

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

FORM 10-K

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

For the fiscal year ended December 31, 2019

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
(State or other jurisdiction of
incorporation or organization)

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

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

19355
(Zip Code)

(484) 395-2440

(Registrant's telephone number, including area code)

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

Title of Each Class
Common Stock, par value \$0.01

Trading Symbol
BXRX

Name of Exchange on Which Registered
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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer
Non-accelerated filer

Accelerated filer
Smaller reporting company
Emerging growth company

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

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

The Registrant was not a public company as of the last business day of its most recently completed second fiscal quarter and, therefore, cannot calculate the aggregate market value of its common equity held by non-affiliates as of such date. Prior to November 21, 2019, all of the issued and outstanding shares of common stock of the Registrant were owned by Recro Pharma, Inc.

As of February 11, 2020, there were 9,435,713 shares of common stock outstanding, par value \$0.01 per share.

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 2020 annual meeting of shareholders to be filed no later than 120 days after the end of the registrant's fiscal year ended December 31, 2019.

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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 post-separation relationships with Recro Pharma, Inc., or Recro, third parties, licensors, collaborators and our employees;
- our business and operations following the separation with Recro, and any benefits or costs of the separation with Recro;
- our ability to operate as a standalone company and execute our strategic priorities;
- our estimates regarding expenses, future revenue, capital requirements and timing and availability of and the need for additional financing;
- whether the FDA will approve our amended New Drug Application, or NDA for IV meloxicam and, if approved, the timing of and the labeling under any such approval that we may obtain;
- if the FDA does not approve our amended NDA, the time frame otherwise associated with resolving the deficiencies identified by the FDA in the CRL and whether the FDA will require additional clinical studies to support the approval of IV meloxicam and the time and cost of such studies;
- our ability to successfully commercialize IV meloxicam or our other product candidates, upon regulatory approval;
- our ability to generate sales and other revenues from IV meloxicam or any of our other product candidates, once approved, including, addressing any FDA action related to the meloxicam NDA, setting an acceptable price for and obtaining adequate coverage and reimbursement of such products;
- the results, timing and outcome of our clinical trials of IV meloxicam or our other product candidates, and any future clinical and preclinical studies;
- our ability to raise future financing and attain profitability for continued development of our business and our product candidates and to meet required debt payments, and any milestone payments owing to Alkermes plc, or Alkermes, or our other licensing and collaboration partners;
- 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 CRO’s, and third-party suppliers, manufacturers, 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, including the ongoing securities class action filed against Recro that 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 comply with stringent U.S. and foreign government regulation in the manufacture of pharmaceutical products, including Good Manufacturing Practice, or cGMP, compliance and U.S. Drug Enforcement Agency, or DEA, compliance and other relevant regulatory authorities; and
- 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.

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, such as our lead product candidate, injectable meloxicam, to the hospital and related acute care markets. We believe we can create value for our shareholders through the development, registration and commercialization of injectable meloxicam and our other pipeline product candidates. In addition to our pipeline, we continue to evaluate acquisition, out-licensing and in-licensing opportunities.

Our lead product candidate is a proprietary injectable form of meloxicam, a once a day, preferential COX-2 inhibitor. IV meloxicam has successfully completed three Phase III clinical trials, 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. In July 2017, we submitted an NDA to the FDA for IV meloxicam. In May 2018, we received a CRL from the FDA regarding our NDA for IV meloxicam. In September 2018, we resubmitted the NDA for IV meloxicam and in March 2019, we received a second CRL from the FDA regarding our NDA for IV meloxicam. The second CRL focused on the onset and duration of IV meloxicam. It cited regulatory concerns about the role of IV meloxicam as a monotherapy in acute pain and how IV meloxicam would meet patient and prescriber needs in that setting, given the FDA's interpretation of the clinical trials data. In October 2019 we received written notification from the FDA that our appeal relating to the NDA seeking approval for IV meloxicam has been granted. The FDA's letter states that the appeal was granted and that the NDA provides sufficient evidence of effectiveness and safety to support approval. The letter also states that before IV meloxicam can be approved and legally marketed, agreed upon labeling (prescribing information) must be negotiated with the Division of Anesthesia, Addiction Medicine and Pain Medicine, or Division. In December 2019, we resubmitted the NDA for IV meloxicam and in January 2020, we announced that the FDA has set a PDUFA goal date of February 20, 2020 for its decision on the NDA for IV meloxicam. We intend to work closely with the FDA to determine the best path forward to obtain approval for IV meloxicam.

We believe that IV meloxicam compares favorably to competitive therapies in onset of pain relief, duration of pain relief, extent of pain relief and time to peak analgesic effect as well as that it has been well tolerated. We believe injectable meloxicam, as a non-opioid product, will overcome many of the issues associated with commonly prescribed opioid therapeutics, including respiratory depression, excessive nausea and vomiting, constipation, as well having no addiction potential, while maintaining analgesic, or pain relieving, effects.

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.

Pipeline

Investigational Product	PC	I	II	III	Rights
Meloxicam					WW
IV formulation - Acute, post-operative pain					Filed NDA/Appeal Granted Oct. 2019
IM formulation - Acute pain					
Neuromuscular Blockade Agents (NMBA) (Anesthesia)					WW
IV Intermediate-action (RP1000)					
IV Ultra-short action (RP2000)					
NMBA Reversal (Anesthesia)					WW
RP3000					
Dexmedetomidine ("Dex")					WW, exc. Europe, Turkey, CIS
Dex-IN (intranasal) Peri-procedural pain					
Dex-IN (intranasal) Cancer breakthrough pain					

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 now 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 injectable meloxicam, to the hospital and acute care markets. We believe we can create value for our shareholders through the development, registration and commercialization of injectable meloxicam and 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:

- *Completing regulatory approval of IV meloxicam.* Our key goal is to obtain FDA approval of IV meloxicam.
- *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 are establishing sales management, marketing and reimbursement functions in anticipation of the commercialization of IV meloxicam in the United States and we believe we can utilize these preparations for the successful commercialization of an acquired or licensed product.
- *Expanding data supporting benefits of IV meloxicam* We are currently evaluating the results of IV meloxicam from a Phase IIIb program that included clinical trials in colorectal surgery patients and orthopedic surgery patients.
- *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 Candidate - IV Meloxicam

Meloxicam is a once a day, preferential COX-2 inhibitor that possesses analgesic, anti-inflammatory, and antipyretic activities. Our proprietary injectable form of the drug, 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 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 IV meloxicam 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.

IV Meloxicam Advantages

We believe IV meloxicam 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. IV meloxicam 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. IV meloxicam has demonstrated the potential to be an effective analgesic for up to 24 hours after a single dose in clinical trials. IV 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 IV meloxicam 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. IV meloxicam has demonstrated the potential to relieve serious pain while reducing overall opioid consumption. IV meloxicam also demonstrated a potential greater reduction in opioid use in patients over 65 years old with mild renal impairment in clinical trials.

Commercial Strategy

If IV meloxicam is approved by the FDA, we believe that it 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.

If IV meloxicam is approved by the FDA, we are hoping to generate early commercial experience with IV meloxicam at settings that have lower barriers to new product adoption and have an appetite for use of newer therapies. To accomplish this goal, we believe it is important to educate surgeons (e.g., orthopedic, colorectal and general) and anesthesiologists that practice at multiple settings of care within the acute care market, including ambulatory surgical centers, or ASCs, hospital outpatient departments, and hospitals (often referred to as the “hospital inpatient setting”). We believe that ASCs may have lower barriers to adoption and be willing to consider newer therapies during our launch phase, based on our market research in this sector. We also believe early success in commercializing IV meloxicam with ASC’s could lead to increased adoption of IV meloxicam in hospital outpatient settings, and ultimately hospital inpatient settings.

Overall, we plan to initially target approximately 1,500 hospitals and associated hospital outpatient departments, or HOPDs, and 600 ASCs, which together represent approximately 12.6 million patients across all settings of care. If IV meloxicam is approved by the FDA, we plan to initially build a sales force with approximately 50 representatives who would market IV meloxicam to health care professionals at our called-on institutions. In addition, we have medical, account-based and reimbursement teams. We believe this focused approach will help educate health care professionals, support formulary review processes and generate early adoption after launch with surgeons and anesthesiologists.

Clinical Development

Multiple clinical trials have been conducted to evaluate the safety, pharmacokinetics and analgesic effect of IV meloxicam. Based on the results of these trials, we believe IV meloxicam has the potential to be a potent analgesic used in the management of moderate to severe pain. IV 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 are currently evaluating the results of IV 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 IV meloxicam and after appropriate regulatory and institutional review board, or IRB, review.

At the end of July 2017, we submitted an NDA to the FDA for IV meloxicam 30mg. In May 2018, we received a Complete Response Letter, or CRL, from the FDA regarding our NDA for IV meloxicam, which stated that the FDA determined it could not approve the NDA in its present form. The CRL stated that data from ad hoc analyses and selective secondary endpoints suggest that the analgesic effect did not meet the expectations of the FDA. In addition, the CRL identified certain CMC related questions on extractable and leachable data provided in the NDA. The CRL did not identify any issues relating to the safety of IV meloxicam. In July 2018, we participated in a Type A End-of-Review meeting with the FDA to discuss the topics covered in the CRL, and we resubmitted the NDA for IV meloxicam in September 2018. In March 2019, we received a second CRL from the FDA regarding our NDA for IV meloxicam, which stated that the FDA determined it could not approve the NDA in its present form. The second CRL focused on onset and duration of IV meloxicam, noting that the delayed onset fails to meet the prescriber expectations for IV drugs. The CRL also cited regulatory concerns about the role of IV meloxicam as a monotherapy in acute pain, as well as how it would meet patient and

prescriber needs in that setting, given the FDA's interpretation of the clinical trials data. In October 2019 received written notification from the FDA that our appeal relating to the NDA seeking approval for IV meloxicam has been granted. The FDA's letter states that the appeal was granted and that the NDA provides sufficient evidence of effectiveness and safety to support approval. The letter also states that before IV meloxicam can be approved and legally marketed, agreed upon labeling (prescribing information) must be negotiated with the Division. In December 2019, we resubmitted the NDA for IV meloxicam and in January 2020, we announced that the FDA has set a PDUFA goal date of February 20, 2020 for its decision on the NDA for IV meloxicam. We intend to work closely with the FDA to determine the best path forward to obtain approval for IV meloxicam.

Phase IIIb Clinical Trials

We are currently evaluating the results of IV 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.

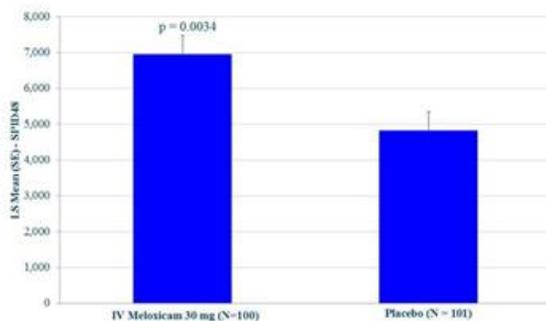
Phase III Clinical Trials

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), IV 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 IV 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 IV 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 IV 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 IV 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 IV meloxicam was well tolerated with no serious adverse events, or SAEs, or bleeding events in the IV meloxicam-treated patients. The most common adverse events, or AEs, occurring in at least 3% of IV meloxicam-treated

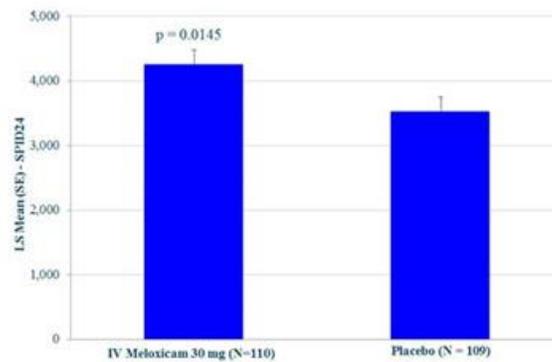
patients, were nausea, headache, pruritus, constipation, vomiting, dizziness, flushing and somnolence, and the incidence of these AEs was generally comparable to the placebo group. The IV meloxicam-treated patients experienced injection site pain and injection site erythema at a rate comparable to placebo. 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), IV 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 IV 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 IV 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 IV 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 IV 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 $\geq 30\%$ 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 $\geq 30\%$ and $\geq 50\%$ Improvement within 6 Hours and $\geq 50\%$ within 24 hours, and PGA of Pain Control at 24 hours were not significantly different between treatment groups.

The safety results demonstrated that IV meloxicam was well tolerated with no difference in SAEs related to bleeding for IV 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 IV 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

IV meloxicam has also successfully completed a double-blind, randomized Phase III safety study evaluating IV meloxicam (30mg bolus injection) or placebo following major surgery. The primary objective of the study was to evaluate the safety and tolerability of IV meloxicam 30mg vs. placebo through Day 28 following treatment. The clinical trial demonstrated that the adverse event profile of IV 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 IV meloxicam 30mg or IV placebo daily for up to 7 doses. A total of 721 patients received at least one dose of study medication.

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

Preferred Term	IV Meloxicam	
	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 IV 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 IV 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 IV 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 IV meloxicam 30mg treatment arm, compared to placebo. Mean opioid consumption in the IV 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.

Population	% reduction in Opioid Use			
	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 IV meloxicam, 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, RP1000, an ultrashort-acting NMBA, RP2000, 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
RP1000	Rapid	Intermediate acting	Phase I
RP2000	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. RP1000, 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 RP1000. We continue to work with the FDA regarding a path forward for the reversal agent. We submitted a new IND for RP1000 in 2019.

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

We intend to conduct a Phase I study with RP1000 beginning 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 plan to file an IND, or equivalent application, for RP2000 in order to conduct a First-in-Human study.

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 IV 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 IV 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, Phase I and Phase II studies will be required to evaluate the safety of Dex-IN as well as the doses required to establish efficacy

Intellectual Property

We own patents and patent applications for injectable meloxicam, that cover pharmaceutical compositions, including compositions produced using NanoCrysta® technology, method of making IV meloxicam and method of treating pain with IV meloxicam. These issued patents expire in 2022 and 2024 in the United States. 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 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 of Dex, in the United States and certain major foreign markets. Several patents have issued outside the United States for transmucosal methods, and the resulting patent protection will last into 2030, subject to any disclaimers or extensions. In addition, patents related to intranasal methods has issued in the United States and certain major foreign markets, and the resulting patent protection will last into 2032, subject to any disclaimers or extensions.

We 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 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 build a sales and marketing infrastructure and effectively market our product candidates, after FDA approval. We are also seeking in-license or acquisition opportunities to add commercial or near-commercial products to our portfolio. We are establishing sales management, marketing and reimbursement functions in anticipation of the commercialization of IV meloxicam in the United States and we believe we can utilize these preparations 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 compete on 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 will compete with all of these compounds in the post-operative pain setting, we believe injectable meloxicam will be used to manage moderate to severe pain, competing with opioids and predominantly systemic 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. and AcelRx Pharmaceuticals, Inc. Mallinckrodt commercializes an injectable formulation of acetaminophen. 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., Innocoll Holdings plc, Trevena, Inc., Avenue Therapeutics, Inc., Neumentum Inc. and Cara Therapeutics, Inc. are currently developing post-operative pain therapeutics that could compete with IV meloxicam in the future.

Manufacturing

We currently rely on contract manufacturers to produce drug product for our clinical studies under cGMPs, with oversight by our internal managers. We plan to continue to rely on contract manufacturers to manufacture development quantities of our product candidates, as well as commercial quantities of our product candidates, if and when approved for marketing by the FDA. We currently rely on a single manufacturer 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 to produce 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.

Injectable Meloxicam

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. If the first commercial sale of injectable meloxicam occurs on or prior to December 31, 2020, the Supply Agreement will have an initial term expiring ten years following the date of such first commercial sale. 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. If the first commercial sale of injectable meloxicam has not occurred by December 31, 2020, the Supply Agreement will expire on that date.

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.

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, including our formulations of injectable meloxicam, 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 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 VA 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. There have been significant ongoing 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 of 1986, as amended, or the Code, commonly referred to as the individual mandate. Further legislative changes to and regulatory changes under the Affordable Care Act remain possible. 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 generally.

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 of \$4.0 billion in 2017, 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 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.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologics, were reduced by 2% under the sequestration (i.e., automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Subsequent legislation extended the 2% reduction, on average, to 2025. Continuation of sequestration or enactment of other reductions in Medicare reimbursement for drugs could affect our ability to achieve a profit on any candidate products that are approved for marketing.

Other Healthcare Laws and Compliance Requirements

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our activities may become 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 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.

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 healthcare laws and compliance requirements. For example, in the European Union,

the EU Data Protection Directive 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 has adopted similar restrictions. Data protection authorities from the different European Union member states 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 the European Union.

Although there are legal mechanisms to allow for the transfer of personal data from the European Union to the U.S., the decision of the European Court of Justice in the Schrems case (Case C-362/14 Maximilian Schrems v. Data Protection Commissioner) invalidated the Safe Harbor framework and increased uncertainty around compliance with European Union restrictions on cross-border data transfers. As a result of the decision, it was no longer possible to rely on Safe Harbor certification as a legal basis for the transfer of personal data from the European Union to entities in the U.S. On February 29, 2016, however, the European Commission announced an agreement with the United States Department of Commerce, or DoC, to replace the invalidated Safe Harbor framework with a new EU-U.S. "Privacy Shield." On July 12, 2016, the European Commission adopted a decision on the adequacy of the protection provided by the Privacy Shield. The Privacy Shield is intended to address the requirements set out by the European Court of Justice in its ruling by imposing more stringent obligations on companies, providing stronger monitoring and enforcement by the DoC and Federal Trade Commission, and making commitments on the part of public authorities regarding access to information. U.S. companies have been able to certify to the DoC their compliance with the privacy principles of the Privacy Shield since August 1, 2016.

On September 16, 2016, the Irish privacy advocacy group Digital Rights Ireland brought an action for annulment of the European Commission decision on the adequacy of the Privacy Shield before the European Court of Justice (Case T-670/16). In October 2016, a further action for annulment was brought by three French digital rights advocacy groups (Case T-738/16). Case T-670/16 and Case T-738/16 are still pending before the European Court of Justice. If, however, the European Court of Justice invalidates the Privacy Shield, it will no longer be possible to rely on the Privacy Shield certification to support transfer of personal data from the European Union to entities in the U.S. Adherence to the Privacy Shield is not, however, mandatory. U.S.-based companies are permitted to rely either on their adherence to the EU-US Privacy Shield or on the other authorized means and procedures to transfer personal data provided by the EU Data Protection Directive.

In December 2015, a proposal for an EU General Data Protection Regulation, intended to replace the current EU Data Protection Directive, introducing new data protection requirements in the EU, as well as substantial fines for breaches of the data protection rules, was agreed between the European Parliament, the Council of the European Union and the European Commission. The EU General Data Protection Regulation has applied since May 25, 2018. The EU Data Protection Regulation increased the responsibility and liability in relation to personal data processed in the European Union and also introduced substantial fines for breaches of the data protection rules. Furthermore, there is a growth towards the public disclosure of clinical trial data in the European Union which adds to the complexity of processing health data from clinical trials. During 2018, we implemented policies and controls to adhere to the EU General Data Protection Regulation.

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, which expires April 16, 2020.

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.

Employees

We currently have 24 full-time employees and 1 temporary employee. None of our employees are covered by collective bargaining agreements, and we consider relations with our employees to be good.

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

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 injectable meloxicam or any of our other 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 anticipate that we will continue to incur significant losses for the foreseeable future. We have never generated revenue and may never be profitable.

Our business has incurred operating losses due to costs incurred in connection with our research and development activities and general and administrative expenses associated with our operations. Our net losses for the years ended December 31, 2019 and 2018 were \$32.6 million and \$73.7 million, respectively. We expect to incur significant losses for at least the next few years, as we continue our research activities and conduct development of, seek regulatory approval for, and prepare for the launch and potential commercialization of our lead product candidate, IV meloxicam. The size of our future net losses and our ability to achieve profitability will depend, in part, on the rate of future expenditures and our ability to obtain regulatory approval of IV meloxicam, successfully commercialize IV meloxicam, if approved, and successfully commercialize our other current or future product candidates. To date, none of our product candidates have been commercialized. Our ability to generate future revenues depends heavily on our success in:

- obtaining regulatory approval of IV meloxicam on our expected timeline;
- launching and commercializing IV meloxicam;
- obtaining the labeling we requested for IV meloxicam, if approved;
- developing a sufficient commercial organization capable of sales, marketing and distribution for IV meloxicam or an acquired or in-licensed new product
- establishing a commercially viable price for IV meloxicam;
- manufacturing commercial quantities of IV meloxicam at acceptable cost levels;
- effectively managing the levels of production, distribution and delivery of IV meloxicam 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 other product candidates.

In addition, as a result of the most recent CRL we received in March 2019 with respect to IV meloxicam, we have incurred additional expenses, including increased legal and consulting fees associated with addressing the CRL, and we expect to continue to incur substantial and increased expenses as we continue to pursue regulatory approval of IV meloxicam, continue to prepare for the potential launch and commercialization of IV meloxicam, expand our research and development activities and advance our clinical programs for our other 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 IV meloxicam or our other product candidates are not successfully developed or commercialized, or if revenues are insufficient following marketing approval, we will not achieve profitability and our business may fail. Even if we successfully obtain regulatory approval for IV meloxicam in the United States, our revenues are also dependent upon the size of the markets outside of the United States, as well as our ability to obtain market approval for IV meloxicam 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 if we are able to generate revenues from the sale of our products, we may not become profitable and may need to obtain additional funding to continue 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, 2019, our cash and cash equivalents were approximately \$17.7 million. Our management believes that such cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements through at least February 14, 2021.

Developing and commercializing pharmaceutical products, including conducting preclinical studies and clinical trials and ramping up commercial manufacturing activities, is expensive. We expect our research and development expenses to increase as we continue our ongoing clinical and pre-commercialization activities in anticipation of a potential commercial launch of IV meloxicam, advance our other clinical programs and, if IV meloxicam is approved, scale up our commercialization activities. If we obtain regulatory approval for IV meloxicam, we anticipate incurring significant costs of sales and general and commercialization expenses in connection with its launch and commercialization. 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.

While we believe that the NDA we resubmitted in December 2019 for IV meloxicam addresses the concerns raised by the FDA and the FDA has set a PDUFA goal date of February 20, 2020, the FDA may not approve the amended NDA, may require additional information, may require the completion of additional clinical trials, preclinical studies and/or chemistry, manufacturing and controls, or CMC, work to resolve issues raised by the FDA in the CRLs for IV meloxicam or may raise additional issues with regard to regulatory approval of IV meloxicam. If this were to occur, we will need to raise additional funding for the costs of conducting such clinical trials, preclinical studies and CMC work. Further, if IV meloxicam is ultimately approved by the FDA, we will need to raise additional funding to implement our commercial launch plans for IV meloxicam and to satisfy the milestone payments due to Alkermes following FDA approval of IV meloxicam. 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 pre-commercialization and commercialization activities for IV meloxicam may lead to additional, unexpected costs related to the commercial manufacture of IV meloxicam 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 other product candidates. Additional funding will be needed to develop our other 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 develop and commercialize IV meloxicam or our other product candidates and could have a material adverse effect on our business, operating results and prospects.

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

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.

Our recurring losses from operations may raise doubt regarding our ability to continue as a going concern.

Our continuing existence will be dependent upon the timing regulatory approval of IV meloxicam and our ability to raise capital to sustain our business, which could raise doubt about our ability to continue as a going concern. If an explanatory paragraph is included in the report of our independent registered public accounting firm on our financial statements stating that there is doubt about our ability to continue as a going concern, such an opinion could materially limit our ability to raise additional funds through an issuance of debt or equity securities or otherwise. There is no assurance that sufficient financing will be available when needed to allow us to continue as a going concern. In addition, if an explanatory paragraph is included in the report of our independent registered public accounting firm on our financial statements, 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.

Risks Related to Regulatory Approval and Commercialization of IV Meloxicam

Considering our receipt of a second CRL from the FDA regarding our NDA for IV meloxicam, the U.S. regulatory pathway for IV meloxicam is uncertain, and we will need to successfully address deficiencies raised by the FDA in order to obtain regulatory approval and successfully commercialize IV meloxicam.

In July 2017, we submitted an NDA for IV meloxicam to the FDA. On May 23, 2018, we received a CRL from the FDA regarding the NDA, which stated that the FDA determined it could not approve the NDA in its present form. Following a Type A End-of-Review meeting with the FDA to discuss the topics covered in the CRL, we resubmitted the NDA for IV meloxicam in September 2018. In March 2019, we received a second CRL from the FDA regarding our NDA for IV meloxicam which stated that the FDA determined it could not approve the NDA in its present form. The second CRL focused on onset and duration of IV meloxicam, noting that the delayed onset fails to meet the prescriber expectations for IV drugs. The CRL also cited regulatory concerns about the role of IV meloxicam as a monotherapy in acute pain, as well as how it would meet patient and prescriber needs in that setting, given the FDA's interpretation of the clinical trials data. We are engaged in resolution of the second CRL, and in October 2019, we received written notification from the FDA that our appeal relating to the NDA seeking approval for IV meloxicam was granted. The FDA's letter stated that the NDA provides sufficient evidence of effectiveness and safety to support approval and that before IV meloxicam can be approved and legally marketed, agreed upon labeling (prescribing information) must be negotiated with the FDA. We resubmitted our NDA in December 2019 and the FDA has set a date of decision on the NDA, or PDUFA date, of February 20, 2020. The review process and the PDUFA date may be extended if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission. We intend to address the deficiencies identified by the FDA in the CRLs and obtain FDA approval, but there can be no guarantee that we will be able to do so in a timely manner, or at all. We intend to work closely with the FDA to determine the best path forward to obtain approval for IV meloxicam, but we cannot guarantee that these efforts will be successful.

Our anticipated commercialization of IV meloxicam has been delayed by the CRLs and we have incurred additional costs, including increased legal and consulting fees, and devoted additional resources to address the FDA's concerns raised in the CRLs. Our receipt of the CRLs and delay in the commercialization of IV meloxicam has adversely affected our business. While we believe that the NDA we resubmitted in December 2019 for IV meloxicam addresses the concerns raised by the FDA and the FDA has set a PDUFA goal date of February 20, 2020, the FDA may not approve the amended NDA, may require additional information, may require the completion of additional clinical trials, preclinical studies and/or CMC work or may raise additional issues with regard to regulatory approval of IV meloxicam. Any of these items could further delay or prevent the approval or limit the product labeling claims for IV meloxicam.

In addition, either the substance of the items identified by the FDA in the CRLs, or the CRLs themselves, could have an adverse impact on future efforts to obtain marketing authorization for IV meloxicam from the EMA and other foreign regulatory authorities, or on our future efforts to commercialize IV meloxicam and gain acceptance of IV meloxicam from third-party payers.

Should we fail to obtain regulatory approval of IV meloxicam, we may be forced to rely on our other product candidates, which are at an earlier development stage and will require significant additional time and resources to obtain regulatory approval and proceed with commercialization which could have a material adverse effect on our business, financial condition and results of operation.

We are substantially dependent on the success of our lead product candidate, IV meloxicam, which is in a later stage of development than our other product candidates. To the extent regulatory approval of IV meloxicam is delayed or not granted, our business, financial condition and results of operations may be materially adversely affected, and the price of our common stock may decline.

We currently have no product candidates approved for sale, and we may never be able to develop marketable products. We are focusing a significant portion of our activities and resources on our lead product candidate, IV meloxicam, and we believe our prospects are highly dependent on, and a significant portion of the value of our company relates to, our ability to successfully obtain regulatory approval for, and successfully commercialize, IV meloxicam. The regulatory approval of IV meloxicam is subject to many risks, including the risks discussed in other risk factors, and IV meloxicam may not receive marketing approval from any regulatory agency. If the results or timing of regulatory filings, the regulatory process, regulatory developments, clinical trials or preclinical studies, or other activities, actions or decisions related to IV meloxicam do not meet our or others' expectations, the market price of our common stock could decline significantly.

We have resubmitted the NDA for IV meloxicam in December 2019 and the FDA has set a PDUFA date of February 20, 2020. If the FDA requires us to conduct additional clinical trials, preclinical studies and/or CMC work in connection with our resubmitted NDA, our timeline for commercialization of IV meloxicam will be further delayed and we will incur additional costs. Further, there can be no assurance that we will complete any additional required clinical and non-clinical studies in a manner that is acceptable to the FDA. In addition, we are evaluating the results of Phase IIIb clinical trials for IV meloxicam in colorectal surgery patients and orthopedic surgery patients, and those clinical trials could produce results that are adverse or inconclusive, which could have a negative impact on regulatory approval. This is a time-consuming and expensive process and does not guarantee approval from the FDA or successful commercialization.

Any further delay or setback in the development or regulatory approval of IV meloxicam could adversely affect our business and cause our stock price to decline. We cannot assure you that we will be able to obtain approval for IV meloxicam from the FDA. Should we fail to obtain regulatory approval of IV meloxicam, we may be forced to rely on our other product candidates, which are at an earlier development stage and will require significant additional time and resources to obtain regulatory approval and proceed with commercialization, which could have a material adverse effect on our business, financial condition and results of operations.

If we fail to obtain approval for the product labeling requested in our NDA for IV meloxicam, our ability to successfully market IV meloxicam may be adversely affected.

If we obtain approval of IV meloxicam and such approval is for a more limited indication than anticipated or different dosing interval our target markets that we are able to market to may be limited. Depending upon the product label, if approved, we may need to significantly revise our launch and commercialization strategy, which could delay our planned commercial launch of IV meloxicam, if approved and could significantly limit our ability to realize the full market potential of IV meloxicam. The approved labeling could decrease the target market to a point where we would be unable to achieve profitability from IV meloxicam, in which case we may be forced to limit or discontinue the commercialization of IV meloxicam, or seek a collaboration partner for the commercialization of IV meloxicam, all of which would have an adverse impact on our business.

In addition, the labeling approved by the FDA in respect to IV meloxicam could also significantly limit the approved indications for use, require that precautions, contraindications or warnings be included on the product labeling, including black box warnings, require expensive and time-consuming post-approval clinical trials, Risk Evaluation and Mitigation Strategy, or REMS, or surveillance as conditions of approval, or, through product labeling limit the claims that we may make, any of which may also impede the successful commercialization of IV meloxicam, which would have an adverse impact on our business.

Our development of IV meloxicam depends, in part, on published scientific literature and the FDA's prior findings regarding the safety and efficacy of approved products containing meloxicam based on data not developed by us, but upon which the FDA may rely in reviewing our NDA.

Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FDCA, permits the filing of an NDA where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. The FDA interprets Section 505(b)(2) of the FDCA, for purposes of approving an NDA, to permit the applicant to rely, in part, upon published literature or the FDA's previous findings of safety and efficacy for an already-approved reference product. The FDA may also require companies to perform additional clinical trials or measurements to support any deviation from the reference product. The FDA may then approve the new product candidate for all or some of the label indications for which the reference product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant. The label, however, may require all or some of the limitations, contraindications, warnings or precautions included in the reference product's label, including a black box warning, or

may require additional limitations, contraindications, warnings or precautions. Our NDA for IV meloxicam was submitted under Section 505(b)(2) and as such the NDA relies, in part, on the FDA's previous findings of safety and efficacy from investigations for approved products containing meloxicam and published scientific literature for which we have not received a right of reference. Even though we may be able to take advantage of Section 505(b)(2) to support potential U.S. approval for IV meloxicam, the FDA may require us to perform additional clinical trials or measurements to support approval. In addition, notwithstanding the approval of many products by the FDA pursuant to 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 our NDA for IV meloxicam or any other Section 505(b)(2) NDAs that we submit. Such a result could require us to conduct additional testing and costly clinical trials, which could substantially delay or prevent the approval and launch of IV meloxicam, which could have a material adverse effect on our business, financial condition and results of operations.

IV meloxicam, if approved, may require REMS, which may significantly increase our costs.

IV meloxicam, if approved, may require REMS. The REMS may include requirements for special labeling or medication guides for patients, special communication plans to health care professionals and restrictions on distribution and use. We cannot predict the specific scope or magnitude of REMS that may be required as part of the FDA's approval of IV meloxicam. Depending on the extent of the REMS requirements, our costs to commercialize IV meloxicam may increase significantly and distribution restrictions could limit sales, which could have a material adverse effect on our business, financial condition and results of operations. Similar obstacles may arise in countries outside of the United States.

IV meloxicam may cause adverse events or other safety concerns or have other properties that could delay or prevent its regulatory approval or limit the scope of any approved label or market acceptance.

Adverse effects, or AEs, caused by IV meloxicam could cause us, other 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 IV meloxicam have generated some AEs, and in some cases serious adverse effects, or SAEs, as those terms are defined by the FDA in its regulations. During the Study REC-15-015 trial, four treatment-related SAEs were observed in one IV meloxicam-treated patient and three placebo-treated patients. The IV meloxicam-treated patient experienced a post-procedural hemorrhage that was determined to be related to the surgical procedure but was not viewed by the investigator as attributable to the drug. The other SAEs occurred in placebo-treated patients and were therefore not attributable to the drug. During the Safety Study two SAEs occurred in a single placebo-treated patient and were therefore not attributable to the drug. Additional AEs or SAEs could be generated during ongoing and future clinical trials. Although the CRLs for IV meloxicam did not raise any safety concerns, our ability to obtain regulatory approval for IV meloxicam could be adversely impacted by these AEs, SAEs or other safety concerns.

Further, if IV meloxicam causes 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 IV meloxicam or impose restrictions on its distribution in a form of a modified REMS;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way IV meloxicam 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 IV meloxicam and could substantially increase the costs of commercializing IV meloxicam, which could have a material adverse effect on our business, financial condition and results of operations.

We will need to obtain approval for any proposed names for IV meloxicam, and any delay associated with doing so could delay commercialization of IV meloxicam, and adversely impact our business.

The proprietary name we propose to use with IV meloxicam in the United States must be reviewed and accepted by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA reviews any proposed product name, including an evaluation of the potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims or contributes to an overstatement of efficacy. Although the FDA has conditionally accepted our proposed proprietary product name for IV meloxicam, it may still object to the proposed proprietary product name at the time of any NDA approval, which would require us to expend significant additional resources in an effort to

identify a suitable proprietary product name that would qualify under applicable laws, not infringe the existing rights of third parties and be acceptable to the FDA, all of which could delay commercialization of IV meloxicam, and adversely impact our business.

Even if we obtain regulatory approval for IV meloxicam, we will still face extensive regulatory requirements and IV meloxicam may face future regulatory difficulties.

Even if we obtain regulatory approval in the United States or other countries, the FDA and state regulatory authorities and the equivalent regulatory authorities in other countries may still impose significant restrictions on the indicated uses or marketing of IV meloxicam, or impose ongoing requirements for potentially costly post-approval studies or post-marketing surveillance. If approved, IV meloxicam will also be 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 current good manufacturing practice, or 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 IV meloxicam, 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 IV meloxicam 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 IV meloxicam, a regulatory authority may:

- issue a warning letter 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 a pending NDA or 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 IV meloxicam and achieve profitability could be negatively impacted, which could have a material adverse effect on our business, financial condition and results of operations.

If we are unable to successfully commercialize IV meloxicam, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.

Even if we receive regulatory approval from the FDA for the labeling that we request, our ability to successfully commercialize IV meloxicam will depend on many factors, including but not limited to:

- our ability to create sufficient capital (through debt, equity or both) to support the product launch;
- any negative perception of IV meloxicam as a result of receipt of two CRLs from the FDA, even if ultimately resolved;
- the evaluation of results from our completed Phase IIIb clinical trials for IV meloxicam;
- our ability to consistently manufacture commercial quantities of IV meloxicam 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 a sales and marketing organization to market IV meloxicam;
- 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 IV meloxicam outside the United States;

- our success in educating physicians, patients and caregivers about the benefits, administration and use of IV meloxicam;
- our share of promotional “voice” during launch versus other existing or new products in our market segment;
- 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 IV meloxicam and to obtain adequate coverage and adequate reimbursement for IV meloxicam;
- 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 profile for IV meloxicam.

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 or generate revenue from IV meloxicam, even if we receive regulatory approval for the labeling that we have requested. 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.

Manufacturing issues may arise that could increase product and regulatory approval costs or delay commercialization of IV meloxicam

As we scale up manufacturing of IV meloxicam and 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 IV meloxicam. In addition, quality issues may arise during scale-up and validation of commercial manufacturing processes. Any issues in IV meloxicam manufacturing could result in increased scrutiny by regulatory authorities, delays in our regulatory approval process, increases in our operating expenses, or failure to obtain or maintain approval for IV meloxicam.

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

Our ability to supply sufficient quantities of IV meloxicam 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 UK Limited, or 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 IV meloxicam, if approved, could expose us to increased costs.

Although our supply agreement and manufacturing agreements for IV meloxicam 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 IV meloxicam is limited. If we encounter any issues with our contract manufacturers or choose to engage a new supplier or contract manufacturer for IV meloxicam, 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 commercialization of IV meloxicam, if approved, which would materially and adversely affect our business.

Our reliance on a limited number of vendors to manufacture IV meloxicam 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 commercial launch and 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 IV meloxicam 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 current Good Manufacturing Practices, or 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 U.S. Drug Enforcement Agency, or 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 IV meloxicam. Any manufacturing defect or error discovered after IV meloxicam 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 IV meloxicam and/or Alkermes could fail to deliver the dedicated space according to the currently agreed timeline.

While we have scaled up our commercial manufacturing of IV meloxicam in anticipation of a potential commercial launch, due to the delay in our anticipated commercial launch of IV meloxicam as a result of the two CRLs, we have launch stock of IV meloxicam that, depending on the approved expiration date, 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 commercial launch of IV meloxicam, if approved 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 IV meloxicam to support commercial launch and meet market demand for IV meloxicam, if approved, 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 IV meloxicam or their performance is substandard, our product launch 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 which could delay or impair the commercialization of IV meloxicam, result in higher costs, or deprive us of potential product revenues. Our carriers may experience technical issues relating to the timing and shipment of IV meloxicam, 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 IV meloxicam, 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 IV meloxicam 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 IV meloxicam 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 commercialization of IV meloxicam, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

In order to market IV meloxicam 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 IV meloxicam 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 IV meloxicam 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, which may make it difficult to predict our ability to commercialize IV meloxicam, if approved, 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 not yet obtained regulatory approval for any of our product candidates. To date, we have not yet demonstrated 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 commercialize IV meloxicam, 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.

The commercial success of IV meloxicam will depend upon the acceptance of IV meloxicam by the medical community, including physicians, patients, health care payers and hospital formularies.

Physicians may not prescribe IV meloxicam if approved by the FDA, in which case we would not generate the revenues we anticipate. The degree of market acceptance of IV meloxicam will depend on a number of factors, including:

- demonstration of clinical safety and efficacy;
- the prevalence and severity of any AEs;
- the indications for which IV meloxicam is approved, including any dosing instructions and potential additional restrictions placed on IV meloxicam in connection with its approval;
- limitations or warnings contained in the FDA-approved label for IV meloxicam;
- the evaluation of results from our completed Phase IIIb clinical trials for IV meloxicam;
- relative convenience and ease of administration of IV meloxicam;
- prevalence of the condition for which IV meloxicam is approved;
- availability of alternative treatments and perceived advantages of IV meloxicam over such alternative treatments;
- the proposed sales price and cost-effectiveness of IV meloxicam and the availability of adequate third-party coverage and reimbursement;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- our ability to convince hospitals to include IV meloxicam on their list of authorized products, referred to as formulary approval;
- consolidation among healthcare providers, which increases the impact of the loss of any relationship;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

In addition, market acceptance of IV meloxicam could be negatively impacted by any negative perception physicians may have of IV meloxicam following announcement of the two CRLs received from the FDA for IV meloxicam, even if subsequently

resolved. If IV meloxicam is approved but does not achieve an adequate level of acceptance by physicians, patients and healthcare payers, we may not generate sufficient revenue and we may not become or remain profitable.

Our anticipated commercial launch of IV meloxicam has been significantly delayed, which has changed our commercialization strategy and could adversely impact our ability to successfully commercialize IV meloxicam.

Due to receipt of the CRLs from the FDA regarding IV meloxicam, our anticipated commercial launch of IV meloxicam has been delayed from 2019 to 2020, if approved. Our initial commercial launch plans have changed. We now intend to initially launch with a sales team of approximately 50 sales representatives and/or collaborate with third parties who would market IV meloxicam to health care professionals at our called-on institutions. This will require us to hire more sales force members, which will increase our costs. In addition, we may face challenges when recruiting a sufficient number of sales representatives. If we are unable to hire the planned sales team for the commercial launch of IV meloxicam, our commercialization of IV meloxicam may be adversely impacted.

If we are unable to establish sales and marketing capabilities or, with respect to markets outside of the United States, identify a strategic partner with appropriate sales and marketing capabilities, to sell IV meloxicam and enter into a strategic partnership on commercially acceptable terms with such partner, we may be unable to generate any revenue for IV meloxicam.

In anticipation of the approval and commercialization of IV meloxicam, we have begun to build out our sales, marketing and distribution capabilities in the United States, and will need to continue to do so. Our sales force expansion was negatively impacted by our receipt of the most recent CRL with respect to IV meloxicam and the delay in potential commercialization of IV meloxicam to 2020. We were forced to withdraw many of the offers of employment we had made to sales force representatives in anticipation of an earlier commercial launch. We are looking to hire additional sales personnel; however, due to the CRLs and other market dynamics, this recruitment and hiring may be more difficult.

In addition, we may discover that the cost of continuing to establish, expand and maintain such sales force may exceed the cost-effectiveness of doing so. In order to market IV meloxicam, if approved, we must continue to build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services.

In the United States, our strategy for IV meloxicam is to develop a specialty sales force to promote the product to healthcare professionals and third-party payers in the United States. To date, we have not entered into any strategic partnerships for IV meloxicam; however, we may enter into a strategic partnership to commercialize IV meloxicam, if approved, 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 IV meloxicam 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 IV meloxicam to healthcare professionals in geographic regions that will not be covered by our own marketing and sales force, or if our potential future collaboration partners do not successfully commercialize IV meloxicam, our ability to generate revenues from IV meloxicam will be adversely affected.

If we are unable to obtain additional financial resources for IV meloxicam, we may be forced to curtail the development, delay potential commercialization, reduce the scope of our sales or marketing activities or undertake all development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities ourselves, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we may not be able to bring IV meloxicam to market or generate product revenue from it, which could have a material adverse effect on our business, financial condition and results of operations.

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

The market for IV meloxicam is characterized by intense competition and rapid technological advances. If IV meloxicam obtains FDA approval, it will compete with a number of existing and future pharmaceuticals and drug delivery devices developed, manufactured and marketed by others. We will 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 painrelief. While we will compete with all of these compounds in the post-operative pain setting, we believe IV meloxicam will be prescribed for moderate to severe pain, 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, and Pacira Pharmaceuticals, Inc. and AcclRx Pharmaceuticals, Inc. Mallinckrodt commercializes an injectable formulation of acetaminophen. Pacira commercializes an intraoperative formulation of bupivacaine, a sodium channel blocker. Additionally, companies such as Adynxx, Inc., Durect Corporation, Heron Therapeutics, Inc., Innocoll Holdings plc, Sandoz AG, Trevena, Inc., Avenue Therapeutics, Inc., Neumentum Inc. and Cara Therapeutics, Inc. are currently developing post-operative pain therapeutics that could compete with IV meloxicam 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 and may obtain regulatory approval of their product candidates before we are able to do so, which may limit our ability to develop or commercialize IV meloxicam. 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 IV meloxicam 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 injectable meloxicam non-competitive or obsolete. These and other risks may materially adversely affect our ability to attain or sustain profitable operations.

If third-party payers do not reimburse physicians or patients for IV meloxicam or if reimbursement levels are, or pricing pressures cause the sales price to be, set too low for us to sell IV meloxicam at a profit, our ability to successfully commercialize IV meloxicam and our results of operations will be harmed.

Our ability to commercialize IV meloxicam successfully will depend in part on the extent to which coverage and adequate reimbursement for IV meloxicam, once approved, 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 IV meloxicam, even if approved.

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 coverage and reimbursement approval for IV meloxicam from government authorities or other third-party payers may be 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 IV meloxicam to each government authority or other third-party payer. For example, if our completed Phase IIIb clinical trials for IV meloxicam in colorectal surgery patients and orthopedic surgery patients do not show improved outcomes relative to the current standard of care, obtaining payer coverage could be more difficult. 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 IV meloxicam as a result of our receipt of two CRLs received from the FDA for IV meloxicam, 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 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 IV meloxicam into our target markets, nor, if formulary approval is obtained, at what price IV meloxicam 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 IV meloxicam.

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 IV meloxicam, which in turn, could negatively impact pricing. If patients are not adequately reimbursed for IV meloxicam, 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 promptly obtain coverage and profitable reimbursement rates from both government-funded and private payers for IV meloxicam, if approved, 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 IV meloxicam outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.

If IV meloxicam is approved for commercialization, we may enter into agreements with third parties to market IV meloxicam 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 IV meloxicam 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 IV meloxicam, and other parties through which we will market, sell and distribute IV meloxicam. 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;
- the 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, 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 IV meloxicam 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 IV meloxicam 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 IV meloxicam. 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 Centers for Medicare and Medicaid Services, or 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 IV meloxicam. 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 Federal Supply Schedule, or 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 IV meloxicam 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 (Department of Veterans Affairs, or VA, Department of Defense, or 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 IV meloxicam 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 prevent or delay marketing approval of IV meloxicam or restrict or regulate post-approval activities and affect our ability to profitably sell IV meloxicam, if approved. 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 IV meloxicam 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 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. Further legislative changes to and regulatory changes under the Affordable Care Act remain possible. 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 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 IV meloxicam, if approved, 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 commercialize IV meloxicam.

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

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 IV meloxicam, if approved. 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 IV meloxicam, if approved, 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 IV meloxicam, if approved, 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 IV meloxicam, if approved, could limit our ability to sell IV meloxicam, if approved, 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 IV meloxicam manufacture and source raw materials outside the United States and we may, in the future, use manufacturers outside the United States for our other product candidates, including IV meloxicam. 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 Other 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. We have not obtained regulatory approval for any product candidate, and 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 any of our other product candidates will receive regulatory approval. If we do not receive regulatory approval or any of our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market one of our product candidates, our revenue will be dependent, to a significant extent, upon the size of the markets in the territories for which we gain regulatory approval. If the markets for patients or indications that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such products, if approved, which could have a material adverse effect on our business, financial condition and results of operations.

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 contract research organizations, or CROs, and clinical trial sites;
- delays in obtaining required institutional review board, or 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 limited sources of supply and manufacturing for our product candidates, and if we encounter any issues with our contract manufacturers or suppliers, we may need to qualify alternative manufacturers or suppliers, which could impair our ability to sufficiently and timely manufacture and supply our product candidates.

We do not own facilities for clinical-scale or commercial manufacturing of our product candidates. We rely on third-party suppliers and contract manufacturers to manufacture clinical supplies of our products candidates, and intend to rely on third-party suppliers and contract manufactures for commercial supplies of any approved product candidates. The number of potential manufacturers that have the necessary equipment, expertise and governmental licenses to produce our product candidates is limited. 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 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 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 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 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.

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 IV meloxicam and our other product candidates, as well as the execution of nonclinical studies. We control only certain aspects of our third parties' activities.

We and our contractors are required to comply with Good Laboratory Practices, or GLPs, and Good Clinical Practices, or 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, or successfully commercialize IV meloxicam or our other product candidates. As a result, our financial results and the commercial prospects for IV meloxicam 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, product liability, labor and employment, wage and hour, commercial and other matters. For example, on May 31, 2018, a securities class action lawsuit, or the Securities Litigation, was filed against Recro and certain of its officers, and we have agreed to assume all of Recro's obligations and indemnify Recro for all liabilities related to the Securities Litigation. See "— Risks Related to the Separation — We have assumed Recro's obligations in connection with its ongoing securities class action lawsuit, which, if resolved unfavorably, could expose us to significant liabilities" for more information.

The outcome of any litigation or government investigation, regardless of its merits, is inherently uncertain. Any lawsuits or government investigations, and the disposition of such lawsuits and government investigations, could be time-consuming and expensive to resolve and divert management attention and resources. Any adverse determination related to litigation or government investigations could adversely affect our operating results, harm our reputation or otherwise negatively impact our business. In addition, depending on the nature and timing of any such dispute, a resolution of a legal matter or government investigation could materially affect our future operating results, our cash flows or both.

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, and Ryan D. Lake, our Chief Financial Officer, the loss of whose services would adversely impact the achievement of our objectives. Ms. Henwood also currently serves as the President and Chief Executive

Officer of Recro and Mr. Lake also currently serves as the Chief Financial Officer of Recro. This may at times adversely affect their ability to devote time, attention, and effort to us. 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, and we may experience difficulties in managing this growth.

We have begun to grow the size of our managerial, operational, sales, marketing, financial and other resources as we prepare for the potential approval and commercialization of IV meloxicam and the ongoing development of our other product candidates. However, our management, personnel and systems currently in place may not be adequate to support this growth or assist us with the potential growth into a commercial stage pharmaceutical company. 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. 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 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.

The use of our product candidates in clinical studies and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability 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;
- withdrawal of clinical study participants;
- termination of clinical trial sites;
- 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;
- the inability to commercialize our product candidates;
- decreased demand for our product candidates, if approved for commercial sale; and/or
- 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 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. If and when we obtain marketing approval for our product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts.

On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated AEs. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

We incur increased costs and demands upon our management as a result of complying with the laws and regulations affecting public companies. If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which 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 Capital Market, or 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 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) the last day of our fiscal year following the fifth anniversary of the Distribution; (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.

We are, however, subject to Section 404(a) of the Sarbanes-Oxley Act, which requires, among other things, annual management assessments of the effectiveness of our internal control over financial reporting beginning in our second annual report filed after the Distribution. 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. 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.

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. The maintenance of such information is governed by various rules and regulations in the jurisdictions in which we conduct our business, including by the General Data Privacy Regulation, or GDPR, in the European Union. 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 believe we have appropriate information security policies and systems in place in order 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.

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 states in which we conduct our business. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act) govern the collection, use, disclosure, and protection of health-related and other personal information. For instance, HIPAA imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information and imposes notification obligations in the event of a breach of the privacy or security of individually identifiable health information on entities subject to HIPAA and their business associates that perform certain activities that involve the use or disclosure of protected health information on their behalf. Certain of these laws and regulations are described in greater detail in the section below under “Business - Government Regulation - Other Healthcare Laws and Compliance Requirements.” 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.

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 NanoCrysta[®] technology, a method of making IV meloxicam and method of treating pain with IV meloxicam. These issued patents expire in 2022 and 2024 in the United States. We also exclusively in-license from Alkermes, on a perpetual royalty-free basis i) composition and methods of making patents, ii) several patents (specifically 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 expire in 2030, and an application directed to injectable, nanoparticulate meloxicam compositions, which, if issued, would expire in 2030 to manufacture and commercialize IV, intramuscular and parenteral meloxicam. As of February 11, 2020, we own six issued U.S. patents and four U.S. pending patent applications, and 43 issued foreign patents (including European validation countries) and six pending PCT or foreign applications related to meloxicam, IV meloxicam, formulations of meloxicam, and methods of using meloxicam. As of February 11, 2020, we exclusively license eleven issued U.S. patents and one U.S. pending patent application, and 45 issued foreign patents (including European validation countries) and three pending foreign applications relating to IV meloxicam, formulations of meloxicam and methods of manufacturing meloxicam to manufacture and commercialize IV meloxicam, intramuscular meloxicam and parenteral meloxicam. As of February 11, 2020, we own one issued U.S. patent, 1 pending U.S. application and 28 issued foreign patents, including European validation countries, and six pending foreign applications 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.

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.

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.

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.

Risks Related to the Separation From Recro

We may not achieve some or all of the expected benefits of the Separation, and the Separation could harm our business, prospects, financial condition and results of operations.

We may not be able to achieve some or all of the anticipated strategic, financial, operational, marketing or other benefits expected to result from the Separation, or such benefits may be delayed or not occur at all. These actions may not provide the benefits we currently expect, and could lead to disruption of our operations, loss of or inability to recruit key personnel needed to operate and grow our businesses following the Separation, weakening of our internal standards, controls or procedures and impairment of our key collaborations and supplier relationships. In addition, completion of the Separation has required and will continue to require significant amounts of management's time and effort, which may divert management's attention from operating and growing our businesses.

By separating from Recro, we may have become more susceptible to market fluctuations and other adverse events than we would have been if we were still a part of the current Recro organizational structure. As part of Recro, we were able to enjoy certain benefits from Recro's operating diversity, purchasing power and opportunities to pursue integrated strategies with Recro's other business activities. As an independent, publicly traded company, we do not have, and may never develop, a comparable market reputation, performance or brand identity of our own, which may limit our ability to recruit and retain personnel, pursue and negotiate strategic transactions, and access the capital markets to finance our operations. As an independent, publicly traded company, we do not have the same historical market reputation and performance or brand identity as Recro. If we fail to achieve some or all of the benefits that we expect to achieve as an independent company, or do not achieve them in the time we expect, our business, prospects, financial condition and results of operations may be materially harmed.

We may be unable to make, on a timely or cost-effective basis, the changes necessary to operate as an independent company, and we will be reliant on Recro for the provision of certain services for a period of time.

We have historically operated as part of Recro's corporate organization, and Recro has assisted us by providing various corporate and other business functions. As a result of the Separation, Recro has no obligation to assist our operations or growth strategy, other than providing certain services or rights pursuant to agreements described under Note 15 to the Consolidated and Combined Financial Statements included in this Annual Report on Form 10-K.

We are and for a period of time will be, substantially reliant on Recro to provide these limited services, and if Recro is unable or unwilling to satisfy its obligations under these agreements, we could incur operational difficulties or losses that could have a material and adverse effect on our business, prospects, financial condition and results of operations.

Furthermore, the services provided by Recro under these agreements do not include every service or all of the information and technology systems that we have received from Recro in the past or that are necessary to successfully operate our business, and Recro is only obligated to provide these services for limited periods of time from the date of the Distribution. Accordingly, we must develop internal capabilities to perform these services, or obtain from other third parties services we currently receive from Recro. If we are unable to efficiently implement our own systems and services, or if we are unable to negotiate agreements with third-party providers of these services in a timely manner or on terms and conditions as favorable as those we receive from Recro, we may not be able to operate our business effectively and our financial condition may decline. Furthermore, if we fail to develop high-quality internal capabilities, or obtain comparable services from third-party providers, in a cost-effective manner, we may be unable to operate our existing business or execute our strategic priorities successfully and efficiently, and our operating results and financial condition may be materially harmed.

We have only operated as an independent company since November 22, 2019 and we expect to incur increased administrative and other costs following the Separation by virtue of our status as an independent public company. Our historical financial

information is not necessarily representative of the results that we would have achieved as a separate, publicly traded company and should not be relied upon as an indicator of our future results.

Our historical information provided in this Annual Report on Form 10-K refers to our business as operated by and integrated with Recro. Our historical financial information included in this Annual Report on Form 10-K, prior to the Separation, is derived from the consolidated financial statements and accounting records of Recro. Accordingly, the historical financial information included in this Annual Report on Form 10-K does not necessarily reflect the operating results, financial condition or cash flows that we would have achieved as a separate, publicly traded company during the periods presented, or the financial results we will achieve in the future. In particular, our future financial results may vary from the historical financial information included in this Annual Report on Form 10-K as a result of the following factors, among others:

- our historical combined financial data does not reflect the Separation prior to November 22, 2019;
- our historical financial data reflects expense allocations for certain business and support functions that are provided on a centralized basis within Recro, such as expenses for research and development and corporate administrative services, including information technology, finance, legal, insurance, compliance and human resources activities, that may be lower than the comparable expenses we would have actually incurred, or will incur in the future, as a standalone company;
- our capital structure is different from that reflected in our historical combined financial statements prior to the Separation;
- significant increases may occur in our cost structure as a result of becoming a standalone public company, including costs related to public company reporting, investor relations and compliance with the Sarbanes-Oxley Act; and
- the Separation may have a material effect on our relationships with our suppliers, collaborators and other business relationships.

Our financial condition and future results of operations, after giving effect to the Separation, are materially different from amounts reflected in our historical financial statements included elsewhere in this Annual Report on Form 10-K. As a result of the Separation, it may be difficult for investors to compare our future results to historical results or to evaluate our relative performance or trends in our business.

Operating as an independent company may result in disruptions to, and in our relationships with, our strategic business partners.

As we begin our operations as an independent company, the suppliers, licensors, research organizations, and other parties with which we currently do business or may do business in the future may terminate or attempt to negotiate changes in our existing business relationships, or delay entering into business relationships with us or consider entering into business relationships with parties other than us. These disruptions could have a material and adverse effect on our business, prospects, financial condition and results of operations.

In connection with the Separation, we assumed and agreed to indemnify Recro for certain liabilities. If we are required to make payments pursuant to these indemnities to Recro, we may need to divert cash to meet those obligations and our financial results could be harmed.

Pursuant to the Separation Agreement and certain other agreements we intend to enter into with Recro, we assumed and agreed to indemnify Recro for certain liabilities for uncapped amounts, which may include, among other items, associated defense costs, settlement amounts and judgments, as discussed further in Note 15 to the Consolidated and Combined Financial Statements included in this Annual Report on Form 10-K. Payments pursuant to these indemnities may be significant and could harm our business. Third parties could also seek to hold us responsible for any of the liabilities of the Recro business. Recro agreed to indemnify us for liabilities of the Recro business, but such indemnity from Recro may not be sufficient to protect us against the full amount of such liabilities, and Recro may not fully satisfy its indemnification obligations. Moreover, even if we ultimately succeed in recovering from Recro any amounts for which we are held liable, we may be temporarily required to bear these losses ourselves. Each of these risks could harm our business, prospects, financial condition and results of operations.

We have assumed Recro's obligations in connection with its ongoing securities class action lawsuit, which, if resolved unfavorably, could expose us to significant liabilities.

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 IV 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, Recro filed its response and briefing was completed on the motion to dismiss. In response to questions from the Judge, the parties submitted supplemental briefs with regard to the motion to dismiss the amended complaint during the fall of 2019. There has been no decision on the motion.

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. We believe that the lawsuit is without merit and we intend to vigorously defend against it. The lawsuit is in the early stages and, 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.

Our agreements with Recro may not reflect terms that would have resulted from negotiations with unaffiliated third parties.

The agreements related to the Separation, including, among others, the Separation Agreement, the transition services agreement, the tax matters agreement and the employee matters agreement, were negotiated in the context of the Separation while we were still controlled by Recro. Until the Distribution occurred, Recro effectively had the sole and absolute discretion to determine and change the terms of the Separation, including the terms of any agreements between Recro and us and the establishment of the record date. As a result, any changes could be unfavorable to us and may not reflect terms that would have resulted from negotiations between unaffiliated third parties.

Certain of our directors and officers may have actual or potential conflicts of interest because of their former or current positions with Recro.

Certain of our directors and officers may own shares of Recro common stock or other equity awards as a result of their prior or concurrent service as directors or officers of Recro. For certain of these individuals, their holdings of Recro common stock or equity awards may be significant compared to their total assets. In addition, our President and Chief Executive Officer and our Chief Financial Officer currently hold the same positions at Recro. This may at times adversely affect their ability to devote time, attention, and effort to us. The ownership of any Recro equity or equity awards, and our executive officers' positions at Recro, creates, or may create the appearance of, conflicts of interest when these directors or officers are faced with decisions that could have different implications for Recro than for us. These potential conflicts could arise, for example, over matters such as the desirability of changes in our business and operations, funding and capital matters, regulatory matters, matters arising with respect to the Separation Agreement and other agreements with Recro relating to the Separation or otherwise, employee retention or recruiting, or our dividend policy.

Risks Relating to Our Securities

An active trading market may not develop for our shares and the market price of these shares may fluctuate widely.

Prior to the first trading day following the Distribution, there had been no public market for our shares of common stock. Although our common stock has been approved for listing on Nasdaq, there can be no assurance that an active trading market for our shares of common stock will develop or be sustained in the future.

We cannot predict the prices at which our shares of common stock may trade. The market price of our shares of common stock may fluctuate widely, depending upon many factors, some of which are beyond our control, including the following:

- our ability to resolve the deficiencies identified by the FDA in the CRLs received for IV meloxicam and obtain regulatory approval of IV meloxicam;
- the approved labeling for IV meloxicam, if any;
- our ability to successfully commercialize IV meloxicam, if approved;
- 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 IV meloxicam, if approved, outside the United States;
- our ability to effectively manage the levels of production, distribution and delivery of IV meloxicam through our supply chain;
- FDA, state or international regulatory actions, including actions on regulatory applications for any of our product candidates;
- our ability to leverage our development experience to progress our other pipeline product candidates;
- legislative or regulatory changes;

- judicial pronouncements interpreting laws and regulations;
- changes in government programs;
- our ability to identify and successfully acquire or in-license new product candidates on acceptable terms;
- announcements of data from clinical studies, new products, services or technologies, commercial relationships, acquisitions or other events by us or our competitors;
- market conditions in the pharmaceutical and biotechnology sectors;
- fluctuations in stock market prices and trading volumes of similar companies;
- changes in accounting principles;
- litigation or public concern about the safety of our product candidates or similar product candidates;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant shareholders;
- our announcement of financing transactions, including debt, convertible notes, etc.; and
- actions by institutional or activist shareholders.

These broad market and industry factors may decrease the market price of our common stock, regardless of our actual operating performance. When the market price of a company's common stock drops significantly, shareholders often institute securities class action litigation against the company. A lawsuit against us could cause us to incur substantial costs and could divert the time and attention of our management and other resources.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us.

Our financial results previously were included within the consolidated results of Recro, and we believe that our reporting and control systems were appropriate for those of divisions of a public company. We are now directly subject to substantial reporting and other obligations under the Exchange Act. These reporting and other obligations will place significant demands on our management and administrative and operational resources, including accounting resources. We may not have sufficient time to meet these obligations by the applicable deadlines.

In addition, ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that will need to be frequently evaluated. Section 404 of the Sarbanes-Oxley Act requires public companies to conduct an annual review and evaluation of their internal controls and attestations of the effectiveness of internal controls by independent auditors (the latter requirement does not apply to smaller reporting companies—we qualify as a smaller reporting company). Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of the Sarbanes-Oxley Act could have a material adverse effect on our business, financial condition, results of operations and cash flows. We could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on the price of our common stock.

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 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.

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. In addition, any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. 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 directors;
- 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.

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, which expires April 16, 2020.

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 IV 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. There has been no decision on the motion. 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. We believe that the lawsuit is without merit and intend to vigorously defend against it. The lawsuit is in the early stages and, 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 11, 2020, there were 9 holders of record of our common stock. We believe that the number of beneficial owners of our common stock at that date was substantially greater.

Dividend Policy

We 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 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, such as our lead product candidate, IV meloxicam, to the hospital and related acute care markets. We believe we can create value for our shareholders through the development, registration and commercialization of injectable meloxicam and our other pipeline product candidates. In addition to our pipeline, we continue to evaluate acquisition, out-licensing and in-licensing opportunities. We have no revenue and our costs consist primarily of expenses incurred in conducting our manufacturing scale-up, clinical trials and preclinical studies, regulatory activities, pre-commercialization of meloxicam, public company and personnel costs.

In July 2017, we submitted an NDA to the FDA for IV meloxicam and in May 2018, we received a CRL from the FDA regarding our NDA for IV meloxicam. In September 2018, we resubmitted the NDA for IV meloxicam and in March 2019, we received a second CRL from the FDA regarding our NDA for IV meloxicam. In October 2019 we received written notification from the FDA that our appeal relating to the NDA seeking approval for IV meloxicam has been granted. The FDA's letter states that the appeal was granted and that the NDA provides sufficient evidence of effectiveness and safety to support approval. The letter also states that before IV meloxicam can be approved and legally marketed, agreed upon labeling (prescribing information) must be negotiated with the Division. In December 2019, we resubmitted the NDA for IV meloxicam and in January 2020, we announced that the FDA has set a PDUFA goal date of February 20, 2020 for its decision on the NDA for IV meloxicam.

We expect to incur significant and increasing operating losses for at least the next few years. We expect substantially all of our operating losses to result from costs incurred in connection with our development programs, including our non-clinical and formulation development activities, manufacturing, clinical trials and pre-commercialization and commercialization activities. Our expenses over the next several years are expected to relate to the acquisition or in-license of a product and successful commercialization of the acquired or in-licensed product, obtaining regulatory approval for IV meloxicam and, if approved, successfully commercializing IV meloxicam, and continuing to develop our other current and future product candidates.

Separation from Recro Pharma, Inc.

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

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. 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

Research and Development Expenses

Research and development expenses currently consist primarily of costs incurred in connection with the development of injectable meloxicam and our other product candidates. 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 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. Costs related to facilities, depreciation and support are not charged to specific programs.

The successful development of IV meloxicam and 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, including, with respect to IV meloxicam, the nature and scope of any activities required to resolve the CRLs issued by the FDA in response to our NDA for IV meloxicam and to determine the best path forward to obtain approval from the FDA for IV meloxicam, which may include the completion of additional studies;
- 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 additional information as we progress through our discussions with the FDA regarding our NDA for IV meloxicam, as well as assess IV meloxicam’s commercial potential and our available capital resources. Accordingly, we cannot currently estimate with any degree of certainty the amount of time or costs that we will expend in the future on IV meloxicam prior to regulatory approval, if such approval is ever granted. 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 continue to relate to IV meloxicam as we seek to obtain regulatory approval for IV meloxicam, and if successful in obtaining regulatory approval, advance IV meloxicam through the commercialization scale-up and other activities. We also expect to have expenses related to work for maintenance 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.

General and Administrative Expenses

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

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 Agreement, relating to the Purchase and Sale Agreement for the acquisition of certain assets, including the worldwide rights to IV meloxicam and Recro's development, formulation and manufacturing business from Alkermes, or the Alkermes Transaction, as amended in December 2018. Pursuant to the Alkermes Agreement, we are required to pay up to \$140.0 million in milestone payments, including \$10.0 million that was paid during 2019, another \$5.0 million due within 180 days of approval of IV meloxicam 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 IV 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, 2019 recorded a \$66.4 million payment obligation, representing the estimated probability adjusted fair value of the liability. Each reporting period we revalue this estimated obligation with changes in fair value recognized as a non-cash operating expense or gain.

Income Taxation

We maintained a valuation allowance against our deferred tax assets as of December 31, 2019 and 2018.

Results of Operations

Comparison of the Twelve Months Ended December 31, 2019 and 2018

	Year ended December 31,	
	2019	2018
	(amounts in thousands)	
Operating expenses:		
Research and development	\$ 20,061	\$ 35,583
General and administrative	27,012	29,453
Change in contingent consideration valuation	(14,554)	8,499
Total operating expenses	<u>32,519</u>	<u>73,535</u>
Operating loss	(32,519)	(73,535)
Other income (expense):		
Other income (expense), net	(38)	(132)
Net loss	<u>\$ (32,557)</u>	<u>\$ (73,667)</u>

Following the receipt of the second CRL, we implemented a strategic restructuring initiative, and corresponding reduction in workforce, aimed at reducing operating expenses, while maintaining key personnel needed to evaluate strategic partnerships and obtain FDA approval of IV meloxicam. The restructuring initiative included a reduction of approximately 50 positions. During the twelve months ended December 31, 2019, we have incurred approximately \$7.2 million (all \$7.2 million was incurred in the first half of 2019) of costs in connection with the strategic restructuring plan which includes severance and related termination benefits and canceled marketing and production costs.

Research and Development. Our research and development expenses were \$20.1 million and \$35.6 million for the twelve months ended December 31, 2019 and 2018, respectively. Excluding \$2.8 million of costs associated with the strategic restructuring initiative recorded during the year ended December 31, 2019, the decrease of \$18.3 million resulted from a decrease in pre-commercialization manufacturing and clinical costs for IV meloxicam of \$13.5 million, a decrease in development costs for other pipeline products of \$2.8 million, and a decrease in personnel costs of \$2.0 million.

General and Administrative. Our general and administrative expenses were \$27.0 million and \$29.5 million for the twelve months ended December 31, 2019 and 2018, respectively. Excluding \$4.4 million of costs associated with the strategic restructuring initiative recorded in the twelve months ended December 31, 2019, the decrease of \$6.9 million was due to a reduction in commercial team personnel of \$6.1 million and reduced pre-commercial consulting costs of \$3.5 million in preparation of the anticipated launch of IV meloxicam following the receipt of the second CRL. These decreases in costs were partially offset by increases in costs associated with the cost of the Separation of \$2.9 million.

Change in Contingent Consideration valuation. Our change in contingent consideration valuation consisted of a reduction of value of \$14.6 million for the twelve months ended December 31, 2019 as compared to an increase in value of \$8.5 million for the twelve months ended December 31 2018. The non-cash charge for contingent consideration in each period relates to the revaluation of the probability adjusted fair value of the Alkermes Transaction payment obligation. The decrease in the fair value of the liability of

\$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. The increase in the fair value of the liability of \$8.5 million in 2018 was primarily due to the increase in milestone payments related to the December 2018 amendment.

Liquidity and Capital Resources

As of December 31, 2019, we had \$17.7 million in cash and cash equivalents. Historically, 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. We have not reported cash or cash equivalents for the periods presented in the combined balance sheets prior to the Separation.

Under the terms of the Separation Agreement, Recro made a cash capital contribution of \$19 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 fund our operations, working capital needs, capital expenditures and other general corporate purposes. We believe that cash and cash equivalents are sufficient to maintain operations through at least February 14, 2021.

Sources and Uses of Cash

Cash used in operations was \$50.0 million and \$59.8 million for the twelve months ended December 31, 2019 and 2018, respectively, which represents our operating losses less our stock-based compensation, depreciation, and changes in fair value of contingent consideration, as well as changes in operating assets and liabilities.

Cash used in investing activities was \$1.5 million and \$3.5 million for the twelve months ended December 31, 2019 and 2018, respectively. During the twelve months ended December 31, 2019 and 2018, our capital expenditures were \$1.3 million and \$3.4 million, respectively.

There was \$69.3 million of cash provided by financing activities in the twelve months 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. There was \$63.2 million of cash provided by financing activities in the twelve months ended December 31, 2018 from net proceeds from parent company investment.

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

- our post-separation relationships with Recro, 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;
- our ability to resolve any deficiencies identified by the FDA for IV meloxicam
- the labeling under any such approval that we may obtain from the FDA;
- the timing of the Alkermes Transaction regulatory milestone payments and other contingent consideration;
- the costs of manufacturing scale-up and commercialization activities, for IV meloxicam, if approved;
- the level of market acceptance of IV meloxicam, if approved;
- 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 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 obtain debt financing, 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, 2019:

Contractual Obligations	Payments Due by Period (in 000s)				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Purchase Obligations (1):	\$ 3,920	\$ 377	\$ —	\$ —	\$ —
Operating Leases (2)	\$ 1,136	401	735	—	—
Other Long-Term Liabilities:					
Other License Commitments and Milestone payments (3), (4)	\$ 52,265	40	130	170	225
Alkermes Payments (5)	\$ 130,000	—	—	—	—
Employment Agreements (6)	\$ 1,018	1,018	—	—	—
Total Contractual Obligations	\$ 188,339	\$ 1,836	\$ 865	\$ 170	\$ 225

- (1) 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 timing of FDA approval or the outcome of other strategic evaluations. In accordance with U.S. GAAP, these obligations are not recorded on our Consolidated and Combined Balance Sheets. See Note 11 to the Consolidated and Combined Financial Statements included in this Annual Report on Form 10-K.
- (2) 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 11(d) to the Consolidated and Combined Financial Statements included in this Annual Report on Form 10-K.
- (3) 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 5 and Note 11(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 established. In accordance with U.S. GAAP, these obligations are not recorded on our Consolidated and Combined Balance Sheets.
- (4) We license the neuromuscular blocking agents, or NMBAs, from Cornell University pursuant to a license agreement under which we are obligated to make annual license maintenance fee payments, milestone payments and patent cost payments and to pay royalties on net sales of the NMBAs. The amount reflects only payment obligations that are fixed and determinable. We are unable to reliably estimate the timing of certain of these payments because they are dependent on the type and complexity of the clinical studies and intended uses of the products, which have not been established. In accordance with U.S. GAAP, certain of these obligations are not recorded on our Combined Balance Sheets. See Note 5 and 11(a) to the Consolidated and Combined Financial Statements included in this Annual Report on Form 10-K.

- (5) Pursuant to the purchase and sale agreement governing the Alkermes Transaction, we agreed to pay to Alkermes milestone and royalty payments. The amount reflects only payment obligations that are fixed and determinable. 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 and Combined Balance Sheets. See Note 4 and Note 11(b) to the Consolidated and Combined Financial Statements included in this Annual Report on Form 10-K.
- (6) We have entered into employment agreements with certain of our named executive officers. As of December 31, 2019, these employment agreements provided for, among other things, annual base salaries in an aggregate amount of not less than this amount, from that date through calendar year 2020. In accordance with U.S. GAAP, these obligations are not recorded on our Consolidated and Combined Balance Sheets. See Note 11 (f) 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.

Impairment of Goodwill and Indefinite-lived Intangible Assets— We are required to review, on an annual basis, the carrying value of goodwill and indefinite-lived intangible assets, 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. The impairment test for indefinite-lived intangible assets is a one-step test, which compares the fair value of the intangible asset to its carrying value. If the carrying value exceeds its fair value, an impairment loss is recognized in an amount equal to the excess. 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 fixed 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 the probability and timing of FDA approval and successful product launch. We estimate IV 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.

Income taxes - We use the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between the financial statement carrying amount and the tax basis of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. We provide a valuation allowance when it is more-likely-than-not that deferred tax assets will not be realized.

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, 2019, we had approximately \$16.5 million invested in money market instruments. We believe our policy of investing in highly-rated securities, whose liquidities are, at December 31, 2019, 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, 2019, 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, 2019. 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, 2019, 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, 2019. 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, 2019, 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.

Prior to the Separation, we relied on certain financial information and resources of Recro to manage specific aspects of our business and report results. These included investor relations, corporate communications, accounting, tax, legal, human resources, benefit plan administration, benefit plan reporting, general management, real estate, treasury, insurance and risk management, and oversight functions, such as Board of Directors and internal audit, which includes Sarbanes-Oxley compliance. In conjunction with the Separation, we revised and adopted policies, as needed, to meet all regulatory requirements applicable to us as a stand-alone public company. We continue to review our internal controls over financial reporting, and may from time to time make changes aimed at enhancing their effectiveness. These efforts may lead to additional changes in our internal controls over financial reporting.

Item 9B. Other Information

Sales Agreement:

On February 13, 2020, we entered into a Sales Agreement, or the Sales Agreement, with JMP Securities LLC, or JMP, pursuant to which we may sell from time to time, at our option, shares of our common stock having an aggregate offering price of up to \$25,000,000, or the Shares, through JMP, as the placement agent. Sales of the Shares, if any, will be made under our previously filed and currently effective Registration Statement on Form S-3 (Reg. No. 333-235408) in transactions that are deemed to be "at the market offerings" as defined in Rule 415 under the Securities Act of 1933, as amended. JMP will use commercially reasonable efforts to sell the Shares from time to time, based upon our instructions (including any price, time or size limits or other customary parameters or conditions we may impose). We cannot provide any assurances that we will sell any shares of our common stock pursuant to the Sales Agreement. We will pay JMP a commission of 3% of the gross proceeds from the sale of the Shares, if any. We have also agreed to provide JMP with customary indemnification rights. The offering of the Shares will terminate upon the earliest of (a) the sale of all of the Shares or (b) the termination of the Sales Agreement by us or JMP.

The foregoing description of the Sales Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Sales Agreement, which is attached hereto as Exhibit 10.29 and incorporated by reference herein.

Pepper Hamilton LLP, our counsel, has issued an opinion to us, dated February 13, 2020, regarding the validity of the Shares to be issued and sold pursuant to the Sales Agreement. A copy of the opinion is filed as Exhibit 5.1 to this Annual Report on Form 10-K.

This Annual Report on Form 10-K shall not constitute an offer to sell or the solicitation of any offer to buy the securities discussed herein, nor shall there be any offer, solicitation, or sale of the securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

Employment Agreements:

On February 12, 2020, the Company entered into Employment Agreements (the "Employment Agreements") with each of Gerri Henwood, the Company's Chief Executive Officer, and Ryan Lake, the Company's Chief Financial Officer (the "Executives"). Pursuant to the Employment Agreements, Ms. Henwood and Mr. Lake are entitled to base salaries of \$600,000 and \$400,000, respectively, subject to review and adjustment from time to time, in the discretion of the Company's Compensation Committee. Pursuant to the Employment Agreements, Ms. Henwood and Mr. Lake are eligible to participate in the Company's incentive bonus plan with target cash bonuses equal to 60% and 40%, respectively, of their annual base salary. Ms. Henwood and Mr. Lake are also each eligible to participate in the Company's benefits programs (including equity incentive plans) and are eligible for annual equity grants from the Company.

Pursuant to each Employment Agreement, if the Company terminates an Executive without cause (as defined in the Employment Agreements) or the Executive resigns for certain reasons described in the Employment Agreements within 12 months after a change of control (as defined in the Employment Agreements), such Executive will be entitled to receive:

- (i) such Executive's base salary and health insurance benefits, at the Company's expense, for a period of 12 months following the date of termination with respect to Mr. Lake and 18 months following the date of separation with respect to Ms. Henwood;
- (ii) any accrued but unused vacation and paid time off, any earned but unpaid bonus, and reimbursement of any proper business expenses as of the date of termination (the "Accrued Benefits");

- (iii) a pro-rata annual bonus in respect of the fiscal year in which the effective date of termination occurs, with such annual bonus (if any) paid at the same time it would have otherwise been paid absent termination of employment; and
- (iv) outplacement services following the date of termination, which shall not exceed \$25,000.

If the Executive's employment is terminated as a result of his or her death or disability (as defined in the Employment Agreements), the Executive or the Executive's estate, as applicable, would be entitled to receive (i) the Accrued Benefits, (ii) continuation of base salary for twelve months from the date of termination with respect to Ms. Henwood and six months from the date of termination with respect to Mr. Lake; and (iii) pro-rata annual bonus as of the date of termination.

The description of the Employment Agreements contained herein does not purport to be complete and is qualified in its entirety by reference to the complete text of the Employment Agreements, copies of which is attached to this Annual Report on Form 10-K as Exhibits 10.26 and 10.27.

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 2019 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 and Combined Balance Sheets as of December 31, 2019 and 2018

Consolidated and Combined Statements of Operations for the years ended December 31, 2019 and 2018

Consolidated and Combined Statements of Shareholders' Equity for the years ended December 31, 2019 and 2018

Consolidated and Combined Statements of Cash Flows for the years ended December 31, 2019 and 2018

(a)(2) Consolidated and Combined Financial Statement Schedules.

Not applicable.

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

Exhibit No.	Description	Method of Filing
2.1	<u>Separation Agreement, dated November 20, 2019, by and between Recro Pharma, Inc. and Baudax Bio, Inc.</u>	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	<u>Amended and Restated Articles of Organization of Baudax Bio, Inc.</u>	Incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on November 26, 2019 (File No. 001-39101).
3.2	<u>Amended and Restated Bylaws of Baudax Bio, Inc.</u>	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).
5.1	<u>Opinion of Pepper Hamilton LLP</u>	Filed herewith.
10.1	<u>Transition Services Agreement, dated November 20, 2019, by and between Recro Pharma, Inc. and Baudax Bio, Inc.</u>	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 26, 2019 (File No. 001-39101).
10.2	<u>Tax Matters Agreement, dated November 20, 2019, by and between Recro Pharma, Inc. and Baudax Bio, Inc.</u>	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).
10.3	<u>Employee Matters Agreement, dated November 20, 2019, by and between Recro Pharma, Inc. and Baudax Bio, Inc.</u>	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).
10.4 •	<u>Form of Indemnification Agreement between Baudax Bio, Inc. and individual directors and officers.</u>	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).
10.5 †	<u>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.</u>	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).
10.6	<u>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.</u>	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).

Exhibit No.	Description	Method of Filing
10.7	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).
10.8 †	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 to the Company's Current Report on Form 8-K filed on November 26, 2019 (File No. 001-39101).
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 †	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).
10.16 †	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).
10.17 †	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).
10.18 †	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).
10.19	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).
10.20 †	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).
10.21 †	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).
10.22 †	Master Manufacturing Services Agreement, dated July 14, 2017, by and between Patheon UK Limited and Recro Ireland Limited	Incorporated herein by reference to Exhibit 10.21 to the Company's Registration Statement on Form 10 filed on October 22, 2019 (File No. 001-39101).
10.23 †	Product Agreement, dated July 14, 2017, by and between Patheon UK Limited and Recro Ireland Limited	Incorporated herein by reference to Exhibit 10.22 to the Company's Registration Statement on Form 10 filed on October 22, 2019 (File No. 001-39101).

Exhibit No.	Description	Method of Filing
10.24 •	Form of Employment Agreement to be entered into between Baudax Bio, Inc. and its executive officers	Incorporated herein by reference to Exhibit 10.23 to the Company's Registration Statement on Form 10 filed on November 5, 2019 (File No. 001-39101).
10.25 †	Amendment to License Agreement, dated October 21, 2019, by and between Cornell University and Recro Pharma, Inc.	Filed herewith.
10.26	Employment Agreement, dated February 12, 2020, between Baudax Bio, Inc. and Gerri Henwood.	Filed herewith.
10.27	Employment Agreement, dated February 12, 2020, between Baudax Bio, Inc. and Ryan D. Lake.	Filed herewith.
10.28	Amendment to Employee Matters Agreement, dated February 12, 2020, by and between Recro Pharma, Inc. and Baudax Bio, Inc.	Filed herewith.
10.29	Sales Agreement, dated February 13, 2020, by and between Baudax Bio, Inc. and JMP Securities LLC.	Filed herewith.
21.1	Subsidiaries of Baudax Bio, Inc.	Filed herewith.
23.1	Consent of KPMG LLP, Independent Registered Public Accounting Firm.	Filed herewith.
23.2	Consent of Pepper Hamilton LLP	Included in Exhibit 5.1
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	XBRL Instance Document	Filed herewith.
101 SCH	XBRL Taxonomy Extension Schema	Filed herewith.
101 CAL	XBRL Taxonomy Extension Calculation Linkbase	Filed herewith.
101 DEF	XBRL Taxonomy Extension Definition Linkbase	Filed herewith.
101 LAB	XBRL Taxonomy Extension Label Linkbase	Filed herewith.
101 PRE	XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith.

• Management contract or compensatory plan or arrangement.

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 406 under the Securities Act of 1933.

(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 13, 2020

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Gerri A. Henwood</u> Gerri A. Henwood	President, Chief Executive Officer and Director (Principal Executive Officer)	February 13, 2020
<u>/s/ Ryan D. Lake</u> Ryan D. Lake	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 13, 2020
<u>/s/ Alfred Altomari</u> Alfred Altomari	Director	February 13, 2020
<u>/s/ William L. Ashton</u> William L. Ashton	Director	February 13, 2020
<u>/s/ Winston J. Churchill</u> Winston J. Churchill	Director	February 13, 2020
<u>/s/ Wayne B. Weisman</u> Wayne B. Weisman	Director	February 13, 2020

BAUDAX BIO, INC. AND SUBSIDIARIES
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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 and combined balance sheets of Baudax Bio, Inc. and subsidiaries (the Company) as of December 31, 2019 and 2018, 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, 2019 and 2018, 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.

Change in Accounting Principle

As discussed in Note 3 to the consolidated and combined financial statements, the Company has changed its method of accounting for leases as of January 1, 2019 due to the adoption of Accounting Standards Update (ASU) No. 2016-02, *Leases* (Topic 842) and ASU No. 2018-11, *Leases* (Topic 842), *Targeted Improvements*.

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 13, 2020

BAUDAX BIO, INC. AND SUBSIDIARIES

Consolidated and Combined Balance Sheets

(amounts in thousands, except share and per share data)	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 17,740	\$ —
Prepaid expenses and other current assets	2,395	2,514
Total current assets	<u>20,135</u>	<u>2,514</u>
Property, plant and equipment, net	4,821	3,982
Right-of-use asset	730	—
Intangible assets	26,400	26,400
Goodwill	2,127	2,127
Total assets	<u>\$ 54,213</u>	<u>\$ 35,023</u>
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 271	\$ 2,653
Accrued expenses and other current liabilities	3,532	9,773
Current portion of operating lease liability	318	—
Current portion of contingent consideration	3,592	10,354
Total current liabilities	<u>7,713</u>	<u>22,780</u>
Long-term operating lease liability	455	—
Other long-term liabilities	—	32
Long-term portion of contingent consideration	62,766	80,558
Total liabilities	<u>70,934</u>	<u>103,370</u>
Commitments and contingencies (Note 11)		
Shareholders' equity:		
Preferred stock, \$0.01 par value. Authorized, 10,000,000 shares; none issued and outstanding at December 31, 2019	—	—
Parent company net investment	—	(68,347)
Common stock, \$0.01 par value. Authorized, 100,000,000 shares; issued and outstanding, 9,350,709 shares at December 31, 2019	94	—
Additional paid-in capital	19,405	—
Accumulated deficit	(36,220)	—
Total shareholders' equity (deficit)	<u>(16,721)</u>	<u>(68,347)</u>
Total liabilities and shareholders' equity	<u>\$ 54,213</u>	<u>\$ 35,023</u>

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,	
	2019	2018
Operating expenses:		
Research and development	\$ 20,061	\$ 35,583
General and administrative	27,012	29,453
Change in contingent consideration valuation	(14,554)	8,499
Total operating expenses	<u>32,519</u>	<u>73,535</u>
Operating loss	(32,519)	(73,535)
Other income (expense):		
Other income (expense)	(38)	(132)
Net loss	<u>\$ (32,557)</u>	<u>\$ (73,667)</u>
Per share information:		
Net loss per share of common stock, basic and diluted	<u>\$ (3.48)</u>	<u>\$ (7.88)</u>
Weighted average common shares outstanding, basic and diluted	<u>9,350,709</u>	<u>9,350,709</u>

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, 2019 and 2018

(amounts in thousands, except share data)	<u>Common Stock</u>		<u>Parent Company Net Investment</u>	<u>Additional paid-in capital</u>	<u>Accumulated Deficit</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>				
Balance, December 31, 2017	—	—	(62,457)	—	—	(62,457)
Recro Pharma allocation - stock-based compensation	—	—	4,574	—	—	4,574
Net transfer from parent company	—	—	63,203	—	—	63,203
Net loss	—	—	(73,667)	—	—	(73,667)
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	<u>9,350,709</u>	<u>\$ 94</u>	<u>\$ -</u>	<u>\$ 19,405</u>	<u>\$ (36,220)</u>	<u>\$ (16,721)</u>

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,	
	2019	2018
Cash flows from operating activities:		
Net loss	\$ (32,557)	\$ (73,667)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	5,463	4,574
Depreciation expense	480	396
Change in contingent consideration valuation	(14,554)	8,499
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	119	(46)
Right-of-use asset	444	—
Accounts payable, accrued expenses and other liabilities	(8,993)	493
Operating lease liability	(446)	—
Net cash used in operating activities	(50,044)	(59,751)
Cash flows from investing activities:		
Purchases of property and equipment	(1,319)	(3,370)
Acquisition of license agreement	(165)	(82)
Net cash used in investing activities	(1,484)	(3,452)
Cash flows from financing activities:		
Payments of contingent consideration	(10,000)	—
Contribution upon separation	19,000	—
Investment from parent company	60,268	63,203
Net cash provided by financing activities	69,268	63,203
Net increase in cash and cash equivalents	17,740	—
Cash and cash equivalents, beginning of year	—	—
Cash and cash equivalents, end of year	\$ 17,740	\$ —
Supplemental disclosure of cash flow information:		
Purchase of property, plant and equipment included in accrued expenses and accounts payable	\$ —	\$ 2,581

See accompanying notes to consolidated and combined financial statements.

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

(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 candidate, intravenous (IV) meloxicam, to the acute care markets.

In March 2019, the Company received a second Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA), regarding the New Drug Application (NDA), for IV meloxicam, and in April 2019 the Company announced it had implemented a strategic restructuring initiative, and corresponding reduction in workforce, aimed at reducing operating expenses, while maintaining key personnel needed to evaluate strategic partnerships and obtain FDA approval of IV meloxicam.

On October 31, 2019, the Company announced that it had received a written decision from the FDA granting its appeal of the CRL relating to the NDA seeking approval for IV meloxicam. The FDA granted the Company's appeal and indicated that the Company's application provides sufficient evidence of effectiveness and safety to support approval. The letter also states that before IV meloxicam can be approved and legally marketed, agreed upon labeling (prescribing information) must be negotiated with the FDA. The Company resubmitted the NDA for IV meloxicam in December 2019 and the FDA has set a PDUFA goal date of February 20, 2020.

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 15 for a description of the agreements entered into between Recro and Baudax Bio following the Separation.

Prior to the Separation, the combined financial statements include certain assets and liabilities that have historically been held at the Recro corporate level, but which are specifically identifiable or allocable to the Company. All intracompany transactions and accounts have been eliminated. All intercompany transactions between the Company and Recro are considered to be effectively settled in the combined financial statements at the time the transaction is 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 and in the combined balance sheet as parent company net investment. The Company does 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 includes 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

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

incurred had the Company operated as an independent, publicly-traded company for the periods presented prior to the Separation. For the years ended December 31, 2019 (prior to the Separation) and 2018, a total of \$7,278 and \$5,165, respectively, 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 and Liquidity

The Company has incurred losses from operations since inception and has an accumulated deficit of \$36,220 as of December 31, 2019.

The Company 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 and the Company will be required to raise additional funds needed to operate as a standalone entity. The Company's ability to generate cash inflows is highly dependent on the approval and commercialization of IV meloxicam and there can be no assurance that such approval will be obtained or that IV meloxicam can be successfully commercialized. In addition, development activities, clinical and pre-clinical testing and commercialization of the Company's product candidates, if approved, 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 future holders of its common stock and may involve significant cash payment obligations and covenants that restrict the Company's ability to operate its business. Management believes that cash and cash equivalents are sufficient to maintain operations through at least February 14, 2021, however, the Company may be required to wind down operations if IV meloxicam is not approved in the near term or cannot be successfully commercialized.

(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 and amortization. Depreciation and amortization are 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 Financial Accounting Standards Board (FASB), Accounting Standards Codification (ASC), Topic 805, “*Business Combinations*,” or ASC 805, 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 (see Note 4). Goodwill is not amortized but assessed for impairment on an annual basis or more frequently if impairment indicators exist. The impairment model prescribes a one-step method for determining impairment.

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

The Company’s intangible asset is 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 will be written-off, and the Company will 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 impairment test for indefinite-lived intangible assets is a one-step test, which compares the fair value of the intangible

asset to its carrying value. If the carrying value exceeds its fair value, an impairment loss is recognized in an amount equal to the excess.

The Company performs its annual goodwill and indefinite-lived intangible asset impairment test as of November 30th, or whenever an event or change in circumstances occurs that would require reassessment of the recoverability of those assets. 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 receipt of the CRL in March 2019, an indicator of potential impairment, the Company performed an impairment test as of March 31, 2019, which indicated that there was no impairment to goodwill or indefinite-lived intangible assets. The Company also performed its annual test as of November 30, 2019 and there was no impairment to goodwill or indefinite-lived intangible assets based on the analysis.

(f) 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.

(g) 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.

(h) Stock-Based Awards

Baudax Awards

Share-based compensation included in the consolidated financial statements following the Separation is based upon the Baudax Bio share-based compensation plan. The plan includes grants of stock options and time-based vesting restricted stock units (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 estimated historical 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 plan includes grants of stock options, time-based vesting restricted stock units (RSUs) and performance-based vesting RSUs. The combined financial statements prior to the Separation reflect share-based compensation related to Recro stock options and RSUs issued to the Company's employees as well as 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.

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. Recro 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. 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.

(i) Income Taxes

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 presented as if the Company was a standalone taxpayer in each of its tax jurisdictions. 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 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.

(j) 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. For the years ending December 31, 2019 and 2018, the outstanding 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 diluted loss per common share, the denominator includes both the weighted average common shares outstanding and the number of common stock equivalents if the inclusion of such common stock equivalents would be dilutive.

Prior to the distribution date of November 21, 2019, there were no Baudax Bio shares outstanding, as such, the shares outstanding immediately after the Distribution were used to calculate the net loss per share for all pre-Separation periods presented.

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

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

	Year ended December 31,	
	2019	2018
Basic Loss Per Share		
Net loss	\$ (32,557)	\$ (73,667)
Weighted average common shares outstanding, basic and diluted	9,350,709	9,350,709
Net loss per share of common stock, basic and diluted	\$ (3.48)	\$ (7.88)

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as of December 31, 2019 and 2018 as they would be anti-dilutive:

	December 31,
	2019
Options and restricted stock units outstanding	2,023,909

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

(k) Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued Accounting Standards Update (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 11 (d).

Accounting Pronouncements Not Yet Adopted

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 is currently evaluating the potential impact on its disclosures.

(4) Acquisition of Gainesville Facility and Meloxicam

On April 10, 2015, the Company completed the acquisition of a manufacturing facility in Gainesville, Georgia and the licensing and commercialization rights to IV meloxicam (the Alkermes Transaction). The consideration paid in connection with the Alkermes Transaction consisted of \$50,000 cash at closing, a \$4,000 working capital adjustment and a seven-year warrant to purchase 350,000 shares of Recro's common stock at an exercise price of \$19.46 per share. In addition, the Company may be required to pay up to an additional \$125,000 in milestone payments including \$45,000 upon regulatory approval of IV meloxicam, as well as net sales milestones related to IV meloxicam and a percentage of future product net sales related to IV meloxicam between 10% and 12% (subject to a 30% reduction when no longer covered by patent). Under the acquisition method of accounting, the consideration paid and the fair value of the contingent consideration and royalties were allocated to the fair value of the assets acquired and liabilities assumed. The contingent consideration obligation is remeasured each reporting date with changes in fair value recognized as a period charge within the statement of operations (see Note 6 for further information regarding fair value).

The assets acquired, including goodwill, and liabilities assumed in the Alkermes Transaction were allocated to the Company's reporting units as of the date of the acquisition. The accompanying consolidated and combined financial statements reflect the IPR&D asset of \$26,400 and goodwill of \$2,127 that were recorded by the Company related to the Alkermes transaction.

The warrant associated with the transaction remains on Recro's Consolidated and Combined Balance Sheets with no allocation to the Company as it is a warrant to purchase Recro common stock. The Company did not assume any obligation in connection with the warrant as of result of the Separation.

In December 2018, the Company entered into a second amendment to the purchase and sale agreement among Alkermes Pharma Ireland Limited, Alkermes US Holdings (together with Alkermes Pharma Ireland Limited, Alkermes), Daravita Limited, Recro and Recro Gainesville LLC (Recro Gainesville) that restructured the \$45,000 milestone to \$60,000 therefore increasing the amount the Company may be required to pay Alkermes to \$140,000, however, the amendment spread the payments of the development milestone over a seven-year period.

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 will be payable upon certain regulatory approval and include (i) a \$5,000 payment due within 180 days following regulatory approval for IV meloxicam 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 meloxicam net sales. During the year ended December 31, 2019, the Company paid the first component consisting of two payments of \$5,000 each to Alkermes.

The fair value of the contingent consideration liability is measured as the reporting date using inputs and assumptions as of the date of the financial statements. 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. The fair value of the second contingent consideration component is estimated by applying a risk-adjusted discount rate to the probability-adjusted contingent payments and the expected approval dates. 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.

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.

(5) NMBA Related License Agreement

In June 2017, the Company acquired the exclusive global rights to two novel neuromuscular blocking agents, or NMBAs, and a proprietary reversal agent from Cornell University, or 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

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Phase I clinical trials and two other agents, a novel short-acting NMBA, and a rapid-acting reversal agent specific to these NMBAs.

The transaction was accounted for as an asset acquisition, with the total cost of the acquisition of \$766 allocated to acquired IPR&D. The Company recorded an upfront payment obligation of \$350, as well as operational liabilities and acquisition-related costs of \$416, primarily consisting of reimbursement to Cornell for specified past patent, legal and pre-clinical costs.

In addition, the Company is obligated to make: (i) an annual license maintenance fee payment until the first commercial sale of the NMBA Related Compounds; and (ii) milestone payments upon the achievement of certain milestones, up to a maximum, for each NMBA, of \$5,000 for U.S. regulatory approval and commercialization milestones and \$3,000 for European regulatory approval and commercialization milestones. The Company is also obligated to pay Cornell royalties on net sales of the NMBA Related Compounds 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 accounted for the transaction as an asset acquisition based on an evaluation of the accounting guidance (ASC Topic 805) and considered the early clinical stage of the novel and unproven NMBA Related Compounds. The Company concluded that the acquired IPR&D of Cornell did not constitute a business as defined under ASC 805 due to the incomplete nature of the inputs and the absence of processes from a market participant perspective. Substantial additional research and development will be required to develop any NMBA Related Compounds into a commercially viable drug candidate, including completion of pre-clinical testing and clinical trials, and, if such clinical trials are successful, application for regulatory approvals and manufacturing repeatability and scale-up. There is risk that a marketable compound may not be well tolerated and may never be approved.

Acquired IPR&D in the asset acquisition was accounted for in accordance with FASB ASC Topic 730, "*Research and Development*." At the date of acquisition, the Company determined that the development of the projects underway at Cornell had not yet reached technological feasibility and that the research in process had no alternative future uses. Accordingly, the acquired IPR&D was charged to expense in the Combined Statements of Operations on the acquisition date. The acquired IPR&D charge is expected to be deductible over a 15-year period for income tax purposes.

(6) 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.

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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, 2018:			
Liabilities:			
Contingent consideration (See Note 4)	\$ —	\$ —	\$ 90,912
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 90,912</u>
At December 31, 2019:			
Assets:			
Cash equivalents			
Money market mutual funds (See Note 7)	\$ 16,514	\$ —	\$ —
Total cash equivalents	<u>\$ 16,514</u>	<u>\$ —</u>	<u>\$ —</u>
Liabilities:			
Contingent consideration (See Note 4)	\$ —	\$ —	\$ 66,358
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 66,358</u>

The reconciliation of the contingent consideration measured at fair value on a recurring basis using unobservable inputs (Level 3) is as follows:

	<u>Contingent Consideration</u>
Balance at December 31, 2017	\$ 82,413
Remeasurement	8,499
Balance at December 31, 2018	<u>\$ 90,912</u>
Payment of contingent consideration	(10,000)
Remeasurement	(14,554)
Total at December 31, 2019	<u>\$ 66,358</u>
Current portion as of December 31, 2019	3,592
Long-term portion as of December 31, 2019	\$ 62,766

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, 2019 (see Note 4 for additional information). The Company plans to reevaluate this classification as it progresses discussions with the FDA regarding the December 2019 resubmission of its NDA and approaches the new PDUFA date of February 20, 2020.

The Company follows the disclosure provisions of FASB ASC Topic 825, "Financial Instruments" (ASC 825), for disclosure purposes for financial assets and financial liabilities that are not measured at fair value. As of December 31, 2019, the financial assets and liabilities recorded on the Consolidated and Combined Balance Sheets that are not measured at fair value on a recurring basis include accounts payable and accrued expenses and approximate fair value due to the short-term nature of these instruments.

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(7) Cash Equivalents

Cash equivalents as of December 31, 2019 include money market funds. The following is a summary of cash equivalents:

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

As of December 31, 2019, the Company's cash equivalents had maturities of one month.

(8) Property, Plant and Equipment

Property, plant and equipment consists of the following:

	December 31, 2019	December 31, 2018
Building and improvements	\$ 196	\$ 196
Furniture, office and computer equipment	1,518	1,688
Manufacturing equipment	101	101
Construction in progress	3,846	2,469
	5,661	4,454
Less: accumulated depreciation and amortization	840	472
Property, plant and equipment, net	\$ 4,821	\$ 3,982

Depreciation expense for the years ended December 31, 2019 and 2018 was \$480 and \$396, respectively.

(9) Intangible Assets

The following represents the balance of the intangible assets at December 31, 2019 and 2018:

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

There was no amortization expense for the years ended December 31, 2019 and 2018.

(10) Accrued Expenses

Accrued expenses consist of the following:

	December 31, 2019	December 31, 2018
Payroll and related costs	\$ 2,181	\$ 2,172
Professional and consulting fees	209	671
Clinical trial and related costs	—	683
Property plant and equipment	—	278
Pre-commercialization scale-up costs	—	4,445
Other research and development costs	538	678
Guarantee liability	548	—
Other	56	846
	\$ 3,532	\$ 9,773

After the receipt of the second CRL, the Company incurred approximately \$7,200 in restructuring costs (all of which were incurred in the first half of 2019). The remaining liability associated with the restructuring plan was retained by Recro and does not represent an obligation of the Company following the Separation.

(11) 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 (\$22,990 as of December 31, 2019) 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, 2019, 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 (\$13,682 as of December 31, 2019) 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, 2019, no such milestones have been achieved.

The Company is party to a license agreement with Cornell for the exclusive license of the NMBA Related Compounds. Under the terms of the agreement, the Company will pay Cornell an initial upfront fee and Cornell is also entitled to receive additional milestone payments, annual license maintenance fees as well as royalties. See Note 5 for further information regarding these payment obligations.

(b) Contingent Consideration for the Alkermes Transaction

Pursuant to the purchase and sale agreement and subsequent amendment governing the Alkermes Transaction, the Company agreed to pay to Alkermes up to an additional \$140,000 in milestone payments including \$50,000 upon regulatory approval payable over a seven-year period, as well as net sales milestones related to IV meloxicam and royalties on future product sales of injectable meloxicam between 10% and 12% (subject to a 30% reduction when no longer covered by patent). As of December 31, 2019, the Company has paid \$10,000 in milestone payments to Alkermes.

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

(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, 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 IV 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

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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. There has been no decision on the motion. 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 intend to vigorously defend against it. The lawsuit is in the early stages and, at this time, no assessment can be made as to its likely outcome or whether the outcome will be material to the Company.

(d) 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, however, all leased facilities are classified as operating leases with remaining lease terms of less than 1 year and 3 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 and Combined Balance Sheets. Lease expense is recognized on a straight-line basis over the lease term.

As of December 31, 2019, undiscounted future lease payments for non-cancellable operating leases are as follows:

	Lease payments
2020	\$ 401
2021	362
2022	373
Total lease payments	1,136
Less imputed interest	(363)
Total operating liabilities	<u>\$ 773</u>

As of December 31, 2018 under legacy ASC 840 "Leases", undiscounted future lease payments for non-cancellable operating leases were as follows:

	Lease payments
2019	\$ 517
2020	414
2021	367
2022	373
Total	<u>\$ 1,671</u>

For the year ended December 31, 2019, the weighted average remaining lease term was 3 years and the weighted average discount rate was 16%.

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The components of the Company’s lease cost were as follows for the year ended December 31, 2019:

Operating lease cost	\$	484
Short-term lease cost		12
Total lease cost	\$	<u>496</u>

(e) Purchase Commitments

As of December 31, 2019, the Company had outstanding non-cancelable and cancelable purchase commitments of \$3,920 related to inventory and other goods and services, including pre-commercial/manufacturing scale-up and clinical activities. The timing of certain purchase commitments cannot be estimated as it is dependent on timing of FDA approval or the outcome of other strategic evaluations and agreements.

(f) Certain Compensation and Employment Agreements

The Company has entered into employment agreements with certain of its named executive officers. As of December 31, 2019, these employment agreements provided for, among other things, annual base salaries in an aggregate amount of not less than \$1,018 from that date through calendar year 2020.

(12) Capital Structure

(a) Common Stock

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

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

On February 13, 2020, the Company entered into a Sales Agreement (the “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. To date, no shares have been sold under the Agreement.

(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, 2019, no preferred stock was issued or outstanding.

(13) Stock-Based Compensation

In connection with the Separation, the Company adopted its own share-based compensation plan, the Baudax Bio, Inc. 2019 Equity Incentive Plan, or the 2019 Plan, which allows for the grant of stock options, stock appreciation rights and stock awards for a total of 3,000,000 shares of common stock. On December 1st of each year, pursuant to the “Evergreen” provision of the 2019 Plan, the number of shares available under the plan shall be increased by an amount equal to 5% of the outstanding common stock on December 1st of that year or such lower amount as determined by the Board of Directors. In December 2019, the number of shares available for issuance under the 2019 Plan was increased by 467,535. The total number of shares authorized for issuance under the 2019 plan as of December 31, 2019 is 3,467,535.

Stock options are exercisable generally for a period of 10 years from the date of grant and generally vest over four years. As of December 31, 2019, 1,443,626 shares are available for future grants under the 2019 Plan.

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The weighted average grant-date fair value of the Baudax Bio options awarded to employees during the year ended December 31, 2019 was \$4.29. 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 assumptions:

	<u>December 31,</u> <u>2019</u>
Range of expected option life	6 years
Expected volatility	77.81%
Risk-free interest rate	1.68%
Expected dividend yield	—

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 as 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 years ended December 31, 2019 (prior to the Separation date) and 2018 was \$5.53 and \$6.07, respectively.

Under the Recro equity incentive plan for the year ended December 31, 2018, 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 assumptions:

	<u>December 31,</u>	
	<u>2019</u>	<u>2018</u>
Range of expected option life	5.5 - 6 years	5.5 - 6 years
Expected volatility	74.69% - 80.59%	73.26% - 82.00%
Risk-free interest rate	1.42 - 2.66%	2.32 - 3.03%
Expected dividend yield	—	—

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

	<u>Number of</u> <u>shares</u>	<u>Weighted</u> <u>average</u> <u>exercise</u> <u>price</u>	<u>Weighted</u> <u>average</u> <u>remaining</u> <u>contractual life</u>
Granted	643,879	\$ 6.33	
Exercised	—	\$ —	
Expired/forfeited/cancelled	—	\$ —	
Balance, December 31, 2019	<u>643,879</u>	<u>\$ 6.33</u>	9.9 years
Vested	—	\$ —	
Vested and expected to vest	643,879	\$ 6.33	9.9 years

The following table summarizes the Baudax Bio restricted stock units activity during the year ended December 31, 2019:

	<u>Number of shares</u>
Granted	1,380,030
Vested and settled	—
Expired/forfeited/cancelled	—
Balance, December 31, 2019	<u>1,380,030</u>
Expected to vest	1,380,030

Stock-based compensation expense for the twelve months ended December 31, 2019 and 2018 was \$5,463 and \$4,574, respectively. This represents the allocated portion of Recro stock-based compensation expense through the Separation date in addition to the Company's expense post-separation.

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As of December 31, 2019, there was \$10,996 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 2.5 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, 2019, the aggregate intrinsic value of the unvested Baudax Bio options was \$380. There are no vested options as of December 31, 2019.

(14) Income Taxes

The components of loss before income tax are as follows:

	December 31,	
	2019	2018
Domestic	\$ (16,417)	\$ (43,505)
Foreign	(16,140)	(30,162)
Loss before income taxes	<u>\$ (32,557)</u>	<u>\$ (73,667)</u>

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

	December 31,	
	2019	2018
Current:		
Federal	\$ —	\$ —
State and local	—	—
Foreign	—	—
Deferred:		
Federal	\$ (3,440)	\$ (10,034)
State and local	(1,206)	(4,026)
Foreign	(2,018)	(3,770)
	<u>(6,664)</u>	<u>(17,830)</u>
Change in valuation allowance	6,664	17,830
	<u>\$ —</u>	<u>\$ —</u>

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,	
	2019	2018
U.S. federal statutory income tax rate	21.0%	21.0%
Foreign tax rate differential	(4.2)%	(3.5)%
State taxes, net of federal benefit	3.7%	5.5%
Nondeductible expenses	—	0.3%
Research and development credits	—	0.7%
Change in federal tax rate	—	0.1%
Change in valuation allowance	(20.5)%	(24.2)%
Other	—	0.1%
Effective income tax rate	<u>—</u>	<u>—</u>

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

	December 31,	
	2019	2018
Net operating loss carryforwards	\$ 1,065	\$ 24,384
Research and development credits	—	972
Capitalized start-up costs	—	1,489
Intangibles	2,056	206
Contingent consideration	10,924	9,746
Stock-based compensation	142	3,924
Other temporary differences	(12)	161
Gross deferred tax asset	14,175	40,882
Valuation allowance	(14,094)	(40,618)
Net deferred tax asset	81	264
Deferred tax liability	(81)	(264)
Net deferred taxes	<u>\$ —</u>	<u>\$ —</u>

For periods prior to the Separation, the income tax provision was prepared on a separate return methodology and presented as if the Company was a standalone taxpayer in each of its tax jurisdictions. Accordingly, deferred tax assets as of December 31, 2018 represent the hypothetical deferred taxes that were applicable to the Company as if it were a separate company during periods prior to the Separation. Within the Company's deferred tax assets as of December 31, 2018 are amounts included for net operating loss carryforwards and research and development credits, as these are the amounts that would have been generated by the Company on a separate basis prior to the transaction for 2018 and 2017. These tax attributes were included as of December 31, 2018, based on the separate return methodology. As a result of the Separation, not all of the tax attributes that existed as of December 31, 2018 carried forward to the Company subsequent to the transaction. As of December 31, 2019, deferred tax assets represent the deferred taxes attributable to the Company following the Separation.

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 2019 and 2018, 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, 2019. 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, 2019:

	Amount	Expiration
Federal net operating losses - 2019	\$ 1,357	No expiration
State net operating losses	\$ 1,357	2028 – 2038
Foreign net operating losses	\$ 672	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 it 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

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limitation of 30%, 35% or 40% of taxable income after modifications and apportionment on state net operating losses utilized in any one year during tax years beginning during 2017, 2018 or 2019 going forward, respectively.

The Company will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2019, 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.

(15) Related Party Transactions

A Non-Executive Director of the Company's Irish subsidiary is a Managing Director and a majority shareholder of HiTech Health Ltd, or 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 \$171 and \$309 of expenses for the twelve months ended December 31, 2019 and 2018, 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 provides certain services to Recro, each related to corporate functions, and are 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 year ended December 31, 2019, for periods subsequent to the Separation, the Company recorded income of \$206 related to the transition services agreement, which is recorded as a reduction in general and administrative expenses. The Company recorded a net receivable of \$273 for such activities and other activity with Recro 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.

(16) Retirement Plan

The Company has a voluntary 401(k) Savings Plan (the 401(k) Plan) in which all employees are eligible to participate. The Company's policy is to match 100% of the employee contributions up to a maximum of 5% of employee compensation. Total Company contributions to the 401(k) plan for the year ended December 31, 2019 and 2018 were \$307 and \$540, respectively.



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February 13, 2020

Board of Directors of Baudax Bio, Inc.
 490 Lapp Road
 Malvern, Pennsylvania 19355

RE: Securities Registered under Registration Statement on Form S-3

Ladies and Gentlemen:

We are acting as counsel to Baudax Bio, Inc., a Pennsylvania corporation (the “**Company**”), in connection with the Company’s issuance of up to \$25,000,000 shares of the Company’s common stock, par value \$0.01 per share (the “**Shares**”), from time to time and at various prices in an “at the market offering” pursuant to that certain Sales Agreement, dated February 13, 2020 (the “**Agreement**”), by and between the Company and JMP Securities LLC (“**JMP**”). The Shares will be sold by the Company pursuant to the Company’s registration statement on Form S-3 under the Securities Act of 1933, as amended (the “**Act**”), filed with the Securities and Exchange Commission (the “**Commission**”) on December 6, 2019 and declared effective by the Commission on December 16, 2019 (the “**Registration Statement**”), a base prospectus dated December 16, 2019 (the “**Base Prospectus**”) and a prospectus supplement dated February 13, 2020 (together with the Base Prospectus, the “**Prospectus**”). This opinion letter is furnished to you at your request to enable you to fulfill the requirements of Item 601(b)(5) of Regulation S-K, 17 C.F.R. § 229.601(b)(5), in connection with the issuance of the Shares.

For purposes of this opinion letter, we have examined copies of such agreements, instruments and documents as we have deemed an appropriate basis on which to render the opinions hereinafter expressed. In our examination of the aforesaid documents, we have assumed the genuineness of all signatures, the legal capacity of all natural persons, the accuracy and completeness of all documents submitted to us, the authenticity of all original documents, and the conformity to authentic original documents of all documents submitted to us as copies (including pdfs). As to all matters of fact, we have relied on the representations and statements of fact made in the documents so reviewed, and we have not independently established the facts so relied on. This opinion letter is given, and all statements herein are made, in the context of the foregoing.

This opinion letter is based as to matters of law solely on the Pennsylvania Business Corporation Law of 1988, as amended. We express no opinion herein as to any other statutes, rules or regulations.

	Boston	Washington, D.C.	Los Angeles	New York	Pittsburgh	Detroit
Philadelphia						
Berwyn	Harrisburg	Orange County	Princeton	Rochester	Silicon Valley	Wilmington

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Baudax Bio, Inc.
Page 2
February 13, 2020

Based upon, subject to and limited by the foregoing, we are of the opinion that following: (i) issuance of the Shares pursuant to the terms of the Agreement and (ii) receipt by the Company of the consideration for the Shares specified in the resolutions of the Board of Directors, the Shares will be validly issued, fully paid, and nonassessable.

This opinion letter has been prepared for use in connection with the filing by the Company of an Annual Report on Form 10-K relating to the offer and sale of the Shares, which Form 10-K will be incorporated by reference into the Registration Statement and Prospectus, and speaks as of the date hereof. We assume no obligation to advise you of any changes in the foregoing subsequent to the delivery of this letter.

We hereby consent to the filing of this opinion letter as Exhibit 5.1 to the above-described Annual Report on Form 10-K and to the reference to this firm under the caption "Legal Matters" in the Prospectus. In giving this consent, we do not thereby admit that we are an "expert" within the meaning of the Act.

Very truly yours,

/s/ PEPPER HAMILTON LLP

PEPPER HAMILTON LLP

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395



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October 21, 2019

Jyrki Mattila, PhD
 Executive Vice President of Business Development
 Recro Pharma, Inc.
 490 Lapp Road, Malvern PA 19355
 Email: [***]

RE: AMENDMENT

to the License Agreement by and between Recro Pharma, Inc. and Cornell University, as represented by its Center for Technology Licensing at Cornell University, effective June 30, 2017, and amended effective October 24, 2017, and November 29, 2018 (Cornell Contract #C2017-12-10946)

Effective as of the date of the last signature below (“Third Amendment Date”), the undersigned parties agree to hereby modify the License Agreement referenced above as follows:

1) Paragraph 3.1(d) shall be replaced in its entirety with the following:

(c) during the Royalty Term, milestone payments (“Milestone Payments”) in the amounts payable according to the following schedule of events upon the specified date or achievement of the specified event:

Amount	Milestone
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

For the avoidance of doubt, the maximum, aggregate Milestone Payments due for each Licensed Product shall be [***].

2) In Paragraph 3.1(d), the table shall be replaced with the following:

When Licensed Product is:	the earned royalty rate is:
A Short-acting Licensed Product, (including any Combination Product in which a Short-acting Licensed Product is sold with a Reversal Agent Licensed Product), in countries where a Valid Claim Covers the applicable Licensed Product	[***]% of Net Sales of the applicable Licensed Product
A Short-acting Licensed Product (including any Combination Product in which a Short-acting Licensed Product is sold with a Reversal Agent Licensed Product), in countries where no Valid Claim Covers the applicable Licensed Product	[***]% of Net Sales of the applicable Licensed Product
An Intermediate-acting Licensed Product (including any Combination Product in which an Intermediate-acting Licensed Product is sold with a Reversal Agent Licensed Product), in countries where a Valid Claim Covers the applicable Licensed Product	[***]% of Net Sales of the applicable Licensed Product
An Intermediate-acting Licensed Product (including any Combination Product in which an Intermediate-acting Licensed Product is sold with a Reversal Agent Licensed Product), in countries where no Valid Claim Covers the applicable Licensed Product	[***]% of Net Sales of the applicable Licensed Product
A Reversal Agent Licensed Product, in countries where a Valid Claim Covers the applicable Licensed Product and solely where such Reversal Agent Licensed Product is sold as a stand-alone product and not as part of a Combination Product	[***]% of Net Sales of the applicable Licensed Product
A Reversal Agent Licensed Product, in countries where no Valid Claim Covers the applicable Licensed Product and solely where such Reversal Agent Licensed Product is sold as a stand-alone product and not as part of a Combination Product	[***]% of Net Sales of the applicable Licensed Product

3) Paragraph 3.3 Due Diligence is hereby replaced with the following:

3.3 Due Diligence.

- (a) [***]:
 - (i) [***];

- (ii) [***];
- (iii) [***];
- (iv) [***];
- (v) [***];
- (vi) [***];
- (vii) [***];
- (viii) [***];
- (ix) [***];
- (x) [***];
- (xi) [***];
- (xii) [***];
- (xiii) [***];
- (xiv) [***]; and
- (xv) [***].

(b) If at any time, Licensee anticipates that it will be unable to meet any of its obligations specified in Paragraphs 3.3(a)(i)-(xv) above, then Licensee will notify Cornell in writing including with such notice a reasonably detailed explanation of the reasons for same. Within a reasonable time period, Cornell and Licensee will review and assess the circumstances to reset and extend the diligence time frame for the obligation in question and later diligence events. In the event that Licensee's failure to achieve one or more diligence events in Paragraphs 3.3(a)(i)-(xv) is due to circumstances outside of Licensee's control, the Parties agree on the new extended timelines and no penalties will be applied on the Licensee. In the event that Licensee's failure to achieve one or more diligence events in Paragraphs 3.3(a)(i)-(xv) is due solely to circumstances within Licensee's control, Licensee will have the right, one time, to extend the performance deadline by one (1) year upon payment of [***] dollars to Cornell. If the Licensee's failure to achieve one or more diligence events in Paragraphs 3.3(a)(i)-(xv) is due solely to circumstances within Licensee's control, and if the LICENSEE fails to make the payment to extend or has already used said right, Cornell shall have the right and option to either terminate this Agreement

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*] HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED.**

or convert Licensee's exclusive license to a nonexclusive license. This right, if exercised by Cornell, supersedes the rights granted in Article 2. In case Cornell decides to convert the license non-exclusive, Licensee has right in its sole discretion to terminate the Agreement.

(c) If at any time during the Term, Licensee has not begun a genuine product or business development program for a specific Licensed Product in any country within the Territory and Cornell receives one or more legitimate inquiries to license Patent Rights for the commercialization of said specific Licensed Product in said country, Cornell shall refer such offers to Licensee. If Licensee fails to satisfy the market demand (within 25%) in said country of the specific Licensed Product, and Licensee is unable to cure such failure within ninety (90) days from the date of notice, or fails to grant Sublicenses to the inquirers to satisfy such market demand (after Licensee has failed to cure such failure as set forth above), Cornell may then exclude said country, and only said country, from the Territory and license such rights to one or more third parties.

4) Paragraph 1.3 Assignability is hereby replaced with the following:

10.3 Assignability. This Agreement may not be assigned by either Party, without the written consent of the other Party, such consent not to be unreasonably withheld.

5) These changes do not otherwise change the terms and conditions of the License Agreement.

IN WITNESS THEREOF, the parties have caused this instrument to be executed in duplicate as of the Third Amendment Date.

Cornell University

Recro Pharma, Inc.

By: /s/ Brian Kelly

By: /s/ Gerri Henwood

Name: Brian J. Kelly, PhD

Name: Gerri Henwood

Title: Director, Technology Licensing

Title: CEO and President

Date: October 22, 2019

Date: October 21, 2019

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the "Agreement") is made and entered into as of the 12th day of February, 2020 (the "Effective Date"), by and between Baudax Bio, Inc., a Pennsylvania corporation (the "Company"), **Gerri Henwood**, an individual (the "Executive") and, solely for purposes of Section 16 hereof, Recro Pharma, Inc., a Pennsylvania corporation ("Recro").

BACKGROUND

WHEREAS, the Company desires to employ the Executive, and the Executive desires to accept such employment, subject to the terms and further conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound hereby, agree as follows:

1. **Employment and Duties.** From and after the Effective Date, the Company shall employ the Executive as Chief Executive Officer. In such capacity, the Executive shall perform all such duties as are assigned to him or her consistent with the Executive's titled position by the Board of Directors of the Company (the "Board"), and shall use his or her reasonable best efforts to promote the interests of the Company. Nothing contained herein shall preclude the Executive from managing personal investments, participating in charitable, community, educational and professional activities, or, with the prior written consent of the Company (which shall not be unreasonably withheld), serving on the board of directors (or comparable governing body), including any board committees, of for-profit businesses that do not compete with the Company, provided that such activities do not materially interfere with the performance of his or her duties for the Company.

2. **Term.** The term of the Executive's employment hereunder shall continue until terminated pursuant to the terms of this Agreement.

3. **Compensation.** From and after the Effective Date, the Company shall pay the Executive in accordance with its normal bi-weekly payroll practices an annual salary at the initial rate of \$600,000 per year (the "Base Salary"). The Executive's Base Salary shall be reviewed not less often than annually and may be increased from time to time in the sole discretion of the Company. The Base Salary, as in effect from time to time, may not be decreased without the prior written consent of the Executive, except as part of an across the board decrease in which the percentage decrease in the Executive's base salary is not greater than the smallest percentage decrease of any other senior executive officer.

4. Other Benefits.

(a) Bonuses.

(i) The Executive will qualify to participate in the Company's incentive bonus program. The Executive's target bonus amount (the "Target Bonus"), tied to set performance goals and measures, is 60% of the Executive's Base Salary. Notwithstanding the foregoing, the Company reserves the right to change or terminate any bonus program at any time in the Board's sole discretion.

(b) Benefits Plans. The Executive shall be eligible to participate in all health insurance, savings and retirement, and other benefit plans, if any, that are from time to time generally applicable to other employees of the Company, subject to the terms and conditions of such plans.

(c) Vacation and Personal Days. The Executive shall be entitled to five (5) weeks of paid vacation time per year and three (3) paid personal days per year, in accordance with the plans, practices, policies, and programs agreed to by Company.

(d) Expense Reimbursement. The Executive shall be entitled to receive reimbursement for all reasonable employment-related expenses incurred by the Executive upon the receipt by the Company of an accounting in accordance with practices, policies and procedures applicable to other employees of the Company.

(e) Equity Grant . The Executive shall be eligible for a regular annual equity grant (with such eligibility determined on the same basis as other senior executives, in the discretion of the Compensation Committee of the Company ("Compensation Committee")) and for other grants under such equity or long-term incentive plan as may be adopted by the Company from time to time. The terms of any such grants shall be determined in the discretion of the Compensation Committee. All stock options granted to the Executive shall be incentive stock options to the fullest extent permitted by law.

(f) Make-Whole and Joining Grants. The parties hereby acknowledge that as of December 5, 2019, the Executive received a grant of (i) 195,387 restricted stock units under the Company's 2019 Equity Incentive Plan (the "Baudax Plan"), which vest in full on the earlier of: a) a change of control of the Company or b) December 5, 2020, subject to continued employment with the Company; (ii) 93,550 restricted stock units under the Recro Pharma, Inc. ("Recro") 2018 Amended and Restated Equity Incentive Plan, which vest in full on the earlier of: a) a change of control of Recro or b) December 5, 2020, subject to continued employment with Recro, ((i) and (ii) together, the "Make-Whole Grants"); (iii) options to purchase 183,673 shares of the Company's common stock under the Baudax Plan, which vest in 48 monthly installments, subject to continued employment with the Company; and (iv) 128,571 restricted stock units under the Baudax Plan, which vest on an annual basis over four years, subject to continued employment with the Company ((iii) and (iv) together, the "Joining Grants"), in each case pursuant to the terms and conditions of the applicable equity incentive plan and award agreement. The Executive understands that any outstanding awards previously granted to him or her under any equity incentive plan maintained by Recro will not be adjusted as a result of the

spin-off of the Company from Recro, as described in Section 16 below, notwithstanding any adjustment provision contained in the applicable Recro equity incentive documents. The Executive understands that the Make-Whole Grants described in this Section 4(f) are in lieu of receiving any adjustments to such awards previously granted by Recro.

5. Confidential Information.

(a) The Executive agrees at all times during the term of his or her employment with the Company and thereafter, to hold in strictest confidence, and not to use, except for the benefit of the Company, or to disclose to any person or entity ("Person") without prior written authorization of the Company, any Confidential Information of the Company. The Executive understands that "Confidential Information" means Inventions (as defined herein) and any other information of the Company and/or its affiliates disclosed or made available to the Executive, whether before or during the term hereof, including but not limited to financial information, technical and non-technical data, services, products, processes, operations, reports, analyses, test results, technology, samples, specifications, protocols, performance standards, formulations, compounds, know-how, methodologies, trade secrets, trade practices, marketing plans and materials, strategies, forecasts, research, concepts, ideas, and names, addresses and any other characteristics or identifying information of the Company's existing or potential investors, licensors, licensees, suppliers, customers or employees. Confidential Information shall not include any information the Executive can establish by competent proof is or becomes public knowledge or part of the public domain through no act or omission of the Executive. Notwithstanding the foregoing, the Executive shall be permitted to disclose Confidential Information pursuant to a court order, government order or any other legal requirement of disclosure if no suitable protective order or equivalent remedy is available, provided that the Executive gives the Company written notice of such court order, government order or legal requirement of disclosure immediately upon knowledge thereof and allows the Company a reasonable opportunity to seek to obtain a protective order or other appropriate remedy prior to such disclosure to the extent permitted by law. Further, it shall not be a violation of the Executive's confidentiality obligations, and the Executive shall not be held criminally or civilly liable under any federal or state trade secret law if disclosure of confidential information (A) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

(b) The Executive agrees that he or she shall not, during his or her employment with Company, improperly use or disclose any proprietary information or trade secrets of any former employer of the Executive or other Person and that the Executive will not bring onto the premises of the Company any unpublished documents or proprietary information belonging to any such former employer or Person unless consented to in writing by such former employer or Person.

(c) The Executive recognizes that the Company has received and in the future will receive from third parties certain confidential or proprietary information subject to a duty on the Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. The Executive agrees to hold all such confidential or

proprietary information in the strictest confidence and not to disclose it to any Person, or to use it except as necessary in carrying out his or her work for the Company consistent with Company's agreement with such third party.

(d) Notwithstanding anything herein to the contrary, nothing in this Agreement shall (x) prohibit the Executive from making reports of possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934, as amended, or Section 806 of the Sarbanes-Oxley Act of 2002, or of any other whistleblower protection provisions of federal law or regulation, or (y) require notification or prior approval by the Company of any such report; provided that, the Executive is not authorized to disclose communications with counsel that were made for the purpose of receiving legal advice or that contain legal advice or that are protected by the attorney work product or similar privilege.

6. Inventions.

(a) The Executive agrees that he or she shall promptly make full written disclosure to the Company, shall hold in trust for the sole right and benefit of the Company, shall assign and hereby does assign to the Company, or its designee, all of the Executive's right, title, and interest in and to any and all inventions, original works of authorship, developments, concepts, improvements, designs, discoveries, ideas, trademarks or trade secrets, whether or not patentable or registerable under copyright or similar laws, which the Executive may, solely or jointly, conceive or develop or reduce to practice during the period of time the Executive is in the employ of the Company that relate to the Company and/or its products (collectively referred to as "Inventions"). The Executive further acknowledges that all original works of authorship which are made by the Executive (solely or jointly with others) within the scope of and during the period of his or her employment with the Company and which are protectable by copyright are "works made for hire", as that term is defined in the United States Copyright Act. The Executive understands and agrees that the decision whether or not to commercialize or market any invention developed by the Executive (solely or jointly with others) is within the Company's sole discretion and for the Company's sole benefit and that no royalty will be due to the Executive as a result of the Company's efforts to commercialize or market any such invention.

(b) The Executive agrees to keep and maintain adequate and current written records of all Inventions made by the Executive (solely or jointly with others) during the term of his or her employment with the Company. The records will be in the form of notes, sketches, drawings, and any other format that may be specified by the Company. The records will be available to and remain the sole property of the Company at all times.

(c) If the Company is unable because of the Executive's mental or physical incapacity or for any other reason to secure his or her signature on any such document, then the Executive hereby irrevocably designates and appoints the Company and its duly authorized officers and agents as his or her agent and attorney-in-fact to act for and in the Executive's behalf and stead to execute and file any such document and to do all other lawfully permitted acts to further the prosecution and issuance of letters patent or copyright registrations thereon with the same legal force and effect as if executed by the Executive.

7. Returning Company Documents. The Executive agrees that, at the time of leaving the employ of the Company, he or she shall deliver to the Company (and will not keep in his or her possession, recreate or deliver to anyone else) any and all devices, records, data, notes, reports, proposals, lists, correspondence, materials, equipment, other documents or property, or reproductions of any of the aforementioned items developed by the Executive pursuant to his or her employment with the Company or otherwise belonging to the Company, its successors or assigns.

8. Nonsolicitation and Noncompetition.

(a) The Executive agrees that during the term of his or her employment with the Company and for a period of one (1) year immediately following the termination of the Executive's employment with the Company for any reason whatsoever, whether with or without cause, (i) the Executive shall not, either directly or indirectly, solicit, induce, recruit or encourage any employees of the Company and/or its affiliates to leave their employment, or take away such employees, or attempt to solicit, induce, recruit, encourage or take away employees of the Company and/or its affiliates, either for the Executive or for any other Person and (ii) neither the Executive, nor any firm, organization or corporation in which he or she is interested, shall, for any reason, directly or indirectly, persuade or attempt to persuade any investor, licensor, licensee, supplier or customer of Company, or any potential investor, licensor, licensee, supplier or customer to which the Company and/or its affiliates have made a presentation or with which the Company and/or its affiliates have been having discussions, to not transact business with the Company and/or its affiliates or to transact business with the Executive or any other Person as an alternative to or in addition to the Company and/or its affiliates.

(b) The Executive agrees that during the term of his or her employment with the Company and for a period of one (1) year immediately following the termination of the Executive's employment with the Company for any reason whatsoever, whether with or without cause, the Executive shall not, anywhere in the world, engage, either directly or indirectly, whether as a principal or as an agent, officer, director, employee, consultant, shareholder, partner or otherwise, alone or in association with any other Person, in any Competing Business. For purposes of this Agreement, the term "Competing Business" shall mean any Person engaged in the development or commercialization of products that are the same or substantially similar to, or that directly compete with, those products developed, commercialized or actively in development or commercialization by the Company.

(c) In the event that the provisions of subparagraphs (a) or (b) above should be determined by a court or other tribunal of competent jurisdiction to exceed the time, geographic, services or product limitations permitted by the applicable law in a jurisdiction in which enforcement of this Agreement is sought, then such provisions shall be deemed reformed in such jurisdiction to the maximum time, geographic, service or product limitations permitted by such applicable law, and the parties hereby expressly grant any court or competent jurisdiction the authority to effect such reformation.

9. Equitable Relief. The parties confirm that a violation by the Executive of the provisions of this Agreement, including but not limited to, the restrictions in Sections 5 through 8, will cause the Company irreparable harm that cannot be remedied adequately by

monetary damages. The Executive agrees that, in the event of such a violation, the Company shall be entitled to seek temporary, preliminary and permanent injunctive relief to restrain any such violation (without the posting of a bond) and to an equitable accounting of all earnings, profits and other benefits arising from the breach or violation, which rights shall be cumulative and in addition to any other rights or remedies to which the Company may be entitled. The Company shall be entitled to commence action for such relief in any state or federal court in the Commonwealth of Pennsylvania, and the Executive waives to the fullest extent permitted by law any objection that he or she may now or hereafter have to the jurisdiction and venue of the court in any such proceeding. In any such action, the prevailing party (once all appeals have been exhausted) shall be entitled to recover such party's reasonable attorney's fees, out-of-pocket costs and disbursements.

10. Termination of Employment.

(a) Notwithstanding the provisions of Section 2 hereof, the Executive's employment shall terminate, or be subject to termination, as follows:

(i) Death or Disability. In the event the Executive dies, this Agreement shall terminate. If the Executive becomes entitled to long-term disability benefits under the Company's then-current disability insurance policy(ies) applicable to the Executive, the Company may, at its option, terminate the Executive's employment hereunder effective immediately upon written notice. If the Company does not have in effect disability insurance covering the Executive and/or if "disabled" is not defined therein, the Executive shall be deemed disabled hereunder at such time that he or she suffers a physical or mental disability that renders him or her unable to perform the duties of his or her employment on substantially a full-time basis, and such period of physical or mental disability continues without substantial interruption for more than one hundred eighty (180) days.

(ii) By Company for Cause. The Company may, at any time, terminate the Executive's employment hereunder for Cause. For purposes of this Agreement, the Company shall have "Cause" to terminate the Executive's employment hereunder upon (a) conduct amounting to fraud or dishonesty against the Company; (b) the willful failure by the Executive to substantially perform his or her duties hereunder or the material violation by the Executive of any of the other provisions of this Agreement, which willful failure or material violation shall continue for thirty (30) days or more following written notice to the Executive; (c) the Executive's loss of any permit, license, accreditation or other authorization necessary to the Executive's performance of his or her duties hereunder, as determined by the Company in its sole discretion; (d) the Executive's conviction of a felony or a plea by the Executive of nolo contendere to a felony; or (e) other willful conduct by the Executive likely, in the reasonable judgment of the Board, to materially adversely affect the reputation of the Company, which conduct shall continue for five (5) days or more following written notice to the Executive. No act, or omission to act, shall be considered "willful" unless such act or omission is done without a good faith belief by the Executive that such act or omission is in, or not opposed to, the best interests of the Company.

(iii) By Company for Convenience. The Company may terminate the Executive's employment hereunder at any time, without Cause, upon no less than thirty (30) days prior written notice to Executive.

(iv) By Executive for Convenience. The Executive may terminate his or her employment hereunder at any time upon no less than thirty (30) days prior written notice to the Company.

(v) By Executive upon a Change of Control. The Executive may terminate his or her employment hereunder at any time during the twelve (12) months following a Change of Control, if during such twelve-month period the Company and/or its successor (a) materially and adversely changes the status, responsibilities or perquisites of the Executive and such change is not cured within thirty (30) days following written notice by the Executive to the Company, (b) reduces the Executive's Base Salary other than as permitted by Section 3 or the amount of the Target Bonus, or (c) requires the Executive to be principally based at any office or location more than fifty (50) miles from the Executive's principal office immediately prior to the Change of Control; provided, however, that the Executive shall not be entitled to resign pursuant to this Section 10(a)(v) unless the Executive notifies the Company in writing of the circumstances outlined in Section 10(a)(v)(a) through 10(a)(v)(c) within thirty (30) days after he or she first has notice of such circumstances, the Company fails to cure such circumstances within thirty (30) days after receipt of such notice, and the Executive resigns his or her employment not later than ten (10) days after the end of such cure period. For purposes of this Agreement, a "Change of Control" shall be deemed to have occurred upon the happening of any of the following events: (i) the consummation of a plan of dissolution or liquidation of the Company; (ii) the consummation of the sale or disposition of all or substantially all of the assets of the Company; (iii) the consummation of a merger, consolidation or other shareholder-approved fundamental business transaction in which the Company is a participant with another entity where the stockholders of the Company, immediately prior to the referenced transaction, will not beneficially own, immediately after the referenced transaction, shares or other equity interests entitling such stockholders to more than 50% of all votes to which all equityholders of the surviving entity would be entitled in the election of directors; (iv) the date any entity, person or group, (within the meaning of Section 13(d)(3) or Section 14(d)(2) of the Securities Exchange Act of 1934, as amended), (other than (A) the Company or any of its subsidiaries or any employee benefit plan (or related trust) sponsored or maintained by the Company or any of its subsidiaries or (B) any person who, on the date the Plan is effective, is the beneficial owner of outstanding securities of the Company), shall have become the beneficial owner of, or shall have obtained voting control over, more than fifty percent (50%) of the outstanding shares of the Common Stock; or (v) the first day after the date hereof when directors are elected such that a majority of the Board shall have been members of the Board for less than twenty-four (24) months, unless the nomination for election of each new director who was not a director at the beginning of such twenty-four (24) month period was approved by a vote of at least two-thirds of the directors then still in office who were directors at the beginning of such period.

(b) Severance.

(i) In the event of any termination of the Executive's employment for any reason, the Executive (or his or her estate) shall be entitled to (A) his or her

Base Salary through the date of termination, (B) the value of his or her accrued but unused vacation and paid time off through the date of termination, (C) except in the case of termination for Cause, any bonus earned in a prior year but not yet paid on the date of termination, (D) reimbursement of all business expenses properly incurred prior to the date of termination consistent with Company policy, and (E) any benefits, including any continuation or conversion rights, provided under any employee benefit plan or policy of the Company (not including any severance, separation pay, or supplemental unemployment benefit plan), in accordance with the terms of such plan or policy (the "Accrued Benefits").

(ii) In the event of termination of the Executive's employment by reason of death or Disability, the Company shall pay or provide to the Executive or the Executive's estate (A) the Accrued Benefits, (B) the Executive's Base Salary, in accordance with its normal payroll practices (but not less frequently than monthly), for a period of twelve (12) months from the effective date of such termination, (C) an amount equal to the Executive's Target Bonus for the fiscal year of termination pro-rated through the date of termination (determined based on the number of days in the calendar year that the Executive is employed by the Company in such year of the effective date of termination) and paid within thirty (30) days following such termination, and (D) continued health benefits for the Executive and his or her eligible dependents at the Company's expense (or such portion thereof as is then funded by the Company for other employees of the Company), if applicable, for the period described above in clause (B).

(iii) In the event of a termination by the Company pursuant to Section 10(a)(iii), or if the Executive terminates this Agreement during the twelve (12) months after a Change of Control pursuant to Section 10(a)(v), the Company shall (A) pay or provide to the Executive the Accrued Benefits, (B) pay the Executive a pro-rata annual bonus in respect of the fiscal year in which the effective date of termination occurs (determined based on the number of days in the calendar year that the Executive is employed by the Company in such fiscal year of the effective date of termination), with such annual bonus (if any) paid at the same time it would have otherwise been paid absent the Executive's termination of employment, (C) continue to pay the Executive his or her Base Salary, in accordance with its normal payroll practices (but not less frequently than monthly), and shall continue the Executive's, and his or her eligible dependents', health insurance benefits at the Company's expense (or such portion thereof as is then funded by the Company for other employees of the Company) for a period of eighteen (18) months from the effective date of such termination, and (D) provide the Executive, at the Company's expense, with senior executive level outplacement services for a period of twelve (12) months from the date of termination, using a reputable provider selected by the Executive with the Company's consent, which shall not be unreasonably withheld, provided that such outplacement expenses shall not exceed \$25,000 in any event.

(iv) Except as expressly provided in this Section 10(b), upon the termination of the Executive's employment, all payments hereunder shall cease.

(v) The payments and benefits described in Sections 10(b)(ii) and 10(b)(iii) are in lieu of, and not in addition to, any other severance arrangement maintained by the Company. The payments and benefits described in Sections 10(b)(ii) and 10(b)(iii), other than the Accrued Benefits, are conditioned on clauses (i) and (ii) below:

i. The Executive's (or in the case of the Executive's death, his/her estate's) execution and delivery to the Company and the expiration of all applicable statutory revocation periods, by the sixtieth (60th) day following the effective date of his or her termination of employment, of a general release of claims against the Company and its affiliates substantially in the form attached hereto as Exhibit A (the "Release"). Subject to Section 11 below, the payments and benefits described in Section 10(b)(ii) and 10(b)(iii) will begin to be paid or provided as soon as administratively practicable after the Release becomes irrevocable, provided that if the sixty (60) day period described above begins in one taxable year and ends in a second taxable year such payments or benefits shall not commence until the second taxable year.

ii. The Executive's continued compliance with the provisions of Sections 5, 6, 7 and 8 of this Agreement.

(vi) The Executive shall not be required to seek or accept other employment, or otherwise to mitigate damages, as a condition to receipt of the benefits described in Sections 10(b)(ii) and 10(b)(iii), and such benefits shall not be reduced or offset by an amounts received by the Executive from any other source, except to the extent the Executive's medical coverage is discontinued by reason of the Executive acquiring other coverage.

(c) The provisions of this Agreement shall survive expiration or termination of this Agreement for any reason to the extent necessary to enable the parties to enforce their respective rights hereunder, including without limitation Sections 4(d), 5, 6, 7, 8, 9, 10(b), 10(c), 11, 12, 13, 14, 15 and 16.

11. Compliance with Section 409A.

(a) Notwithstanding anything to the contrary in this Agreement, all benefits or payments provided by the Company to the Executive that would be deemed to constitute "nonqualified deferred compensation" within the meaning of Section 409A of the Code are intended to comply with Section 409A of the Code. Notwithstanding anything in this Agreement to the contrary, distributions of benefits which constitute "nonqualified deferred compensation" within the meaning of Section 409A of the Code may be made under this Agreement upon an event and in a manner permitted by Section 409A of the Code or an applicable exemption.

(b) Notwithstanding anything to the contrary in this Agreement, no portion of the benefits or payments to be made under Section 10(b) hereof will be payable until the Executive has a "separation from service" from the Company within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"). In addition, to the extent compliance with the requirements of Treas. Reg. § 1.409A-3(i)(2) (or any successor provision) is necessary to avoid the application of an additional tax under Section 409A of the Code to payments due to the Executive upon or following his or her "separation from service", then notwithstanding any other provision of this Agreement (or any otherwise applicable plan, policy, agreement or arrangement), any such payments that are otherwise due within six months following the Executive's "separation from service" (taking into account the preceding sentence of this paragraph) will be deferred without interest and paid to the Executive in a lump sum

immediately following that six month period. This paragraph should not be construed to prevent the application of Treas. Reg. § 1.409A-1(b)(9)(iii) (or any successor provision) to amounts payable hereunder. For purposes of the application of Section 409A of the Code, each payment in a series of payments will be deemed a separate payment.

(c) Notwithstanding anything to the contrary in this Agreement, except to the extent any expense, reimbursement or in-kind benefit provided to the Executive does not constitute a “deferral of compensation” within the meaning of Section 409A of the Code, and its implementing regulations and guidance, (i) the amount of expenses eligible for reimbursement or in-kind benefits provided to the Executive during any calendar year will not affect the amount of expenses eligible for reimbursement or in-kind benefits provided to the Executive in any other calendar year, (ii) the reimbursements for expenses for which the Executive is entitled to be reimbursed shall be made on or before the last day of the calendar year following the calendar year in which the applicable expense is incurred and (iii) the right to payment or reimbursement or in-kind benefits hereunder may not be liquidated or exchanged for any other benefit.

12. Parachute Payment.

(a) If any payment or benefit the Executive would receive under this Agreement or otherwise in connection with a Change of Control, as defined herein (the “Total Payments”) would (i) constitute a “Parachute Payment” within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the “Excise Tax”), then such Total Payment shall be equal to the Reduced Amount. The “Reduced Amount” shall be either (x) the largest portion of the Total Payment that would result in no portion of the Total Payment being subject to the Excise Tax or (y) the largest portion, up to and including the total of the Total Payment, whichever amount, after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in the Executive’s receipt, on an after-tax basis, of the greatest economic benefit notwithstanding that all or some portion of the Total Payment may be subject to the Excise Tax. If a reduction in payments or benefits constituting Parachute Payments is necessary so that the Total Payment equals the Reduced Amount, reduction shall occur in the manner that results in the greatest economic benefit for the Executive. In applying this principle, the reduction shall be made in a manner consistent with the requirements of Section 409A of the Code, and where two economically equivalent amounts are subject to reduction but payable at different times, such amounts shall be reduced on a pro rata basis but not below zero.

(b) In the event it is subsequently determined by the Internal Revenue Service that some portion of the Reduced Amount (as determined pursuant to clause (x) in the preceding paragraph) is subject to the Excise Tax, the Executive agrees to promptly return to the Company a sufficient amount of the Total Payment so that no portion of the Reduced Amount is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount is determined in accordance with clause (y) in the preceding paragraph, the Executive will have no obligation to return any portion of the Total Payment pursuant to the preceding sentence. Unless the Executive and the Company agree on an alternative accounting or law firm, the accounting firm then engaged by the Company for general tax compliance purposes shall perform the foregoing

calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Change of Control, the Company shall appoint a nationally recognized accounting, law or consulting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such accounting, law or consulting firm required to be made hereunder.

(c) The Company shall use commercially reasonable efforts such that the accounting, law or consulting firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to the Executive and the Company within fifteen (15) calendar days after the date on which the Executive's right to a Total Payment is triggered (if requested at that time by the Executive or the Company) or such other time as requested by the Executive or the Company.

13. Notices. All notices, consents, waivers or other communications which are required or permitted hereunder will be sufficient if given in writing and delivered personally, by overnight mail service, by fax transmission (which is confirmed) or by registered or certified mail, return receipt requested, postage prepaid, to the parties at the addresses set forth below (or to such other addressee or address as will be set forth in a notice given in the same manner):

<u>If to the Company:</u>	Baudax Bio, Inc. 490 Lapp Road Malvern, PA 19355 Attn: Board of Directors
<u>If to the Executive:</u>	Gerri Henwood Address on file.

All such notices will be deemed to have been given three business days after mailing if sent by registered or certified mail, one business day after mailing if sent by overnight courier service, or on the date delivered or transmitted if delivered personally or sent by fax transmission.

14. Indemnification. To the maximum extent permitted by applicable law, both during the term of this Agreement and at all times thereafter, regardless of the reason for termination, the Company shall indemnify the Executive and hold the Executive harmless against any cost, fee, expense, fine or penalty (a "cost") to which he or she may be subject as a result of serving as an employee or officer of the Company or any other entity at the Company's direction, shall advance to the Executive, as incurred, the reasonable costs (including fees and disbursements of legal counsel) incurred by him in defending any judicial or administrative proceeding, including any investigation, that may give rise to a cost, subject to the Executive's obligation to repay any such advance if it is subsequently determined that he or she was not entitled to indemnification, and shall provide for the Executive to be covered by its directors and officers, or any similar, insurance policy at the level applicable to its most senior active officers.

15. Nondisparagement. Both during the term of this Agreement and at all times thereafter, regardless of the reason for termination, the Executive shall not publicly disparage the Company, and the Company shall instruct the members of the Board and its senior

executives not to publicly disparage the Executive. Notwithstanding the foregoing, nothing in this Agreement will prohibit the Executive or the Company from (a) responding to any inquiry from, or providing truthful testimony before any self-regulatory organization or any state or federal regulatory authority, (b) making any other truthful disclosure required by law or legal process, or (c) defending any charge, action, investigation or proceeding initiated by or on behalf of the other.

16. Dual Employment with Recro.

(a) The Company and the Executive acknowledge and agree that this Agreement is being entered into in connection with the Executive's commencement of employment with the Company following the spin-off of the Company from Recro, pursuant to that certain Separation Agreement by and between the Company and Recro dated as of November 20, 2019. The Company acknowledges that the Executive will remain an employee, officer and director of Recro following the Effective Date and will simultaneously provide services to both the Company and Recro. Similarly, Recro acknowledges that the Executive is also an employee, officer and director of the Company and will simultaneously provide services to both the Company and Recro. During this period of dual employment, the Executive agrees to devote such time and energy to each of the Company and Recro as is necessary to fulfill her duties to each company, and each of the Company and Recro agree to exercise commercially reasonable efforts to schedule, limit and coordinate their demands on Executive's time, so as not to interfere with her ability to discharge her duties to the other company. Except as otherwise provided below in Section 16(b)(iii), Executive will no longer receive compensation or benefits from Recro (although Recro may be or become obligated to reimburse the Company for certain portions of the Executive's compensation from the Company, as determined based on agreements between Recro and the Company).

(b) In connection with the entry into this Agreement, and in consideration of the rights and benefits described herein, the Executive hereby represents, acknowledges and agrees that:

(i) Except as otherwise provided in Section 16(b)(ii) and 16(b)(iii) below, Executive's rights under that certain Employment Agreement dated as of October 8, 2013, as amended from time to time (the "Recro Agreement") are hereby terminated and Recro has or no current or contingent obligation to Executive (compensatory or otherwise). Without limiting the generality of the foregoing: (A) Executive is not now entitled to any severance payment or benefit from Recro, and no future cessation of her employment with Recro will entitle her to any severance payment or benefit, and (B) Executive will not be entitled to any annual cash incentive payment from Recro with respect to any portion of 2019 (although Executive's 2019 annual cash incentive from the Company will not be pro-rated and may take into account Executive's performance at Recro during the portion of 2019 that preceded the spin-off of the Company);

(ii) Any rights the Executive had immediately prior to the Effective Date (i) to indemnification by Recro in respect of her acts or omissions as an employee, officer or director of Recro (whether arising under Recro's governing documents or

otherwise), and (ii) to the benefit of any directors' and officers' insurance coverage maintained by Recro will, in each case, remain in full force and effect;

(iii) Executive's outstanding equity incentive awards made pursuant to the Recro 2018 Amended and Restated Equity Incentive Plan and the Recro 2008 Stock Option Plan shall not be adjusted as a result of the spin-off of the Company from Recro, as described in Section 4(f) above. However, all such equity awards remain outstanding in accordance with their terms and will continue to vest based on Executive's continued service with Recro;

(iv) Executive's obligations under the confidentiality, non-solicitation, non-competition, non-disparagement and intellectual property assignment provisions of the Recro Agreement remain in full force and effect and Executive hereby reaffirms those obligations;

(c) The Executive, for herself and on behalf of her heirs, assigns, executors, agents and representatives, hereby fully and forever releases and discharges Recro, its predecessors, successors (by merger or otherwise), parents, subsidiaries, affiliates and assigns, together with each and every of their present, past and future officers, directors, shareholders, general partners, limited partners, employees and agents (in their official, individual and all other capacities), and all other persons or entities acting with, for, through or in concert with any of them from any and all claims, demands, liens, agreements, contracts, covenants, actions, suits, causes of action, obligations, controversies, debts, costs, expenses, damages, judgments, orders and liabilities, of whatever kind or nature, direct or indirect, in law, equity or otherwise, whether known or unknown, which the Executive now has, or hereafter can, shall or may have for, upon or by reason of any act, transaction, practice, conduct, matter, cause or thing of any kind or nature whatsoever arising or occurring through the Effective Date, except as otherwise expressly provided above in Section 16(a), 16(b)(ii) and 16(b)(iii).

17. Miscellaneous.

(a) No provision of this Agreement may be amended unless such amendment, modification or discharge is agreed to in writing signed by the parties hereto.

(b) No waiver by any party hereto of any breach of, or compliance with, any condition or provision of this Agreement by the other party shall be deemed a waiver of similar or dissimilar provisions or conditions at the same or at any prior or subsequent time. No such waiver shall be enforceable unless expressed in a written instrument executed by the party against whom enforcement is sought.

(c) This Agreement constitutes the entire agreement of the parties on the subject matter and no agreements or representations, oral or otherwise, expressed or implied, with respect to the subject matter hereof have been made by either party which are not set forth expressly in this Agreement. For the avoidance of doubt, any prior agreements or representations made by either party which are not set forth expressly in this Agreement, are hereby superseded. In the event of any conflict between this Agreement and any policy of the Company, the terms of this Agreement will control.

(d) This Agreement shall be binding upon and inure to the benefit of the Company, its successors and assigns, and the Executive and his or her heirs, executors, administrators and legal representatives. The Company may not assign its rights and obligations under this Agreement to any person without the prior written consent of the Executive, except to a successor to the Company's business that expressly adopts and agrees to be bound by this Agreement.

(e) This Agreement shall be governed by, and construed in accordance with, the laws of the Commonwealth of Pennsylvania without giving effect to its principles of conflicts of law. Exclusive jurisdiction for any dispute between the parties arising from or in connection with this Agreement and/or the relationship between the Executive and the Company shall lie with the federal and state courts located in the Commonwealth of Pennsylvania, and each party hereby consents to the personal jurisdiction of such courts.

(f) This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original but all of which together shall constitute one and the same instrument.

(g) This Agreement has been jointly drafted by the respective representatives of the Company and the Executive and no party shall be considered as being responsible for such drafting for the purpose of applying any rule construing ambiguities against the drafter or otherwise. No draft of this Agreement shall be taken into account in construing this Agreement.

(h) The Executive agrees to be bound by Company policies as in effect from time to time, including without limitation any policies regarding clawbacks, securities trading, and hedging or pledging of securities.

[Execution page follows]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year first above written.

EXECUTIVE:

/s/ Gerri Henwood
GERRI HENWOOD

COMPANY:

BAUDAX BIO, INC.

By: /s/ Ryan D. Lake

**Solely for purposes of agreeing to Section 16 herein, RECRO PHARMA,
INC.:**

By: /s/ Ryan D. Lake

Exhibit A

SEPARATION AND MUTUAL RELEASE AGREEMENT

THIS SEPARATION AND MUTUAL RELEASE AGREEMENT (this “**Release**”) is made by and between Gerri Henwood (the “**Executive**”) and Baudax Bio, Inc. (the “**Company**”).

WHEREAS, the Executive’s employment with the Company has terminated; and

WHEREAS, pursuant to Section 10(b)[ii][iii] of the Employment Agreement by and between the Company and the Executive dated as of _____ (the “**Employment Agreement**”), the Company has agreed to pay the Executive certain amounts and to provide certain benefits, subject to his or her execution and non-revocation of this Release. All terms used but not defined herein shall have the meanings ascribed to such terms in the Employment Agreement.

NOW THEREFORE, in consideration of these premises and the mutual promises contained herein, and intending to be legally bound hereby, the parties agree as follows:

1. Consideration. The Executive acknowledges that : (i) the payments set forth in Section 10(b)[ii][iii] of the Employment Agreement constitute full settlement of all his or her rights under the Employment Agreement, (ii) he or she has no entitlement under any other severance or similar arrangement maintained by the Company or any of its affiliates, and (iii) except as otherwise provided specifically in this Release, the Company does not and will not have any other liability or obligation to the Executive by reason of the cessation of his or her employment. The Executive further acknowledges that, in the absence of his or her execution of this Release, the payments and benefits specified in Section 10(b)[ii][iii] of the Employment Agreement would not otherwise be due to him or her.

2. Mutual Release and Covenant Not to Sue.

2.1. Mutual Release. The Executive, on his or her own behalf and together with his or her heirs, assigns, executors, agents and representatives hereby fully and forever releases and discharges the Company, its predecessors, successors (by merger or otherwise), parents, subsidiaries, affiliates and assigns, together with each and every of their present, past and future officers, directors, shareholders, general partners, limited partners, employees and agents (in their official, individual and all other capacities), and all other persons or entities acting with, for, through or in concert with any of them (herein collectively referred to as the “**Company Releasees**”) from any and all claims, demands, liens, agreements, contracts, covenants, actions, suits, causes of action, obligations, controversies, debts, costs, expenses, damages, judgments, orders and liabilities, of whatever kind or nature, direct or indirect, in law, equity or otherwise, whether known or unknown, which the Executive now has, or hereafter can, shall or may have for, upon or by reason of any act, transaction, practice, conduct, matter, cause or thing of any kind or nature whatsoever (each, a “**Claim**”) arising or occurring through the Effective Date of this Release. The Company hereby fully and forever releases and discharges the Executive from any Claim arising or occurring through the Effective Date of this Release,

including, but not limited to, any Claim arising out of the Executive's employment by the Company or the termination thereof.

2.2. Covenant Not to Sue. The Executive expressly represents that he or she has not filed a lawsuit or initiated any other administrative proceeding against the Company and that he or she has not assigned any claim against the Company to any other person or entity. The Company expressly represents that it has not filed a lawsuit or initiated any other administrative proceeding against the Executive and that it has not assigned any claim against the Executive to any other person or entity. Both the Executive and Company further promise not to initiate a lawsuit or to bring any other claim against the other arising out of or in any way related to the Executive's employment by the Company or the termination of that employment (other than claims described in Section 2.3). Notwithstanding anything in this Release to the contrary, this Release will not prevent the Executive from filing a charge with the Equal Employment Opportunity Commission (or similar state agency) or participating in any investigation conducted by the Equal Employment Opportunity Commission (or similar state agency); provided, however, that any claims by the Executive for personal relief in connection with such a charge or investigation (such as reinstatement or monetary damages) will be barred.

2.3. Claims Not Released. Notwithstanding Section 2.1, the forgoing release of any Claim does not release the Company or the Executive from claims : (a) to enforce this Release, (b) claims to enforce the Executive's rights under any employee benefit plan in accordance with the terms of the applicable plan(s), or (c) for indemnification under the Company's By-Laws, under applicable law, or under any indemnification agreement between the Company and the Executive. Additionally, the foregoing does not release the Executive from claims the Company may have arising out of or related to: (w) any obligation the Company may have under applicable law or an exchange listing requirement to pursue the recoupment of compensation or other payments made to the Executive, (x) Executive's criminal or other serious misconduct related to the Company, (y) Executive's breach of fiduciary duty to the Company, or (z) Executive's material breach of any agreement with the Company.

2.4. Claims Released. The Executive understands and agrees that the claims released in Section 2.1 include, but are not limited to : (a) any Claim based on any law, statute, or constitution or based on contract or in tort or based on common law; (b) any Claim based on or arising under any civil rights laws, labor laws, or employment laws, such as the Pennsylvania Human Relations Act, or the civil rights laws of any other state or jurisdiction, or Title VII of the Civil Rights Act of 1964 ("**Title VII**"), or the federal Age Discrimination in Employment Act of 1967 ("**ADEA**"), or the Americans with Disabilities Act of 1990 ("**ADA**"), or the Civil Rights Act of 1991, or the Worker Adjustment and Retraining Notification Act ("**WARN**"); (c) any Claim under any grievance or complaint procedure of any kind; (d) any Claim based on or arising out of or related to the Executive's recruitment by, employment with, the termination of the Executive's employment with, the Executive's performance of any services in any capacity for, or any business transaction with, any or all of the Company Releasees (including, but not limited to any claim for wrongful or retaliatory discharge); (e) any Claim for a personal recovery by the Executive in connection with, or arising from, any lawsuit or proceeding brought by any person or entity other than the Executive (including, but not limited to, any Claim brought by any administrative agency, department or commission); (f) any

Claim for the Executive's attorneys' fees, costs or expenses relating to this Release; and (g) any other Claim for compensation of any kind.

3. Cooperation. The Executive further agrees that he or she will cooperate fully with the Company and its counsel with respect to any matter (including litigation, investigations, or governmental proceedings) in which the Executive was in any way involved during his or her employment with the Company. The Executive shall render such cooperation in a timely manner on reasonable notice from the Company.
4. Mutual Non-Disparagement. The Company's officers and directors will not disparage the Executive or the Executive's performance or otherwise take any action which could reasonably be expected to adversely affect the Executive's personal or professional reputation. Similarly, the Executive will not disparage the Company or any of its directors, officers, agents or employees or otherwise take any action which could reasonably be expected to adversely affect the personal or professional reputation of the Company or any of its directors, officers, agents or employees.
5. Permitted Conduct. Notwithstanding anything in this Release to the contrary, nothing in this Release shall prohibit or restrict the Executive or the Company from : (a) initiating communications directly with, or responding to any inquiry from, or providing testimony before, the SEC, FINRA, any other self-regulatory organization or any other state or federal regulatory authority; (b) making any disclosure of relevant, necessary and truthful information or documents : (i) pursuant to the Sarbanes-Oxley Act; (ii) as otherwise required by law or legal process; (iii) in connection with any charge, action, investigation or proceeding relating to this Release; or (iv) to the Company's Legal Department.
6. Restrictive Covenants. The Executive acknowledges that the restrictive covenants contained in Sections 5, 6, 7, 8 and 9 of the Employment Agreement will survive the termination of his or her employment (the "**Restrictive Covenants**"). The Executive affirms that the Restrictive Covenants are reasonable and necessary to protect the legitimate interests of the Company, that he or she received adequate consideration in exchange for agreeing to the Restrictive Covenants and that he or she will abide by the Restrictive Covenants.
7. Rescission Right. The Executive expressly acknowledges and recites that : (a) Executive has read and understands the terms of this Release in its entirety, (b) Executive has entered into this Release knowingly and voluntarily, without any duress or coercion, (c) Executive has been advised orally and is hereby advised in writing to consult with an attorney with respect to this Release before signing it, (d) Executive was provided at least twenty-one (21) calendar days after receipt of the Release to consider its terms before signing it, and (e) Executive is provided seven (7) calendar days from the date of signing to terminate and revoke this Release, in which case this Release shall be unenforceable, null and void. The Executive may revoke this Release during those seven (7) days by providing written notice of revocation to Baudax Bio, Inc., 490 Lapp Road, Malvern, PA, 19355, Attn: Board of Directors. Provided that the Executive does not revoke this Release, the Release shall become effective on the eighth (8th) day following the Executive's execution of the Release (the "**Effective Date**").

8. Medicare Beneficiary Representation. The Executive warrants that, as of the date the Executive signs this Agreement, the Executive is not a Medicare beneficiary, is not Medicare eligible, is not within 30 months of becoming Medicare eligible, is not 65 years of age or older, is not suffering from end stage renal failure or amyotrophic lateral sclerosis, has not received Social Security benefits for 24 months or longer, has not applied for Social Security benefits, and has not been denied Social Security disability benefits and is appealing the denial. The Executive affirms, covenants, and warrants that the Executive has made no claim, nor is he or she aware of any facts supporting any claim, against any of the Company Releasees under which any of the Company Releasees could be liable for medical expenses incurred by the Executive before or after the execution of this Agreement. Furthermore, the Executive is aware of no medical expenses for which Medicare has paid and for which any of the Company Releasees is or could be liable. The Executive agrees and affirms that, to the best of his or her knowledge, no liens of any governmental entities, including those for Medicare conditional payments, exist. The Executive acknowledges and agrees that the payment(s) made to the Executive under this Agreement may be reported as provided in Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007, 42 U.S.C. § 1395y(b)(8). The Executive also agrees to indemnify, defend, and hold the Company Releasees harmless from Medicare claims, liens, damages, conditional payments, and rights to payment, if any, including attorneys' fees. The Executive specifically waives any related claims for damages against any and all of the Company Releasees including, without limitation, a private cause of action provided by 42 U.S.C. § 1395y(b)(3) (A).

9. Miscellaneous.

9.1. Tax Withholding. All payments provided to the Executive will be subject to tax withholding in accordance with applicable law.

9.2. No Admission of Liability. This Release is not to be construed as an admission of any violation of any federal, state or local statute, ordinance or regulation or of any duty owed by the Company to the Executive. There have been no such violations, and the Company specifically denies any such violations.

9.3. No Reinstatement. The Executive agrees that the Executive will not apply for reinstatement with the Company or seek in any way to be reinstated, re-employed or hired by the Company in the future.

9.4. Successors and Assigns. This Release shall inure to the benefit of and be binding upon the Company and the Executive and their respective successors, permitted assigns, executors, administrators and heirs. The Executive may not make any assignment of this Release or any interest herein, by operation of law or otherwise. The Company may assign this Release to any successor to all or substantially all of its assets and business by means of liquidation, dissolution, merger, consolidation, transfer of assets, or otherwise.

9.5. Severability. Whenever possible, each provision of this Release will be interpreted in such manner as to be effective and valid under applicable law. However, if any provision of this Release is held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other provision, and this Release will

be reformed, construed and enforced as though the invalid, illegal or unenforceable provision had never been herein contained.

9.6. Entire Agreement; Amendments. Except as otherwise provided herein, this Release contains the entire agreement and understanding of the parties hereto relating to the subject matter hereof, and merges and supersedes all prior and contemporaneous discussions, agreements and understandings of every nature relating to the subject matter hereof. This Release may not be changed or modified, except by an agreement in writing signed by each of the parties hereto.

9.7. Governing Law. This Release 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.

9.8. Execution Date; Counterparts and Facsimiles. This Release may not be signed by the Executive prior to the date of Executive's termination of employment. This Release may be executed in multiple counterparts (including by facsimile signature), each of which will be deemed to be an original, but all of which together will constitute but one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

[space intentionally left blank; signature page follows]

IN WITNESS WHEREOF, the Company has caused this Release to be executed by its duly authorized officer, and the Executive has executed this Release, on the date(s) below written.

BAUDAX BIO, INC.

By:

Name & Title:

Date:

GERRI HENWOOD

Date:

A-6

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the "Agreement") is made and entered into as of the 12th day of February, 2020 (the "Effective Date"), by and between Baudax Bio, Inc., a Pennsylvania corporation (the "Company"), and **Ryan Lake**, an individual (the "Executive") and, solely for purposes of Section 16 hereof, Recro Pharma, Inc., a Pennsylvania corporation ("Recro").

BACKGROUND

WHEREAS, the Company desires to employ the Executive, and the Executive desires to accept such employment, subject to the terms and further conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound hereby, agree as follows:

1. **Employment and Duties.** From and after the Effective Date, the Company shall employ the Executive as Chief Financial Officer. In such capacity, the Executive shall perform all such duties as are assigned to him or her consistent with the Executive's titled position by the Company's Chief Executive Officer and/or Board of Directors of the Company (the "Board"), and shall use his or her reasonable best efforts to promote the interests of the Company. Nothing contained herein shall preclude the Executive from managing personal investments, participating in charitable, community, educational and professional activities, or, with the prior written consent of the Company (which shall not be unreasonably withheld), serving on the board of directors (or comparable governing body), including any board committees, of for-profit businesses that do not compete with the Company, provided that such activities do not materially interfere with the performance of his or her duties for the Company.

2. **Term.** The term of the Executive's employment hereunder shall continue until terminated pursuant to the terms of this Agreement.

3. **Compensation.** From and after the Effective Date, the Company shall pay the Executive in accordance with its normal bi-weekly payroll practices an annual salary at the initial rate of \$400,000 per year (the "Base Salary"). The Executive's Base Salary shall be reviewed not less often than annually and may be increased from time to time in the sole discretion of the Company. The Base Salary, as in effect from time to time, may not be decreased without the prior written consent of the Executive, except as part of an across the board decrease in which the percentage decrease in the Executive's base salary is not greater than the smallest percentage decrease of any other senior executive officer.

4. Other Benefits.

(a) Bonuses.

(i) The Executive will qualify to participate in the Company's incentive bonus program. The Executive's target bonus amount (the "Target Bonus"), tied to set performance goals and measures, is 40% of the Executive's Base Salary. Notwithstanding the foregoing, the Company reserves the right to change or terminate any bonus program at any time in the Board's sole discretion.

(b) Benefits Plans. The Executive shall be eligible to participate in all health insurance, savings and retirement, and other benefit plans, if any, that are from time to time generally applicable to other employees of the Company, subject to the terms and conditions of such plans.

(c) Vacation and Personal Days. The Executive shall be entitled to five (5) weeks of paid vacation time per year and three (3) paid personal days per year, in accordance with the plans, practices, policies, and programs agreed to by Company.

(d) Expense Reimbursement. The Executive shall be entitled to receive reimbursement for all reasonable employment-related expenses incurred by the Executive upon the receipt by the Company of an accounting in accordance with practices, policies and procedures applicable to other employees of the Company.

(e) Equity Grant . The Executive shall be eligible for a regular annual equity grant (with such eligibility determined on the same basis as other senior executives, in the discretion of the Compensation Committee of the Company ("Compensation Committee")) and for other grants under such equity or long-term incentive plan as may be adopted by the Company from time to time. The terms of any such grants shall be determined in the discretion of the Compensation Committee. All stock options granted to the Executive shall be incentive stock options to the fullest extent permitted by law.

(f) Make-Whole and Joining Grants. The parties hereby acknowledge that as of December 5, 2019, the Executive received a grant of (i) 36,096 restricted stock units under the Company's 2019 Equity Incentive Plan (the "Baudax Plan"), which vest in full on the earlier of: a) a change of control of the Company or b) December 5, 2020, subject to continued employment with the Company; (ii) 17,283 restricted stock units under the Recro Pharma, Inc. ("Recro") 2018 Amended and Restated Equity Incentive Plan, which vest in full on the earlier of: a) a change of control of Recro or b) December 5, 2020, subject to continued employment with Recro, ((i) and (ii) together, the "Make-Whole Grants"); (iii) options to purchase 66,327 shares of the Company's common stock under the Baudax Plan, which vest in 48 monthly installments, subject to continued employment with the Company; and (iv) 46,429 restricted stock units under the Baudax Plan, which vest on an annual basis over four years, subject to continued employment with the Company ((iii) and (iv) together, the "Joining Grants"), in each case pursuant to the terms and conditions of the applicable equity incentive plan and award agreement. The Executive understands that any outstanding awards previously granted to him or her under any equity incentive plan maintained by Recro will not be adjusted as a result of the

spin-off of the Company from Recro, as described in Section 16 below, notwithstanding any adjustment provision contained in the applicable Recro equity incentive documents. The Executive understands that the Make-Whole Grants described in this Section 4(f) are in lieu of receiving any adjustments to such awards previously granted by Recro.

5. Confidential Information.

(a) The Executive agrees at all times during the term of his or her employment with the Company and thereafter, to hold in strictest confidence, and not to use, except for the benefit of the Company, or to disclose to any person or entity ("Person") without prior written authorization of the Company, any Confidential Information of the Company. The Executive understands that "Confidential Information" means Inventions (as defined herein) and any other information of the Company and/or its affiliates disclosed or made available to the Executive, whether before or during the term hereof, including but not limited to financial information, technical and non-technical data, services, products, processes, operations, reports, analyses, test results, technology, samples, specifications, protocols, performance standards, formulations, compounds, know-how, methodologies, trade secrets, trade practices, marketing plans and materials, strategies, forecasts, research, concepts, ideas, and names, addresses and any other characteristics or identifying information of the Company's existing or potential investors, licensors, licensees, suppliers, customers or employees. Confidential Information shall not include any information the Executive can establish by competent proof is or becomes public knowledge or part of the public domain through no act or omission of the Executive. Notwithstanding the foregoing, the Executive shall be permitted to disclose Confidential Information pursuant to a court order, government order or any other legal requirement of disclosure if no suitable protective order or equivalent remedy is available, provided that the Executive gives the Company written notice of such court order, government order or legal requirement of disclosure immediately upon knowledge thereof and allows the Company a reasonable opportunity to seek to obtain a protective order or other appropriate remedy prior to such disclosure to the extent permitted by law. Further, it shall not be a violation of the Executive's confidentiality obligations, and the Executive shall not be held criminally or civilly liable under any federal or state trade secret law if disclosure of confidential information (A) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

(b) The Executive agrees that he or she shall not, during his or her employment with Company, improperly use or disclose any proprietary information or trade secrets of any former employer of the Executive or other Person and that the Executive will not bring onto the premises of the Company any unpublished documents or proprietary information belonging to any such former employer or Person unless consented to in writing by such former employer or Person.

(c) The Executive recognizes that the Company has received and in the future will receive from third parties certain confidential or proprietary information subject to a duty on the Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. The Executive agrees to hold all such confidential or

proprietary information in the strictest confidence and not to disclose it to any Person, or to use it except as necessary in carrying out his or her work for the Company consistent with Company's agreement with such third party.

(d) Notwithstanding anything herein to the contrary, nothing in this Agreement shall (x) prohibit the Executive from making reports of possible violations of federal law or regulation to any governmental agency or entity in accordance with the provisions of and rules promulgated under Section 21F of the Securities Exchange Act of 1934, as amended, or Section 806 of the Sarbanes-Oxley Act of 2002, or of any other whistleblower protection provisions of federal law or regulation, or (y) require notification or prior approval by the Company of any such report; provided that, the Executive is not authorized to disclose communications with counsel that were made for the purpose of receiving legal advice or that contain legal advice or that are protected by the attorney work product or similar privilege.

6. Inventions.

(a) The Executive agrees that he or she shall promptly make full written disclosure to the Company, shall hold in trust for the sole right and benefit of the Company, shall assign and hereby does assign to the Company, or its designee, all of the Executive's right, title, and interest in and to any and all inventions, original works of authorship, developments, concepts, improvements, designs, discoveries, ideas, trademarks or trade secrets, whether or not patentable or registerable under copyright or similar laws, which the Executive may, solely or jointly, conceive or develop or reduce to practice during the period of time the Executive is in the employ of the Company that relate to the Company and/or its products (collectively referred to as "Inventions"). The Executive further acknowledges that all original works of authorship which are made by the Executive (solely or jointly with others) within the scope of and during the period of his or her employment with the Company and which are protectable by copyright are "works made for hire", as that term is defined in the United States Copyright Act. The Executive understands and agrees that the decision whether or not to commercialize or market any invention developed by the Executive (solely or jointly with others) is within the Company's sole discretion and for the Company's sole benefit and that no royalty will be due to the Executive as a result of the Company's efforts to commercialize or market any such invention.

(b) The Executive agrees to keep and maintain adequate and current written records of all Inventions made by the Executive (solely or jointly with others) during the term of his or her employment with the Company. The records will be in the form of notes, sketches, drawings, and any other format that may be specified by the Company. The records will be available to and remain the sole property of the Company at all times.

(c) If the Company is unable because of the Executive's mental or physical incapacity or for any other reason to secure his or her signature on any such document, then the Executive hereby irrevocably designates and appoints the Company and its duly authorized officers and agents as his or her agent and attorney-in-fact to act for and in the Executive's behalf and stead to execute and file any such document and to do all other lawfully permitted acts to further the prosecution and issuance of letters patent or copyright registrations thereon with the same legal force and effect as if executed by the Executive.

7. Returning Company Documents. The Executive agrees that, at the time of leaving the employ of the Company, he or she shall deliver to the Company (and will not keep in his or her possession, recreate or deliver to anyone else) any and all devices, records, data, notes, reports, proposals, lists, correspondence, materials, equipment, other documents or property, or reproductions of any of the aforementioned items developed by the Executive pursuant to his or her employment with the Company or otherwise belonging to the Company, its successors or assigns.

8. Nonsolicitation and Noncompetition.

(a) The Executive agrees that during the term of his or her employment with the Company and for a period of one (1) year immediately following the termination of the Executive's employment with the Company for any reason whatsoever, whether with or without cause, (i) the Executive shall not, either directly or indirectly, solicit, induce, recruit or encourage any employees of the Company and/or its affiliates to leave their employment, or take away such employees, or attempt to solicit, induce, recruit, encourage or take away employees of the Company and/or its affiliates, either for the Executive or for any other Person and (ii) neither the Executive, nor any firm, organization or corporation in which he or she is interested, shall, for any reason, directly or indirectly, persuade or attempt to persuade any investor, licensor, licensee, supplier or customer of Company, or any potential investor, licensor, licensee, supplier or customer to which the Company and/or its affiliates have made a presentation or with which the Company and/or its affiliates have been having discussions, to not transact business with the Company and/or its affiliates or to transact business with the Executive or any other Person as an alternative to or in addition to the Company and/or its affiliates.

(b) The Executive agrees that during the term of his or her employment with the Company and for a period of one (1) year immediately following the termination of the Executive's employment with the Company for any reason whatsoever, whether with or without cause, the Executive shall not, anywhere in the world, engage, either directly or indirectly, whether as a principal or as an agent, officer, director, employee, consultant, shareholder, partner or otherwise, alone or in association with any other Person, in any Competing Business. For purposes of this Agreement, the term "Competing Business" shall mean any Person engaged in the development or commercialization of products that are the same or substantially similar to, or that directly compete with, those products developed, commercialized or actively in development or commercialization by the Company.

(c) In the event that the provisions of subparagraphs (a) or (b) above should be determined by a court or other tribunal of competent jurisdiction to exceed the time, geographic, services or product limitations permitted by the applicable law in a jurisdiction in which enforcement of this Agreement is sought, then such provisions shall be deemed reformed in such jurisdiction to the maximum time, geographic, service or product limitations permitted by such applicable law, and the parties hereby expressly grant any court or competent jurisdiction the authority to effect such reformation.

9. Equitable Relief. The parties confirm that a violation by the Executive of the provisions of this Agreement, including but not limited to, the restrictions in Sections 5 through 8, will cause the Company irreparable harm that cannot be remedied adequately by

monetary damages. The Executive agrees that, in the event of such a violation, the Company shall be entitled to seek temporary, preliminary and permanent injunctive relief to restrain any such violation (without the posting of a bond) and to an equitable accounting of all earnings, profits and other benefits arising from the breach or violation, which rights shall be cumulative and in addition to any other rights or remedies to which the Company may be entitled. The Company shall be entitled to commence action for such relief in any state or federal court in the Commonwealth of Pennsylvania, and the Executive waives to the fullest extent permitted by law any objection that he or she may now or hereafter have to the jurisdiction and venue of the court in any such proceeding. In any such action, the prevailing party (once all appeals have been exhausted) shall be entitled to recover such party's reasonable attorney's fees, out-of-pocket costs and disbursements.

10. Termination of Employment.

(a) Notwithstanding the provisions of Section 2 hereof, the Executive's employment shall terminate, or be subject to termination, as follows:

(i) Death or Disability. In the event the Executive dies, this Agreement shall terminate. If the Executive becomes entitled to long-term disability benefits under the Company's then-current disability insurance policy(ies) applicable to the Executive, the Company may, at its option, terminate the Executive's employment hereunder effective immediately upon written notice. If the Company does not have in effect disability insurance covering the Executive and/or if "disabled" is not defined therein, the Executive shall be deemed disabled hereunder at such time that he or she suffers a physical or mental disability that renders him or her unable to perform the duties of his or her employment on substantially a full-time basis, and such period of physical or mental disability continues without substantial interruption for more than one hundred eighty (180) days.

(ii) By Company for Cause. The Company may, at any time, terminate the Executive's employment hereunder for Cause. For purposes of this Agreement, the Company shall have "Cause" to terminate the Executive's employment hereunder upon (a) conduct amounting to fraud or dishonesty against the Company; (b) the willful failure by the Executive to substantially perform his or her duties hereunder or the material violation by the Executive of any of the other provisions of this Agreement, which willful failure or material violation shall continue for thirty (30) days or more following written notice to the Executive; (c) the Executive's loss of any permit, license, accreditation or other authorization necessary to the Executive's performance of his or her duties hereunder, as determined by the Company in its sole discretion; (d) the Executive's conviction of a felony or a plea by the Executive of nolo contendere to a felony; or (e) other willful conduct by the Executive likely, in the reasonable judgment of the Board, to materially adversely affect the reputation of the Company, which conduct shall continue for five (5) days or more following written notice to the Executive. No act, or omission to act, shall be considered "willful" unless such act or omission is done without a good faith belief by the Executive that such act or omission is in, or not opposed to, the best interests of the Company.

(iii) By Company for Convenience. The Company may terminate the Executive's employment hereunder at any time, without Cause, upon no less than thirty (30) days prior written notice to Executive.

(iv) By Executive for Convenience. The Executive may terminate his or her employment hereunder at any time upon no less than thirty (30) days prior written notice to the Company.

(v) By Executive upon a Change of Control. The Executive may terminate his or her employment hereunder at any time during the twelve (12) months following a Change of Control, if during such twelve-month period the Company and/or its successor (a) materially and adversely changes the status, responsibilities or perquisites of the Executive and such change is not cured within thirty (30) days following written notice by the Executive to the Company, (b) reduces the Executive's Base Salary other than as permitted by Section 3 or the amount of the Target Bonus, or (c) requires the Executive to be principally based at any office or location more than fifty (50) miles from the Executive's principal office immediately prior to the Change of Control; provided, however, that the Executive shall not be entitled to resign pursuant to this Section 10(a)(v) unless the Executive notifies the Company in writing of the circumstances outlined in Section 10(a)(v)(a) through 10(a)(v)(c) within thirty (30) days after he or she first has notice of such circumstances, the Company fails to cure such circumstances within thirty (30) days after receipt of such notice, and the Executive resigns his or her employment not later than ten (10) days after the end of such cure period. For purposes of this Agreement, a "Change of Control" shall be deemed to have occurred upon the happening of any of the following events: (i) the consummation of a plan of dissolution or liquidation of the Company; (ii) the consummation of the sale or disposition of all or substantially all of the assets of the Company; (iii) the consummation of a merger, consolidation or other shareholder-approved fundamental business transaction in which the Company is a participant with another entity where the stockholders of the Company, immediately prior to the referenced transaction, will not beneficially own, immediately after the referenced transaction, shares or other equity interests entitling such stockholders to more than 50% of all votes to which all equityholders of the surviving entity would be entitled in the election of directors; (iv) the date any entity, person or group, (within the meaning of Section 13(d)(3) or Section 14(d)(2) of the Securities Exchange Act of 1934, as amended), (other than (A) the Company or any of its subsidiaries or any employee benefit plan (or related trust) sponsored or maintained by the Company or any of its subsidiaries or (B) any person who, on the date the Plan is effective, is the beneficial owner of outstanding securities of the Company), shall have become the beneficial owner of, or shall have obtained voting control over, more than fifty percent (50%) of the outstanding shares of the Common Stock; or (v) the first day after the date hereof when directors are elected such that a majority of the Board shall have been members of the Board for less than twenty-four (24) months, unless the nomination for election of each new director who was not a director at the beginning of such twenty-four (24) month period was approved by a vote of at least two-thirds of the directors then still in office who were directors at the beginning of such period.

(b) Severance.

(i) In the event of any termination of the Executive's employment for any reason, the Executive (or his or her estate) shall be entitled to (A) his or her

Base Salary through the date of termination, (B) the value of his or her accrued but unused vacation and paid time off through the date of termination, (C) except in the case of termination for Cause, any bonus earned in a prior year but not yet paid on the date of termination, (D) reimbursement of all business expenses properly incurred prior to the date of termination consistent with Company policy, and (E) any benefits, including any continuation or conversion rights, provided under any employee benefit plan or policy of the Company (not including any severance, separation pay, or supplemental unemployment benefit plan), in accordance with the terms of such plan or policy (the "Accrued Benefits").

(ii) In the event of termination of the Executive's employment by reason of death or Disability, the Company shall pay or provide to the Executive or the Executive's estate (A) the Accrued Benefits, (B) the Executive's Base Salary, in accordance with its normal payroll practices (but not less frequently than monthly), for a period of six (6) months from the effective date of such termination, (C) an amount equal to the Executive's Target Bonus for the fiscal year of termination pro-rated through the date of termination (determined based on the number of days in the calendar year that the Executive is employed by the Company in such year of the effective date of termination) and paid within thirty (30) days following such termination, and (D) continued health benefits for the Executive and his or her eligible dependents at the Company's expense (or such portion thereof as is then funded by the Company for other employees of the Company), if applicable, for the period described above in clause (B).

(iii) In the event of a termination by the Company pursuant to Section 10(a)(iii), or if the Executive terminates this Agreement during the twelve (12) months after a Change of Control pursuant to Section 10(a)(v), the Company shall (A) pay or provide to the Executive the Accrued Benefits, (B) pay the Executive a pro-rata annual bonus in respect of the fiscal year in which the effective date of termination occurs (determined based on the number of days in the calendar year that the Executive is employed by the Company in such fiscal year of the effective date of termination), with such annual bonus (if any) paid at the same time it would have otherwise been paid absent the Executive's termination of employment, (C) continue to pay the Executive his or her Base Salary, in accordance with its normal payroll practices (but not less frequently than monthly), and shall continue the Executive's, and his or her eligible dependents', health insurance benefits at the Company's expense (or such portion thereof as is then funded by the Company for other employees of the Company) for a period of twelve (12) months from the effective date of such termination, and (D) provide the Executive, at the Company's expense, with senior executive level outplacement services for a period of twelve (12) months from the date of termination, using a reputable provider selected by the Executive with the Company's consent, which shall not be unreasonably withheld, provided that such outplacement expenses shall not exceed \$25,000 in any event.

(iv) Except as expressly provided in this Section 10(b), upon the termination of the Executive's employment, all payments hereunder shall cease.

(v) The payments and benefits described in Sections 10(b)(ii) and 10(b)(iii) are in lieu of, and not in addition to, any other severance arrangement maintained by the Company. The payments and benefits described in Sections 10(b)(ii) and 10(b)(iii), other than the Accrued Benefits, are conditioned on clauses (i) and (ii) below:

i. The Executive's (or in the case of the Executive's death, his/her estate's) execution and delivery to the Company and the expiration of all applicable statutory revocation periods, by the sixtieth (60th) day following the effective date of his or her termination of employment, of a general release of claims against the Company and its affiliates substantially in the form attached hereto as Exhibit A (the "Release"). Subject to Section 11 below, the payments and benefits described in Section 10(b)(ii) and 10(b)(iii) will begin to be paid or provided as soon as administratively practicable after the Release becomes irrevocable, provided that if the sixty (60) day period described above begins in one taxable year and ends in a second taxable year such payments or benefits shall not commence until the second taxable year.

ii. The Executive's continued compliance with the provisions of Sections 5, 6, 7 and 8 of this Agreement.

(vi) The Executive shall not be required to seek or accept other employment, or otherwise to mitigate damages, as a condition to receipt of the benefits described in Sections 10(b)(ii) and 10(b)(iii), and such benefits shall not be reduced or offset by an amounts received by the Executive from any other source, except to the extent the Executive's medical coverage is discontinued by reason of the Executive acquiring other coverage.

(c) The provisions of this Agreement shall survive expiration or termination of this Agreement for any reason to the extent necessary to enable the parties to enforce their respective rights hereunder, including without limitation Sections 4(d), 5, 6, 7, 8, 9, 10(b), 10(c), 11, 12, 13, 14, 15 and 16.

11. Compliance with Section 409A.

(a) Notwithstanding anything to the contrary in this Agreement, all benefits or payments provided by the Company to the Executive that would be deemed to constitute "nonqualified deferred compensation" within the meaning of Section 409A of the Code are intended to comply with Section 409A of the Code. Notwithstanding anything in this Agreement to the contrary, distributions of benefits which constitute "nonqualified deferred compensation" within the meaning of Section 409A of the Code may be made under this Agreement upon an event and in a manner permitted by Section 409A of the Code or an applicable exemption.

(b) Notwithstanding anything to the contrary in this Agreement, no portion of the benefits or payments to be made under Section 10(b) hereof will be payable until the Executive has a "separation from service" from the Company within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"). In addition, to the extent compliance with the requirements of Treas. Reg. § 1.409A-3(i)(2) (or any successor provision) is necessary to avoid the application of an additional tax under Section 409A of the Code to payments due to the Executive upon or following his or her "separation from service", then notwithstanding any other provision of this Agreement (or any otherwise applicable plan, policy, agreement or arrangement), any such payments that are otherwise due within six months following the Executive's "separation from service" (taking into account the preceding sentence of this paragraph) will be deferred without interest and paid to the Executive in a lump sum

immediately following that six month period. This paragraph should not be construed to prevent the application of Treas. Reg. § 1.409A-1(b)(9)(iii) (or any successor provision) to amounts payable hereunder. For purposes of the application of Section 409A of the Code, each payment in a series of payments will be deemed a separate payment.

(c) Notwithstanding anything to the contrary in this Agreement, except to the extent any expense, reimbursement or in-kind benefit provided to the Executive does not constitute a “deferral of compensation” within the meaning of Section 409A of the Code, and its implementing regulations and guidance, (i) the amount of expenses eligible for reimbursement or in-kind benefits provided to the Executive during any calendar year will not affect the amount of expenses eligible for reimbursement or in-kind benefits provided to the Executive in any other calendar year, (ii) the reimbursements for expenses for which the Executive is entitled to be reimbursed shall be made on or before the last day of the calendar year following the calendar year in which the applicable expense is incurred and (iii) the right to payment or reimbursement or in-kind benefits hereunder may not be liquidated or exchanged for any other benefit.

12. Parachute Payment.

(a) If any payment or benefit the Executive would receive under this Agreement or otherwise in connection with a Change of Control, as defined herein (the “Total Payments”) would (i) constitute a “Parachute Payment” within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the “Excise Tax”), then such Total Payment shall be equal to the Reduced Amount. The “Reduced Amount” shall be either (x) the largest portion of the Total Payment that would result in no portion of the Total Payment being subject to the Excise Tax or (y) the largest portion, up to and including the total of the Total Payment, whichever amount, after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in the Executive’s receipt, on an after-tax basis, of the greatest economic benefit notwithstanding that all or some portion of the Total Payment may be subject to the Excise Tax. If a reduction in payments or benefits constituting Parachute Payments is necessary so that the Total Payment equals the Reduced Amount, reduction shall occur in the manner that results in the greatest economic benefit for the Executive. In applying this principle, the reduction shall be made in a manner consistent with the requirements of Section 409A of the Code, and where two economically equivalent amounts are subject to reduction but payable at different times, such amounts shall be reduced on a pro rata basis but not below zero.

(b) In the event it is subsequently determined by the Internal Revenue Service that some portion of the Reduced Amount (as determined pursuant to clause (x) in the preceding paragraph) is subject to the Excise Tax, the Executive agrees to promptly return to the Company a sufficient amount of the Total Payment so that no portion of the Reduced Amount is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount is determined in accordance with clause (y) in the preceding paragraph, the Executive will have no obligation to return any portion of the Total Payment pursuant to the preceding sentence. Unless the Executive and the Company agree on an alternative accounting or law firm, the accounting firm then engaged by the Company for general tax compliance purposes shall perform the foregoing

calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Change of Control, the Company shall appoint a nationally recognized accounting, law or consulting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such accounting, law or consulting firm required to be made hereunder.

(c) The Company shall use commercially reasonable efforts such that the accounting, law or consulting firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to the Executive and the Company within fifteen (15) calendar days after the date on which the Executive's right to a Total Payment is triggered (if requested at that time by the Executive or the Company) or such other time as requested by the Executive or the Company.

13. Notices. All notices, consents, waivers or other communications which are required or permitted hereunder will be sufficient if given in writing and delivered personally, by overnight mail service, by fax transmission (which is confirmed) or by registered or certified mail, return receipt requested, postage prepaid, to the parties at the addresses set forth below (or to such other addressee or address as will be set forth in a notice given in the same manner):

<u>If to the Company:</u>	Baudax Bio, Inc. 490 Lapp Road Malvern, PA 19355 Attn: Gerri Henwood, CEO
<u>If to the Executive:</u>	Ryan Lake Address on file.

All such notices will be deemed to have been given three business days after mailing if sent by registered or certified mail, one business day after mailing if sent by overnight courier service, or on the date delivered or transmitted if delivered personally or sent by fax transmission.

14. Indemnification. To the maximum extent permitted by applicable law, both during the term of this Agreement and at all times thereafter, regardless of the reason for termination, the Company shall indemnify the Executive and hold the Executive harmless against any cost, fee, expense, fine or penalty (a "cost") to which he or she may be subject as a result of serving as an employee or officer of the Company or any other entity at the Company's direction, shall advance to the Executive, as incurred, the reasonable costs (including fees and disbursements of legal counsel) incurred by him in defending any judicial or administrative proceeding, including any investigation, that may give rise to a cost, subject to the Executive's obligation to repay any such advance if it is subsequently determined that he or she was not entitled to indemnification, and shall provide for the Executive to be covered by its directors and officers, or any similar, insurance policy at the level applicable to its most senior active officers.

15. Nondisparagement. Both during the term of this Agreement and at all times thereafter, regardless of the reason for termination, the Executive shall not publicly disparage the Company, and the Company shall instruct the members of the Board and its senior

executives not to publicly disparage the Executive. Notwithstanding the foregoing, nothing in this Agreement will prohibit the Executive or the Company from (a) responding to any inquiry from, or providing truthful testimony before any self-regulatory organization or any state or federal regulatory authority, (b) making any other truthful disclosure required by law or legal process, or (c) defending any charge, action, investigation or proceeding initiated by or on behalf of the other.

16. Dual Employment with Recro.

(a) The Company and the Executive acknowledge and agree that this Agreement is being entered into in connection with the Executive's commencement of employment with the Company following the spin-off of the Company from Recro, pursuant to that certain Separation Agreement by and between the Company and Recro dated as of November 20, 2019. The Company acknowledges that the Executive will remain an employee, officer and director of Recro following the Effective Date and will simultaneously provide services to both the Company and Recro. Similarly, Recro acknowledges that the Executive is also an employee, officer and director of the Company and will simultaneously provide services to both the Company and Recro. During this period of dual employment, the Executive agrees to devote such time and energy to each of the Company and Recro as is necessary to fulfill his duties to each company, and each of the Company and Recro agree to exercise commercially reasonable efforts to schedule, limit and coordinate their demands on Executive's time, so as not to interfere with his ability to discharge his duties to the other company. Except as otherwise provided below in Section 16(b)(iii), Executive will no longer receive compensation or benefits from Recro (although Recro may be or become obligated to reimburse the Company for certain portions of the Executive's compensation from the Company, as determined based on agreements between Recro and the Company).

(b) In connection with the entry into this Agreement, and in consideration of the rights and benefits described herein, the Executive hereby represents, acknowledges and agrees that:

(i) Except as otherwise provided in Section 16(b)(ii) and 16(b)(iii) below, Executive's rights under that certain Employment Agreement dated as of June 5, 2017, as amended from time to time (the "Recro Agreement") are hereby terminated and Recro has or no current or contingent obligation to Executive (compensatory or otherwise). Without limiting the generality of the foregoing: (A) Executive is not now entitled to any severance payment or benefit from Recro, and no future cessation of his employment with Recro will entitle him to any severance payment or benefit, and (B) Executive will not be entitled to any annual cash incentive payment from Recro with respect to any portion of 2019 (although Executive's 2019 annual cash incentive from the Company will not be pro-rated and may take into account Executive's performance at Recro during the portion of 2019 that preceded the spin-off of the Company);

(ii) Any rights the Executive had immediately prior to the Effective Date (i) to indemnification by Recro in respect of his acts or omissions as an employee, officer or director of Recro (whether arising under Recro's governing documents or otherwise),

and (ii) to the benefit of any directors' and officers' insurance coverage maintained by Recro will, in each case, remain in full force and effect;

(iii) Executive's outstanding equity incentive awards made pursuant to the Recro 2018 Amended and Restated Equity Incentive Plan and the Recro 2008 Stock Option Plan shall not be adjusted as a result of the spin-off of the Company from Recro, as described in Section 4(f) above. However, all such equity awards remain outstanding in accordance with their terms and will continue to vest based on Executive's continued service with Recro;

(iv) Executive's obligations under the confidentiality, non-solicitation, non-competition, non-disparagement and intellectual property assignment provisions of the Recro Agreement remain in full force and effect and Executive hereby reaffirms those obligations;

(c) The Executive, for himself and on behalf of his heirs, assigns, executors, agents and representatives, hereby fully and forever releases and discharges Recro, its predecessors, successors (by merger or otherwise), parents, subsidiaries, affiliates and assigns, together with each and every of their present, past and future officers, directors, shareholders, general partners, limited partners, employees and agents (in their official, individual and all other capacities), and all other persons or entities acting with, for, through or in concert with any of them from any and all claims, demands, liens, agreements, contracts, covenants, actions, suits, causes of action, obligations, controversies, debts, costs, expenses, damages, judgments, orders and liabilities, of whatever kind or nature, direct or indirect, in law, equity or otherwise, whether known or unknown, which the Executive now has, or hereafter can, shall or may have for, upon or by reason of any act, transaction, practice, conduct, matter, cause or thing of any kind or nature whatsoever arising or occurring through the Effective Date, except as otherwise expressly provided above in Section 16(a), 16(b)(ii), and 16(b)(iii).

17. Miscellaneous.

(a) No provision of this Agreement may be amended unless such amendment, modification or discharge is agreed to in writing signed by the parties hereto.

(b) No waiver by any party hereto of any breach of, or compliance with, any condition or provision of this Agreement by the other party shall be deemed a waiver of similar or dissimilar provisions or conditions at the same or at any prior or subsequent time. No such waiver shall be enforceable unless expressed in a written instrument executed by the party against whom enforcement is sought.

(c) This Agreement constitutes the entire agreement of the parties on the subject matter and no agreements or representations, oral or otherwise, expressed or implied, with respect to the subject matter hereof have been made by either party which are not set forth expressly in this Agreement. For the avoidance of doubt, any prior agreements or representations made by either party which are not set forth expressly in this Agreement, are hereby superseded. In the event of any conflict between this Agreement and any policy of the Company, the terms of this Agreement will control.

(d) This Agreement shall be binding upon and inure to the benefit of the Company, its successors and assigns, and the Executive and his or her heirs, executors, administrators and legal representatives. The Company may not assign its rights and obligations under this Agreement to any person without the prior written consent of the Executive, except to a successor to the Company's business that expressly adopts and agrees to be bound by this Agreement.

(e) This Agreement shall be governed by, and construed in accordance with, the laws of the Commonwealth of Pennsylvania without giving effect to its principles of conflicts of law. Exclusive jurisdiction for any dispute between the parties arising from or in connection with this Agreement and/or the relationship between the Executive and the Company shall lie with the federal and state courts located in the Commonwealth of Pennsylvania, and each party hereby consents to the personal jurisdiction of such courts.

(f) This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original but all of which together shall constitute one and the same instrument.

(g) This Agreement has been jointly drafted by the respective representatives of the Company and the Executive and no party shall be considered as being responsible for such drafting for the purpose of applying any rule construing ambiguities against the drafter or otherwise. No draft of this Agreement shall be taken into account in construing this Agreement.

(h) The Executive agrees to be bound by Company policies as in effect from time to time, including without limitation any policies regarding clawbacks, securities trading, and hedging or pledging of securities.

[Execution page follows]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year first above written.

EXECUTIVE:

/s/ Ryan D. Lake
RYAN LAKE

COMPANY:
BAUDAX BIO, INC.

By: /s/ Gerri Henwood
Gerri Henwood, President

**Solely for purposes of agreeing to Section 16 herein, RECRO PHARMA,
INC.:**

By: /s/ Gerri Henwood_____

Exhibit A

SEPARATION AND MUTUAL RELEASE AGREEMENT

THIS SEPARATION AND MUTUAL RELEASE AGREEMENT (this “**Release**”) is made by and between Ryan Lake (the “**Executive**”) and Baudax Bio, Inc. (the “**Company**”).

WHEREAS, the Executive’s employment with the Company has terminated; and

WHEREAS, pursuant to Section 10(b)[ii][iii] of the Employment Agreement by and between the Company and the Executive dated as of _____ (the “**Employment Agreement**”), the Company has agreed to pay the Executive certain amounts and to provide certain benefits, subject to his or her execution and non-revocation of this Release. All terms used but not defined herein shall have the meanings ascribed to such terms in the Employment Agreement.

NOW THEREFORE, in consideration of these premises and the mutual promises contained herein, and intending to be legally bound hereby, the parties agree as follows:

1. Consideration. The Executive acknowledges that : (i) the payments set forth in Section 10(b)[ii][iii] of the Employment Agreement constitute full settlement of all his or her rights under the Employment Agreement, (ii) he or she has no entitlement under any other severance or similar arrangement maintained by the Company or any of its affiliates, and (iii) except as otherwise provided specifically in this Release, the Company does not and will not have any other liability or obligation to the Executive by reason of the cessation of his or her employment. The Executive further acknowledges that, in the absence of his or her execution of this Release, the payments and benefits specified in Section 10(b)[ii][iii] of the Employment Agreement would not otherwise be due to him or her.

2. Mutual Release and Covenant Not to Sue.

2.1. Mutual Release. The Executive, on his or her own behalf and together with his or her heirs, assigns, executors, agents and representatives hereby fully and forever releases and discharges the Company, its predecessors, successors (by merger or otherwise), parents, subsidiaries, affiliates and assigns, together with each and every of their present, past and future officers, directors, shareholders, general partners, limited partners, employees and agents (in their official, individual and all other capacities), and all other persons or entities acting with, for, through or in concert with any of them (herein collectively referred to as the “**Company Releasees**”) from any and all claims, demands, liens, agreements, contracts, covenants, actions, suits, causes of action, obligations, controversies, debts, costs, expenses, damages, judgments, orders and liabilities, of whatever kind or nature, direct or indirect, in law, equity or otherwise, whether known or unknown, which the Executive now has, or hereafter can, shall or may have for, upon or by reason of any act, transaction, practice, conduct, matter, cause or thing of any kind or nature whatsoever (each, a “**Claim**”) arising or occurring through the Effective Date of this Release. The Company hereby fully and forever releases and discharges the Executive from any Claim arising or occurring through the Effective Date of this Release,

including, but not limited to, any Claim arising out of the Executive's employment by the Company or the termination thereof.

2.2. Covenant Not to Sue. The Executive expressly represents that he or she has not filed a lawsuit or initiated any other administrative proceeding against the Company and that he or she has not assigned any claim against the Company to any other person or entity. The Company expressly represents that it has not filed a lawsuit or initiated any other administrative proceeding against the Executive and that it has not assigned any claim against the Executive to any other person or entity. Both the Executive and Company further promise not to initiate a lawsuit or to bring any other claim against the other arising out of or in any way related to the Executive's employment by the Company or the termination of that employment (other than claims described in Section 2.3). Notwithstanding anything in this Release to the contrary, this Release will not prevent the Executive from filing a charge with the Equal Employment Opportunity Commission (or similar state agency) or participating in any investigation conducted by the Equal Employment Opportunity Commission (or similar state agency); provided, however, that any claims by the Executive for personal relief in connection with such a charge or investigation (such as reinstatement or monetary damages) will be barred.

2.3. Claims Not Released. Notwithstanding Section 2.1, the forgoing release of any Claim does not release the Company or the Executive from claims : (a) to enforce this Release, (b) claims to enforce the Executive's rights under any employee benefit plan in accordance with the terms of the applicable plan(s), or (c) for indemnification under the Company's By-Laws, under applicable law, or under any indemnification agreement between the Company and the Executive. Additionally, the foregoing does not release the Executive from claims the Company may have arising out of or related to: (w) any obligation the Company may have under applicable law or an exchange listing requirement to pursue the recoupment of compensation or other payments made to the Executive, (x) Executive's criminal or other serious misconduct related to the Company, (y) Executive's breach of fiduciary duty to the Company, or (z) Executive's material breach of any agreement with the Company.

2.4. Claims Released. The Executive understands and agrees that the claims released in Section 2.1 include, but are not limited to : (a) any Claim based on any law, statute, or constitution or based on contract or in tort or based on common law; (b) any Claim based on or arising under any civil rights laws, labor laws, or employment laws, such as the Pennsylvania Human Relations Act, or the civil rights laws of any other state or jurisdiction, or Title VII of the Civil Rights Act of 1964 ("**Title VII**"), or the federal Age Discrimination in Employment Act of 1967 ("**ADEA**"), or the Americans with Disabilities Act of 1990 ("**ADA**"), or the Civil Rights Act of 1991, or the Worker Adjustment and Retraining Notification Act ("**WARN**"); (c) any Claim under any grievance or complaint procedure of any kind; (d) any Claim based on or arising out of or related to the Executive's recruitment by, employment with, the termination of the Executive's employment with, the Executive's performance of any services in any capacity for, or any business transaction with, any or all of the Company Releasees (including, but not limited to any claim for wrongful or retaliatory discharge); (e) any Claim for a personal recovery by the Executive in connection with, or arising from, any lawsuit or proceeding brought by any person or entity other than the Executive (including, but not limited to, any Claim brought by any administrative agency, department or commission); (f) any

Claim for the Executive's attorneys' fees, costs or expenses relating to this Release; and (g) any other Claim for compensation of any kind.

3. Cooperation. The Executive further agrees that he or she will cooperate fully with the Company and its counsel with respect to any matter (including litigation, investigations, or governmental proceedings) in which the Executive was in any way involved during his or her employment with the Company. The Executive shall render such cooperation in a timely manner on reasonable notice from the Company.
4. Mutual Non-Disparagement. The Company's officers and directors will not disparage the Executive or the Executive's performance or otherwise take any action which could reasonably be expected to adversely affect the Executive's personal or professional reputation. Similarly, the Executive will not disparage the Company or any of its directors, officers, agents or employees or otherwise take any action which could reasonably be expected to adversely affect the personal or professional reputation of the Company or any of its directors, officers, agents or employees.
5. Permitted Conduct. Notwithstanding anything in this Release to the contrary, nothing in this Release shall prohibit or restrict the Executive or the Company from : (a) initiating communications directly with, or responding to any inquiry from, or providing testimony before, the SEC, FINRA, any other self-regulatory organization or any other state or federal regulatory authority; (b) making any disclosure of relevant, necessary and truthful information or documents : (i) pursuant to the Sarbanes-Oxley Act; (ii) as otherwise required by law or legal process; (iii) in connection with any charge, action, investigation or proceeding relating to this Release; or (iv) to the Company's Legal Department.
6. Restrictive Covenants. The Executive acknowledges that the restrictive covenants contained in Sections 5, 6, 7, 8 and 9 of the Employment Agreement will survive the termination of his or her employment (the "**Restrictive Covenants**"). The Executive affirms that the Restrictive Covenants are reasonable and necessary to protect the legitimate interests of the Company, that he or she received adequate consideration in exchange for agreeing to the Restrictive Covenants and that he or she will abide by the Restrictive Covenants.
7. Rescission Right. The Executive expressly acknowledges and recites that : (a) Executive has read and understands the terms of this Release in its entirety, (b) Executive has entered into this Release knowingly and voluntarily, without any duress or coercion, (c) Executive has been advised orally and is hereby advised in writing to consult with an attorney with respect to this Release before signing it, (d) Executive was provided at least twenty-one (21) calendar days after receipt of the Release to consider its terms before signing it, and (e) Executive is provided seven (7) calendar days from the date of signing to terminate and revoke this Release, in which case this Release shall be unenforceable, null and void. The Executive may revoke this Release during those seven (7) days by providing written notice of revocation to Baudax Bio, Inc., 490 Lapp Road, Malvern, PA 19355, Attn: Chief Executive Officer. Provided that the Executive does not revoke this Release, the Release shall become effective on the eighth (8th) day following the Executive's execution of the Release (the "**Effective Date**").

8. Medicare Beneficiary Representation. The Executive warrants that, as of the date the Executive signs this Agreement, the Executive is not a Medicare beneficiary, is not Medicare eligible, is not within 30 months of becoming Medicare eligible, is not 65 years of age or older, is not suffering from end stage renal failure or amyotrophic lateral sclerosis, has not received Social Security benefits for 24 months or longer, has not applied for Social Security benefits, and has not been denied Social Security disability benefits and is appealing the denial. The Executive affirms, covenants, and warrants that the Executive has made no claim, nor is he or she aware of any facts supporting any claim, against any of the Company Releasees under which any of the Company Releasees could be liable for medical expenses incurred by the Executive before or after the execution of this Agreement. Furthermore, the Executive is aware of no medical expenses for which Medicare has paid and for which any of the Company Releasees is or could be liable. The Executive agrees and affirms that, to the best of his or her knowledge, no liens of any governmental entities, including those for Medicare conditional payments, exist. The Executive acknowledges and agrees that the payment(s) made to the Executive under this Agreement may be reported as provided in Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007, 42 U.S.C. § 1395y(b)(8). The Executive also agrees to indemnify, defend, and hold the Company Releasees harmless from Medicare claims, liens, damages, conditional payments, and rights to payment, if any, including attorneys' fees. The Executive specifically waives any related claims for damages against any and all of the Company Releasees including, without limitation, a private cause of action provided by 42 U.S.C. § 1395y(b)(3) (A).

9. Miscellaneous.

9.1. Tax Withholding. All payments provided to the Executive will be subject to tax withholding in accordance with applicable law.

9.2. No Admission of Liability. This Release is not to be construed as an admission of any violation of any federal, state or local statute, ordinance or regulation or of any duty owed by the Company to the Executive. There have been no such violations, and the Company specifically denies any such violations.

9.3. No Reinstatement. The Executive agrees that the Executive will not apply for reinstatement with the Company or seek in any way to be reinstated, re-employed or hired by the Company in the future.

9.4. Successors and Assigns. This Release shall inure to the benefit of and be binding upon the Company and the Executive and their respective successors, permitted assigns, executors, administrators and heirs. The Executive may not make any assignment of this Release or any interest herein, by operation of law or otherwise. The Company may assign this Release to any successor to all or substantially all of its assets and business by means of liquidation, dissolution, merger, consolidation, transfer of assets, or otherwise.

9.5. Severability. Whenever possible, each provision of this Release will be interpreted in such manner as to be effective and valid under applicable law. However, if any provision of this Release is held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other provision, and this Release will

be reformed, construed and enforced as though the invalid, illegal or unenforceable provision had never been herein contained.

9.6. Entire Agreement; Amendments. Except as otherwise provided herein, this Release contains the entire agreement and understanding of the parties hereto relating to the subject matter hereof, and merges and supersedes all prior and contemporaneous discussions, agreements and understandings of every nature relating to the subject matter hereof. This Release may not be changed or modified, except by an agreement in writing signed by each of the parties hereto.

9.7. Governing Law. This Release 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.

9.8. Execution Date; Counterparts and Facsimiles. This Release may not be signed by the Executive prior to the date of Executive's termination of employment. This Release may be executed in multiple counterparts (including by facsimile signature), each of which will be deemed to be an original, but all of which together will constitute but one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

[space intentionally left blank; signature page follows]

IN WITNESS WHEREOF, the Company has caused this Release to be executed by its duly authorized officer, and the Executive has executed this Release, on the date(s) below written.

BAUDAX BIO, INC.

By:

Name & Title:

Date:

RYAN LAKE

Date:

A-6

FIRST AMENDMENT TO EMPLOYEE MATTERS AGREEMENT

THIS FIRST AMENDMENT TO EMPLOYEE MATTERS AGREEMENT (this “Agreement”), dated as of February 12, 2020, is entered into by and between Recro Pharma, Inc., a Pennsylvania corporation (“Recro”), and Baudax Bio, Inc., a Pennsylvania corporation (“Baudax”). “Party” or “Parties” means Recro or Baudax, individually or collectively, as the case may be.

RECITALS

WHEREAS, Baudax and Recro are parties to that certain Employee Matters Agreement, dated as of November 20, 2019 (the “Agreement”), pursuant to which each of Baudax and Recro have agreed to provide to the other certain transition services, as more particularly described and upon the terms and subject to the conditions set forth in the Agreement;

WHEREAS, pursuant to Section 7.1 of the Agreement, which incorporated by reference Section 10.10 of that certain Separation Agreement, by and between Recro and Baudax dated as of November 20, 2019 (the “Separation Agreement”), the Agreement may not be terminated, modified or amended except by an agreement in writing signed by Recro and Baudax;

WHEREAS, Baudax and Recro desire to amend the Agreement as set forth herein in accordance with Section 10.10 of the Separation Agreement.

NOW, THEREFORE, in consideration of the foregoing and the respective covenants and agreements set forth herein, and intending to be legally bound hereby, the Parties agree as follows:

AGREEMENT

Definitions. Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to such terms in the Agreement.

Amendments to Agreement.

Section 1.3 is hereby amended and restated in its entirety as follows:

“Baudax Employee” means any individual who, as of the Distribution Effective Time, is either actively employed by or then on a short-term leave of absence from Baudax or a Baudax Group member (including maternity, paternity, family, sick, short-term disability leave, qualified military service under the Uniformed Services Employment and Reemployment Rights Act of 1994, and leave under the Family Medical Leave Act and other approved leaves) or who is employed by Recro or a Recro Group member and who becomes a Baudax Employee pursuant to the operation of this Agreement or who is employed by Baudax or a Baudax Group member after the Distribution Effective Time but prior to the Benefits Commencement Date.

Section 1.8 is hereby amended and restated in its entirety as follows:

“Benefits Commencement Date” means the later of January 1, 2021 unless otherwise negotiated between the Parties.

No Other Changes. Except as expressly provided in this Amendment, all provisions of the Agreement shall remain in full force and effect and are not modified by this Amendment.

GENERAL

Governing Law. This Amendment and any Dispute related hereto shall be governed by and construed in accordance with the Laws of the Commonwealth of Pennsylvania, U.S.A., without giving effect to the conflicts of laws principles thereof that might lead to the application of laws other than the Laws of the Commonwealth of Pennsylvania.

Miscellaneous. The provisions of Article VII of the Agreement shall apply, *mutatis mutandis*, as if fully set forth in this Amendment.

Counterparts. This Amendment may be executed in any one or more counterparts, all of which shall be considered one and the same agreement, and shall become effective when one or more counterparts have been signed by each of the Parties and delivered to each of the Parties.

[Signature page follows]

IN WITNESS WHEREOF, the Parties have caused this First Amendment to Employee Matters Agreement to be duly executed as of the day and year first above written.

RECRO PHARMA, INC.

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

BAUDAX BIO, INC.

By: /s/ Ryan D. Lake
Name: Ryan Lake
Title: Chief Financial Officer and Treasurer

BAUDAX BIO, INC.**\$25,000,000****COMMON STOCK****SALES AGREEMENT**

February 13, 2020

JMP Securities LLC
600 Montgomery Street, Suite 1100
San Francisco, California 94111

Ladies and Gentlemen:

Baudax Bio, Inc. (the "**Company**"), confirms its agreement (this "**Agreement**") with JMP Securities LLC ("**JMP**"), as follows:

1. **Issuance and Sale of Shares.** The Company agrees that, from time to time during the term of this Agreement, on the terms and subject to the conditions set forth herein, it may issue and sell through or to JMP, acting as agent and/or principal, shares (the "**Placement Shares**") of the Company's common stock, par value \$0.01 per share (the "**Common Stock**"), having an aggregate offering price of up to \$25,000,000. Notwithstanding anything to the contrary contained herein, the parties hereto agree that compliance with the limitation set forth in this Section 1 on the number of shares of Common Stock issued and sold under this Agreement shall be the sole responsibility of the Company, and JMP shall have no obligation in connection with such compliance. The issuance and sale of Common Stock through JMP will be effected pursuant to the Registration Statement (as defined below) filed by the Company and declared effective by the Securities and Exchange Commission (the "**Commission**"), although nothing in this Agreement shall be construed as requiring the Company to use the Registration Statement (as defined below) to issue the Common Stock.

The Company has filed, in accordance with the provisions of the Securities Act of 1933, as amended, and the rules and regulations thereunder (collectively, the "**Securities Act**"), with the Commission a registration statement on Form S-3 (File No. 333-235408), including a base prospectus, relating to certain securities, including the Common Stock, to be issued from time to time by the Company, and which incorporates by reference documents that the Company has filed or will file in accordance with the provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder (collectively, the "**Exchange Act**"). The Company has prepared a prospectus supplement specifically relating to the Placement Shares (the "**Prospectus Supplement**") to the base prospectus included as part of such registration statement. The Company has furnished to JMP, for use by JMP, copies of the prospectus included as part of such registration statement, as supplemented by the Prospectus Supplement, relating to the Placement Shares. Except where the context otherwise requires, such registration statement, and any post-

effective amendment thereto, as amended when it became effective, including all documents filed as part thereof or incorporated by reference therein, and including any information contained in a Prospectus (as defined below) subsequently filed with the Commission pursuant to Rule 424(b) under the Securities Act or deemed to be a part of such registration statement pursuant to Rule 430B or 462(b) of the Securities Act or any subsequent registration statement on Form S-3 filed pursuant to Rule 415(a)(6) under the Securities Act by the Company to cover any Placement Shares is herein called the “**Registration Statement**.” The base prospectus, including all documents incorporated therein by reference, included in the Registration Statement, as it may be supplemented by the Prospectus Supplement, in the form in which such prospectus and/or Prospectus Supplement have most recently been filed by the Company with the Commission pursuant to Rule 424(b) under the Securities Act, together with any “issuer free writing prospectus,” as defined in Rule 433 of the Securities Act regulations (“**Rule 433**”), relating to the Placement Shares that (i) is required to be filed with the Commission by the Company or (ii) is exempt from filing pursuant to Rule 433(d)(5)(i), in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company’s records pursuant to Rule 433(g), is herein called the “**Prospectus**.” Any reference herein to the Registration Statement, the Prospectus or any amendment or supplement thereto shall be deemed to refer to and include the documents incorporated by reference therein, and any reference herein to the terms “amend,” “amendment” or “supplement” with respect to the Registration Statement or the Prospectus shall be deemed to refer to and include the filing after the execution hereof of any document with the Commission deemed to be incorporated by reference therein. For purposes of this Agreement, all references to the Registration Statement, the Prospectus or to any amendment or supplement thereto shall be deemed to include any copy filed with the Commission pursuant to the Electronic Data Gathering Analysis and Retrieval System (“**EDGAR**”).

2. **Placements.** Each time that the Company wishes to issue and sell the Placement Shares hereunder (each, a “**Placement**”), it will notify JMP by email notice (or other method mutually agreed to in writing by the parties) (a “**Placement Notice**”) containing the parameters in accordance with which it desires the Placement Shares to be sold, which shall at a minimum include the number of shares of Placement Shares to be issued, the time period during which sales are requested to be made, any limitation on the number of Placement Shares that may be sold in any one Trading Day (as defined in Section 3) and any minimum price below which sales may not be made, a form of which containing such minimum sales parameters necessary is attached hereto as **Schedule 1**. The Placement Notice shall originate from any of the individuals from the Company set forth on **Schedule 2** (with a copy to each of the other individuals from the Company listed on such schedule), and shall be addressed to each of the individuals from JMP set forth on **Schedule 2**, as such **Schedule 2** may be amended from time to time. The Placement Notice shall be effective upon receipt by JMP unless and until (i) in accordance with the notice requirements set forth in Section 4, JMP declines to accept the terms contained therein for any reason, in its sole discretion, (ii) the entire amount of the Placement Shares have been sold, (iii) in accordance with the notice requirements set forth in Section 4, the Company suspends or terminates the Placement Notice for any reason, in its sole discretion, (iv) the Company issues a subsequent Placement Notice with parameters superseding those on the earlier dated Placement Notice, or (v) the Agreement has been terminated under the provisions of Section 11. The amount of any discount, commission or other compensation to be paid by the Company to JMP in connection with the sale of the Placement Shares shall be calculated in accordance with the terms set forth in **Schedule 3**. It is expressly acknowledged and agreed that neither the Company nor JMP will have any

obligation whatsoever with respect to a Placement or any Placement Shares unless and until the Company delivers a Placement Notice to JMP and JMP does not decline such Placement Notice pursuant to the terms set forth above, and then only upon the terms specified therein and herein. In the event of a conflict between the terms of this Agreement and the terms of a Placement Notice, the terms of the Placement Notice will control.

3. Sale of Placement Shares by JMP. Subject to the terms and conditions herein set forth, upon the Company's delivery of a Placement Notice, and unless the sale of the Placement Shares described therein has been declined, suspended, or otherwise terminated in accordance with the terms of this Agreement, JMP, for the period specified in the Placement Notice, will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of The Nasdaq Capital Market ("**Nasdaq**") to sell such Placement Shares up to the amount specified, and otherwise in accordance with the terms of such Placement Notice. JMP will provide written confirmation to the Company (including by email correspondence to each of the individuals of the Company set forth on **Schedule 2**, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply) no later than the opening of the Trading Day (as defined below) immediately following the Trading Day on which it has made sales of Placement Shares hereunder setting forth the number of Placement Shares sold on such day, the volume-weighted average price of the Placement Shares sold, and the Net Proceeds (as defined below) payable to the Company. Subject to the terms of the Placement Notice, JMP may sell Placement Shares by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415 of the Securities Act. Notwithstanding the provisions of **Section 6(ii)**, JMP shall not purchase Placement Shares for its own account as principal unless expressly authorized to do so by the Company in a Placement Notice. The Company acknowledges and agrees that (i) there can be no assurance that JMP will be successful in selling Placement Shares, and (ii) JMP will incur no liability or obligation to the Company or any other person or entity if it does not sell Placement Shares for any reason other than a failure by JMP to use its commercially reasonable efforts consistent with its normal trading and sales practices to sell such Placement Shares as required under this **Section 3**. For the purposes hereof, "**Trading Day**" means any day on which the Company's Common Stock is purchased and sold on the principal market on which the Common Stock is listed or quoted.

4. Suspension of Sales.

(a) The Company or JMP may, upon notice to the other party in writing (including by email correspondence to each of the individuals of the other party set forth on **Schedule 2**, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply) or by telephone (confirmed immediately by verifiable facsimile transmission or email correspondence to each of the individuals of the other party set forth on **Schedule 2**), suspend any sale of Placement Shares; *provided, however*, that such suspension shall not affect or impair either party's obligations with respect to any Placement Shares sold hereunder prior to the receipt of such notice. Each of the parties agrees that no such notice under this **Section 4** shall be effective against the other unless it is made to one of the individuals named on **Schedule 2** hereto, as such schedule may be amended from time to time.

(b) Notwithstanding any other provision of this Agreement, during any period in which the Company is in possession of material non-public information, the Company and JMP agree

that (i) no sale of Placement Shares will take place, (ii) the Company shall not request the sale of any Placement Shares, and (iii) JMP shall not be obligated to sell or offer to sell any Placement Shares.

5. Settlement.

(a) Settlement of Placement Shares. Unless otherwise specified in the applicable Placement Notice, settlement for sales of Placement Shares will occur on the second (2nd) Trading Day (or such earlier day as is industry practice for regular-way trading) following the date on which such sales are made (each, a “**Settlement Date**” and the first such settlement date, the “**First Delivery Date**”). The amount of proceeds to be delivered to the Company on a Settlement Date against receipt of the Placement Shares sold (the “**Net Proceeds**”) will be equal to the aggregate sales price received by JMP at which such Placement Shares were sold, after deduction for (i) JMP’s commission, discount or other compensation for such sales payable by the Company pursuant to Section 2 hereof, (ii) any other amounts due and payable by the Company to JMP hereunder pursuant to Section 7(g) (Expenses) hereof, and (iii) any transaction fees imposed by any governmental or self-regulatory organization in respect of such sales.

(b) Delivery of Placement Shares. On or before each Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Placement Shares being sold by crediting JMP’s or its designee’s account (provided JMP shall have given the Company written notice of such designee at least one (1) Trading Day prior to the Settlement Date) at The Depository Trust Company through its Deposit and Withdrawal at Custodian System or by such other means of delivery as may be mutually agreed upon by the parties hereto which in all cases shall be freely tradeable, transferable, registered shares in good deliverable form. On each Settlement Date, JMP will deliver the related Net Proceeds in same day funds to an account designated by the Company on, or prior to, the Settlement Date. The Company agrees that if the Company, or its transfer agent (if applicable), defaults in its obligation to deliver duly authorized Placement Shares on a Settlement Date, the Company agrees that in addition to and in no way limiting the rights and obligations set forth in Section 9(a) (Indemnification and Contribution) hereto, it will (i) hold JMP harmless against any loss, claim, damage, or reasonable and documented expense (including reasonable and documented legal fees and expenses), as incurred, arising out of or in connection with such default by the Company and (ii) pay to JMP (without duplication) any commission, discount, or other compensation to which it would otherwise have been entitled absent such default.

6. Representations and Warranties of the Company. The Company represents and warrants to, and agrees with, JMP that as of the date of this Agreement, each Representation Date (as defined in Section 7(m)), each date on which a Placement Notice is given, and any date on which Placement Shares are sold hereunder:

(a) Compliance with Registration Requirements. The Registration Statement and, if applicable, any Rule 462(b) Registration Statement, have been declared effective by the Commission under the Securities Act. The Company has complied to the Commission’s satisfaction with all requests of the Commission for additional or supplemental information. No stop order suspending the effectiveness of the Registration Statement or any Rule 462(b) Registration Statement is in effect and no proceedings for such purpose have been instituted or are pending or, to the knowledge of the Company, contemplated or threatened by the Commission.

The Company meets the requirements for use of Form S-3 under the Securities Act. The sale of the Placement Shares hereunder meets the requirements or General Instruction I.B.1 of Form S-3.

(b) No Misstatement or Omission. The Prospectus when filed complied and, as amended or supplemented, if applicable, will comply in all material respects with the Securities Act. Each of the Registration Statement, any Rule 462(b) Registration Statement, the Prospectus and any post-effective amendments or supplements thereto, at the time it became effective or its date, as applicable, complied and as of each of the Settlement Dates, if any, will comply in all material respects with the Securities Act and did not and, as of each Settlement Date, if any, did not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. The Prospectus, as amended or supplemented, as of its date, did not and, as of each of the Settlement Dates, if any, will not contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The representations and warranties set forth in the two immediately preceding sentences do not apply to statements in or omissions from the Registration Statement, any Rule 462(b) Registration Statement, or any post-effective amendment thereto, or the Prospectus, or any amendments or supplements thereto, made in reliance upon and in conformity with information relating to JMP furnished to the Company in writing by JMP expressly for use therein. There are no contracts or other documents required to be described in the Prospectus or to be filed as exhibits to the Registration Statement which have not been described or filed as required.

(c) Offering Materials Furnished to JMP. The Company has delivered to JMP one complete copy of the Registration Statement and a copy of each consent and certificate of experts filed as a part thereof, and conformed copies of the Registration Statement (without exhibits) and the Prospectus, as amended or supplemented, in such quantities and at such places as JMP has reasonably requested.

(d) Not an Ineligible Issuer. The Company currently is not an “ineligible issuer,” as defined in Rule 405 under the Securities Act. The Company agrees to notify JMP promptly upon the Company becoming an “ineligible issuer.”

(e) Distribution of Offering Material By the Company. The Company has not distributed and will not distribute, prior to the completion of JMP’s distribution of the Placement Shares, any offering material in connection with the offering and sale of the Placement Shares other than the Prospectus or the Registration Statement.

(f) The Sales Agreement. This Agreement has been duly authorized, executed and delivered by, and is a valid and binding agreement of, the Company, enforceable in accordance with its terms, except as rights to indemnification hereunder may be limited by applicable law and except as the enforcement hereof may be limited by bankruptcy, insolvency, reorganization, moratorium or other similar laws relating to or affecting the rights and remedies of creditors or by general equitable principles.

(g) Authorization of the Common Stock. The Placement Shares, when issued and delivered, will be duly authorized for issuance and sale pursuant to this Agreement and, when

issued and delivered by the Company against payment therefor pursuant to this Agreement, will be duly authorized, validly issued, fully paid and nonassessable.

(h) No Applicable Registration or Other Similar Rights. There are no persons with registration or other similar rights to have any equity or debt securities registered for sale under the Registration Statement or included in the offering contemplated by this Agreement, except for such rights as have been duly waived.

(i) No Material Adverse Change. Except as otherwise disclosed in the Prospectus, subsequent to the respective dates as of which information is given in the Prospectus: (i) there has been no material adverse change, or any development that could reasonably be expected to result in a material adverse change, in the condition, financial or otherwise, or in the earnings, business or operations, whether or not arising from transactions in the ordinary course of business, of the Company and its subsidiaries, considered as one entity (any such change is called a “**Material Adverse Change**”); (ii) the Company and its subsidiaries, considered as one entity, have not incurred any material liability or obligation, indirect, direct or contingent, not in the ordinary course of business nor entered into any material transaction or agreement not in the ordinary course of business; and (iii) there has been no dividend or distribution of any kind declared, paid or made by the Company or, dividends paid to the Company or other subsidiaries, by any of its subsidiaries on any class of capital stock or repurchase or redemption by the Company or any of its subsidiaries of any class of capital stock.

(j) Independent Accountants . KPMG LLP, who has expressed its opinion with respect to the financial statements (which term as used in this Agreement includes the related notes thereto) and supporting schedules filed with the Commission or incorporated by reference as a part of the Registration Statement and included in the Prospectus, is an independent registered public accounting firm as required by the Securities Act and the Exchange Act.

(k) Preparation of the Financial Statements. The financial statements filed with the Commission as a part of or incorporated by reference in the Registration Statement and included in the Prospectus present fairly in all material respects the consolidated financial position of the Company and its subsidiaries as of and at the dates indicated and the results of their operations and cash flows for the periods specified. The supporting schedules, if any, included in or incorporated in the Registration Statement present fairly the information required to be stated therein. Such financial statements and supporting schedules, if any, have been prepared in conformity with generally accepted accounting principles as applied in the United States applied on a consistent basis throughout the periods involved, except as may be expressly stated in the related notes thereto. No other financial statements or supporting schedules are required to be included in or incorporated in the Registration Statement.

(l) Extensible Business Reporting Language. The interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration Statement fairly presents the information called for in all material respects and has been prepared in all material respects in accordance with the Commission’s rules and guidelines applicable thereto.

(m) Incorporation and Good Standing of the Company and its Subsidiaries. The Company has been duly incorporated and is validly existing as a corporation in good standing under the laws of the State of Pennsylvania and has corporate power and authority to own, lease

and operate its properties and to conduct its business as described in the Prospectus and to enter into and perform its obligations under this Agreement. Baudax Bio N.A. LLC and Baudax Bio Limited are the Company's only subsidiaries (the "**Subsidiaries**"). Each of the Subsidiaries has been duly incorporated or organized (as the case may be) and is validly existing and in good standing under the laws of the jurisdiction of its organization and has the requisite power and authority to own, lease and operate its properties and to conduct its business as described in the Prospectus. Each of the Company and the Subsidiaries is duly qualified as a foreign corporation or foreign partnership to transact business and is in good standing in each jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except for such jurisdictions where the failure to so qualify or to be in good standing would not reasonably be expected to, individually or in the aggregate, result in a Material Adverse Change. Except as described in the Prospectus, all of the issued and outstanding equity interests of the Subsidiaries have been duly authorized and validly issued, are fully paid and nonassessable and are owned by the Company free and clear of any security interest, mortgage, pledge, lien, encumbrance or claim. The Company does not own or control, directly or indirectly, any corporation, association or other entity other than the subsidiaries listed in Exhibit 21.1 to the Company's Annual Report on Form 10-K for the most recently ended fiscal year and other than (i) those subsidiaries not required to be listed on Exhibit 21.1 by Item 601 of Regulation S-K under the Exchange Act and (ii) those subsidiaries formed since the last day of the most recently ended fiscal year.

(n) Capital Stock Matters. The Common Stock conforms in all material respects to the description thereof contained in the Prospectus. All of the issued and outstanding shares of Common Stock have been duly authorized and validly issued, are fully paid and nonassessable and have been issued in compliance with federal and state securities laws. None of the outstanding shares of Common Stock were issued in violation of any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase securities of the Company. There are no authorized or outstanding options, warrants, preemptive rights, rights of first refusal or other rights to purchase, or equity or debt securities convertible into or exchangeable or exercisable for, any capital stock of the Company or any of its subsidiaries other than those accurately described in all material respects in the Prospectus. The description of the Company's stock option, stock bonus and other stock plans or arrangements, and the options or other rights granted thereunder, set forth in the Prospectus accurately and fairly presents in all material respects the information required to be shown with respect to such plans, arrangements, options and rights.

(o) Non-Contravention of Existing Instruments; No Further Authorizations or Approvals Required. Neither the Company nor any of its subsidiaries is in violation of its charter, by-laws, operating agreement or similar organization document, as applicable, or is in default (or, with the giving of notice or lapse of time, would be in default) ("**Default**") under any indenture, mortgage, loan or credit agreement, note, contract, franchise, lease or other instrument to which the Company or any of its subsidiaries is a party or by which it or any of them may be bound, or to which any of the material property or assets of the Company or any of its subsidiaries is subject (each, an "**Existing Instrument**"), except for such Defaults as would not, reasonably be expected to, individually or in the aggregate, result in a Material Adverse Change. The Company's execution, delivery and performance of this Agreement and consummation of the transactions contemplated hereby and by the Prospectus (i) have been duly authorized by all necessary corporate action and will not result in any violation of the provisions of the charter, by-laws,

operating agreement or similar organization document, as applicable, of the Company or any subsidiary, (ii) will not conflict with or constitute a breach of, or Default under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company or any of its subsidiaries pursuant to, or require the consent of any other party to, any Existing Instrument, except for such conflicts, breaches, Defaults, liens, charges or encumbrances as would not, reasonably be expected to, individually or in the aggregate, result in a Material Adverse Change and (iii) will not result in any violation of any law, administrative regulation or administrative or court decree having jurisdiction over the Company or any subsidiary except for such violations that would not, individually or in the aggregate, result in a Material Adverse Change. No consent, approval, authorization or other order of, or registration or filing with, any court or other governmental or regulatory authority or agency, is required for the Company's execution, delivery and performance of this Agreement and consummation of the transactions contemplated hereby and by the Prospectus, except such as have been obtained or made by the Company and are in full force and effect under the Securities Act, applicable state securities or blue sky laws and from the Financial Industry Regulatory Authority ("**FINRA**").

(p) No Material Actions or Proceedings. Except as disclosed in the Prospectus, there are no legal or governmental actions, suits or proceedings pending or, to the Company's knowledge, threatened (i) to which the Company or any of its subsidiaries is a party, (ii) which has as the subject thereof any officer or director of, or property owned or leased by, the Company or any of its subsidiaries or (iii) relating to environmental or discrimination matters, where in any such case (A) there is a reasonable possibility that such action, suit or proceeding might be determined adversely to the Company or such subsidiary and (B) any such action, suit or proceeding, if so determined adversely, would reasonably be expected to, individually or in the aggregate, result in a Material Adverse Change or adversely affect the consummation of the transactions contemplated by this Agreement. No material labor dispute with the employees of the Company or any of its subsidiaries exists or, to the Company's knowledge, is threatened or imminent.

(q) All Necessary Permits, etc. Except as otherwise disclosed in the Prospectus, the Company and each subsidiary possess such valid and current certificates, authorizations or permits issued by the appropriate state, federal or foreign regulatory agencies or bodies necessary to conduct their respective businesses, other than those the failure to possess or own would not reasonably be expected to, individually or in the aggregate, result in a Material Adverse Change, and neither the Company nor any subsidiary has received any notice of proceedings relating to the revocation or modification of, or non-compliance with, any such certificate, authorization or permit which, would reasonably be expected to singly or in the aggregate, if the subject of an unfavorable decision, ruling or finding, result in a Material Adverse Change.

(r) Tax Law Compliance. The Company and its consolidated subsidiaries have filed all federal, state and foreign income, property and franchise tax returns required to be filed or have properly requested extensions thereof, except insofar as the failure to file such returns would, individually or in the aggregate, be expected to result in a Material Adverse Change, and have paid all taxes required to be paid by any of them and, if due and payable, any related or similar assessment, fine or penalty levied against any of them except as may be being contested in good faith and by appropriate proceedings except where the failure to pay such taxes, assessments, fines or penalties would not individually or in the aggregate, be expected to result in a Material Adverse

Change. There is no pending dispute with any taxing authority relating to any of such returns, and the Company has no knowledge of any proposed liability for any tax to be imposed upon the properties or assets of the Company for which there is not an adequate reserve reflected in the Company's financial statements included in the Registration Statement and the Prospectus.

(s) Company Not an "Investment Company". The Company is not, and after receipt of payment for the Common Stock will not be, an "investment company" within the meaning of the Investment Company Act of 1940, as amended.

(t) Insurance. Except as otherwise described in the Prospectus, each of the Company and its subsidiaries are insured by insurers of recognized financial responsibility with policies in such amounts and with such deductibles and covering such risks as the Company believes are customary for the business for which it is engaged. The Company has no reason to believe that it or any subsidiary will not be able (i) to renew its existing insurance coverage as and when such policies expire or (ii) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not reasonably be expected to, individually or in the aggregate, result in a Material Adverse Change.

(u) No Price Stabilization or Manipulation. The Company has not taken and will not take, directly or indirectly, any action designed to or that might be reasonably expected to cause or result in stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Placement Shares.

(v) Related Party Transactions. There are no business relationships or related-party transactions involving the Company or any subsidiary or any other person required to be described in the Prospectus which have not been described as required.

(w) Exchange Act Compliance. The documents incorporated or deemed to be incorporated by reference in the Prospectus, at the time they were or hereafter are filed with the Commission, complied and will comply in all material respects with the requirements of the Exchange Act, and, when read together with the other information in the Prospectus, at the Settlement Dates, will not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(x) No Unlawful Contributions or Other Payments. Neither the Company nor any of its subsidiaries nor, to the Company's knowledge, any director, officer, employee or agent of the Company or any subsidiary has (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; (ii) made any direct or indirect unlawful payment to any foreign or domestic government official or employee from corporate funds; (iii) violated or is in violation of any provision of the Foreign Corrupt Practices Act of 1977, as amended; or (iv) made any bribe, rebate, payoff, influence payment, kickback or other unlawful payment.

(y) Compliance with Money Laundering Laws. The operations of the Company and its subsidiaries are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting

Act of 1970, as amended, the money laundering statutes of all jurisdictions, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the “**Money Laundering Laws**”) and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(z) Compliance with OFAC. None of the Company, any of its subsidiaries or, to the knowledge of the Company, any director, officer, agent, employee or affiliate of the Company or any of its subsidiaries is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury (“**OFAC**”); and the Company will not, directly or indirectly, use the proceeds of the offering of the Placement Shares hereunder, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity, for the purpose of financing the activities of any person currently subject to any U.S. sanctions administered by OFAC.

(aa) Company’s Accounting System. The Company maintains a system of “internal control over financial reporting” (as such term is defined in Rule 13a-15(f) of the General Rules and Regulations under the Exchange Act (the “**Exchange Act Rules**”)) that complies with the requirements of the Exchange Act and has been designed by the principal executive and principal financial officers, or under their supervision, to provide reasonable assurances that (i) transactions are executed in accordance with management’s general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with U.S. GAAP and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management’s general or specific authorization; and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company’s internal control over financial reporting is effective. Except as described in the Prospectus, since the end of the Company’s most recent audited fiscal year, there has been (A) no material weakness in the Company’s internal control over financial reporting (whether or not remediated) and (B) no change in the Company’s internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company’s internal control over financial reporting.

(bb) Disclosure Controls. The Company maintains disclosure controls and procedures (as such is defined in Rule 13a-15(e) of the Exchange Act Rules) that comply with the requirements of the Exchange Act; such disclosure controls and procedures are effective in all material respects to perform the functions for which they were established. The Company has conducted evaluations of the effectiveness of its disclosure controls as required by Rule 13a-15 of the Exchange Act.

(cc) Compliance with Environmental Laws. Except as otherwise described in the Prospectus, and except as would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change: (i) neither the Company nor any of its subsidiaries is in violation of any federal, state, local or foreign law or regulation relating to pollution or protection of human health or the environment (including, without limitation, ambient air, surface water, groundwater, land surface or subsurface strata) or wildlife, including without limitation, laws and regulations relating to emissions, discharges, releases or threatened releases of chemicals, pollutants, contaminants, wastes, toxic substances, hazardous substances, petroleum and petroleum products (collectively, “**Materials of Environmental Concern**”), or otherwise relating

to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Materials of Environmental Concern (collectively, "**Environmental Laws**"), which violation includes, but is not limited to, noncompliance with any permits or other governmental authorizations required for the operation of the business of the Company or its subsidiaries under applicable Environmental Laws, or noncompliance with the terms and conditions thereof, nor has the Company or any of its subsidiaries received any written communication, whether from a governmental authority, citizens group, employee or otherwise, that alleges that the Company or any of its subsidiaries is in violation of any Environmental Law; (ii) there is no claim, action or cause of action filed with a court or governmental authority, no investigation with respect to which the Company has received written notice, and no written notice by any person or entity alleging potential liability for investigatory costs, cleanup costs, governmental responses costs, natural resources damages, property damages, personal injuries, attorneys' fees or penalties arising out of, based on or resulting from the presence, or release into the environment, of any Material of Environmental Concern at any location owned, leased or operated by the Company or any of its subsidiaries, now or in the past (collectively, "**Environmental Claims**"), pending or, to the Company's knowledge, threatened against the Company or any of its subsidiaries or any person or entity whose liability for any Environmental Claim the Company or any of its subsidiaries has retained or assumed either contractually or by operation of law; and (iii) to the Company's knowledge, there are no past or present actions, activities, circumstances, conditions, events or incidents, including, without limitation, the release, emission, discharge, presence or disposal of any Material of Environmental Concern, that reasonably could result in a violation of any Environmental Law or form the basis of a potential Environmental Claim against the Company or any of its subsidiaries or against any person or entity whose liability for any Environmental Claim the Company or any of its subsidiaries has retained or assumed either contractually or by operation of law.

(dd) **Intellectual Property.** The Company and its subsidiaries own or possess the valid right to use all (i) patents, patent applications, trademarks, trademark registrations, service marks, service mark registrations, Internet domain name registrations, copyrights, copyright registrations, licenses, trade secret rights ("**Intellectual Property Rights**") and (ii) inventions, software, works of authorships, trademarks, service marks, trade names, databases, formulae, know how, Internet domain names and other intellectual property (including trade secrets and other unpatented and/or unpatentable proprietary confidential information, systems, or procedures) (collectively, "**Intellectual Property Assets**") necessary to conduct their respective businesses as currently conducted, except where the failure to possess or acquire such rights would not reasonably be expected to, individually or in the aggregate, result in a Material Adverse Change. All licenses for the use of the Intellectual Property Rights described in the Prospectus are valid, binding upon, and enforceable by or against the parties thereto in accordance to its terms. Except as described in the Prospectus, (A) to the Company's knowledge, there is no infringement, misappropriation or violation by third parties of any such Intellectual Property Rights, except as such infringement, misappropriation or violation would not reasonably be expected to, individually or in the aggregate, result in a Material Adverse Change; (B) there is no pending or, to the Company's knowledge, threatened, action, suit, proceeding or claim by others challenging the Company's or any of its subsidiaries' rights in or to any such Intellectual Property Rights, and the Company is unaware of any objective facts which would form a reasonable basis for any such claim; (C) the Intellectual Property Rights and Intellectual Property Assets owned by the Company and its subsidiaries, and to the Company's knowledge, the Intellectual Property Rights and Intellectual

Property Assets licensed to the Company and its subsidiaries, has not been adjudged invalid or unenforceable, in whole or in part, and there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others challenging the validity or scope of any such Intellectual Property Rights or Intellectual Property Assets; (D) there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others that the Company or any of its subsidiaries infringes, misappropriates or otherwise violates any Intellectual Property Rights or other proprietary rights of others, and neither the Company or any of its subsidiaries has received any written notice of such claim; and (E) to the Company's knowledge, no employee of the Company or any of its subsidiaries is in or has ever been in violation of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement or any restrictive covenant to or with a former employer where the basis of such violation relates to such employee's employment with the Company or any of its subsidiaries or actions undertaken by the employee while employed with the Company or any of its subsidiaries, except as such violation would not reasonably be expected to, individually or in the aggregate, result in a Material Adverse Change. The Company has taken all reasonable steps to protect, maintain and safeguard its Intellectual Property Rights, including the execution of appropriate nondisclosure and confidentiality agreements. The consummation of the transactions contemplated by this Agreement will not result in the loss or impairment of or payment of any additional amounts with respect to, nor require the consent of any other person in respect of, the Company's right to own, use, or hold for use any of the Intellectual Property Rights as owned, used or held for use in the conduct of the business as currently conducted.

(ee) FDA. Except as described in the Prospectus, as to each product subject to the jurisdiction of the U.S. Food and Drug Administration ("**FDA**") under the Federal Food, Drug and Cosmetic Act, as amended, and the regulations thereunder ("**FDCA**") that is manufactured, packaged, labeled, tested, distributed, sold, and/or marketed by the Company or any of its subsidiaries (each such product, a "**Product**"), such Product is being manufactured, packaged, labeled, tested, distributed, sold and/or marketed by the Company in compliance with all applicable requirements under FDCA and similar laws, rules and regulations relating to registration, investigational use, premarket clearance, licensure, or application approval, good manufacturing practices, good laboratory practices, good clinical practices, product listing, quotas, labeling, advertising, record keeping and filing of reports, except where the failure to be in compliance would not reasonably be expected to, individually or in the aggregate, have a Material Adverse Change. Except as described in the Prospectus, there is no pending, completed or, to the Company's knowledge, threatened, action (including any lawsuit, arbitration, or legal or administrative or regulatory proceeding, charge, complaint, or investigation) against the Company or any of its subsidiaries, and none of the Company or any of its subsidiaries has received any notice, warning letter or other communication from the FDA or any other governmental entity, which (i) contests the premarket clearance, licensure, registration, or approval of, the uses of, the distribution of, the manufacturing or packaging of, the testing of, the sale of, or the labeling and promotion of any Product, (ii) withdraws its approval of, requests the recall, suspension, or seizure of, or withdraws or orders the withdrawal of advertising or sales promotional materials relating to, any Product, (iii) imposes a clinical hold on any clinical investigation by the Company or any of its subsidiaries, (iv) enjoins production at any facility of the Company or any of its subsidiaries, (v) enters or proposes to enter into a consent decree of permanent injunction with the Company or any of its subsidiaries, or (vi) otherwise alleges any violation of any laws, rules or regulations by

the Company or any of its subsidiaries, and which, in each of clauses (i) through (vi) either individually or in the aggregate, would have a Material Adverse Change. The properties, business and operations of the Company have been and are being conducted in all material respects in accordance with all applicable laws, rules and regulations of the FDA. The Company has not been informed by the FDA that the FDA will prohibit the marketing, sale, license or use in the United States of any product proposed to be developed, produced or marketed by the Company nor has the FDA expressed any concern as to approving or clearing for marketing any product being developed or proposed to be developed by the Company.

(ff) Listing. The Company is subject to and in compliance in all material respects with the reporting requirements of Section 13 or Section 15(d) of the Exchange Act. The Common Stock is registered pursuant to Section 12(b) of the Exchange Act and is listed on Nasdaq, and the Company has taken no action designed to, or reasonably likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from Nasdaq, nor has the Company received any notification that the Commission or Nasdaq is contemplating terminating such registration or listing.

(gg) Brokers. Except for JMP, there is no broker, finder or other party that is entitled to receive from the Company any brokerage or finder's fee or other fee or commission as a result of any transactions contemplated by this Agreement.

(hh) No Outstanding Loans or Other Indebtedness. Except as described in the Prospectus, there are no outstanding loans, advances (except normal advances for business expenses in the ordinary course of business) or guarantees or indebtedness by the Company to or for the benefit of any of the officers or directors of the Company or any of the members of any of them.

(ii) No Reliance. The Company has not relied upon JMP or legal counsel for JMP for any legal, tax or accounting advice in connection with the offering and sale of the Placement Shares.

(jj) JMP Purchases. The Company acknowledges and agrees that JMP has informed the Company that JMP may, to the extent permitted under the Securities Act and the Exchange Act, purchase and sell shares of Common Stock for its own account while this Agreement is in effect; *provided, that* (i) no such purchase or sales shall take place while a Placement Notice is in effect (except to the extent JMP may engage in sales of Placement Shares purchased or deemed to be purchased from the Company as a "riskless principal" or similar capacity) and (ii) the Company shall not be deemed to have authorized or consented to any such purchases or sales by JMP.

(kk) Compliance with Laws. The Company and each of its subsidiaries is conducting business in compliance with all applicable laws, rules and regulations of the jurisdictions in which it is conducting business, except where failure to be so in compliance would not reasonably be expected to, individually or in the aggregate, result in a Material Adverse Change.

Any certificate signed by an officer of the Company and delivered to JMP or to counsel for JMP shall be deemed to be a representation and warranty by the Company to JMP as to the matters set forth therein.

The Company acknowledges that JMP and, for purposes of the opinions to be delivered pursuant to Section 7 hereof, counsel to the Company and counsel to JMP, will rely upon the accuracy and truthfulness of the foregoing representations and hereby consents to such reliance.

7. Covenants of the Company. The Company covenants and agrees with JMP that:

(a) Registration Statement Amendments. After the date of this Agreement and during any period in which a Prospectus relating to any Placement Shares is required to be delivered by JMP under the Securities Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), (i) the Company will notify JMP promptly of the time when any subsequent amendment to the Registration Statement, other than documents incorporated by reference, has been filed with the Commission and/or has become effective or any subsequent supplement to the Prospectus has been filed and of any request by the Commission for any amendment or supplement to the Registration Statement or Prospectus or for additional information, (ii) the Company will prepare and file with the Commission, promptly upon JMP's reasonable request, any amendments or supplements to the Registration Statement or Prospectus that, in JMP's reasonable opinion, may be necessary or advisable in connection with the distribution of the Placement Shares by JMP (*provided, however*, that the failure of JMP to make such request shall not relieve the Company of any obligation or liability hereunder, or affect JMP's right to rely on the representations and warranties made by the Company in this Agreement; and *provided, further*, that the only remedy JMP shall have with respect to the failure to make such filing (other than JMP's rights under Section 9 hereof) will be to cease making sales under this Agreement); (iii) the Company will not file any amendment or supplement to the Registration Statement or Prospectus, other than documents incorporated by reference, relating to the Placement Shares or a security convertible into the Placement Shares unless a copy thereof has been submitted to JMP within a reasonable period of time before the filing and JMP has not reasonably objected thereto (*provided, however*, that the failure of JMP to make such objection shall not relieve the Company of any obligation or liability hereunder, or affect JMP's right to rely on the representations and warranties made by the Company in this Agreement; and *provided, further*, that the only remedy JMP shall have with respect to the failure to make such filing (other than JMP's rights under Section 9 hereof) will be to cease making sales under this Agreement) and the Company will furnish to JMP at the time of filing thereof a copy of any document that upon filing is deemed to be incorporated by reference into the Registration Statement or Prospectus, except for those documents available via EDGAR; and (iv) the Company will cause each amendment or supplement to the Prospectus, other than documents incorporated by reference, to be filed with the Commission as required pursuant to the applicable paragraph of Rule 424(b) of the Securities Act.

(b) Notice of Commission Stop Orders. The Company will advise JMP, promptly after it receives notice or obtains knowledge thereof, of the issuance or threatened issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement, of the suspension of the qualification of the Placement Shares for offering or sale in any jurisdiction, or of the initiation or threatening of any proceeding for any such purpose; and it will promptly use its commercially reasonable efforts to prevent the issuance of any stop order or to obtain its withdrawal if such a stop order should be issued.

(c) Delivery of Prospectus; Subsequent Changes. During any period in which a Prospectus relating to the Placement Shares is required to be delivered by JMP under the Securities

Act with respect to a pending sale of the Placement Shares, (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), the Company will comply with all requirements imposed upon it by the Securities Act, as from time to time in force, and to file on or before their respective due dates (taking into account any extensions available under the Exchange Act that would permit the Company to continue to meet the eligibility requirements of Form S-3) all reports and any definitive proxy or information statements required to be filed by the Company with the Commission pursuant to Sections 13(a), 13(c), 14, 15(d) or any other provision of or under the Exchange Act. If during such period any event occurs as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances then existing, not misleading, or if during such period it is necessary to amend or supplement the Registration Statement or Prospectus to comply with the Securities Act, the Company will promptly notify JMP to suspend the offering of Placement Shares during such period and the Company will promptly amend or supplement the Registration Statement or Prospectus (at the expense of the Company) so as to correct such statement or omission or effect such compliance; *provided, however*, that the Company may delay any such amendment or supplement if, as a result of a pending transaction or other development with respect to the Company, in the reasonable judgement of the Company, it is in the best interest of the Company to do so, provided that no Placement Notice is in effect during such time.

(d) Listing of Placement Shares. During any period in which the Prospectus relating to the Placement Shares is required to be delivered by JMP under the Securities Act with respect to a pending sale of the Placement Shares (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), the Company will use its commercially reasonable efforts to cause the Placement Shares to continue to be listed on Nasdaq and to qualify the Placement Shares for sale under the securities laws of such jurisdictions as JMP reasonably designates and to continue such qualifications in effect so long as required for the distribution of the Placement Shares; *provided, however*, that the Company shall not be required in connection therewith to qualify as a foreign corporation or dealer in securities or file a general consent to service of process in any jurisdiction.

(e) Delivery of Registration Statement and Prospectus. The Company will furnish to JMP and its counsel (at the expense of the Company) copies of the Registration Statement, the Prospectus (including all documents incorporated by reference therein) and all amendments and supplements to the Registration Statement or Prospectus that are filed with the Commission during any period in which a Prospectus relating to the Placement Shares is required to be delivered under the Securities Act (including all documents filed with the Commission during such period that are deemed to be incorporated by reference therein), in each case as soon as reasonably practicable and in such quantities as JMP may from time to time reasonably request and, at JMP's request, will also furnish copies of the Prospectus to each exchange or market on which sales of the Placement Shares may be made; *provided, however*, that the Company shall not be required to furnish any document (other than the Prospectus) to JMP or its counsel to the extent such document is available on EDGAR.

(f) Earnings Statement. The Company will make generally available to its security holders as soon as practicable, but in any event not later than 15 months after the end of the

Company's current fiscal quarter, an earnings statement covering a 12-month period that satisfies the provisions of Section 11(a) and Rule 158 of the Securities Act.

(g) Expenses. The Company, whether or not the transactions contemplated hereunder are consummated or this Agreement is terminated, in accordance with the provisions of Section 11 hereunder, will pay the following expenses all incident to the performance of its obligations hereunder, including, but not limited to, expenses relating to (i) the preparation, printing and filing of the Registration Statement and each amendment and supplement thereto, of each Prospectus and of each amendment and supplement thereto, (ii) the preparation, issuance and delivery of the Placement Shares, (iii) the qualification of the Placement Shares under securities laws in accordance with the provisions of Section 7(d) of this Agreement, including filing fees (provided, however, that any fees or disbursements of counsel for JMP in connection therewith shall be paid by JMP except as set forth in (vii) below), (iv) the printing and delivery to JMP of copies of the Prospectus and any amendments or supplements thereto, and of this Agreement, (v) the fees and expenses incurred in connection with the listing or qualification of the Placement Shares for trading on Nasdaq, (vi) the filing fees and expenses, if any, of the Commission, (vii) the filing fees and associated legal expenses of JMP's outside counsel for filings with the FINRA Corporate Financing Department, such legal expense reimbursement not to exceed \$12,500 and, (viii) the reasonable fees and disbursements of JMP's counsel in an amount not to exceed \$50,000.

(h) Use of Proceeds. The Company will use the Net Proceeds as described in the Prospectus in the section entitled "Use of Proceeds."

(i) Notice of Other Sales. During the pendency of any Placement Notice given hereunder, and for three (3) Trading Days following the termination of any Placement Notice given hereunder, the Company shall provide JMP notice as promptly as reasonably possible before it offers to sell, contracts to sell, sells, grants any option to sell or otherwise disposes of any shares of Common Stock (other than Placement Shares offered pursuant to the provisions of this Agreement) or securities convertible into or exchangeable for Common Stock, warrants or any rights to purchase or acquire Common Stock; *provided*, that such notice shall not be required in connection with the (i) issuance, grant or sale of Common Stock, options to purchase shares of Common Stock, restricted stock units or other equity awards or Common Stock issuable upon the exercise or settlement of options, restricted stock units or other equity awards pursuant to any stock option, stock bonus or other stock plan or arrangement described in the Prospectus, (ii) the issuance of securities in connection with an acquisition, merger or sale or purchase of assets, (iii) the issuance or sale of Common Stock pursuant to any dividend reinvestment plan that the Company may adopt from time to time provided the implementation of such is disclosed to JMP in advance, (iv) any shares of Common Stock issuable upon the exchange, conversion or redemption of securities or the exercise of warrants, options or other rights in effect or outstanding or (v) any shares of Common Stock, or securities convertible into or exercisable for Common Stock, offered and sold in a privately negotiated transaction to vendors, customers, investors, strategic partners or potential strategic partners and otherwise conducted in a manner so as not to be integrated with the offering of the Placement Shares hereby. Notwithstanding the foregoing provisions, nothing herein shall be construed to restrict the Company's ability to file a registration statement under the Securities Act.

(j) Change of Circumstances. The Company will, at any time during a fiscal quarter in which the Company intends to tender a Placement Notice or sell Placement Shares, advise JMP

promptly after it shall have received notice or obtained knowledge thereof, of any information or fact that would alter or affect in any material respect any opinion, certificate, letter or other document provided to JMP pursuant to this Agreement.

(k) Due Diligence Cooperation. During the term of this Agreement the Company will cooperate with any reasonable due diligence review conducted by JMP or its agents in connection with the transactions contemplated hereby, including, without limitation, providing information and making available documents and senior corporate officers, during regular business hours and at the Company's principal offices, as JMP may reasonably request.

(l) Required Filings Relating to Placement of Placement Shares. The Company agrees that on such dates as the Securities Act shall require, the Company will either (i) include in its quarterly reports on Form 10-Q and its annual reports on Form 10-K, a summary detailing, within the relevant period, the amount of Placement Shares sold through JMP, the Net Proceeds to the Company and the compensation payable by the Company to JMP with respect to such Placement Shares or (ii) file a prospectus supplement with the Commission under the applicable paragraph of Rule 424(b) under the Securities Act (each and every filing under Rule 424(b), a "**Filing Date**"), which prospectus supplement will set forth, within the relevant period, the amount of Placement Shares sold through JMP, the Net Proceeds to the Company and the compensation payable by the Company to JMP with respect to such Placement Shares, and deliver such number of copies of each such prospectus supplement to each exchange or market on which such sales were effected as may be required by the rules or regulations of such exchange or market.

(m) Representation Dates; Certificate. On or prior to the First Delivery Date and each time during the term of this Agreement the Company (i) files the Prospectus relating to the Placement Shares or amends or supplements the Registration Statement or the Prospectus relating to the Placement Shares (other than a prospectus supplement filed in accordance with Section 7(l) of this Agreement) by means of a post-effective amendment, sticker, or supplement but not by means of incorporation of document(s) by reference to the Registration Statement or the Prospectus relating to the Placement Shares; (ii) files an annual report on Form 10-K under the Exchange Act; (iii) files its quarterly reports on Form 10-Q under the Exchange Act; or (iv) files a report on Form 8-K containing amended financial information (other than an earnings release or other information "furnished" pursuant to Items 2.02 or 7.01 of Form 8-K) under the Exchange Act (each date of filing of one or more of the documents referred to in clauses (i) through (iv) shall be a "**Representation Date**"); the Company shall furnish JMP with a certificate, in the form attached hereto as Exhibit 7(m) within three (3) Trading Days of any Representation Date if requested by JMP. The requirement to provide a certificate under this Section 7(m) shall be automatically waived for any Representation Date occurring at a time at which no Placement Notice is pending, which waiver shall continue until the earlier to occur of the date the Company delivers a Placement Notice hereunder (which for such calendar quarter shall be considered a Representation Date) and the next occurring Representation Date. Notwithstanding the foregoing, if the Company subsequently decides to sell Placement Shares following a Representation Date when the Company relied on such waiver and did not provide JMP with a certificate under this Section 7(m), then before the Company delivers the Placement Notice or JMP sells any Placement Shares, the Company shall provide JMP with a certificate, in the form attached hereto as Exhibit 7(m), dated the date of the Placement Notice.

(n) Legal Opinion . On or prior to the First Delivery Date and within three (3) Trading Days of each Representation Date with respect to which the Company is obligated to deliver a certificate in the form attached hereto as Exhibit 7(m) for which no waiver is applicable, the Company shall cause to be furnished to JMP a written opinion of Pepper Hamilton LLP (“Company Counsel”), or other counsel satisfactory to JMP, in form and substance satisfactory to JMP and its counsel, dated the date that the opinion is required to be delivered; *provided, however*, that in lieu of such opinions for subsequent Representation Dates, counsel may furnish JMP with a letter (a “Reliance Letter”) to the effect that JMP may rely on a prior opinion delivered under this Section 7(n) to the same extent as if it were dated the date of such letter (except that statements in such prior opinion shall be deemed to relate to the Registration Statement and the Prospectus as amended or supplemented at such Representation Date).

(o) Comfort Letter. On or prior to the First Delivery Date and within three (3) Trading Days of each Representation Date with respect to which the Company is obligated to deliver a certificate in the form attached hereto as Exhibit 7(m) for which no waiver is applicable, the Company shall cause KPMG LLP, and PricewaterhouseCoopers LLP, if at the time of such Representation Date the audited financial statements related to the DARA acquisition prepared by PricewaterhouseCoopers LLP are incorporated into the Registration Statement, to furnish JMP letters (the “Comfort Letters”), dated the date the applicable Comfort Letter is delivered, in form and substance satisfactory to JMP, (i) confirming that they are an independent registered public accounting firm within the meaning of the Securities Act and the PCAOB, (ii) stating, as of such date, the conclusions and findings of such firm with respect to the financial information and other matters ordinarily covered by accountants’ “comfort letters” to JMP in connection with registered public offerings (the first such letter, the “Initial Comfort Letter”) and (iii) updating the Initial Comfort Letter with any information that would have been included in the Initial Comfort Letter had it been given on such date and modified as necessary to relate to the Registration Statement and the Prospectus, as amended and supplemented to the date of such letter. In connection with any such comfort letter issued by PricewaterhouseCoopers LLP, the Company will also deliver to JMP a CFO certificate in form and substance satisfactory to JMP and its counsel, dated the date of such comfort letter.

(p) Market Activities. The Company will not, directly or indirectly, (i) take any action designed to cause or result in, or that constitutes or might reasonably be expected to constitute, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Placement Shares or (ii) sell, bid for, or purchase the Common Stock to be issued and sold pursuant to this Agreement, or pay anyone any compensation for soliciting purchases of the Placement Shares other than JMP; provided, however, that the Company may bid for and purchase shares of its Common Stock in accordance with Rule 10b-18 under the Exchange Act.

(q) Insurance. The Company and its subsidiaries shall maintain, or cause to be maintained, insurance in such amounts and covering such risks as is reasonable and customary for the business for which it is engaged.

(r) Compliance with Laws. The Company and each of its subsidiaries shall use commercially reasonable efforts to maintain, or cause to be maintained, all material environmental permits, licenses and other authorizations required by federal, state and local law in order to conduct their businesses as described in the Prospectus, and the Company and each of its subsidiaries shall conduct their businesses, or cause their businesses to be conducted, in substantial

compliance with such permits, licenses and authorizations and with applicable environmental laws, except where the failure to maintain or be in compliance with such permits, licenses and authorizations would not reasonably be expected to, individually or in the aggregate, result in a Material Adverse Change.

(s) Investment Company Act. The Company will conduct its affairs in such a manner so as to reasonably ensure that neither it nor its subsidiaries will be or become, at any time prior to the termination of this Agreement, an “investment company,” as such term is defined in the Investment Company Act, assuming no change in the Commission’s current interpretation as to entities that are not considered an investment company.

(t) Securities Act and Exchange Act. The Company will use its reasonable best efforts to comply with all requirements imposed upon it by the Securities Act and the Exchange Act as from time to time in force, so far as necessary to permit the continuance of sales of, or dealings in, the Placement Shares as contemplated by the provisions hereof and the Prospectus.

(u) No Offer to Sell. Other than the Prospectus or a free writing prospectus (as defined in Rule 405 under the Securities Act) approved in advance by the Company and JMP in its capacity as principal or agent hereunder, neither JMP nor the Company (including its agents and representatives, other than JMP in its capacity as such) will make, use, prepare, authorize, approve or refer to any written communication (as defined in Rule 405 under the Securities Act), required to be filed with the Commission, that constitutes an offer to sell or solicitation of an offer to buy Common Stock hereunder.

(v) Sarbanes-Oxley Act. The Company and its subsidiaries will use their reasonable best efforts to comply with all effective applicable provisions of the Sarbanes-Oxley Act.

8. Conditions to JMP’s Obligations. The obligations of JMP hereunder with respect to a Placement will be subject to the continuing accuracy and completeness of the representations and warranties made by the Company herein, to the due performance by the Company of its obligations hereunder, to the completion by JMP of a due diligence review satisfactory to JMP in its reasonable judgment, and to the continuing satisfaction (or waiver by JMP in its sole discretion) of the following additional conditions:

(a) Registration Statement Effective. The Registration Statement shall be effective and shall be available for the sale of all Placement Shares contemplated to be issued by any Placement Notice.

(b) No Material Notices. None of the following events shall have occurred and be continuing: (i) receipt by the Company or any of its subsidiaries of any request for additional information from the Commission or any other federal or state governmental authority during the period of effectiveness of the Registration Statement, the response to which would require any post-effective amendments or supplements to the Registration Statement or the Prospectus; (ii) the issuance by the Commission or any other federal or state governmental authority of any stop order suspending the effectiveness of the Registration Statement or the initiation of any proceedings for that purpose; (iii) receipt by the Company of any notification with respect to the suspension of the qualification or exemption from qualification of any of the Placement Shares for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose; or (iv) the

occurrence of any event that makes any material statement made in the Registration Statement or the Prospectus or any material document incorporated or deemed to be incorporated therein by reference untrue in any material respect or that requires the making of any changes in the Registration Statement, related Prospectus or such documents so that, in the case of the Registration Statement, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading and, that in the case of the Prospectus, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(c) No Misstatement or Material Omission. JMP shall not have advised the Company that the Registration Statement or Prospectus, or any amendment or supplement thereto, contains an untrue statement of fact that in JMP's reasonable opinion is material, or omits to state a fact that in JMP's reasonable opinion is material and is required to be stated therein or is necessary to make the statements therein not misleading.

(d) Material Changes. Except as contemplated in the Prospectus, or disclosed in the Company's reports filed with the Commission, there shall not have been any material adverse change, on a consolidated basis, in the authorized capital stock of the Company or any Material Adverse Change or any development that could reasonably be expected to result in a Material Adverse Change, or any downgrading in or withdrawal of the rating assigned to any of the Company's securities (other than asset backed securities) by any rating organization or a public announcement by any rating organization that it has under surveillance or review its rating of any of the Company's securities (other than asset backed securities), the effect of which, in the case of any such action by a rating organization described above, in the reasonable judgment of JMP (without relieving the Company of any obligation or liability it may otherwise have), is so material as to make it impracticable or inadvisable to proceed with the offering of the Placement Shares on the terms and in the manner contemplated in the Prospectus.

(e) Company Counsel Legal Opinion. JMP shall have received the opinions of Company Counsel required to be delivered pursuant to Section 7(n) on or before the date on which such delivery of such opinion is required pursuant to Section 7(n).

(f) JMP Counsel Legal Opinion. JMP shall have received from Duane Morris LLP, counsel for JMP, such opinion or opinions, on or before the date on which the delivery of the Company Counsel legal opinion is required pursuant to Section 7(n), with respect to such matters as JMP may reasonably require, and the Company shall have furnished to such counsel such documents as they request for enabling them to pass upon such matters.

(g) Comfort Letter. JMP shall have received the Comfort Letter required to be delivered pursuant to Section 7(o) on or before the date on which such delivery of such Comfort Letter is required pursuant to Section 7(o).

(h) Representation Certificate. JMP shall have received the certificate required to be delivered pursuant to Section 7(m) on or before the date on which delivery of such certificate is required pursuant to Section 7(m).

(i) Secretary's Certificate. On or prior to the First Delivery Date, JMP shall have received a certificate, signed on behalf of the Company by its corporate Secretary, in form and substance satisfactory to JMP and its counsel.

(j) No Suspension. Trading in the Common Stock shall not have been suspended on Nasdaq.

(k) Other Materials. On each date on which the Company is required to deliver a certificate pursuant to Section 7(m), the Company shall have furnished to JMP such appropriate further information, certificates and documents as JMP may have reasonably requested. All such opinions, certificates, letters and other documents shall have been in compliance with the provisions hereof. The Company will furnish JMP with such conformed copies of such opinions, certificates, letters and other documents as JMP shall have reasonably requested.

(l) Securities Act Filings Made. All filings with the Commission required by Rule 424 under the Securities Act to have been filed prior to the issuance of any Placement Notice hereunder shall have been made within the applicable time period prescribed for such filing by Rule 424.

(m) Approval for Listing. The Placement Shares shall either have been (i) approved for listing on Nasdaq, subject only to notice of issuance, or (ii) the Company shall have filed an application for listing of the Placement Shares on Nasdaq at, or prior to, the issuance of any Placement Notice.

(n) No Termination Event. There shall not have occurred any event that would permit JMP to terminate this Agreement pursuant to Section 11(a).

9. Indemnification and Contribution.

(a) Company Indemnification. The Company agrees to indemnify and hold harmless JMP, the directors, officers, partners, employees and agents of JMP and each person, if any, who (i) controls JMP within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, or (ii) is controlled by or is under common control with JMP from and against any and all losses, claims, liabilities, expenses and damages (including, but not limited to, any and all reasonable investigative, legal and other expenses incurred in connection with, and any and all amounts paid in settlement (in accordance with Section 9(c)) of, any action, suit or proceeding between any of the indemnified parties and any indemnifying parties or between any indemnified party and any third party, or otherwise, or any claim asserted), as and when incurred, to which JMP, or any such person, may become subject under the Securities Act, the Exchange Act or other federal or state statutory law or regulation, at common law or otherwise, insofar as such losses, claims, liabilities, expenses or damages arise out of or are based, directly or indirectly, on (x) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement or the Prospectus or any amendment or supplement to the Registration Statement or the Prospectus or in any free writing prospectus or in any application or other document executed by or on behalf of the Company or based on written information furnished by or on behalf of the Company filed in any jurisdiction in order to qualify the Common Stock under the securities laws thereof or filed with the Commission, (y) the omission or alleged omission to state in any such document a material fact required to be stated in it or necessary to make the statements in it not misleading or (z) any breach by the Company of any of its representations, warranties and

agreements contained in this Agreement; *provided, however*, that this indemnity agreement shall not apply to the extent that such loss, claim, liability, expense or damage arises from the sale of the Placement Shares pursuant to this Agreement and is caused directly or indirectly by an untrue statement or omission or alleged untrue statement or omission made in reliance upon and in conformity with the Agent's Information. This indemnity agreement will be in addition to any liability that the Company might otherwise have.

(b) JMP Indemnification. JMP agrees to indemnify and hold harmless the Company and its directors and each officer of the Company that signed the Registration Statement, and each person, if any, who (i) controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act or (ii) is controlled by or is under common control with the Company against any and all loss, liability, claim, damage and expense described in the indemnity contained in Section 9(a), as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions, made in the Registration Statement (or any amendments thereto) or the Prospectus (or any amendment or supplement thereto) or in any free writing prospectus in reliance upon and in conformity with the Agent's Information.

(c) Procedure. Any party that proposes to assert the right to be indemnified under this Section 9 will, promptly after receipt of notice of commencement of any action against such party in respect of which a claim is to be made against an indemnifying party or parties under this Section 9, notify each such indemnifying party of the commencement of such action, enclosing a copy of all papers served, but the omission so to notify such indemnifying party will not relieve the indemnifying party from (i) any liability that it might have to any indemnified party otherwise than under this Section 9 and (ii) any liability that it may have to any indemnified party under the foregoing provision of this Section 9 unless, and only to the extent that, such omission results in the forfeiture of substantive rights or defenses by the indemnifying party. If any such action is brought against any indemnified party and it notifies the indemnifying party of its commencement, the indemnifying party will be entitled to participate in and, to the extent that it elects by delivering written notice to the indemnified party promptly after receiving notice of the commencement of the action from the indemnified party, jointly with any other indemnifying party similarly notified, to assume the defense of the action, with counsel reasonably satisfactory to the indemnified party, and after notice from the indemnifying party to the indemnified party of its election to assume the defense, the indemnifying party will not be liable to the indemnified party for any legal or other expenses except as provided below and except for the reasonable costs of investigation subsequently incurred by the indemnified party in connection with the defense. The indemnified party will have the right to employ its own counsel in any such action, but the fees, expenses and other charges of such counsel will be at the expense of such indemnified party unless (1) the employment of counsel by the indemnified party has been authorized in writing by the indemnifying party, (2) the indemnified party has reasonably concluded (based on advice of counsel) that there may be legal defenses available to it or other indemnified parties that are different from or in addition to those available to the indemnifying party, (3) a conflict or potential conflict exists (based on advice of counsel to the indemnified party) between the indemnified party and the indemnifying party (in which case the indemnifying party will not have the right to direct the defense of such action on behalf of the indemnified party) or (4) the indemnifying party has not in fact employed counsel to assume the defense of such action within a reasonable time after receiving notice of the commencement of the action, in each of which cases the reasonable fees, disbursements and other charges of counsel will be at the expense of the indemnifying party or

parties. It is understood that the indemnifying party or parties shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable fees, disbursements and other charges of more than one separate firm admitted to practice in such jurisdiction at any one time for all such indemnified party or parties. All such fees, disbursements and other charges will be reimbursed by the indemnifying party promptly as they are incurred after the indemnifying party receives a written invoice relating to fees, disbursements and other charges in reasonable detail. An indemnifying party will not, in any event, be liable for any settlement of any action or claim effected without its written consent. No indemnifying party shall, without the prior written consent of each indemnified party, settle or compromise or consent to the entry of any judgment in any pending or threatened claim, action or proceeding relating to the matters contemplated by this Section 9 (whether or not any indemnified party is a party thereto), unless such settlement, compromise or consent includes an unconditional release of each indemnified party from all liability arising or that may arise out of such claim, action or proceeding.

(d) Contribution. In order to provide for just and equitable contribution in circumstances in which the indemnification provided for in the foregoing paragraphs of this Section 9 is applicable in accordance with its terms but for any reason is held to be unavailable from the Company or JMP, the Company and JMP will contribute to the total losses, claims, liabilities, expenses and damages (including any investigative, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claim asserted, but after deducting any contribution received by the Company from persons other than JMP, such as persons who control the Company within the meaning of the Securities Act, officers of the Company who signed the Registration Statement and directors of the Company, who also may be liable for contribution) to which the Company and JMP may be subject in such proportion as shall be appropriate to reflect the relative benefits received by the Company on the one hand and JMP on the other. The relative benefits received by the Company on the one hand and JMP on the other hand shall be deemed to be in the same proportion as the total Net Proceeds from the sale of the Placement Shares (before deducting expenses) received by the Company bear to the total compensation received by JMP (before deducting expenses) from the sale of Placement Shares on behalf of the Company. If, but only if, the allocation provided by the foregoing sentence is not permitted by applicable law, the allocation of contribution shall be made in such proportion as is appropriate to reflect not only the relative benefits referred to in the foregoing sentence but also the relative fault of the Company, on the one hand, and JMP, on the other, with respect to the statements or omission that resulted in such loss, claim, liability, expense or damage, or action in respect thereof, as well as any other relevant equitable considerations with respect to such offering. Such relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or JMP, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and JMP agree that it would not be just and equitable if contributions pursuant to this Section 9(d) were to be determined by pro rata allocation or by any other method of allocation that does not take into account the equitable considerations referred to herein. The amount paid or payable by an indemnified party as a result of the loss, claim, liability, expense, or damage, or action in respect thereof, referred to above in this Section 9(d) shall be deemed to include, for the purpose of this Section 9(d), any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim to the extent consistent with Section 9(c) hereof. Notwithstanding the foregoing provisions of this Section 9(d),

JMP shall not be required to contribute any amount in excess of the commissions received by it under this Agreement and no person found guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 9(d), any person who controls a party to this Agreement within the meaning of the Securities Act, and any officers, directors, partners, employees or agents of JMP, will have the same rights to contribution as that party, and each director and officer of the Company who signed the Registration Statement will have the same rights to contribution as the Company, subject in each case to the provisions hereof. Any party entitled to contribution, promptly after receipt of notice of commencement of any action against such party in respect of which a claim for contribution may be made under this Section 9(d), will notify any such party or parties from whom contribution may be sought, but the omission to so notify will not relieve that party or parties from whom contribution may be sought from any other obligation it or they may have under this Section 9(d) except to the extent that the failure to so notify such other party materially prejudiced the substantive rights or defenses of the party from whom contribution is sought. Except for a settlement entered into pursuant to the last sentence of Section 9(c) hereof, no party will be liable for contribution with respect to any action or claim settled without its written consent if such consent is required pursuant to Section 9(c) hereof.

10. Representations and Agreements to Survive Delivery. The indemnity and contribution agreements contained in Section 9 of this Agreement and all representations and warranties of the Company herein or in certificates delivered pursuant hereto shall survive, as of their respective dates, regardless of (i) any investigation made by or on behalf of JMP, any controlling persons, or the Company (or any of their respective officers, directors or controlling persons), (ii) delivery and acceptance of the Placement Shares and payment therefor or (iii) any termination of this Agreement.

11. Termination.

(a) JMP shall have the right by giving notice as hereinafter specified at any time to terminate this Agreement if (i) any Material Adverse Change, or any development that could reasonably be expected to result in a Material Adverse Change has occurred that, in the reasonable judgment of JMP, may materially impair the ability of JMP to sell the Placement Shares hereunder, (ii) the Company shall have failed, refused or been unable to perform any agreement on its part to be performed hereunder; *provided, however*, in the case of any failure of the Company to deliver (or cause another person to deliver) any certification, opinion, or letter required under Sections 7(m), 7(n), or 7(o), JMP's right to terminate shall not arise unless such failure to deliver (or cause to be delivered) continues for more than thirty (30) days from the date such delivery was required; (iii) any other condition of JMP's obligations hereunder is not fulfilled; or (iv), any suspension or limitation of trading in the Placement Shares or in securities generally on Nasdaq shall have occurred. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g) (Expenses), Section 9 (Indemnification and Contribution), Section 10 (Representations and Agreements to Survive Delivery), Section 16 (Applicable Law; Consent to Jurisdiction) and Section 17 (Waiver of Jury Trial) hereof shall remain in full force and effect notwithstanding such termination. If JMP elects to terminate this Agreement as provided in this Section 11(a), JMP shall provide the required notice as specified in Section 12 (Notices).

(b) The Company shall have the right, by giving two (2) days' notice as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g), Section 9, Section 10, Section 16 and Section 17 hereof shall remain in full force and effect notwithstanding such termination.

(c) JMP shall have the right, by giving two (2) days' notice as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g), Section 9, Section 10, Section 16 and Section 17 hereof shall remain in full force and effect notwithstanding such termination.

(d) Unless earlier terminated pursuant to this Section 11, this Agreement shall automatically terminate upon the issuance and sale of all of the Placement Shares through JMP on the terms and subject to the conditions set forth herein; *provided* that the provisions of Section 7(g), Section 9, Section 10, Section 16 and Section 17 hereof shall remain in full force and effect notwithstanding such termination.

(e) This Agreement shall remain in full force and effect unless terminated pursuant to Sections 11(a), (b), (c), or (d) above or otherwise by mutual agreement of the parties; *provided, however*, that any such termination by mutual agreement shall in all cases be deemed to provide that Section 7(g), Section 9, Section 10, Section 16 and Section 17 shall remain in full force and effect.

(f) Any termination of this Agreement shall be effective on the date specified in such notice of termination; *provided, however*, that such termination shall not be effective until the close of business on the date of receipt of such notice by JMP or the Company, as the case may be. If such termination shall occur prior to the Settlement Date for any sale of Placement Shares, such Placement Shares shall settle in accordance with the provisions of this Agreement.

12. Notices. All notices or other communications required or permitted to be given by any party to any other party pursuant to the terms of this Agreement shall be in writing, unless otherwise specified in this Agreement, and if sent to JMP, shall be delivered to JMP at 600 Montgomery Street, Suite 1100, San Francisco, California 94111, Facsimile: (415) 835-8920, Attention: Equity Securities, Attention: General Counsel with a copy to Duane Morris LLP, attention: James T. Seery, e-mail jtseery@duanemorris.com; or if sent to the Company, shall be delivered to Baudax Bio, Inc. attention: Gerri Henwood, e-mail: ghenwood@baudaxbio.com with a copy to Pepper Hamilton LLP, 3000 Two Logan Square, Eighteenth and Arch Streets, Philadelphia, PA 19103-2799, attention: Rachael Bushey, e-mail: bushey@pepperlaw.com. Each party to this Agreement may change such address for notices by sending to the parties to this Agreement written notice of a new address for such purpose. Each such notice or other communication shall be deemed given (i) when delivered personally or by verifiable facsimile transmission (with an original to follow) on or before 4:30 p.m., New York City time, on a Business Day (as defined below), or, if such day is not a Business Day on the next succeeding Business Day, (ii) on the next Business Day after timely delivery to a nationally-recognized overnight courier and (iii) on the Business Day actually received if deposited in the U.S. mail (certified or registered mail, return receipt requested, postage prepaid). For purposes of this Agreement, "**Business Day**" shall

mean any day on which the Nasdaq and commercial banks in the City of New York are open for business.

13. Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the Company and JMP and their respective successors and the affiliates, controlling persons, officers and directors referred to in Section 9 hereof. References to any of the parties contained in this Agreement shall be deemed to include the successors and permitted assigns of such party. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assigns any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement. Neither party may assign its rights or obligations under this Agreement without the prior written consent of the other party; *provided, however*, that JMP may assign its rights and obligations hereunder to an affiliate of JMP without obtaining the Company's consent.

14. Adjustments for Share Splits. The parties acknowledge and agree that all share-related numbers contained in this Agreement shall be adjusted to take into account any share split, share dividend or similar event effected with respect to the Common Stock.

15. Entire Agreement; Amendment; Severability. This Agreement (including all schedules and exhibits attached hereto and Placement Notices issued pursuant hereto) constitutes the entire agreement and supersedes all other prior and contemporaneous agreements and undertakings, both written and oral, among the parties hereto with regard to the subject matter hereof. Neither this Agreement nor any term hereof may be amended except pursuant to a written instrument executed by the Company and JMP. In the event that any one or more of the provisions contained herein, or the application thereof in any circumstance, is held invalid, illegal or unenforceable as written by a court of competent jurisdiction, then such provision shall be given full force and effect to the fullest possible extent that it is valid, legal and enforceable, and the remainder of the terms and provisions herein shall be construed as if such invalid, illegal or unenforceable term or provision was not contained herein, but only to the extent that giving effect to such provision and the remainder of the terms and provisions hereof shall be in accordance with the intent of the parties as reflected in this Agreement.

16. Applicable Law; Consent to Jurisdiction. This Agreement shall be governed by, and construed in accordance with, the internal laws of the State of New York without regard to the principles of conflicts of laws. Each party hereby irrevocably submits to the non-exclusive jurisdiction of the state and federal courts sitting in the City of New York, borough of Manhattan, for the adjudication of any dispute hereunder or in connection with any transaction contemplated hereby, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is brought in an inconvenient forum or that the venue of such suit, action or proceeding is improper. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof (certified or registered mail, return receipt requested) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law.

17. Waiver of Jury Trial. The Company and JMP each hereby irrevocably waives any right it may have to a trial by jury in respect of any claim based upon or arising out of this Agreement or any transaction contemplated hereby.

18. Absence of Fiduciary Relationship. The Company acknowledges and agrees that:

(a) JMP has been retained solely to act as sales agent in connection with the sale of the Common Stock and that no fiduciary, advisory or agency relationship between the Company and JMP has been created in respect of any of the transactions contemplated by this Agreement, irrespective of whether JMP has advised or is advising the Company on other matters;

(b) the Company is capable of evaluating and understanding and understands and accepts the terms, risks and conditions of the transactions contemplated by this Agreement;

(c) the Company has been advised that JMP and its affiliates are engaged in a broad range of transactions which may involve interests that differ from those of the Company and that JMP has no obligation to disclose such interests and transactions to the Company by virtue of any fiduciary, advisory or agency relationship; and

(d) the Company waives, to the fullest extent permitted by law, any claims it may have against JMP, for breach of fiduciary duty or alleged breach of fiduciary duty and agrees that JMP shall have no liability (whether direct or indirect) to the Company in respect of such a fiduciary claim or to any person asserting a fiduciary duty claim on behalf of or in right of the Company, including stockholders, partners, employees or creditors of the Company.

19. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Delivery of an executed Agreement by one party to the other may be made by facsimile or electronic transmission.

20. Definitions. As used in this Agreement, the following terms have the meaning set forth below:

(a) “*Applicable Time*” means the date of this Agreement, each Representation Date, the date on which a Placement Notice is given, and any date on which Placement Shares are sold hereunder.

(b) “*Agent’s Information*” means, solely the following information in the Prospectus: the third sentence of the eighth paragraphs under the caption “Plan of Distribution” in the Prospectus.

[Remainder of Page Intentionally Blank]

If the foregoing correctly sets forth the understanding between the Company and JMP, please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding agreement between the Company and JMP.

Very truly yours,

JMP SECURITIES LLC

By: /s/ Shawn Cross
Name: Shawn Cross
Title: Managing Director
Co-Head of Healthcare Investment Banking

**ACCEPTED as of the date
first-above written:**

BAUDAX BIO, INC.

By: /s/ Ryan D. Lake
Name: Ryan D. Lake
Title: Chief Financial Officer

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FORM OF PLACEMENT NOTICE

From: []
Cc: []
To: []
Subject: JMP at the Market Offering—Placement Notice
Date: _____, 20__

Gentlemen:

Pursuant to the terms and subject to the conditions contained in the Sales Agreement between Baudax Bio, Inc. (the “Company”), and JMP Securities LLC (“JMP”) dated February 13, 2020 (the “Agreement”), I hereby request on behalf of the Company that JMP sell up to [] shares of the Company’s common stock, par value [_____] per share, at a minimum market price of \$ _____ per share. Sales should begin on the date of this Notice and shall continue until [DATE] [all shares are sold].

Notice Parties

The Company

Gerri Henwood ghenwood@baudaxbio.com

Ryan Lake ghenwood@baudaxbio.com

JMP

Raymond Han, Director rhan@jmpsecurities.com

Gil Mogavero, Chief Compliance Officer gmogavero@jmpsecurities.com

Andrew Mertz, Managing Director amertz@jmpsecurities.com

Compensation

JMP shall be paid compensation equal to 3% of the gross proceeds from the sales of Common Stock pursuant to the terms of this Agreement.

OFFICER CERTIFICATE

The undersigned, the duly qualified and elected _____, of Baudax Bio, Inc. ("**Company**"), a Pennsylvania corporation, does hereby certify in such capacity and on behalf of the Company, pursuant to Section 7(m) of the Sales Agreement dated February 13, 2020 (the "**Sales Agreement**") between the Company and JMP Securities LLC, that to the knowledge of the undersigned.

- (i) The representations and warranties of the Company in Section 6 of the Sales Agreement (A) to the extent such representations and warranties are subject to qualifications and exceptions contained therein relating to materiality or Material Adverse Change, are true and correct on and as of the date hereof with the same force and effect as if expressly made on and as of the date hereof, except for those representations and warranties that speak solely as of a specific date and which were true and correct as of such date, and (B) to the extent such representations and warranties are not subject to any qualifications or exceptions, are true and correct in all material respects as of the date hereof as if made on and as of the date hereof with the same force and effect as if expressly made on and as of the date hereof except for those representations and warranties that speak solely as of a specific date and which were true and correct as of such date; and

- (ii) The Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied pursuant to the Sales Agreement at or prior to the date hereof.

By:
Name:
Title:

Date:

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Baudax Bio, Inc.:

We consent to the incorporation by reference in the registration statement (No. 333-235408) 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 13, 2020, with respect to the consolidated and combined balance sheets of Baudax Bio, Inc. as of December 31, 2019 and 2018, the related consolidated and combined statements of operations, shareholders' equity, and cash flows for each of the years in the period then ended, and the related notes, which report appears in the December 31, 2019 annual report on Form 10-K of Baudax Bio, Inc.

Our report refers to a change in accounting principle for leases due to the adoption of a new accounting standard.

/s/ KPMG LLP

Philadelphia, Pennsylvania
February 13, 2020

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 most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 13, 2020

/s/ Gerri A. Henwood

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

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 most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 13, 2020

/s/ Ryan D. Lake

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

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

In connection with the Annual Report of Baudax Bio, Inc. (the "Company") on Form 10-K for the year ended December 31, 2019, 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 13, 2020

/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)