,100	$ 4.59	May 29, 2027
November Series A Warrants	10,126,583	$ 1.20	November 24, 2025
November Placement Warrants	607,595	$ 1.48125	November 24, 2025
December Series A Warrants	10,300,430	$ 1.18	December 18, 2025
December Placement Warrants	618,026	$ 1.45625	December 18, 2025

With the exception of the March Series A Warrants to purchase 32,438 shares of common stock and March Series B Warrants to purchase 32,438 shares of common stock related to the public offering and held by non-participating investors in the Exchange that are liability classified as they contain antidilution provisions that do not meet the standard definition of antidilution provisions, the remaining warrants outstanding are equity classified.

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, 2020	
	Series A Warrants	Series B Warrants
Fair value	$ 33	$ 32
Expected dividend yield	— %	— %
Expected volatility	75.18 %	77.22 %
Risk-free interest rates	0.27 %	0.09 %
Remaining contractual term	4.24 years	0.32 years

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

On January 21, 2021, the Company entered into an agreement with an institutional investor, pursuant to which the Company agreed to issue and sell, in an offering (the "January Offering"), warrants exercisable for an aggregate of 10,300,430 shares of common stock of the Company (the "January Warrants") at an offering price of $0.125 per warrant in exchange for the exercise of the institutional investor's existing December Series A warrants that were issued to them on December 21, 2020, at an exercise price of $1.18 per warrant. The January Warrants have an exercise price of $1.60 per share and are exercisable for one share of common stock. The January Warrants were immediately exercisable and will expire five years from the issuance date.

As compensation to the Placement Agent, as placement agent in connection with the January Offering, the Company agreed to pay to the Placement Agent a cash fee of 6.0% of the aggregate gross proceeds raised in the January Offering (including the proceeds relating to the exercise of the December Series A Warrants), plus a management fee equal to 1.0% of the gross proceeds raised in the January Offering (including the proceeds relating to the exercise of the December Series A Warrants) and reimbursement of certain expenses and legal fees. The Company also issued to designees of the Placement Agent warrants to purchase up to 6.0% of the aggregate number of shares of common stock underlying the January Warrants issued in the January Offering, or warrants to purchase up to 618,026 shares of common stock (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 125% of the offering price per January Warrant (or $2.00 per share).

On February 8, 2021, the Company entered into an agreement with institutional investors, pursuant to which the Company agreed to issue and sell, in a registered direct offering, 11,000,000 shares of common stock (the "February Offering") at an offering price of $1.60 per share.

As compensation to the Placement Agent, as placement agent in connection with the February Offering, 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 up to 6.0% of the aggregate number of shares of common stock issued in the February Offering, or warrants to purchase up to 660,000 shares of common stock (the "February Placement Agent Warrants"). The February Placement Agent Warrants have an exercise price of $ 2.00 per share and are exercisable for one share of common stock. The February Placement Agent Warrants will be exercisable immediately upon approval by the Company's board of directors and shareholders of an increase in the number of shares of the Company's authorized common stock.

(14) Stock-Based Compensation

The Company has adopted the 2019 Plan that allows for the grant of stock options, stock appreciation rights and stock awards for a total of 8,000,000 shares of common stock. On December 1st of each year, pursuant to the "Evergreen" provision of the 2019 Plan, the number of shares available under the plan shall be increased by an amount equal to 5% of the outstanding common stock on December 1st of that year or such lower amount as determined by the Board of Directors. In December 2020, the number of shares available for issuance under the 2019 Plan was increased by 1,522,171. The total number of shares authorized for issuance under the 2019 plan as of December 31, 2020 is 4,989,706. As of December 31, 2020, 1,486,534 shares are available for future grants under the 2019 Plan.

Stock Options:

Stock options are exercisable generally for a period of 10 years from the date of grant and generally vest over four years. The weighted average grant-date fair value of the Baudax Bio options awarded to employees during the years ended December 31, 2020 and 2019 was $1.36 and $4.29, respectively. Under the 2019 Plan, the fair value of the Baudax Bio options was estimated on the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions:

	December 31,	
	2020	2019
Expected option life	5.7 years	6 years
Expected volatility	74.24%	77.81%
Risk-free interest rate	0.50%	1.68%
Expected dividend yield	—	—

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

Certain employees of the Company participated in Recro's stock-based compensation plan, which provides for the grants of stock options and RSUs. The combined financial statements prior to the Separation reflect stock-based compensation expense related to Recro stock options and RSUs issued to the Company's employees as well an allocation of a portion of Recro share-based compensation issued to corporate employees and members of the Board of Directors until the Separation date. The weighted average grant-date fair value of the options awarded to employees under the Recro plan during the year ended December 31, 2019 (prior to the Separation date) was $5.53.

Under the Recro equity incentive plan for the year ended December 31, 2019, the fair value of the options granted to employees of the Company was estimated on the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions:

	December 31, 2019
Expected option life	6 years
Expected volatility	79.96%
Risk-free interest rate	2.60%
Expected dividend yield	—

The following table summarizes the Baudax Bio stock option activity during the years ended December 31, 2020 and 2019:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life
Balance, December 31, 2018	—	$ —	
Granted	643,879	6.33	
Exercised	—	—	
Expired/forfeited/cancelled	—	—	
Balance, December 31, 2019	643,879	6.33	9.9 years
Granted	1,931,919	2.15	
Exercised	—	—	
Expired/forfeited/cancelled	(291,500)	3.87	
Balance, December 31, 2020	2,284,298	$ 3.10	9.1 years
Vested	160,965	$ 6.33	8.7 years
Vested and expected to vest	2,284,298	$ 3.10	9.1 years

Included in the table above are 373,003 stock options outstanding as of December 31, 2020 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 the Baudax Bio restricted stock units activity during the year ended December 31, 2020 and 2019:

	Number of shares
Balance, December 31, 2018	—
Granted	1,380,030
Vested and settled	—
Expired/forfeited/cancelled	—
Balance, December 31, 2019	1,380,030
Granted	741,221
Vested and settled	(1,052,239)
Expired/forfeited/cancelled	(78,000)
Balance, December 31, 2020	991,012
Expected to vest	991,012

Included in the table above are 106,307 time-based RSUs outstanding as of December 31, 2020 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, 2020 and 2019 was $9,341 and $5,463, respectively. For the current year, this represents stock-based compensation from the Baudax Bio awards as well as stock-based compensation from the Recro Equity Plan for certain Baudax Bio employees who are continuing to vest in their Recro awards but are not performing services to Recro. For the prior year, this represents the allocated portion of Recro stock-based compensation expense for employees of the Company.

As of December 31, 2020, there was $8,879 of unrecognized compensation expense related to unvested options and time-based RSUs that are expected to vest and will be expensed over a weighted average period of 2.3 years.

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, 2020, there was no aggregate intrinsic value of the vested and unvested Baudax Bio options.

(15) Income Taxes

The components of loss before income tax are as follows:

	December 31,	
	2020	2019
Domestic	$ (74,277)	$ (16,417)
Foreign	(1,823)	(16,140)
Loss before income taxes	$ (76,100)	$ (32,557)

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

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

	December 31,	
	2020	2019
Current:		
Federal	$ —	$ —
State and local	—	—
Foreign	—	—
	—	—
Deferred:		
Federal	(11,196)	(3,440)
State and local	(4,318)	(1,206)
Foreign	(228)	(2,018)
	(15,742)	(6,664)
Change in valuation allowance	15,742	6,664
	$ —	$ —

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,	
	2020	2019
U.S. federal statutory income tax rate	21.0%	21.0%
Foreign tax rate differential	(0.2)%	(4.2)%
State taxes, net of federal benefit	5.7%	3.7%
Nondeductible expenses	(5.8)%	—
Change in valuation allowance	(20.7)%	(20.5)%
Effective income tax rate	—	—

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

	December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 15,289	$ 1,065
Intangibles	2,469	2,056
Contingent consideration	11,485	10,924
Stock-based compensation	853	142
Operating lease liability	43	(12)
Other temporary differences	420	—
Gross deferred tax asset	30,559	14,175
Valuation allowance	(29,714)	(14,094)
Net deferred tax asset	845	81
Deferred tax liabilities:		
Prepaid expenses	(792)	—
Right-of-use asset	(43)	—
Other	(10)	(81)
Deferred tax liabilities	(845)	(81)
Net deferred taxes	$ —	$ —

As of December 31, 2020 and 2019, deferred tax assets represent the deferred taxes attributable to the Company following the Separation.

(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 2020 and 2019, 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 as if the Company was a standalone entity for all periods presented. 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, 2020. 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, 2020:

	Amount	Expiration
Federal net operating losses	$ 49,610	No expiration
State net operating losses	$ 50,480	2039 – 2040
Foreign net operating losses	$ 900	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. The Company determined that its experienced ownership changes, as defined by the Act, during the 2008, 2014 and 2016 tax years as a result of past financings; accordingly, the Company's ability to utilize the aforementioned carryforwards will be limited. 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 will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2020, 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

A Non-Executive Director of the Company's Irish subsidiary is a Managing Director and a majority shareholder of HiTech Health Ltd ("HiTech Health") a consultancy firm for the biotech, pharmaceutical and medical device industry. Since 2016, HiTech Health has provided the Company with certain consulting services and in November 2017 both parties entered into a Service Agreement to engage in both regulatory and supply chain project support and consultancy. In consideration for such services, the Company recorded $154 and $171 of expenses for the years ended December 31, 2020 and 2019, respectively. A portion of the amount relates to consultancy services provided by the Non-Executive Director.

Recro became a related party to the Company following the Separation. As part of the Separation, the Company entered into a transition services agreement with Recro. Under the transition services agreement, the Company provided certain services to Recro, each related to corporate functions, which were charged to Recro. Additionally, Recro may incur expenses that are directly related to the Company after the Separation, which are billed to the Company. For the years ended December 31, 2020 and 2019, for periods subsequent to the Separation, the Company recorded income of $1,964 and $206, respectively, related to the transition services agreement, which is recorded as a reduction in general and administrative expenses. The Company recorded a net payable of $52 for activities with Recro as of December 31, 2020 and a net receivable of $273 as of December 31, 2019.

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

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

(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 match100% 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, 2020 and 2019 were $628 and $307, respectively.

Exhibit 4.10

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

Baudax Bio, Inc. (the "Company") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The Company's common stock, par value $0.01 per share ("Common Stock") is registered under Section 12(b) of the Exchange Act. The following description of our Common Stock is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our amended and restated articles of incorporation ("Articles of Incorporation") and amended and restated bylaws ("Bylaws") each of which is incorporated by reference as an exhibit to our Annual Report on Form 10-K filed with the SEC on February 16, 2021. We encourage you to read our Articles of Incorporation, Bylaws and the applicable provisions of the Pennsylvania Business Corporation Law ("PBCL"), for additional information.

References to "Baudax," "we," and the "Company" herein are, unless the context otherwise indicates, only to Baudax Bio, Inc. and not to any of its subsidiaries.

Common Stock

Authorized Capital Stock: Our authorized capital stock consists of 110,000,000 shares, 100,000,000 of which are designated as Common Stock and 10,000,000 of which are designated as undesignated preferred stock with a par value of $0.01 ("Preferred Stock"). Shares of our Common Stock have the following rights, preferences and privileges:

Voting Rights: Holders of our Common Stock are entitled to one vote for each share held on all matters submitted to a vote of shareholders, including the election of directors, and do not have cumulative voting rights. Directors are elected by a plurality of the votes cast.

Dividends: Subject to preferences that may be applicable to any then-outstanding shares of Preferred Stock, holders of our Common Stock may be entitled to receive ratably dividends when, as, and if declared by our board of directors out of funds legally available therefor, subject to any preferential dividend rights of outstanding Preferred Stock. In the event of our liquidation, dissolution, or winding up, holders of our Common Stock will be entitled to ratably receive the net assets of our company available after the payments of all debts and other liabilities and subject to the prior rights of the holders of any then-outstanding shares of Preferred Stock.

No Preemptive or Similar Rights: Holders of our Common Stock have no preemptive, subscription, redemption or conversion rights.

Transfer Agent and Registrar: The transfer agent and registrar for our Common Stock is Broadridge Corporate Issuer Solutions, Inc.

Listing: Our Common Stock is listed on the Nasdaq Capital Market under the symbol "BXRX."

Preferred Stock

Our board of directors has the authority, without further action by our shareholders, to issue up to 10,000,000 shares of Preferred Stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the dividend, voting and other rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding. Our board of directors may authorize the issuance of Preferred Stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our Common Stock. The issuance of Preferred Stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control and may adversely affect the market price of the Common Stock and the voting and other rights of the holders of our Common Stock.

We have no current plans to issue any shares of Preferred Stock.

Anti-Takeover Effects of Our Articles of Incorporation and Our Bylaws

Provisions of our Articles of Incorporation and Bylaws may delay or discourage transactions involving an actual or potential change of control or change in our management, including transactions in which shareholders might otherwise receive a premium for their shares, or transactions that our shareholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our Common Stock. Among other things, our Articles of Incorporation and Bylaws:

- 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, the chief executive officer or the 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 directors;
- provide that shareholders may only act at a duly organized meeting;
- provide that certain provisions of the amended and restated articles of incorporation may only be amended with the affirmative vote of 66 2/3% of the holders of the outstanding shares of capital stock; 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.

Our Articles of Incorporation also 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 the PBCL, or (iv) any action asserting a claim peculiar to the relationships among or between our company and our officers, directors and shareholders.

The exclusive forum provision described above is intended to apply to the fullest extent permitted by law, including to actions arising under the Securities Act of 1933, as amended (the "Securities Act") or the Exchange Act. However, the enforceability of exclusive forum provisions in the governing documents of other companies has been challenged in legal proceedings, and it is possible that a court could find our forum selection provision to be inapplicable or unenforceable with respect to actions arising under the Securities Act or the Exchange Act. Even if it is accepted that our exclusive forum provision applies to actions arising under the Securities Act, shareholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

Anti-Takeover Provisions under Pennsylvania Law

Pennsylvania Anti-Takeover Law

Provisions of the PBCL applicable to us provide, among other things, that:

- we may not engage in a business combination with an "interested shareholder," generally defined as a holder of 20% of a corporation's voting stock, during the five-year period after the interested shareholder became such except under certain specified circumstances;
- holders of our Common Stock may object to a "control transaction" involving us (a control transaction is defined as the acquisition by a person or group of persons acting in concert of at least 20% of the outstanding voting stock of a corporation), and demand that they be paid a cash payment for the "fair value" of their shares from the "controlling person or group";
- holders of "control shares" will not be entitled to voting rights with respect to any shares in excess of specified thresholds, including 20% voting control, until the voting rights associated with such shares are restored by the affirmative vote of a majority of disinterested shares and the outstanding voting shares of the Company; and
- any "profit," as defined, realized by any person or group who is or was a "controlling person or group" with respect to us from the disposition of any equity securities of within 18 months after the person or group became a "controlling person or group" shall belong to and be recoverable by us.

Pennsylvania-chartered corporations may exempt themselves from these and other anti-takeover provisions. Our Articles of Incorporation do not provide for exemption from the applicability of these or other anti-takeover provisions in the PBCL.

The provisions noted above may have the effect of discouraging a future takeover attempt that is not approved by our board of directors but which individual shareholders may consider to be in their best interests or in which shareholders may receive a substantial premium for their shares over the then current market price. As a result, shareholders who might wish to participate in such a transaction may not have an opportunity to do so. The provisions may make the removal of our board of directors or management more difficult. Furthermore, such provisions could result our company being deemed less attractive to a potential acquiror and/or could result in our shareholders receiving a lesser amount of consideration for their shares of our Common Stock than otherwise could have been available either in the market generally and/or in a takeover.

Exhibit 10.34

STOCK OPTION AWARD AGREEMENT

UNDER THE BAUDAX BIO, INC.
2019 EQUITY INCENTIVE PLAN

THIS STOCK OPTION AWARD AGREEMENT (this "Agreement") is made by Baudax Bio, Inc. (the "Company") and the participant named on the grant schedule attached hereto (the "Grantee").

RECITALS

WHEREAS, the Company desires to award a stock option to the Grantee under the Baudax Bio, Inc. 2019 Equity Incentive Plan (the "Plan"), pursuant to the terms of this Agreement.

NOW, THEREFORE, in consideration of these premises and the agreements set forth herein, the parties, intending to be legally bound hereby, agree as follows:

1. Grant Schedule. Certain terms of this Nonqualified Option are set forth on the grant schedule attached hereto (the "Grant Schedule"), which Grant Schedule constitutes a part of this Agreement.

2. Grant of an Option. On the grant date set forth on the Grant Schedule (the "Grant Date") and pursuant to the Plan, the Company has awarded to the Grantee a Nonqualified Option to purchase the number of shares of Common Stock set forth on the Grant Schedule, subject to the restrictions and on the terms and conditions set forth in this Agreement and the Plan (the "Option"). The terms of the Plan are hereby incorporated into this Agreement by this reference, as though fully set forth herein. Capitalized terms used but not defined herein will have the same meaning as defined in the Plan.

3. Vesting.

(a) Subject to the further provisions of this Agreement, the Option will vest and become exercisable as set forth on the Grant Schedule.

(b) For purposes of any service-based portions of the vesting schedule applicable to the Option, service with the Company will be deemed to include service with any Affiliate of the Company (for only so long as such entity remains an Affiliate).

(c) Neither the Plan nor this Option will confer upon the Grantee any right to continue in employment or service with the Company or any of its Affiliates, or limit in any respect the right of the Company or its Affiliates to discharge the Grantee at any time, with or without cause and with or without notice.

(d) If the Grantee goes on a leave of absence, the Company may adjust any service-based portions of vesting schedule applicable to the Option in accordance with the terms of such leave. Except as provided in the preceding sentence, service will be deemed to continue while the Grantee is on a bona fide leave of absence, if (i) such leave was approved by the Company in writing and (ii) continued crediting of service for such purpose is expressly required by the terms of such leave or by applicable law. Service will be deemed to terminate when such leave ends, unless the Grantee then immediately returns to active work.

4. Transferability. The Option is not transferable or assignable other than by will or by the laws of descent and distribution. Any other attempt to transfer the Option, whether voluntary or involuntary, by operation of law or otherwise, will be ineffective. During the Grantee's lifetime, the Option is exercisable only by the Grantee. Subject to the foregoing and the terms of the Plan, the terms and conditions of the Option will be binding upon the Grantee's executors, administrators and heirs.

5. Expiration.

(a) *Unvested Portion of Option*. In the event of the Grantee's termination of service with the Company, any unvested portion of the Option will be forfeited immediately and automatically, without any action on the part of the Company.

(b) *Vested Portion of Option*. The Grantee's right to exercise any vested portion of the Option shall expire on the earliest to occur of the following:

i. immediately upon the termination of the Grantee's service with the Company for Cause, as described in Section 7(e)(iv) of the Plan;

ii. one year after termination of the Grantee's service with the Company due to death or Disability;

iii. three months after termination of the Grantee's service with the Company for any other reason; or

iv. the tenth anniversary of the Grant Date.

6. Exercise of Option.

(a) To exercise any vested portion of the Option, the Grantee must (i) provide the Company with written notice of the Grantee's intention to exercise the Option and the number of Option Shares (which must be a whole number) that the Grantee intends to acquire, and (ii) deliver a check for the Option Price (as set forth on the Grant Schedule) multiplied by the number of Option Shares being acquired. As an alternative to delivering a check the Grantee may choose to exercise any vested portion of the Option hereunder on a "cashless" basis. Under this method, the Grantee does not have to remit the Option Price in cash. Instead, the Option Price is paid by reducing the number of Option Shares otherwise issuable to the Grantee upon exercise by such number of Option Shares having a Fair Market Value (determined at the time of exercise) equal to the Option Price. The Board may also approve a different method of exercise in accordance with Section 7 of the Plan.

(b) In addition, any exercise of this Option will be conditioned on the Grantee making arrangements satisfactory to the Company to satisfy any tax withholding obligations arising in connection with such exercise.

(c) The Option may not be exercised, and any purported exercise will be void, if the issuance of Common Stock upon such exercise would constitute a violation of any law, regulation or exchange listing requirement. The Board may from time to time modify the terms of the Option or impose additional conditions on the exercise of the Option as it deems necessary or appropriate to facilitate compliance with any law, regulation or exchange listing requirement. As a further condition to the exercise of the Option, the Company may require the Grantee to make any representation or warranty as may be required by or advisable under any applicable law or regulation.

7. Issuance of Shares.

(a) Upon exercise of all or a portion of the Option, the Company shall issue to the Grantee, either by book-entry registration or issuance of a stock certificate or certificates, the applicable number of shares of Common Stock. Any shares of Common Stock issued to the Grantee hereunder shall be fully paid and non-assessable.

(b) The Grantee will not be deemed for any purpose to be, or have rights as, a stockholder of the Company by virtue of the grant of the Option, unless and until the Grantee has exercised the Option and shares of Common Stock are issued in respect thereof. Upon the issuance of a stock certificate or the making of an appropriate book entry on the books of the transfer agent, the Grantee will have all of the rights of a stockholder.

8. Applicable Policies. In consideration for the grant of this Option, the Grantee agrees to be subject to any policies of the Company and its Affiliates regarding clawbacks, securities trading and hedging or pledging of securities that may be in effect from time to time.

9. Change in Control. Notwithstanding anything to the contrary set forth herein and without limiting the authority of the Board to take additional or different actions under the Plan, upon or immediately prior to (but contingent upon the occurrence of) a Change in Control the Board may, in its sole and absolute discretion and without the need for the Grantee's consent, cancel the Option in exchange for cash and/or other substitute consideration (which cash or substitute consideration may be subject to vesting on the same basis as the Option) with a value equal to (A) the number of Option Shares, multiplied by (B) the amount, if any, by which the Fair Market Value on the date of the Change in Control exceeds the Option Price; provided, that if the Fair Market Value on the date of the Change in Control does not exceed the Option Price, the Board may cancel the Option without any payment of consideration therefor.

10. Delays or Omissions. No delay or omission to exercise any right, power or remedy accruing to any party hereto upon any breach or default of any party under this Agreement, will impair any such right, power or remedy of such party, nor will it be construed to be a waiver of any such breach or default, or an acquiescence therein, or of any similar breach or default thereafter occurring, nor will any waiver of any single breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. Any waiver, permit, consent or approval of any kind or character of any breach or default under this Agreement, or any waiver on the part of any party of any provisions or conditions of this Agreement, must be in a writing signed by such party and will be effective only to the extent specifically set forth in such writing.

11. Tax Consequences. The Grantee acknowledges that the Company has not advised the Grantee regarding the tax treatment of the Option and that the Company does not guarantee any particular tax treatment.

12. The Plan. The Grantee acknowledges that the Grantee has received a copy of the Plan, has read the Plan and is familiar with its terms, and accepts the Option subject to all of the terms and provisions of the Plan. Pursuant to the Plan, the Board is authorized to interpret this Agreement and the Plan and to adopt rules and regulations not inconsistent with the Plan as it deems appropriate. The Grantee agrees to accept as binding, conclusive and final all decisions or interpretations of the Board upon any questions arising under this Agreement or the Plan.

13. Electronic Delivery of Documents. The Grantee authorizes the Company to deliver electronically any prospectuses or other documentation related to this Option, the Plan and any other compensation or benefit plan or arrangement in effect from time to time (including, without limitation, reports, proxy statements or other documents that are required to be delivered to participants in such plans or arrangements pursuant to federal or state laws, rules or regulations). For this purpose, electronic delivery will include, without limitation, delivery by means of e-mail or e-mail notification that such documentation is available on the Company's Intranet site. Upon written request, the Company will provide to the Grantee a paper copy of any document also delivered to the Grantee electronically. The authorization described in this paragraph may be revoked by the Grantee at any time by written notice to the Company.

14. Entire Agreement. This Agreement, including terms of the Grant Schedule and Plan incorporated herein, contains the parties' entire agreement regarding the Option evidenced hereby and merges and supersedes all prior and contemporaneous discussions, agreements and understandings of every nature relating thereto.

15. Governing Law. This Agreement and all claims or causes of action (whether in contract or tort) that may be based upon, arise out of or relate to this Agreement or the negotiation, execution or performance of this Agreement shall be governed by, and enforced in accordance with, the laws of the Commonwealth of Pennsylvania, without regard to the application of the principles of conflicts of laws.

BAUDAX BIO, INC.

By:

Exhibit 10.35

Award Agreement for
Restricted Stock Units under the Baudax Bio, Inc.
2019 Equity Incentive Plan

THIS AWARD AGREEMENT FOR RESTRICTED STOCK UNITS (this "Agreement") is made by Baudax Bio, Inc. (the "Company") to the participant named on the grant schedule attached hereto (the "Grantee"), dated as of the date set forth on the grant schedule attached hereto (the "Grant Date").

RECITALS

WHEREAS, the Company desires to award Restricted Stock Units to the Grantee under the Baudax Bio, Inc. 2019 Equity Incentive Plan (the "Plan"), pursuant to the terms of this Agreement.

NOW, THEREFORE, in consideration of these premises and the agreements set forth herein, the parties, intending to be legally bound hereby, agree as follows:

1. Grant Schedule. Certain terms of the grant of Restricted Stock Units are set forth on the grant schedule (the "Grant Schedule") that is attached to, and is a part of, this Agreement.

2. Grant of Restricted Stock Units. As of the Grant Date, pursuant to the Plan, the Company hereby awards to the Grantee the number of Restricted Stock Units set forth on the Grant Schedule (the "Award"), subject to the restrictions and on the terms and conditions set forth in this Agreement and the Plan. The terms of the Plan are hereby incorporated into this Agreement by this reference, as though fully set forth herein. Capitalized terms used but not defined herein will have the same meaning as defined in the Plan.

3. Grant Date. The Grant Date of the Restricted Stock Units is set forth on the Grant Schedule.

4. Vesting. Subject to the further provisions of this Agreement, the Restricted Stock Units will vest as set forth on the Grant Schedule (each date on which Restricted Stock Units vest being referred to as a "Vesting Date").

5. Transferability. The Restricted Stock Units are not transferable or assignable otherwise than by will or by the laws of descent and distribution. Any attempt to transfer Restricted Stock Units, whether by transfer, pledge, hypothecation or otherwise and whether voluntary or involuntary, by operation of law or otherwise, will not vest the transferee with any interest or right in or with respect to such Restricted Stock Units.

6. Termination of Employment or Service. In the event of the Grantee's termination of service with the Company and its Affiliates, all then unvested Restricted Stock Units (determined after giving effect to any accelerated vesting occurring in connection with such termination under the terms of the Grant Schedule, if any) will be forfeited.

7. Issuance of Shares.

a. Within thirty (30) days following each Vesting Date (including any accelerated vesting date provided in the Grant Schedule), the Company shall issue to the Grantee, either by book-entry registration or issuance of a stock certificate or certificates, a number of shares of Common Stock equal to the number of Restricted Stock Units granted hereunder that have vested as of such date. Any shares of Common Stock issued to the Grantee hereunder shall be fully paid and non-assessable.

b. The Grantee will not be deemed for any purpose to be, or have rights as, a stockholder of the Company by virtue of the grant of Restricted Stock Units, until shares of Common Stock are issued in settlement of such Restricted Stock Units pursuant to Section 7.a hereof. Upon the issuance of a stock certificate or the making of an appropriate book entry on the books of the transfer agent, the Grantee will have all of the rights of a stockholder.

c. In consideration for the grant of this Award, the Grantee agrees to be subject to any policies of the Company and its Affiliates regarding clawbacks, securities trading and hedging or pledging of securities that may be in effect from time to time.

8. Delays or Omissions. No delay or omission to exercise any right, power or remedy accruing to any party hereto upon any breach or default of any party under this Agreement, will impair any such right, power or remedy of such party, nor will it be construed to be a waiver of any such breach or default, or an acquiescence therein, or of any similar breach or default thereafter occurring, nor will any waiver of any single breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. Any waiver, permit, consent or approval of any kind or character of any breach or default under this Agreement, or any waiver on the part of any party of any provisions or conditions of this Agreement, must be in a writing signed by such party and will be effective only to the extent specifically set forth in such writing.

9. Withholding. In accordance with Section 15 of the Plan, the Company reserves the right to (i) withhold, in accordance with any applicable laws, from any consideration payable or property transferable to Grantee, or (ii) require the Grantee to remit to the Company an amount sufficient to satisfy, any taxes required to be withheld by federal, state or local law as a result of the grant or vesting of this Award or other disposition of the shares.

10. Right of Discharge Preserved. The grant of Restricted Stock Units hereunder will not confer upon the Grantee any right to continue in service with the Company or any of its subsidiaries or Affiliates.

11. The Plan. By accepting this Award, the Grantee acknowledges that the Grantee has received a copy of the Plan, has read the Plan and is familiar with its terms, and accepts the Restricted Stock Units subject to all of the terms and provisions of the Plan, as amended from time to time. Pursuant to the Plan, the Board or its committee is authorized to interpret the Plan and to adopt rules and regulations not inconsistent with the Plan as it deems appropriate. By accepting this Award, the Grantee acknowledges and agrees to accept as binding, conclusive and final all decisions or interpretations of the Board or its committee upon any questions arising under the Plan.

12. Governing Law. This Agreement and all claims or causes of action (whether in contract or tort) that may be based upon, arise out of or relate to this Agreement or the negotiation, execution or performance of this Agreement shall be governed by, and enforced in accordance with, the laws of the Commonwealth of Pennsylvania, without regard to the application of the principles of conflicts of laws.

13. Electronic Delivery of Documents. The Grantee authorizes the Company to deliver electronically any prospectuses or other documentation related to this Award, the Plan and any other compensation or benefit plan or arrangement in effect from time to time including, without limitation, reports, proxy statements or other documents that are required to be delivered to participants in such plans or arrangements pursuant to federal or state laws, rules or regulations). For this purpose, electronic delivery will include, without limitation, delivery by means of e-mail or e-mail notification that such documentation is available on the Company's Intranet site. Upon written request, the Company will provide to the Grantee a paper copy of any document also delivered to the Grantee electronically. The authorization described in this paragraph may be revoked by the Grantee at any time by written notice to the Company.

The Award is made by the Company as of the date stated in the introductory paragraph.

BAUDAX BIO, INC.

By:

Exhibit 10.36

Award Agreement for
Performance-Based Restricted Stock Units under the Baudax Bio, Inc.
2019 Equity Incentive Plan

THIS AWARD AGREEMENT FOR PERFORMANCE-BASED RESTRICTED STOCK UNITS (this "Agreement") is made by Baudax Bio, Inc. (the "Company") to the participant named on the grant schedule attached hereto (the "Grantee").

RECITALS

WHEREAS, the Company desires to award Performance-Based Restricted Stock Units to the Grantee under the Baudax Bio, Inc. 2019 Equity Incentive Plan (the "Plan") pursuant to the terms of this Agreement.

NOW, THEREFORE, in consideration of these premises and the agreements set forth herein, the parties, intending to be legally bound hereby, agree as follows:

1. Grant Schedule. Certain terms of the grant of Performance-Based Restricted Stock Units are set forth on the grant schedule (the "Grant Schedule") that is attached to, and is a part of, this Agreement.

2. Grant of Performance-Based Restricted Stock Units. Pursuant to the Plan, the Company hereby awards to the Grantee the number of Performance-Based Restricted Stock Units set forth on the Grant Schedule (the "Award"), subject to the restrictions and on the terms and conditions set forth in this Agreement. The terms of the Plan are hereby incorporated into this Agreement by this reference, as though fully set forth herein. Capitalized terms used but not defined herein will have the same meanings as defined in the Plan.

3. Grant Date. The Award is effective as of the Grant Date set forth on the Grant Schedule.

4. Vesting. Subject to the further provisions of this Agreement, the Performance-Based Restricted Stock Units will vest as set forth on the Grant Schedule. For this purpose, service with the Company will be deemed to include service with Affiliates for the period of such affiliation.

5. Transferability. The Performance-Based Restricted Stock Units are not transferable or assignable otherwise than by will or by the laws of descent and distribution. Any attempt to transfer Performance-Based Restricted Stock Units, whether by transfer, pledge, hypothecation or otherwise and whether voluntary or involuntary, by operation of law or otherwise, will not vest the transferee with any interest or right in or with respect to such Performance-Based Restricted Stock Units.

6. Termination of Employment or Service. Unless otherwise provided on the Grant Schedule, if the Grantee's termination of service with the Company ceases for any reason, all then unvested Performance-Based Restricted Stock Units (determined after giving effect to any accelerated vesting occurring in connection with such termination) will be forfeited.

7. Settlement.

a. In the event that the Company is required to settle all or a portion of this Award in accordance with the terms of the Grant Schedule, the Company shall issue to the Grantee, either by book-entry registration or issuance of a stock certificate or certificates, a number of shares of Common Stock equal to the applicable number of Performance-Based Restricted Stock Units then being settled. Any shares of Common Stock issued to the Grantee hereunder shall be fully paid and non-assessable.

b. The Grantee will not be deemed for any purpose to be, or have rights as, a stockholder of the Company by virtue of the grant of Performance-Based Restricted Stock Units, unless and until shares of Common Stock

are issued in settlement of such Performance-Based Restricted Stock Units pursuant to Section 7.a hereof. Upon the issuance of a stock certificate or the making of an appropriate book entry on the books of the transfer agent, the Grantee will have all of the rights of a stockholder.

c. In consideration for the grant of this Award, the Grantee agrees to be subject to any policies of the Company and its Affiliates regarding clawbacks, securities trading and hedging or pledging of securities that may be in effect from time to time.

8. Delays or Omissions. No delay or omission to exercise any right, power or remedy accruing to any party hereto upon any breach or default of any party under this Agreement, will impair any such right, power or remedy of such party, nor will it be construed to be a waiver of any such breach or default, or an acquiescence therein, or of any similar breach or default thereafter occurring, nor will any waiver of any single breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. Any waiver, permit, consent or approval of any kind or character of any breach or default under this Agreement, or any waiver on the part of any party of any provisions or conditions of this Agreement, must be in a writing signed by such party and will be effective only to the extent specifically set forth in such writing.

9. Withholding. In accordance with Section 15 of the Plan, the Company reserves the right to (i) withhold, in accordance with any applicable laws, from any consideration payable or property transferable to Grantee, or (ii) require the Grantee to remit to the Company an amount sufficient to satisfy, any taxes required to be withheld by federal, state or local law as a result of the grant or vesting of this Award or other disposition of the shares.

10. Tax Consequences. This Award is intended to be exempt from Section 409A of the Code and should be interpreted accordingly. Nonetheless, the Company does not guarantee the tax treatment of this Award.

11. Right of Discharge Preserved. The grant of Performance-Based Restricted Stock Units hereunder will not confer upon the Grantee any right to continue in service with the Company or any of its subsidiaries or Affiliates.

12. The Plan. By accepting this Award, the Grantee acknowledges that the Grantee has received a copy of the Plan, has read the Plan and is familiar with its terms, and accepts the Performance-Based Restricted Stock Units subject to all of the terms and provisions of the Plan, as amended from time to time. Pursuant to the Plan, the Board is authorized to interpret the Plan and to adopt rules and regulations not inconsistent with the Plan as it deems appropriate. By accepting this Award, the Grantee acknowledges and agrees to accept as binding, conclusive and final all decisions or interpretations of the Board upon any questions arising under the Plan.

13. Governing Law. This Agreement and all claims or causes of action (whether in contract or tort) that may be based upon, arise out of or relate to this Agreement or the negotiation, execution or performance of this Agreement shall be governed by, and enforced in accordance with, the laws of the Commonwealth of Pennsylvania, without regard to the application of the principles of conflicts of laws.

14. Electronic Delivery of Documents. The Grantee authorizes the Company to deliver electronically any prospectuses or other documentation related to this Award, the Plan and any other compensation or benefit plan or arrangement in effect from time to time including, without limitation, reports, proxy statements or other documents that are required to be delivered to participants in such plans or arrangements pursuant to federal or state laws, rules or regulations). For this purpose, electronic delivery will include, without limitation, delivery by means of e-mail or e-mail notification that such documentation is available on the Company's Intranet site. Upon written request, the Company will provide to the Grantee a paper copy of any document also delivered to the Grantee electronically. The authorization described in this paragraph may be revoked by the Grantee at any time by written notice to the Company.

BAUDAX BIO, INC.

By:

Exhibit 10.37

INDUCEMENT AWARD AGREEMENT FOR STOCK OPTIONS

THIS INDUCEMENT AWARD AGREEMENT FOR STOCK OPTIONS (this "Agreement") is made by Baudax Bio, Inc. (the "Company") and the participant named on the grant schedule attached hereto (the "Grantee").

RECITALS

WHEREAS, the Company desires to award a stock option, pursuant to the terms of this Agreement, as an inducement to the Grantee's acceptance of the Company's offer of employment.

NOW, THEREFORE, in consideration of these premises and the agreements set forth herein, the parties, intending to be legally bound hereby, agree as follows:

1. Grant Schedule. Certain terms of this Nonqualified Option are set forth on the grant schedule attached hereto (the "Grant Schedule"), which Grant Schedule constitutes a part of this Agreement.

2. Grant of an Option. On the grant date set forth on the Grant Schedule (the "Grant Date"), the Company has awarded to the Grantee a nonqualified stock option to purchase the number of shares of Common Stock set forth on the Grant Schedule, subject to the restrictions and on the terms and conditions set forth in this Agreement (the "Option"). This Award constitutes a non-plan "inducement award" as contemplated by NASDAQ Listing Rule 5635(c)(4) and is therefore not made pursuant to the Baudax Bio, Inc. 2019 Equity Incentive Plan (the "Plan"). Nonetheless, the terms and provisions of the Plan are hereby incorporated into this Agreement by this reference, as though fully set forth herein, as if this Award was granted pursuant to the Plan. Capitalized terms used but not defined herein will have the same meaning as defined in the Plan. A copy of the Plan has been provided to the Grantee along with this Agreement.

3. Vesting.

(a) Subject to the further provisions of this Agreement, the Option will vest and become exercisable as set forth on the Grant Schedule.

(b) For purposes of any service-based portions of the vesting schedule applicable to the Option, service with the Company will be deemed to include service with any Affiliate of the Company (for only so long as such entity remains an Affiliate).

(c) The grant of this Option will not confer upon the Grantee any right to continue in employment or service with the Company or any of its Affiliates, or limit in any respect the right of the Company or its Affiliates to discharge the Grantee at any time, with or without cause and with or without notice.

(d) If the Grantee goes on a leave of absence, the Company may adjust any service-based portions of vesting schedule applicable to the Option in accordance with the terms of such leave. Except as provided in the preceding sentence, service will be deemed to continue while the Grantee is on a bona fide leave of absence, if (i) such leave was approved by the Company in writing and (ii) continued crediting of service for such purpose is expressly required by the terms of such leave or by applicable law. Service will be deemed to terminate when such leave ends, unless the Grantee then immediately returns to active work.

4. Transferability. The Option is not transferable or assignable other than by will or by the laws of descent and distribution. Any other attempt to transfer the Option, whether voluntary or involuntary, by operation of law or otherwise, will be ineffective. During the Grantee's lifetime, the Option is exercisable only by the Grantee. Subject to the foregoing and the terms of the Plan, the terms and conditions of the Option will be binding upon the Grantee's executors, administrators and heirs.

5. Expiration.

(a) *Unvested Portion of Option*. In the event of the Grantee's termination of service with the Company, any unvested portion of the Option will be forfeited immediately and automatically, without any action on the part of the Company.

(b) *Vested Portion of Option*. The Grantee's right to exercise any vested portion of the Option shall expire on the earliest to occur of the following:

i. immediately upon the termination of the Grantee's service with the Company for Cause, as described in Section 7(e)(iv) of the Plan;

ii. one year after termination of the Grantee's service with the Company due to death or Disability;

iii. three months after termination of the Grantee's service with the Company for any other reason; or

iv. the tenth anniversary of the Grant Date.

6. Exercise of Option.

(a) To exercise any vested portion of the Option, the Grantee must (i) provide the Company with written notice of the Grantee's intention to exercise the Option and the number of Option Shares (which must be a whole number) that the Grantee intends to acquire, and (ii) deliver a check for the Option Price (as set forth on the Grant Schedule) multiplied by the number of Option Shares being acquired. As an alternative to delivering a check the Grantee may choose to exercise any vested portion of the Option hereunder on a "cashless" basis. Under this method, the Grantee does not have to remit the Option Price in cash. Instead, the Option Price is paid by reducing the number of Option Shares otherwise issuable to the Grantee upon exercise by such number of Option Shares having a Fair Market Value (determined at the time of exercise) equal to the Option Price. The Board may also approve a different method of exercise in accordance with Section 7 of the Plan.

(b) In addition, any exercise of this Option will be conditioned on the Grantee making arrangements satisfactory to the Company to satisfy any tax withholding obligations arising in connection with such exercise.

(c) The Option may not be exercised, and any purported exercise will be void, if the issuance of Common Stock upon such exercise would constitute a violation of any law, regulation or exchange listing requirement. The Board may from time to time modify the terms of the Option or impose additional conditions on the exercise of the Option as it deems necessary or appropriate to facilitate compliance with any law, regulation or exchange listing requirement. As a further condition to the exercise of the Option, the Company may require the Grantee to make any representation or warranty as may be required by or advisable under any applicable law or regulation.

7. Issuance of Shares.

(a) Upon exercise of all or a portion of the Option, the Company shall issue to the Grantee, either by book-entry registration or issuance of a stock certificate or certificates, the applicable number of shares of Common Stock. Any shares of Common Stock issued to the Grantee hereunder shall be fully paid and non-assessable.

(b) The Grantee will not be deemed for any purpose to be, or have rights as, a stockholder of the Company by virtue of the grant of the Option, unless and until the Grantee has exercised the Option and shares of Common Stock are issued in respect thereof. Upon the issuance of a stock certificate or the making of an appropriate book entry on the books of the transfer agent, the Grantee will have all of the rights of a stockholder.

8. Applicable Policies. In consideration for the grant of this Option, the Grantee agrees to be subject to any policies of the Company and its Affiliates regarding clawbacks, securities trading and hedging or pledging of securities that may be in effect from time to time.

9. Change in Control. Notwithstanding anything to the contrary set forth herein and without limiting the authority of the Board to take additional or different actions as set forth in the Plan, upon or immediately prior to (but contingent upon the occurrence of) a Change in Control the Board may, in its sole and absolute discretion and without the need for the Grantee's consent, cancel the Option in exchange for cash and/or other substitute consideration (which cash or substitute consideration may be subject to vesting on the same basis as the Option) with a value equal to (A) the number of Option Shares, multiplied by (B) the amount, if any, by which the Fair Market Value on the date of the Change in Control exceeds the Option Price; provided, that if the Fair Market Value on the date of the Change in Control does not exceed the Option Price, the Board may cancel the Option without any payment of consideration therefor.

10. Delays or Omissions. No delay or omission to exercise any right, power or remedy accruing to any party hereto upon any breach or default of any party under this Agreement, will impair any such right, power or remedy of such party, nor will it be construed to be a waiver of any such breach or default, or an acquiescence therein, or of or in any similar breach or default thereafter occurring, nor will any waiver of any single breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. Any waiver, permit, consent or approval of any kind or character by any party of any breach or default under this Agreement, or any waiver on the part of any party or any provisions or conditions of this Agreement, must be in a writing signed by such party and will be effective only to the extent specifically set forth in such writing.

11. Tax Consequences. The Grantee acknowledges that the Company has not advised the Grantee regarding the tax treatment of the Option and that the Company does not guarantee any particular tax treatment.

12. Administration. The Grantee acknowledges that the Grantee has received a copy of the Plan, has read the Plan and is familiar with its terms, and accepts the Option subject to all of the terms and provisions of the Plan. The Board or any committee thereof is hereby authorized to interpret this Agreement and the Plan and to adopt such rules and regulations for the administration of this Option as it deems appropriate. By accepting this Award, the Grantee acknowledges and agrees to accept as binding, conclusive and final all decisions or interpretations of the Board or its committee upon any questions arising under this Agreement.

13. Electronic Delivery of Documents. The Grantee authorizes the Company to deliver electronically any prospectuses or other documentation related to this Option and any other compensation or benefit plan or arrangement in effect from time to time (including, without limitation, reports, proxy statements or other documents that are required to be delivered to participants in such arrangements pursuant to federal or state laws, rules or regulations). For this purpose, electronic delivery will include, without limitation, delivery by means of e-mail or e-mail notification that such documentation is available on the Company's Intranet site. Upon written request, the Company will provide to the Grantee a paper copy of any document also delivered to the Grantee electronically. The authorization described in this paragraph may be revoked by the Grantee at any time by written notice to the Company.

14. Entire Agreement. This Agreement, including terms of the Grant Schedule and Plan incorporated herein, contains the parties' entire agreement regarding the Option evidenced hereby and merges and supersedes all prior and contemporaneous discussions, agreements and understandings of every nature relating thereto.

15. Governing Law. This Agreement and all claims or causes of action (whether in contract or tort) that may be based upon, arise out of or relate to this Agreement or the negotiation, execution or performance of this Agreement shall be governed by, and enforced in accordance with, the laws of the Commonwealth of Pennsylvania, without regard to the application of the principles of conflicts of laws.

BAUDAX BIO, INC.

By:

Exhibit 10.38

INDUCEMENT AWARD AGREEMENT FOR RESTRICTED STOCK UNITS

THIS INDUCEMENT AWARD AGREEMENT FOR RESTRICTED STOCK UNITS (this "Agreement") is made by Baudax Bio, Inc. (the "Company") and the participant named on the grant schedule attached hereto (the "Grantee").

RECITALS

WHEREAS, the Company desires to award Restricted Stock Units to the Grantee, pursuant to the terms of this Agreement, as an inducement to the Grantee's acceptance of the Company's offer of employment.

NOW, THEREFORE, in consideration of these premises and the agreements set forth herein, the parties, intending to be legally bound hereby, agree as follows:

1. Grant Schedule. Certain terms of the grant of Restricted Stock Units are set forth on the grant schedule (the "Grant Schedule") that is attached to, and is a part of, this Agreement.

2. Grant of Restricted Stock Units. On the grant date set forth on the Grant Schedule (the "Grant Date"), the Company hereby awards to the Grantee the number of Restricted Stock Units set forth on the Grant Schedule (the "Award"), subject to the restrictions and on the terms and conditions set forth in this Agreement. This Award constitutes a non-plan "inducement award" as contemplated by NASDAQ Listing Rule 5635(c)(4) and is therefore not made pursuant to the Baudax Bio, Inc. 2019 Equity Incentive Plan (the "Plan"). Nonetheless, the terms and provisions of the Plan are hereby incorporated into this Agreement by this reference, as though fully set forth herein, as if this Award was granted pursuant to the Plan. Capitalized terms used but not defined herein will have the same meaning as defined in the Plan. A copy of the Plan has been provided to the Grantee along with this Agreement.

3. Vesting. Subject to the further provisions of this Agreement, the Restricted Stock Units will vest as set forth on the Grant Schedule (each date on which Restricted Stock Units vest being referred to as a "Vesting Date").

4. Transferability. The Restricted Stock Units are not transferable or assignable otherwise than by will or by the laws of descent and distribution. Any attempt to transfer Restricted Stock Units, whether by transfer, pledge, hypothecation or otherwise and whether voluntary or involuntary, by operation of law or otherwise, will not vest the transferee with any interest or right in or with respect to such Restricted Stock Units.

5. Termination of Employment or Service. In the event of the Grantee's termination of service with the Company and its Affiliates, all then unvested Restricted Stock Units (determined after giving effect to any accelerated vesting occurring in connection with such termination under the terms of the Grant Schedule or otherwise) will be forfeited.

6. Issuance of Shares.

a. Within thirty (30) days following each Vesting Date (including any accelerated Vesting Date occurring under the terms of the Grant Schedule or otherwise), the Company shall issue to the Grantee, either by book-entry registration or issuance of a stock certificate or certificates, a number of Shares equal to the number of Restricted Stock Units granted hereunder that have vested as of such date. Any Shares issued to the Grantee hereunder shall be fully paid and non-assessable.

b. The Grantee will not be deemed for any purpose to be, or have rights as, a stockholder of the Company by virtue of the grant of Restricted Stock Units, until shares of Common Stock are issued in settlement of such Restricted Stock Units pursuant to Section 6.a hereof. Upon the issuance of a stock certificate or the making of an appropriate book entry on the books of the transfer agent, the Grantee will have all of the rights of a stockholder.

7. Applicable Policies. In consideration for the grant of this Award, the Grantee agrees to be subject to any policies of the Company and its Affiliates regarding clawbacks, securities trading and hedging or pledging of securities that may be in effect from time to time.

8. Delays or Omissions. No delay or omission to exercise any right, power or remedy accruing to any party hereto upon any breach or default of any party under this Agreement, will impair any such right, power or remedy of such party, nor will it be construed to be a waiver of any such breach or default, or an acquiescence therein, or of or in any similar breach or default thereafter occurring, nor will any waiver of any single breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. Any waiver, permit, consent or approval of any kind or character by any party of any breach or default under this Agreement, or any waiver on the part of any party or any provisions or conditions of this Agreement, must be in a writing signed by such party and will be effective only to the extent specifically set forth in such writing.

9. Tax Consequences. This Award is intended to be exempt from Section 409A of the Code and should be interpreted accordingly. Nonetheless, the Company does not guarantee the tax treatment of this Award.

10. Right of Discharge Preserved. The grant of Restricted Stock Units hereunder will not confer upon the Grantee any right to continue in service with the Company or any of its subsidiaries or Affiliates.

11. Administration. The Grantee acknowledges that the Grantee has received a copy of the Plan, has read the Plan and is familiar with its terms, and accepts the Restricted Stock Units subject to all of the terms and provisions of the Plan. The Board or any committee thereof is hereby authorized to interpret this Agreement and the Plan and to adopt such rules and regulations for the administration of this Award as it deems appropriate. By accepting this Award, the Grantee acknowledges and agrees to accept as binding, conclusive and final all decisions or interpretations of the Board or its committee upon any questions arising under this Agreement.

12. Electronic Delivery of Documents. The Grantee authorizes the Company to deliver electronically any prospectuses or other documentation related to this Award and any other compensation or benefit plan or arrangement in effect from time to time (including, without limitation, reports, proxy statements or other documents that are required to be delivered to participants in such arrangements pursuant to federal or state laws, rules or regulations). For this purpose, electronic delivery will include, without limitation, delivery by means of e-mail or e-mail notification that such documentation is available on the Company's Intranet site. Upon written request, the Company will provide to the Grantee a paper copy of any document also delivered to the Grantee electronically. The authorization described in this paragraph may be revoked by the Grantee at any time by written notice to the Company.

13. Entire Agreement. This Agreement, including terms of the Grant Schedule and Plan incorporated herein, contains the parties' entire agreement regarding the grant of Restricted Stock Units evidenced hereby and merges and supersedes all prior and contemporaneous discussions, agreements and understandings of every nature relating thereto.

14. Governing Law. This Agreement and all claims or causes of action (whether in contract or tort) that may be based upon, arise out of or relate to this Agreement or the negotiation, execution or performance of this Agreement shall be governed by, and enforced in accordance with, the laws of the Commonwealth of Pennsylvania, without regard to the application of the principles of conflicts of laws.

BAUDAX BIO, INC.

By:

Exhibit 21.1

SUBSIDIARIES OF BAUDAX BIO, INC.

Subsidiary	State or Country of Incorporation
Baudax Bio N.A. LLC	Delaware
Baudax Bio Limited	Ireland

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Baudax Bio, Inc.:

We consent to the incorporation by reference in the registration statements (Nos. 333-235408 and 333-243488) on Form S-3 and in the registration statement (No. 333-235377) on Form S-8 of Baudax Bio, Inc. of our report dated February 16, 2021, with respect to the consolidated balance sheets of Baudax Bio, Inc. as of December 31, 2020 and 2019, the related consolidated and combined statements of operations, shareholders' equity, and cash flows for each of the years then ended, and the related notes, which report appears in the December 31, 2020 annual report on Form 10-K of Baudax Bio, Inc.

Our report dated February 16, 2021 contains an explanatory paragraph that states that Baudax Bio, Inc. has incurred recurring losses and negative cash flows from operations and has an accumulated deficit of $112.3 million as of December 31, 2020 that raise substantial doubt about its ability to continue as a going concern. The consolidated and combined financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KPMG LLP

Philadelphia, Pennsylvania
February 16, 2021

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 16, 2021

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

Exhibit 31.2

CERTIFICATION

I, Ryan D. Lake, 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 16, 2021

/s/ Ryan D. Lake

Ryan D. Lake
Chief Financial Officer
(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, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to such officer's knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 16, 2021

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

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