INFORMATION STATEMENT

Baudax Bio, Inc.

This information statement is being furnished to you as a holder of common stock of Recro Pharma, Inc., or Recro, in connection with the distribution of shares of common stock of Baudax Bio, Inc. or Baudax Bio. Baudax Bio is a wholly owned subsidiary of Recro that will hold, directly or indirectly, assets and liabilities related to Recro's acute care business. The transfer of the acute care assets and liabilities to Baudax Bio is referred to herein as the Restructuring. To implement the distribution, Recro will distribute all of the outstanding shares of Baudax Bio common stock on a pro rata basis to holders of Recro common stock, which is referred to herein as the Distribution. We refer to the Distribution and the Restructuring together as the Separation.

You will receive one share of Baudax Bio common stock for every two and one-half shares of Recro common stock held of record by you as of the close of business on November 15, 2019, the record date for the Distribution. Registered holders of Recro common stock will receive cash in lieu of any fractional shares of Baudax Bio common stock that those holders would have received after application of the above ratio. As discussed under "The Separation and Distribution—Trading Between the Record Date and Distribution Date," if you sell your shares of Recro common stock in the "regular way" market after the record date and before the Distribution, you also will be selling your right to receive shares of Baudax Bio common stock in connection with the Distribution. Baudax Bio expects the shares of Baudax Bio common stock to be distributed by Recro to you on November 21, 2019. The date of distribution of Baudax Bio common stock is referred to in this information statement as the "distribution date."

No vote or other action is required by you to receive shares of Baudax Bio common stock in the Distribution. We are not asking you for a proxy, and you should not send us a proxy or your share certificates. You do not need to pay any consideration, exchange or surrender your existing shares of Recro common stock or take any other action to receive your shares of Baudax Bio common stock.

There currently is no trading market for Baudax Bio common stock. Baudax Bio expects that a limited market, commonly known as a "when issued" trading market, will develop on or shortly before the record date for the Distribution, and that "regular way" trading of Baudax Bio common stock will begin on the first trading day following the completion of the Distribution. We intend to have Baudax Bio common stock listed on the Nasdaq Capital Market under the symbol "BXRX."

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we will be subject to reduced public company reporting requirements.

In reviewing this information statement, you should carefully consider the matters described under the caption "Risk Factors" beginning on page 18.

Neither the U.S. Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined if this information statement is truthful or complete. Any representation to the contrary is a criminal offense.

This information statement does not constitute an offer to sell or the solicitation of an offer to buy any securities.

The date of this information statement is November 8, 2019.

A Notice of Internet Availability of Information Statement Materials containing instructions for how to access this information statement is first being mailed to Recro shareholders on or about November 12, 2019.

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PRESENTATION OF INFORMATION

Except as otherwise indicated or unless the context otherwise requires, the information included in this information statement about Baudax Bio assumes the completion of all of the transactions referred to in this information statement in connection with the Separation and Distribution.

Unless the context otherwise requires, references in this information statement to the following terms shall have the following respective meanings:

- "Recro" refers to Recro Pharma, Inc., a Pennsylvania corporation, and its consolidated subsidiaries;
- "Recro Board" refers to the board of directors of Recro;
- "CDMO business" refers to Recro's contract development and manufacturing business;
- "acute care business" refers to Recro's acute care business; and
- "Baudax Bio," "we," "us," "our," "our company" and "the company" refer to Baudax Bio, Inc., a Pennsylvania corporation, together with its subsidiaries, Baudax Bio Limited and Baudax Bio N.A. LLC, as the context requires, in each case as they will exist, assuming the completion of all the transactions referred to in this information statement in connection with the Separation and the Distribution.

This information statement describes the business to be transferred to Baudax Bio by Recro in the Separation as if the transferred business was Baudax Bio's business for all historical periods described. References in this information statement to Baudax Bio's historical assets, liabilities, products, businesses or activities of Baudax Bio's business are generally intended to refer to the historical assets, liabilities, products, businesses or activities of the transferred businesses as the business was conducted as part of Recro prior to the Separation.

You should not assume that the information contained in this information statement is accurate as of any date other than the date set forth on the cover. Changes to the information contained in this information statement may occur after that date, and we undertake no obligation to update the information, except in the normal course of our public disclosure obligations or as required by applicable law.

Websites described in this information statement and the content therein or connected thereto shall not be deemed incorporated into this information statement.

Trademarks, Trade Names and Service Marks

Solely for convenience, tradenames referred to in this information statement 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 in this information statement are the property of their respective owners, including, without limitation, the NanoCrystal® mark owned by Alkermes plc and/or its affiliates.

Industry and Other Data

We obtained the industry and market data in this information statement from our own internal estimates and from industry and general publications and research, surveys, studies and trials conducted by third parties. We are responsible for all of the disclosure contained in this information statement, and we believe that this third-party data is generally reliable; however, we have not independently verified industry and market data from third-party sources. In addition, while we believe our estimates are reliable, they have not been verified by any independent source.

Estimates in this information statement of the patient populations for the diseases that we are targeting are based on published estimates of the rates of incidence of the diseases from scientific and general publications and research, surveys and studies conducted by third parties that we consider to be reliable, although such publications do not guarantee the accuracy or completeness of this information.

QUESTIONS AND ANSWERS ABOUT THE SEPARATION AND DISTRIBUTION

What is Baudax Bio and why is Recro separating Baudax Bio's business and distributing Baudax Bio's common stock?

Baudax Bio, which is currently a wholly-owned subsidiary of Recro, was formed to hold Baudax Bio Limited, an Irish limited company. The contribution of Recro's acute care business to Baudax Bio is occurring over a period of time prior to the Distribution. The Separation and the Distribution are intended to provide you with equity investments in two separate, independent public companies, each of which is able to focus on its respective business strategies. With regard to Baudax Bio, this will be Recro's existing acute care business, which is primarily focused on developing and commercializing innovative products for hospital and related acute care settings. With regard to Recro, this will be Recro's existing CDMO business, which develops and manufactures pharmaceutical products using proprietary delivery technologies and know-how for partners who plan to develop and commercialize such products. Recro and Baudax Bio believe the Separation will enable each business to pursue focused growth and investment strategies in its respective area of business resulting in the enhanced long-term performance of each business, as discussed in "The Separation and Distribution—Overview" and "The Separation and Distribution—Reasons for the Separation."

Why am I receiving this document?

Recro is delivering this information statement to you because you are a holder of record of shares of Recro common stock. If you remain a holder of shares of Recro common stock as of the close of business on November 15, 2019, you will be entitled to receive one share of Baudax Bio common stock for every two and one-half shares of Recro common stock that you held of record at the close of business on such date. This information statement will help you understand how the Separation will affect your investment in Recro and your investment in Baudax Bio after the Distribution.

How will the separation of Baudax Bio from Recro work?

To accomplish the Separation, Recro will distribute all of the outstanding shares of Baudax Bio common stock to Recro shareholders on a pro rata basis.

Why is the separation of Baudax Bio structured as a Distribution?

Recro believes that a distribution of shares of Baudax Bio common stock to the Recro shareholders is an efficient way to separate its acute care business in a manner that will create long-term value for Recro, Baudax Bio and their respective shareholders. For more information, see "The Separation and Distribution—Conditions to the Distribution."

What is the record date for the Distribution?

The record date for the Distribution will be November 15, 2019.

When will the Distribution occur?

It is expected that all of the shares of Baudax Bio common stock will be distributed by Recro on November 21, 2019, to holders of record of Recro common stock at the close of business on November 15, 2019. We refer to the date on which shares of Baudax Bio common stock are distributed as the "distribution date."

What do shareholders need to do to participate in the Distribution?

Nothing. Shareholders of Recro as of the record date will not be required to take any action to receive Baudax Bio common stock, but are urged to read this entire information statement carefully. No shareholder approval of the Distribution is required or sought. Therefore, you are not being asked for a proxy to vote on the Separation, and you should not send us a proxy. You will neither be required to pay anything for the shares of Baudax Bio common stock nor be required to surrender any shares of Recro common stock to participate in the Distribution. Please do not send in your Recro stock certificates.

The Distribution will not affect the number of outstanding shares of Recro common stock or any rights of Recro shareholders, although it will affect the market value of each outstanding share of Recro common stock. See "Questions and Answers about the Separation and Distribution—Will the Distribution affect the market price of my Recro common stock?" for more information.

How will Recro distribute shares of Baudax Bio common stock?

Registered shareholders: If you are a registered shareholder (meaning you hold physical Recro stock certificates or you own your shares of Recro common stock directly through an account with Recro's transfer agent, Broadridge Corporate Issuer Solutions, Inc., or Broadridge) the distribution agent will credit the number of whole shares of Baudax Bio common stock you receive in the Distribution to your book-entry account on or shortly after the distribution date, and the distribution agent will mail you a check for any cash in lieu of fractional shares you are entitled to receive.

"Street name" or beneficial shareholders: If you own your shares of Recro common stock beneficially through a bank, broker or other nominee, your bank, broker or other nominee will credit your account with the number of whole shares of Baudax Bio common stock you receive in the Distribution on or shortly after the distribution date, and the distribution agent will mail you a check for any cash in lieu of fractional shares you are entitled to receive. Please contact your

bank, broker or other nominee for further information about your account.

We will not issue any physical stock certificates to any shareholders receiving shares in the Distribution, even if requested. See "The Separation and Distribution—When and How You Will Receive the Distribution" for more information.

How many shares of Baudax Bio common stock will I receive in the Distribution?

Recro will distribute to you one share of Baudax Bio common stock for every two and one-half shares of Recro common stock you hold of record as of the close of business on November 15, 2019, the record date. Based on approximately 22,696,748 shares of Recro common stock outstanding as of October 31, 2019, a total of approximately 9,078,700 shares of Baudax Bio common stock will be distributed. For more information, see "The Separation and Distribution—The Number of Shares of Baudax Bio Common Stock You Will Receive."

Will Baudax Bio issue fractional shares in the Distribution?

Baudax Bio will not distribute fractional shares of its common stock in the Distribution. Instead, all fractional shares that Recro registered shareholders would otherwise have been entitled to receive will be aggregated into whole shares and sold in the open market by the distribution agent. We expect the distribution agent, acting on behalf of Recro, to take approximately two weeks after the distribution date to fully distribute the aggregate net cash proceeds of these sales on a pro rata basis (based on the fractional share such holder would otherwise be entitled to receive) to those shareholders who would otherwise have been entitled to receive fractional shares. Recipients of cash in lieu of fractional shares will not be entitled to any interest on the amounts of payment made in lieu of fractional shares. For more information, see "The Separation and Distribution—The Number of Shares of Baudax Bio Common Stock You Will Receive."

What are the conditions to the Distribution?

The Distribution is subject to the satisfaction (or waiver by Recro in its sole and absolute discretion) of a number of conditions to be set forth in the Separation Agreement, including, among others:

- the U.S. Securities and Exchange Commission, or SEC, declaring effective Baudax Bio's registration statement on Form 10 of which this information statement forms a part, and no stop order relating to the registration statement being in effect and no proceedings for such purpose being pending before or threatened by the SEC, and the distribution of the information statement (or the Notice of Internet

Availability of the Information Statement) to all holders of record of shares of Recro common stock as of the close of business on the record date;

- the receipt and continuing validity of an opinion from an independent appraisal firm to the Recro Board, that is in form and substance acceptable to Recro in its sole and absolute discretion, confirming the solvency of Baudax Bio after the Distribution;

- the shares of Baudax Bio common stock to be delivered in the Distribution shall have been approved for listing on the Nasdaq Capital Market, subject to official notice of issuance.

- all permits, registrations and consents required under the securities or blue sky laws of states or other political subdivisions of the United States or of other foreign jurisdictions in connection with the Distribution shall have been received;

- no order, injunction, or decree issued by any court of competent jurisdiction or other legal restraint or prohibition preventing the consummation of the Distribution or any of the related transactions shall be pending, threatened, issued or in effect;

- the Recro Board shall have declared the Distribution and approved all related transactions (and such declaration and approval not having been withdrawn);

- Baudax Bio shall have executed and delivered the transaction agreements relating to the Separation; and

- no other event or development existing or having occurred that, in the sole and absolute judgment of the Recro Board, makes it inadvisable to effect the Distribution and other related transactions.

Recro and Baudax Bio cannot assure you that any or all of these conditions will be met, and Recro may waive any of these conditions to the Distribution. In addition, Recro can determine, at any time, not to proceed with the Distribution. For more information, see "The Separation and Distribution—Conditions to the Distribution."

What is the expected date of completion of the Distribution?

The completion and timing of the Distribution are dependent upon a number of conditions. It is expected that the shares of Baudax Bio common stock will be distributed by Recro on November 21, 2019 to the holders of record of shares of Recro common stock at the close of business on the record date. However, no assurance can be provided as to the timing of the Distribution or that all conditions to the Distribution will be met.

Can Recro decide to cancel the Distribution even if all the conditions have been met?

Yes, until the Distribution has occurred, Recro has the right to terminate the Distribution, even if all of the conditions are satisfied. See "The Separation and Distribution—Conditions to the Distribution" for more information.

What if I want to sell my Recro common stock or my Baudax Bio common stock?

You should consult with your advisors, such as your broker, bank or tax advisor.

What is "regular way" and "ex-distribution" trading of Recro stock?

Beginning on or shortly before the record date and continuing up to and including the distribution date, it is expected that there will be two markets in shares of Recro common stock: a "regular-way" market and an "ex-distribution" market. Shares of Recro common stock that trade in the "regular-way" market will trade with an entitlement to shares of Baudax Bio common stock distributed pursuant to the Distribution. Shares that trade in the "ex-distribution" market will trade without an entitlement to shares of Baudax Bio common stock distributed pursuant to the Distribution.

If you hold shares of Recro common stock on the record date and you decide to sell any shares of Recro common stock before the distribution date, you should make sure your broker, bank or other nominee understands whether you want to sell your shares of Recro common stock with or without your entitlement to receive Baudax Bio common stock pursuant to the Distribution. See "The Separation and Distribution—Trading Between the Record Date and Distribution Date" for more information.

Where will I be able to trade shares of Baudax Bio common stock?

Currently, there is no public market for Baudax Bio common stock. Baudax Bio has applied to have its common stock authorized for listing on the Nasdaq Capital Market under the symbol "BXRX."

Baudax Bio anticipates that trading in shares of its common stock will begin on a "when issued" basis on or shortly before the record date for the Distribution and will continue up to and including the distribution date. "When issued" trading in the context of a separation refers to a sale or purchase made

conditionally on or before the distribution date because the securities of the separated entity have not yet been distributed. If you own shares of Recro common stock as of the close of business on the record date, you would be entitled to receive shares of Baudax Bio common stock in the Distribution. You may trade this entitlement to receive shares of Baudax Bio common stock, without trading the shares of Recro common stock you own, in the "when-issued" market. "When issued" trades generally settle within two weeks after the distribution date. On the first trading day following the distribution date, any "when issued" trading of Baudax Bio common stock will end and "regular way" trading will begin. "Regular way" trading refers to trading after the security has been distributed and typically involves a trade that settles on the second full trading day following the date of the trade. See "The Separation and Distribution—Trading Between the Record Date and Distribution Date" for more information. We cannot predict the trading prices for Baudax Bio common stock before, on or after the distribution date.

What will happen to the listing of shares of Recro common stock?

Shares of Recro common stock will continue to trade on the Nasdaq Capital Market after the Distribution.

Will the number of shares of Recro common stock that I own change as a result of the Distribution?

No. The number of shares of Recro common stock that you own will not change as a result of the Distribution.

Will the Distribution affect the market price of my Recro common stock?

Yes. As a result of the Distribution, the trading price of shares of Recro common stock immediately following the Distribution may be lower than the "regular way" trading price of such shares immediately prior to the Distribution because the trading price will no longer reflect the value of the acute care business. Furthermore, as the market assesses Recro following the Separation, the trading price of shares of Recro common stock may fluctuate. There can be no assurance that, following the Distribution, the combined trading prices of Recro common stock and Baudax Bio common stock will equal or exceed what the trading price of Recro common stock would have been in the absence of the Separation, and it is possible the post-Distribution combined equity value of Recro and Baudax Bio will be less than Recro's equity value prior to the Distribution.

What are the material U.S. federal income tax consequences of the Distribution?

Each Recro shareholder's receipt of shares of Baudax Bio common stock in the Distribution (including any fractional shares sold on each recipient's behalf) will generally be a taxable dividend to the extent of such

	holder's allocable share of Recro's current and accumulated earnings and profits, with the excess treated first as a non-taxable return of capital to the extent such holder's tax basis in its shares of Recro's common stock and then as capital gain. For a more detailed discussion see "Material U.S. Income Tax Consequences," included elsewhere in this information statement. You should consult your own tax advisor as to the particular tax consequences of the Distribution to you, including the applicability of any U.S. federal, state, local and foreign tax laws
What will Baudax Bio's relationship be with Recro following the Distribution?	To effect an efficient separation into two companies, Baudax Bio intends to enter into a Separation Agreement and certain other agreements with Recro, including a tax matters agreement, an employee matters agreement, and a transition services agreement under which Baudax Bio will temporarily provide certain services to Recro. These agreements will provide for the separation between Recro and Baudax Bio of the assets, liabilities and obligations (including employee benefits, intellectual property and tax-related assets and liabilities) attributable to periods prior to, at and after the Distribution and will govern the relationship between Recro and Baudax Bio after the Separation. For additional information regarding the Separation Agreement and other transaction agreements, see "Risk Factors—Risks Related to the Separation" and "Certain Relationships and Related Person Transactions—Agreements with Recro."
Following the Separation, will Baudax Bio have cash on hand to fund its operating expenses and capital expenditures?	Prior to or upon the completion of the Distribution, Recro plans to make a cash capital contribution of $19 million to Baudax Bio to fund Baudax Bio's operations. This cash capital contribution is in an amount that Baudax Bio estimates will, based on its current plans and expectations, meet its cash needs for at least 12 months after the completion of the Separation. Prior to or after such time, Baudax Bio expects that it will be able to access the equity or debt capital markets for additional funding.
Who will manage Baudax Bio after the Distribution?	Baudax Bio will benefit from having in place a management team with a substantial background in the specialty pharmaceutical business. Baudax Bio's management team possesses deep knowledge of and experience in its industry. Baudax Bio's management team is expected to include Gerri Henwood, Recro's President and Chief Executive Officer who is expected to be Baudax Bio's President and Chief Executive

	Officer after the Distribution and Ryan Lake, Recro's Chief Financial Officer who is expected to be Baudax Bio's Chief Financial Officer after the Distribution. For more information regarding Recro's management team and leadership structure, see "Management."
Are there risks associated with owning Baudax Bio common stock?	Yes. Ownership of Baudax Bio common stock is subject to both general and specific risks related to Baudax Bio's business, the industry in which it operates, its ongoing relationships with Recro and its status as a separate, publicly traded company. Ownership of Baudax Bio common stock is also subject to risks related to the Separation. These risks are described in the "Risk Factors" section of this information statement beginning on page 18. You are encouraged to read that section carefully.
Does Baudax Bio plan to pay dividends?	Baudax Bio does not expect to pay a regular cash dividend following the Distribution. The payment of any dividends in the future, and the timing and amount thereof, is within the discretion of Baudax Bio's board of directors. See "Dividend Policy."
Who will be the distribution agent, transfer agent and registrar for the Baudax Bio common stock?	The distribution agent, transfer agent and registrar for Baudax Bio common stock will be Broadridge. For registered holders with questions relating to the transfer or mechanics of the stock distribution, you should contact: Tel: (877) 830-4935 E-mail: shareholder@broadridge.com
How can I contact Recro or Baudax Bio with any questions?	Before the Distribution, if you have any questions relating to Recro or Baudax Bio's business performance, you should contact: Investor Relations Contact: Argot Partners Sam Martin/Claudia Styslinger Tel: (212) 600-1902 E-mail: sam@argotpartners.com; claudia@argotpartners.com Recro Pharma, Inc. Ryan D. Lake Tel: (484) 395-2436 E-mail: rlake@recropharma.com After the Distribution, Baudax Bio shareholders who have any questions relating to Baudax Bio's business performance should contact Baudax Bio at: Baudax Bio, Inc. Address: 490 Lapp Road Tel: (484) 395-2470 E-mail: info@baudaxbio.com

INFORMATION STATEMENT SUMMARY

The following is a summary of material information discussed in this information statement. This summary may not contain all the details concerning the Separation or other information that may be important to you. To better understand the Separation and Baudax Bio's business and financial position, you should carefully review this entire information statement, including the risks discussed under "Risk Factors."

Except as otherwise indicated or unless the context otherwise requires, the information included in this information statement assumes the completion of all of the transactions referred to in this information statement in connection with the Separation. Some of the statements in this summary constitute forward-looking statements. See "Cautionary Statement Concerning Forward-Looking Statements."

Baudax Bio

Overview

We are a specialty 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 Product Candidates

Our lead product candidate is a proprietary injectable form of meloxicam, a long-acting preferential COX-2 inhibitor, or IV meloxicam. 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 new drug application, or NDA, program included over 1,400 patients. In July 2017, we submitted an NDA to the Food and Drug Administration, or FDA, for IV meloxicam for the management of moderate to severe pain. In May 2018, we received a Complete Response Letter, or 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. We are engaged in resolution of the IV meloxicam CRL, and 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. We are consulting with regulatory counsel and expert advisors on both process and potential language for the IV meloxicam product label. We are working to prepare a comprehensive response to the FDA that includes refiling the NDA with proposed labeling that addresses the FDA's concerns and to provide the relevant evidence from the filed NDA that supports the proposed label. We anticipate that this process will continue until late 2019 or early 2020 and will require an estimated $1.3 million to $1.8 million in capital.

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. We are pursuing a Section 505(b)(2) regulatory strategy for IV meloxicam.

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

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 for the management of moderate to severe pain.
- *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 previously established 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 IV meloxicam in a Phase IIIb program that includes clinical trials in colorectal surgery patients and orthopedic surgery patients. We anticipate completing the Phase IIIb program during 2019.
- *Entering into strategic partnerships to maximize the potential of IV meloxicam and other product candidates outside of the United States*. We intend to pursue strategic collaborations with other pharmaceutical companies to develop and commercialize IV meloxicam outside of the United States. We believe that our development expertise and unique product candidates make us an attractive partner to potential strategic collaborators.
- *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.

Summary of Risk Factors

An investment in Baudax Bio common stock is subject to a number of risks, including risks related to our business, risks related to the Separation and risks related to our common stock. The following list of risk factors is not exhaustive. Please read the information in the section captioned “Risk Factors” for a more thorough description of these and other risks.

- 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.
- 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 from product sales and may never be profitable.
- We depend substantially on obtaining FDA approval of our lead product candidate, IV meloxicam. If regulatory approval of IV meloxicam is not granted, our business, financial condition and results of operations may be materially adversely affected.

- Even if IV meloxicam is approved by the FDA, our success is dependent on our ability to commercialize IV meloxicam. We have never commercialized a product, and our ability to successfully commercialize IV meloxicam will depend on, among other things, the labeling of any such FDA approval, our ability to manufacture sufficient quantities of IV meloxicam to meet demand and the acceptance of IV meloxicam in the medical community.

- We depend substantially on the successful completion of clinical trials for our product candidates. The positive results obtained for our product candidates in earlier pre-clinical and clinical studies may not be repeated and, thus, we may never receive regulatory approval of our product candidates.

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

- We have assumed Recro's potential liabilities in connection with ongoing litigation, which could result in substantial costs and a diversion of management's resources and attention. Any adverse determination in such litigation could expose us to significant liabilities.

- We are subject to intense competition and, if we are unable to compete effectively, our product candidates may not reach their commercial potential.

The Separation and Distribution

In August 2019, Recro announced its plans to separate its acute care business from its CDMO business. The Distribution generally will be taxable to Recro shareholders for U.S. federal income tax purposes.

In furtherance of this plan, on November 4, 2019, the Recro Board approved the distribution of all of the issued and outstanding shares of Baudax Bio common stock on the basis of one share of Baudax Bio common stock for every two and one-half shares of Recro common stock issued and outstanding on November 15, 2019, the record date for the Distribution. As a result of the Distribution, Baudax Bio will become an independent company.

Immediately following the Distribution, we estimate that 9,078,700 shares of Baudax Bio common stock will be issued and outstanding based on the number of shares of Recro common stock outstanding as of October 31, 2019. The actual number of shares of Baudax Bio common stock issued in the Distribution will be determined on November 15, 2019, the record date.

Baudax Bio's Post-Distribution Relationship with Recro

Baudax Bio intends to enter into a Separation Agreement with Recro, which is referred to in this information statement as the "Separation Agreement," and various other agreements with Recro, including a tax matters agreement, an employee matters agreement, and a transition services agreement under which Recro and Baudax will temporarily provide certain services to each other. These agreements will effectuate the Separation and govern Baudax Bio's relationship with Recro after the Distribution. These agreements will provide for the separation between Recro and Baudax Bio of the assets, liabilities and obligations (including employee benefits, intellectual property and tax-related assets and liabilities) attributable to periods prior to, at and after the Distribution and will govern the relationship between Recro and Baudax Bio after the Separation. For additional information regarding the Separation Agreement and the other related agreements, see "Risk Factors—Risks Related to the Separation" and "Certain Relationships and Related Person Transactions—Agreements with Recro."

Reasons for the Separation

The Recro Board believes that separating the acute care business from the remainder of Recro is in the best interests of Recro and its shareholders for a number of reasons, including that:

- the Separation will allow each business to pursue its own operational and strategic priorities and more quickly respond to trends, developments and opportunities in its respective markets;
- the Separation will give each business the opportunity and flexibility to pursue its own investment, capital allocation and growth strategies consistent with its long-term objectives;
- the Separation will create two separate and distinct management teams focused on each business's unique strategic priorities, target markets and corporate development opportunities;
- the Separation will enable the boards and management teams of each business to better align corporate performance goals with the specific vision, strategy and objectives of each business; and
- the Separation will allow investors to separately value each business based on the unique merits, performance and future prospects of each business, providing investors with two distinct investment opportunities.

The Recro Board considered a number of other factors in evaluating the Separation, including risks relating to the creation of a standalone company and possible increased overall costs as well as one-time separation costs, and concluded that the potential benefits of the Separation outweighed these factors. For more information, see "The Separation and Distribution—Reasons for the Separation" and "Risk Factors" included elsewhere in this information statement.

Corporate Information

Baudax Bio was incorporated as a Delaware corporation in 2015 and converted to a Pennsylvania corporation on September 13, 2019. The contribution of Recro's acute care business to Baudax Bio is expected to occur over a period of time prior to the Distribution. At the time of the Distribution, the address of Baudax Bio's principal executive offices will be 490 Lapp Road, Malvern, PA 19355. Baudax Bio's telephone number will be (484) 395-2470. Baudax Bio will also maintain a website at www.baudaxbio.com.

Reason for Furnishing this Information Statement

This information statement is being furnished solely to provide information to shareholders of Recro who will receive shares of Baudax Bio common stock in the Distribution. It is not, and is not to be construed as, an inducement or encouragement to buy or sell any of Baudax Bio's securities.

Implications of Being an Emerging Growth Company

We qualify as an "emerging growth company" as defined in the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other obligations that are otherwise applicable generally to public companies. These may include the following:

- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements;

- exemption from the requirements for holding a non-binding advisory vote on executive compensation or golden parachute arrangements; and

- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. 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 date of our sale of common equity securities pursuant to an effective registration statement under the Securities Act of 1933, as amended, or the Securities Act; (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.

In addition, Section 102(b)(1) of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we are subject to the same new or revised accounting standards as other public companies that are not “emerging growth companies.”

SUMMARY HISTORICAL AND UNAUDITED PRO FORMA COMBINED FINANCIAL INFORMATION

The following table presents Baudax Bio's summary historical and unaudited pro forma combined financial information. Baudax Bio derived the summary historical combined financial data as of and for the years ended December 31, 2018 and 2017 from Baudax Bio's audited combined financial statements included elsewhere in this information statement. Baudax Bio derived the summary historical combined financial data as of and for the six months ended June 30, 2019 and 2018 from Baudax Bio's unaudited combined financial statements included elsewhere in this information statement. In Baudax Bio's management's opinion, the unaudited combined financial statements as of June 30, 2019 and for the six months ended June 30, 2019 and 2018 have been prepared on the same basis as the audited combined financial statements and include all adjustments, consisting only of normal recurring adjustments and allocations, necessary for a fair presentation of the information for the periods presented.

The summary historical combined financial data includes certain expenses of Recro that were allocated to us for certain corporate functions including information technology, research and development, finance, legal, insurance, compliance and human resources activities. These costs may not be representative of the future costs we will incur as an independent company. In addition, Baudax Bio's historical financial information does not reflect changes that we expect to experience in the future as a result of the Separation, including changes in our cost structure, personnel needs, tax structure, capital structure, financing and business operations. The following summary unaudited pro forma combined financial information gives effect to the Separation, as if it had occurred on January 1, 2018. The unaudited pro forma adjustments are based on assumptions that Baudax Bio's management believes are reasonable under the circumstances and given the information available at this time. Refer to the notes to the unaudited pro forma combined financial statements included elsewhere in this information statement for a discussion of adjustments reflected in the unaudited pro forma combined financial statements. Consequently, the financial information included here may not necessarily reflect Baudax Bio's financial position, results of operations and cash flows in the future or what Baudax Bio's financial position, results of operations and cash flows would have been had Baudax Bio been an independent company during the periods presented.

For a better understanding, this section should be read in conjunction with the discussion in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the "Unaudited Pro Forma Combined Financial Statements" and corresponding notes and the audited combined financial statements and corresponding notes included elsewhere in this information statement.

	Year Ended December 31,			Six Months Ended June 30,		
(in thousands)	2017	2018	Pro Forma 2018 (unaudited)	2018	2019	Pro Forma 2019 (unaudited)
Statement of Operations:						
Research and development	$ 28,635	$ 35,583	$ 35,583	$ 15,826	$ 16,734	$ 16,734
General and administrative	$ 19,626	$ 29,453	$ 29,453	$ 19,062	$ 17,284	$ 17,284
Change in contingent payment valuation	$ 12,839	$ 8,499	$ 8,499	$ 2,916	$ (19,150)	$ (19,150)
Net loss	$ (61,084)	$ (73,667)	$ (73,667)	$ (37,894)	$ (14,917)	$ (14,917)

(in thousands)	As of December 31, 2017	2018	As of June 30, 2019	Pro Forma 2019 (unaudited)
Balance Sheet:				
Total current assets	$ 2,468	$ 2,514	$ 3,586	$ 22,586
Total assets	$ 32,761	$ 35,023	$ 38,147	$ 57,147
Total current liabilities	$ 44,750	$ 22,780	$ 4,985	$ 4,985
Total liabilities	$ 95,218	$ 103,370	$ 67,334	$ 67,334
Parent company net investments	$ (62,457)	$ (68,347)	$ (29,187)	$ (10,187)

RISK FACTORS

You should consider carefully the following risks and conditions, together with all the other information in this information statement, including our financial statements and notes thereto, when evaluating our common stock. The impact from these risks and conditions may be materially adverse to our business, prospects, financial condition and results of operations. The risks described below are not the only risks we face. Additional risks and uncertainties not currently known to us or those we currently view to be immaterial also may materially harm our business, prospects, financial condition and results of operations. As a result, the trading price of our common stock could decline, which could decrease the value of the shares you hold. 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 from product sales 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, 2017 and 2018 were $61.1 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, and seek regulatory approval for, our lead product candidate, IV meloxicam. Our ability to generate future revenues from product sales depends heavily on our success in:

- identifying and completing the acquisition or in-licensing of a new commercial or near-commercial product;
- developing a sufficient commercial organization capable of sales, marketing and distribution for an acquired or in-licensed new product;
- manufacturing commercial quantities of an acquired or in-licensed new product at acceptable cost levels;
- obtaining the labeling we requested for IV meloxicam, if approved;
- launching and commercializing IV meloxicam;
- 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;
- obtaining and maintaining patent protection for our product candidates; and
- completing the clinical development of our other product candidates.

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 our 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 or acquire or in-license a commercial stage or near-commercial stage product, 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. 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.

Following the completion of the Separation, we expect that our cash and cash equivalents will be approximately $19 million, after the payment of certain Separation-related expenses. Our management believes that such cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements for at least 12 months after the completion of the Separation.

We will require significant additional funding to advance our lead product candidate, IV meloxicam, as well as to continue advancing our research and development efforts with our other product candidates. We may also require additional funding to finance the acquisition or in-license of new product candidates. Raising funds in the then 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.

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 of rejection or approval of IV meloxicam and raising capital to sustain our business, which could raise doubt about our ability to continue as a going concern as a standalone entity. If an explanatory paragraph is included in the report of our independent registered public accounting firm on our financial statements as a standalone entity 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 as a standalone entity. 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.

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. Regardless of the terms of our debt or equity

financing, our agreements and obligations under the tax matters agreement with Recro may limit our ability to issue stock. See "Risks Related to the Separation."

We may also seek funds through collaborations, strategic alliances, or licensing arrangements with third parties, and such agreements may involve relinquishing rights to our product candidates or technologies, future revenue streams, research programs or products candidates or to grant licenses on terms that may not be favorable to us. Such arrangements will limit our participation in the success of any of our product candidates that receive regulatory approval.

Risks Related to Approval and Potential Labeling 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 has been delayed, and we will need to refile our NDA and propose labeling that addresses the FDA's concerns in order to successfully commercialize IV meloxicam.

In July 2017 we submitted an NDA for IV meloxicam for the management of moderate to severe pain 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. 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 Chemistry Manufacturing and Controls, or 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. Upon receipt and review of the meeting minutes, 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.

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. We are engaged in resolution of the IV meloxicam CRL, and 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. We are consulting with regulatory counsel and expert advisors on both process and potential language for the IV meloxicam product label. We are working to prepare a comprehensive response to the FDA that includes refiling the NDA with proposed labeling that addresses the FDA's concerns and to provide the relevant evidence from the filed NDA that supports the proposed label, but there can be no guarantee that we will be able to do so in a timely manner, or at all.

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.

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 not granted, our business, financial condition and results of operations may be materially adversely affected.

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.

Any further delay or setback in the development or regulatory approval of IV meloxicam could adversely affect our business. 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 and 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, which would have an adverse impact on our business.

The labeling approved by the FDA for IV meloxicam may limit the approved indication for use, establish undesirable product labeling requirements or limit the marketing claims we may make, which could may adversely affect IV meloxicam's ability to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community necessary for its commercial success.

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.

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.

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

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.

Adverse effects, or AEs, caused by our product candidates 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 and our other product candidates 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. Further AEs or SAEs could be generated during our on-going Phase IIIb clinical trials for IV meloxicam. Our ability to obtain regulatory approval for our product candidates may be adversely impacted by these AEs, SAEs, or other safety concerns. Further, if our products

cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product 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 the product 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 the affected product candidate and could substantially increase the costs of commercializing our product candidates, which could have a material adverse effect on our business, financial condition and results of operations.

Any of our product candidates, if approved, may require REMS, which may significantly increase our costs.

Any of our product candidates, 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 our product candidates. Depending on the extent of the REMS requirements, our costs to commercialize our product candidates 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.

Even if we obtain regulatory approval for our product candidates, we will still face extensive regulatory requirements and our products 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 our product candidates, or impose ongoing requirements for potentially costly post-approval studies or post-marketing surveillance. Any approved products 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 a product, 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 that product 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 any of our product candidates, 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 any approved product candidates and achieve profitability could be negatively impacted, which could have a material adverse effect on our business, financial condition and results of operations.

Even if we obtain any of our product candidates in the United States, we may never obtain approval for or commercialize our products outside of the United States, which would limit our ability to realize their full market potential.

In order to market any products 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 our products 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 our products 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.

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.

For example, we received two CRLs from the FDA with regard to our NDA and resubmitted NDA for IV meloxicam and have incurred substantial losses in connection with our resolution of the issues raised by the FDA in such CRLs. We cannot be certain that any of our 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.

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.

Risks Related to Commercialization of Our Product Candidates

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

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 our product candidates, any predictions about 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.

We are subject to intense competition and, if we are unable to compete effectively, our product candidates may not reach their commercial potential.

The market for our product candidates is characterized by intense competition and rapid technological advances. If our product candidates obtain FDA approval, they will compete with a number of existing and future pharmaceuticals 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 pain relief. 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, Purdue Pharma, L.P., Mallinckrodt plc, Teva Pharmaceutical Industries, Inc. and Pacira Pharmaceuticals, Inc. and AcelRx Pharmaceuticals, Inc. Purdue is the primary competitor in the manufacture of opioid therapeutics. 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 our product candidates. 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 and our other product candidates 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 we are unable to identify a strategic partner with appropriate sales and marketing capabilities and enter into a strategic partnership on commercially acceptable terms with such partner, we may be unable to generate any revenue for our product candidates.

To date, we have not entered into any strategic partnerships for any of our product candidates. 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.

Our strategy for IV meloxicam has been to develop a specialty sales force and/or collaborate with third parties to promote product to healthcare professionals and third-party payers in the United States. Our future collaboration partners, if any, may not dedicate sufficient resources to the commercialization of our product candidates 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 our product candidates to healthcare professionals and in geographic regions, including the United States, that will not be covered by our own marketing and sales force, or if our potential future collaboration partners do not successfully commercialize our product candidates, our ability to generate revenues from product sales will be adversely affected.

If we are unable to negotiate a strategic partnership or obtain additional financial resources for our other product candidates, we may be forced to curtail the development of them, delay potential commercialization, reduce the scope of our sales or marketing activities or undertake development or commercialization activities at our own expense. In addition, without a partnership, we will bear all the risk related to the development of these other product candidates. 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 will not be able to bring our other product candidates to market or generate product revenue from them, 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 results of our ongoing 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 success in educating physicians, patients and caregivers about the benefits, administration and use of injectable 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.

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

Physicians may not prescribe IV meloxicam or any of our other product candidates if approved by the FDA, in which case we would not generate the revenues we anticipate. The degree of market acceptance of any of our product candidates 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 each of our product candidates is approved, including any dosing instructions and potential additional restrictions placed on each product candidate in connection with its approval;
- limitations or warnings contained in the FDA-approved label for each product candidate;
- the results of our ongoing Phase IIIb clinical trials for IV meloxicam;
- relative convenience and ease of administration of our product candidates;
- prevalence of the condition for which each product candidate is approved;
- availability of alternative treatments and perceived advantages of our product candidates 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 and our other product candidates 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 as a result of our receipt of two CRLs from the FDA for IV meloxicam,

even if subsequently resolved. If IV meloxicam or any of our other product candidates are approved but do 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.

If we fail to supply IV meloxicam in sufficient quantities and at acceptable quality 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 plc, or 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 for injectable meloxicam.

We and our contract manufacturers must comply with federal, state and foreign regulations, including FDA's regulations governing current 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 to ensure compliance with these regulations. 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.

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 our third-party manufacturer of IV meloxicam is no longer able or willing to continue producing IV meloxicam, we may not be able to locate an alternative manufacturer, enter into a commercially acceptable agreement with them or qualify and obtain FDA approval for such manufacturer in a timely manner, or at all, which could be adversely affect our business.

Although our supply agreement and manufacturing agreements for injectable 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, 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 its commercialization, 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. If we experience significant delays or other obstacles in producing a sufficient supply to meet demand, our ability to market and sell IV meloxicam may be adversely affected and our business could suffer.

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

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 our product candidates, 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 our product candidates, 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 our product candidates, 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 our product candidates, if approved, could limit our ability to sell our product candidates, if approved, or decrease our revenues, which could have a material adverse effect on our business, results of operations and financial condition.

The Affordable Care Act and any changes in healthcare law may increase the difficulty and cost for us to commercialize our product candidates 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 our product candidates or restrict or regulate post-approval activities and affect our ability to profitably sell our product candidates for which we obtain marketing approval. 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 our product candidates 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 any approved products 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 our products.

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

Our ability to commercialize our product candidates successfully will depend in part on the extent to which coverage and adequate reimbursement for such products, 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 our product candidates, 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 our product candidates 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 our product candidates to each government authority or other third-party payer. For example, if our ongoing Phase Illb 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 from the FDA for IV meloxicam, 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 our products into our target markets, nor, if formulary approval is obtained, at what price our products 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 or our other product candidates.

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 our other product candidates, which in turn, could negatively impact pricing. If patients are not adequately reimbursed for our product candidates, they may reduce or discontinue purchases of it.

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 and our other product candidates, 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 are able to successfully commercialize our product candidates 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 or our other product candidates. 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 or our other product candidates. 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 or our other product candidates 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.

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 our product candidates 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 our product candidates, and other parties through which we will market, sell and distribute our product candidates. 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 our product candidates and generate revenues which would have a material adverse effect on our business, financial condition and results of operations.

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

If our product candidates are approved for commercialization, we may enter into agreements with third parties to market our product candidates 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 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 our product candidates 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. 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 Our Reliance on Third Parties

Relying on third-parties to manufacture our product candidates exposes us to risks that may delay testing, development, regulatory approval, commercialization and overall manufacturing of our product candidates.

We currently lack the internal resources to manufacture our product candidates and we rely on third-party suppliers and contract manufacturers to manufacture injectable meloxicam. For example, Alkermes is currently our sole supplier of bulk injectable meloxicam formulation and is the only established supplier of bulk injectable meloxicam formulation. We have committed to purchase our current requirements of injectable meloxicam formulation from Alkermes, and we have commissioned dedicated space in Alkermes' manufacturing facility for the production of bulk injectable meloxicam. Patheon provides sterile fill and finish services, and we have committed to purchase a certain percentage of our annual requirements of sterile fill and finish services from Patheon. Our agreement with Patheon also obligates us to a minimum annual order quantity, which, if higher than the commercial demand for IV meloxicam, if approved, could expose us to increased costs. Although our supply agreement and manufacturing agreements for injectable meloxicam and our other product candidates 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. 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, 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.

Our reliance on a limited number of third-party manufacturers also exposes us to the following risks:

- third-party manufacturers might be unable to manufacture our products in the volume and of the quality required to meet our clinical and commercial needs, if any;
- contract manufacturers may not perform as agreed, and operate their business independently from us. Contract manufacturers are directly responsible for their own FDA cGMP interactions and we may not be privy to all ongoing discussions and information concerning products or process unrelated to us. Additionally, contract manufacturers may not remain in the contract manufacturing business for the time required to successfully produce, store and distribute our products;
- product 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 cGMP and other government regulations and corresponding foreign standards.

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 candidates; and

- if any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation.

Each of these risks could delay our preclinical studies and clinical trials, the submission of regulatory applications or the approval, if any, of our product candidates by the FDA, or the commercialization of our product candidates or could result in higher costs or deprive us of potential product revenues. If we do not successfully navigate each of these risks in a timely manner or at all, we could experience significant delays or an inability to successfully develop and commercialize our product candidates, which would materially harm our business.

If third-party service providers, including carriers, logistics providers and distributors, fail to devote sufficient time and resources to our product candidates 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 our product candidates, result in higher costs, or deprive us of potential product revenues. Our carriers may experience technical issues relating to the timing and shipment of our products, 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 our products, 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 our product candidates 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 our products 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 our product candidates, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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.

Manufacturing issues may arise that could increase product and regulatory approval costs or delay commercialization.

As we scale up manufacturing of our product candidates 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 marketing of our product candidates. In addition, quality issues may arise during scale-up and validation of commercial manufacturing processes. Any issues in our product or delivery devices 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 our products, which could have a material adverse effect on our business, financial condition, and results of operations.

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 directors, and we have agreed to assume all of Recro's obligations and indemnify Recro for all liabilities related to the Securities Litigation. 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.

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 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. We have not yet entered into employment agreements with each of our executive officers. 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 may acquire other assets or businesses, or form collaborations or make investments in other companies or technologies, that 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. In connection with the Separation, we will adopt a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business, operating results and financial condition.

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

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 will incur increased costs as a result of operating as a public company. 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.

Following the Distribution, we will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act. Additionally, we intend to apply to list our common stock on Nasdaq and, upon listing, will be subject to the rules and regulations of the Nasdaq Capital Market. Our financial results historically were included within the consolidated results of Recro, and until the Distribution occurs, we have not been and will not be directly subject to reporting and other requirements of the Exchange Act and Section 404 of the Sarbanes-Oxley Act. After the Distribution, we will qualify as an "emerging growth company" and 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 date of our sale of common equity securities pursuant to an effective registration statement under the Securities Act; (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 information statement 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 will, however, be subject to Section 404(a) of the Sarbanes-Oxley Act beginning with our first Annual Report on Form 10-K following the Separation 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 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 compositions, including compositions produced using NanoCrystal® technology, a method of making and method of treating. These issued patents expire in 2022 in the United States. We also in-license from Alkermes, on a perpetual royalty-free basis i) composition and methods of making patents, one of which we anticipate to be Orange-Book listable 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. As of November 8, 2019, we own or license a total of four issued U.S. patents and nine U.S. pending patent applications, and 59 issued foreign patents (including European validation countries) and six pending foreign applications related to meloxicam. As of November 8, 2019, we are the owner of record of one issued U.S. patent, 1 pending U.S. application and 28 issued foreign patents, including European validation countries, and ten pending foreign applications to Dex. In addition, we have licensed four patent families containing several U.S. and foreign issued patents and pending applications 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 case 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.

As we enter our target markets, it is possible that competitors or other third parties will claim that our products and/or processes infringe their intellectual property rights. These third parties may have obtained and may in the future obtain patents covering products or processes that are similar to, or may include compositions or methods that encompass our technology, allowing them to claim that the use of our technologies infringes these patents. If such third-party patent is listed in the Orange Book, we would be required to file a certification, known as a Paragraph IV certification, that we are not infringing the patent, or that the patent is invalid. The third-party

would then have 45 days to file a patent infringement lawsuit against us, and if so brought, we could be subject to a stay of up to 30 months (unless before that time the patent expires or is judged to be invalid or not infringed), in which we would be unable to have our 505(b)(2) application approved.

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 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. 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 an 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. 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 by obtaining FDA approval for an ANDA, the generic company may choose to launch a generic version of a drug candidate. Any launch of a generic 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

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 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 have been able to benefit from opportunities to pursue integrated strategies with Recro's other business activities. As a newly formed, independent company, we will not have, and may never develop, any market reputation, which may limit our ability to recruit and retain personnel, pursue and negotiate strategic transactions, and access the capital markets to finance our operations. 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.

We have historically operated as part of Recro's corporate organization, and Recro has assisted us by providing various corporate and other business functions. Following the Separation, Recro will have no obligation to assist our operations or growth strategy, other than providing certain services or rights pursuant to agreements described under "Certain Relationships and Related Person Transactions—Agreements with Recro."

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 no history of operating as an independent company 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 and pro forma 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 information statement refers to our business as operated by and integrated with Recro. Our historical and pro forma financial information included in this information statement is derived from the consolidated financial statements and accounting records of Recro. Accordingly, the historical and pro forma financial information included in this information statement may not 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 and pro forma financial information included in this information statement as a result of the following factors, among others:

- our historical combined financial data does not reflect the Separation;
- 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 will be different from that reflected in our historical combined financial statements;
- 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, will be materially different from amounts reflected in our historical financial statements included elsewhere in this information statement. 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.

The Separation may impede our ability to attract and retain key personnel, which could materially harm our business.

Our success depends in large part upon the leadership and performance of our management team and other key employees. Operating as an independent company will demand a significant amount of time and effort from our

management and other employees and may give rise to increased employee turnover. If we lose the services of members of our management team or other key employees, we may not be able to successfully manage our business or achieve our business objectives.

Following the Separation, we will need to continue to attract and retain qualified key personnel in a highly competitive environment. Our ability to attract, recruit and retain such talent will depend on a number of factors, including the hiring practices of our competitors, the performance of our development programs, our compensation and benefits, work location and work environment and economic conditions affecting our industry generally. If we cannot effectively hire and retain qualified employees, our business, prospects, financial condition and results of operations could suffer.

The Separation may result in disruptions to, and harm our relationships with, our strategic business partners.

Uncertainty related to the Separation may lead the suppliers, licensors, research organizations, and other parties with which we currently do business or may do business in the future to terminate or attempt to negotiate changes in our existing business relationships, or cause them to 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. The effect of such disruptions could be exacerbated by any delays in the completion of the Separation.

The Distribution likely will not qualify for tax-free treatment and may be taxable to you as a dividend.

The Distribution likely will not qualify for tax-free treatment and may be taxable to you as a dividend. An amount equal to the fair market value of the Baudax Bio common stock received by you in the Distribution will be treated as a taxable dividend to the extent of your ratable share of current and accumulated earnings and profits of Recro for the taxable year of the Distribution. To the extent that the fair market value of such Baudax Bio common stock exceeds your ratable share of such earnings and profits, any such excess will be treated first as a nontaxable return of capital to the extent of your tax basis in Recro shares, and thereafter as capital gain recognized on a sale or exchange of such shares. See "Material U.S. Tax Consequences" later in this document.

Although Recro will be ascribing a value to the shares of Baudax Bio common stock it distributes for tax purposes, this valuation is not binding on the Internal Revenue Service, or the IRS, or any other tax authority. These taxing authorities could ascribe a higher valuation to the shares of Baudax Bio common stock, particularly if such shares trade at prices significantly above the value ascribed to them by Recro in the period following the Distribution. Such a higher valuation may cause a larger reduction in the tax basis of a shareholder's shares of Recro common stock or may cause a shareholder to recognize additional dividend or capital gain income. You should consult your own tax advisor as to the particular tax consequences of the Distribution to you.

Until the Distribution occurs, Recro has sole discretion to change the terms of the Separation in ways that may be unfavorable to us.

Until the Distribution occurs, we will be a subsidiary of Recro. Completion of the Separation remains subject to the satisfaction or waiver of certain conditions, some of which are in the sole and absolute discretion of Recro, including final approval by the Recro Board. Additionally, Recro has the sole and absolute discretion to change certain terms of the Separation, which changes could be unfavorable to us. In addition, Recro may decide at any time prior to the completion of the Separation not to proceed with the Separation.

In connection with the Separation, we will assume and agree 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 will assume and agree 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 "Certain Relationships and Related Person Transactions—Agreements with Recro" and "Index to Financial Statements—Notes to Combined Financial Statements." 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 will agree 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 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 and directors 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 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, will have been entered into in the context of the Separation while we are still controlled by Recro. Until the Distribution occurs, Recro will effectively have 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 and distribution 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. In addition, Recro may decide at any time not to proceed with all or any part of the Separation. For a more detailed description, see "Certain Relationships and Related Person Transactions—Agreements with Recro."

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.

The combined post-Separation value of Recro and our common stock may not equal or exceed the pre-Separation value of Recro common stock.

As a result of the Distribution, Recro expects the trading price of Recro common stock immediately following the Distribution to be lower than the trading price of such common stock immediately prior to the Distribution because the trading price will no longer reflect the value of our business held by Recro. Furthermore, following the Distribution, the trading price of our common stock may not reflect the full value of our business and assets, due to market inefficiencies in the initial trading of our shares or variations in investor views regarding our business and prospects, among other market forces. The aggregate market value of Recro common stock and our common stock following the Separation may be higher or lower than the market value of Recro common stock immediately prior to the Separation, and may fluctuate, particularly during the period immediately following the Distribution.

No vote of Recro shareholders is required in connection with this Distribution. As a result, if the Distribution occurs and you do not want to receive our common stock in the Distribution, your sole recourse will be to divest yourself of your Recro common stock prior to the record date.

No vote of the Recro shareholders is required in connection with the Distribution. Accordingly, if the Distribution occurs and you do not want to receive our common stock in the Distribution, your only recourse will be to divest yourself of your Recro common stock prior to the record date for the Distribution.

Risks Relating to Our Securities

There is no existing market for our shares of common stock and an active trading market may not develop for our shares. Once our shares of common stock begin trading, the market price of these shares may fluctuate widely.

There is currently no public market for our shares of common stock. It is anticipated that on or prior to the record date for the Distribution, trading of our shares of common stock will begin on a "when issued" basis and will continue up to and including through the distribution date. On the first trading day following the distribution date, any "when issued" trading of our common stock would end and "regular way" trading would begin. However, there can be no assurance that an active trading market for our shares of common stock will develop as a result of the Distribution 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 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 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 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.

Substantial sales of shares of our common stock may occur immediately following the Distribution which could cause the market price of shares of our common stock to decline.

It is possible that many of Recro's shareholders will sell the shares of our common stock that they receive in the Distribution immediately in the public market because our business profile or market capitalization does not fit their investment objectives, because the shares are not included in certain indices or for other reasons. The sale of significant amounts of our shares or the perception in the market that this will occur may result in the lowering of the market price of our shares. We can offer no assurance that Recro's shareholders will continue to hold the shares they receive in the Distribution.

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.

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. 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 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 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.

Your percentage ownership in the company may be diluted in the future.

In the future, your 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. See “Description of Our Capital 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 director;
- 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.

CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This information statement and other materials we have filed or will file with the SEC include, or will include, forward-looking statements. All statements in this information statement, in other materials we have filed or will file with the SEC and in related comments by our management, other than statements of historical facts, including statements about future events, financing plans, future financial position, business strategy, budgets, projected costs, plans and objectives of management for future operations, are forward-looking statements that involve certain risks and uncertainties. Use of the words "may," "will," "would," "could," "should," "believes," "estimates," "projects," "potential," "expects," "plans," "seeks," "intends," "evaluates," "pursues," "anticipates," "continues," "designs," "impacts," "affects," "forecasts," "target," "outlook," "initiative," "objective," "designed," "priorities," "goal" or the negative of those words or other similar expressions may identify forward-looking statements that represent our current judgment about possible future events, but the absence of these words does not necessarily mean that a statement is not forward-looking.

Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. Because forward-looking statements relate to the future, by their nature, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. As a result, our actual results may differ materially from those contemplated by the forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward-looking statements include regional, national or global political, economic, business, competitive, market and regulatory conditions and the following:

- the completion and timing of the Separation, the business and operations of Baudax Bio following the Separation and any benefits or costs of the Separation, including the tax treatment;
- 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 Baudax Bio may owe to Recro after the Separation;
- the tax treatment of the Distribution and any limitations imposed on Baudax Bio under the tax matters agreements that Baudax Bio will enter into with Recro;
- whether the FDA will approve our amended NDA for IV meloxicam and, if approved, the labeling under any such approval that we may obtain;
- 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 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 any milestone payments owing to 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 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 the securities class action lawsuit filed against Recro, or any future material litigation filed against us;
- our ability to recruit or retain key scientific, technical, commercial, and management personnel or to retain our executive officers; 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 tax strategy, changes in the valuation of deferred tax assets and liabilities 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 information statement, 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 information statement 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.

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 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 and any other factors deemed relevant by our board of directors.

CAPITALIZATION

The following table sets forth Baudax Bio's capitalization as of June 30, 2019 on a historical basis and on a pro forma basis to give effect to the pro forma adjustments included in Baudax Bio's unaudited pro forma combined financial information. The information below is not necessarily indicative of what Baudax Bio's capitalization would have been had the Separation, Distribution and related financing transactions been completed as of June 30, 2019. In addition, it is not indicative of Baudax Bio's future capitalization. This table should be read in conjunction with "Unaudited Pro Forma Combined Financial Statements," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Summary Historical and Unaudited Pro Forma Combined Financial Information" and the audited and unaudited combined financial statements and corresponding notes included elsewhere in this information statement.

	As of June 30, 2019 (unaudited)	
(In thousands)	**Actual**	**Pro Forma**
Cash and cash equivalents	$ —	$ 19,000
Capitalization:		
Debt:		
Long-term debt	$ —	$ —
Total Debt	$ —	$ —
Equity:		
Common stock, par value $0.01 per share	$ —	$ —
Additional paid-in capital	$ —	$ —
Parent company net investment	$ (29,187)	$ (10,187)
Total Capitalization	$ (29,187)	$ (10,187)

UNAUDITED PRO FORMA COMBINED FINANCIAL STATEMENTS

The unaudited pro forma combined financial data of Baudax Bio consists of unaudited pro forma combined statements of operations for the year ended December 31, 2018 and six months ended June 30, 2019, and an unaudited pro forma combined balance sheet as of June 30, 2019 prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The unaudited pro forma combined financial data reported below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Summary Historical and Unaudited Pro Forma Combined Financial Information" and the audited and unaudited combined financial statements and corresponding notes included elsewhere in this information statement.

The following unaudited pro forma combined financial data is subject to assumptions and adjustments described in the accompanying notes. Baudax Bio's management believes these assumptions and adjustments are reasonable under the circumstances and given the information available at this time. However, these adjustments are subject to change as Recro and Baudax Bio finalize the terms of the Separation, including the Separation Agreement and related transaction agreements. The unaudited pro forma combined financial data does not purport to represent what Baudax Bio's financial position and results of operations actually would have been had the Separation occurred on the dates indicated, or to project Baudax Bio's financial performance for any future period following the Separation.

The unaudited pro forma combined financial data as of June 30, 2019, and for the year ended December 31, 2018 and the six months ended June 30, 2019 gives effect to the Separation as if it had occurred on January 1, 2018. The unaudited pro forma combined financial data includes adjustments to reflect the following:

- the contribution by Recro to Baudax Bio, pursuant to the Separation Agreement, of all the assets and liabilities that comprise Baudax Bio's business; and

- the expected transfer to Baudax Bio, upon completion of the Separation, of $19 million of cash that was not included in Baudax Bio's historical combined financial statements.

Baudax Bio's historical financial information, which was the basis for the unaudited pro forma combined financial statements, was prepared on a carve-out basis as Baudax Bio was not operated as a separate, independent company for the periods presented. Accordingly, such historical financial information reflects an allocation 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. These historical allocations may not be indicative of Baudax Bio's future cost structure; however, the pro forma results have not been adjusted to reflect any potential changes associated with Baudax Bio being an independent public company as such amounts are estimates that are not factually supportable.

Recro expects to incur approximately $5 million of one-time separation costs in connection with the Separation during 2019, including costs related to consulting, legal, auditing and information technology.

Baudax Bio, Inc.

Unaudited Pro Forma Combined Statement of Operations

Year Ended December 31, 2018

(in thousands)

	Historical	Pro forma Adjustments	Notes	Adjusted
Cost and expenses:				
Research and development	$ 35,583	—		$ 35,583
General and administrative	29,453	—		29,453
Change in contingent consideration valuation	8,499	—		8,499
Total operating expenses	73,535	—		73,535
Operating loss	(73,535)			(73,535)
Other income (expenses):				
Other expense, net	(132)	—		(132)
Net loss	$ (73,667)	—		$ (73,667)

See Notes to Unaudited Pro forma Combined Financial Data

Baudax Bio, Inc.

Unaudited Pro Forma Combined Statement of Operations

Six Months Ended June 30, 2019

(in thousands)

	Historical	Pro forma Adjustments	Notes	Adjusted
Cost and expenses:				
Research and development	$ 16,734	—		$ 16,734
General and administrative	17,284	—		17,284
Change in contingent consideration valuation	(19,150)	—		(19,150)
Total operating expenses	14,868	—		14,868
Operating loss	(14,868)			(14,868)
Other income (expenses):				
Other expense, net	(49)	—		(49)
Net loss	$ (14,917)	—		$ (14,917)

See Notes to Unaudited Pro forma Combined Financial Data

Baudax Bio, Inc.

Unaudited Pro Forma Combined Balance Sheet

As of June 30, 2019

(in thousands)

	Historical	Pro Forma Adjustments	Notes	Adjusted
Assets				
Current assets:				
Cash and cash equivalents	$ —	$ 19,000	(A)	$ 19,000
Prepaid expenses and other current assets	3,586	—		3,586
Total current assets	3,586	19,000		22,586
Property, plant and equipment, net	5,091	—		5,091
Right of use asset	943	—		943
Intangible assets	26,400	—	(B)	26,400
Goodwill	2,127	—	(B)	2,127
Total assets	$ 38,147	$ 19,000		$ 57,147
Liabilities and Parent Company Net Investment				
Current liabilities:				
Accounts payable	$ 352	$ —		$ 352
Accrued expenses and other current liabilities	4,233	—		4,233
Current operating lease liability	400	—		400
Current portion of contingent consideration	—	—		—
Total current liabilities	4,985	—		4,985
Long-term operating lease liability	587	—		587
Long-term portion of contingent consideration	61,762	—	(B)	61,762
Total liabilities	67,334	—		67,334
Common Stock	—	2	(C)	2
Additional paid-in capital	—	(10,189)	(A),(B),(C),(D)	(10,189)
Parent company net investment	(29,187)	29,187	(D)	—
Total equity	(29,187)	19,000		(10,187)
Total liabilities and equity	$ 38,147	$ 19,000		$ 57,147

See Notes to Unaudited Pro forma Combined Financial Data

Baudax Bio, Inc.

Notes to Unaudited Pro Forma Combined Financial Data

(A) Pursuant to the Separation Agreement, Recro plans to provide Baudax Bio with a total of $19 million in cash funding upon the completion of the Separation to be used to fund our operations.

(B) Our historical and pro forma balance sheet reflects assets and contingent liabilities associated with IV meloxicam based on estimates that include various assumptions and inputs, including the expectation that IV meloxicam will be approved, and estimates of timing of approval and future cash inflows; however there can be no assurance that IV meloxicam will be approved. The supplemental financial information is provided to reflect the elmination of the book value of assets and liabilities associated with IV Meloxicam if we received an unfavorable outcome with respect to approval.

	Pro Forma	Supplemental Illustrative Adjustments		Adjusted
Total current assets	22,586	—		22,586
Total assets	57,147	(28,527)		28,620
Current liabilities	4,985	—		4,985
Total liabilities	67,334	(61,762)		5,572
Stockholders' equity	(10,187)	33,235	(1)	23,048

(1) We currently expect the total equity as reflected in the table above to be in a similar range as of the time of Separation, and at a minimum no less than the $19 million in cash funding Pursuant to the Separation Agreement.

(C) Reflects the elimination of Recro's parent company investment in Baudax Bio.

(D) Reflects the 1:2.5 distribution of Baudax Bio stock to Recro shareholders using Recro shares outstanding as of June 30, 2019 of 22.4 million.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with "Unaudited Pro Forma Combined Financial Statements," "Summary Historical and Unaudited Pro Forma Combined Financial Information" and the audited and unaudited combined financial statements and corresponding notes included elsewhere in this information statement. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, including those set forth under "Risk Factors" appearing elsewhere in this information statement, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are a specialty 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 and personnel costs.

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 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 Baudax Bio common stock to shareholders of Recro. As a part of the Separation, Recro intends to transfer the assets, liabilities and operations of its acute care business to Baudax Bio, pursuant to the terms of a Separation Agreement, to be entered into between Recro and Baudax Bio. On November 21, 2019, the distribution date, each Recro shareholder will receive 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, the record date for the Distribution. Registered shareholders will receive cash in lieu of any fractional shares of Baudax Bio's common stock that they would have received as a result of the application of the distribution ratio. Following the Distribution, Baudax Bio will operate as a separate, independent company. The Distribution is subject to the satisfaction or waiver by Recro of certain conditions. For a more detailed description of these conditions, see "The Separation and Distribution—Conditions to the Distribution."

Baudax Bio's historical combined financial statements 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. Baudax Bio's financial position, results of operations and cash flows historically operated, and will continue to operate, 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 may not be indicative of Baudax Bio's future performance and do not necessarily reflect what Baudax Bio's combined results of operations, financial condition and cash flows would have been had Baudax Bio operated as a separate company during the periods presented. Baudax Bio expects that changes will occur in its operating structure and its capitalization as a result of the Separation from Recro. See "The Separation and Distribution" for additional detail.

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 other pipeline activities. These expenses consist primarily of:

- expenses incurred under agreements with contract research organizations, 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;
- 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 information statement.

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 obtaining regulatory approval 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 professional fees for legal, including patent-related expenses, consulting, auditing and tax services.

Change in Fair Value of Contingent Consideration

Pursuant to the Purchase and Sale Agreement for the acquisition of certain assets, including the worldwide rights to IV meloxicam and the development, formulation and manufacturing business that comprises Recro's CDMO segment from Alkermes, or the Gainesville Transaction, as amended in December 2018, we are required to pay up to an additional $140.0 million in milestone payments, including $10.0 million during the first half of 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 Gainesville Transaction. We have continued to reevaluate the fair value each subsequent period and as of June 30, 2019 recorded a $61.8 million payment obligation, representing the estimated probability adjusted fair value. Each reporting period we revalue this estimated obligation with changes in fair value recognized as a non-cash operating expense or gain. During the six months ended June 30, 2019, we have paid $10.0 million in milestone payments to Alkermes.

Income Taxation

In December 2017, the federal government enacted numerous amendments to the Internal Revenue Code of 1986 pursuant to the Tax Cuts and JOBS Act, or the Tax Act. The Tax Act will impact our income tax expense/(benefit) from operations in the current and in future periods. The Tax Act resulted in the following impacts to us:

- Our federal statutory income tax rate was reduced from 34% to 21% for 2018 and tax years following.
- We will be able to claim an immediate deduction for investments in qualified fixed assets acquired and placed in service from September 27, 2017 through 2022. This provision phases out through 2026.
- Given our taxable losses in the U.S., we will be limited in our ability to deduct interest expense, if any, and any disallowed interest expense for 2018 and tax years following will result in an indefinite carry forward until such time as we meet the taxable income thresholds required to deduct interest expense.

Results of Operations

Comparison of the Twelve Months Ended December 31, 2018 and 2017

	Year ended December 31,	
	2018	2017
	(amounts in thousands)	
Operating expenses:		
Research and development	$ 35,583	$ 28,635
General and administrative	29,453	19,626
Change in contingent consideration valuation	8,499	12,839
Total operating expenses	73,535	61,100
Operating loss	(73,535)	(61,100)
Other income (expense):		
Other income (expense), net	(132)	16
Net loss	$ (73,667)	$ (61,084)

Research and Development. Our research and development expenses were $35.6 million and $28.6 million for the twelve months ended December 31, 2018 and 2017, respectively. The increase of $7.0 million in 2018 was primarily due to an increase in pre-commercialization manufacturing costs for IV meloxicam of $7.8 million, an increase in development costs for other pipeline products of $4.1 million, an increase in Phase IIIb clinical trial costs of $2.0 million, and an increase in salaries and benefits expense of $0.7 million. These increases were partially offset by a decrease in Phase III clinical trial costs of $5.2 million and NDA costs due to the prior year NDA filing fee of $2.4 million.

General and Administrative. Our general and administrative expenses were $29.5 million and $19.6 million for the twelve months ended December 31, 2018 and 2017, respectively. The increase of $9.9 million was primarily due to commercial team personnel and pre-commercial consulting costs in the first half of the year in preparation of the anticipated launch of IV meloxicam of $8.8 million, and public company costs of $1.1 million, including legal fees as well as increased professional fees associated with addressing the first CRL issued by the FDA regarding our NDA for IV meloxicam.

Change in Contingent Consideration valuation. Our change in contingent consideration expenses was $8.5 million and $12.8 million for the twelve months ended December 31, 2018 and 2017, respectively. The non-cash charge for contingent consideration in each period related to the revaluation of the probability adjusted fair value of the Gainesville Transaction payment obligation. The decrease of $4.3 million was due to the adjusted timing of estimated milestone and royalty payments after the receipt of the first CRL from the FDA.

Comparison of the Six Months Ended June 30, 2019 and 2018

	For the Six Months ended June 30,	
	2019	2018
	(amounts in thousands)	
Operating expenses:		
Research and development	$ 16,734	$ 15,826
General and administrative	17,284	19,062
Change in contingent consideration valuation	(19,150)	2,916
Total operating expenses	14,868	37,804
Operating loss	(14,868)	(37,804)
Other expense:		
Other expense, net	(49)	(90)
Net loss	$ (14,917)	$ (37,894)

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 obtain FDA approval of IV meloxicam. The restructuring initiative included a reduction of approximately 50 positions. During the six months ended June 30, 2019, we have incurred approximately $7.2 million 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 $16.7 million and $15.8 million for the six months ended June 30, 2019 and 2018, respectively. Excluding $2.8 of costs associated with the strategic restructuring initiative recorded in the six months ended June 30, 2019, the decrease of $1.9 million resulted from a decrease in pre-commercialization manufacturing costs for IV meloxicam of $1.8 million and a decrease in personnel costs of $1.1 million. These decreases were partially offset by an increase in development costs for clinical trial costs and other pipeline products of $1.0 million prior to the second CRL.

General and Administrative. Our general and administrative expenses were $17.3 million and $19.1 million for the six months ended June 30, 2019 and 2018, respectively. Excluding $4.4 million of costs associated with the strategic restructuring initiative recorded in the six months ended June 30, 2019, the decrease of $6.2 million was primarily due to decreased commercial team personnel costs of $3.7 million and pre-commercial consulting costs of $2.5 million following the receipt of the second CRL for IV meloxicam.

Change in Contingent Consideration Valuation. Our change in contingent consideration valuation was a reduction of value of $19.2 million for the six months ended June 30, 2019 and an increase in value of $2.9 million for the six months ended June 30, 2018. The non-cash charge for contingent consideration in each period related to the revaluation of the probability adjusted fair value of the Gainesville Transaction payment obligation. The decrease of $22.1 million was due to the adjusted timing of estimated milestone and royalty payments after the receipt of the second CRL from the FDA.

Liquidity and Capital Resources

Historically, the primary source of liquidity for our business was cash flow allocated to us from Recro. Prior to the Separation, transfers of cash to and from Recro have been 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. We expect Recro to continue to fund our cash needs through the date of the Separation.

Under the terms of the Separation Agreement, prior to or upon the completion of the Distribution, Recro will make a cash capital contribution of $19 million to Baudax Bio to fund Baudax Bio's operations. This cash capital contribution is in an amount that Baudax Bio estimates will, based on its current plans and expectations, meet its cash needs for at least 12 months after the completion of the Separation. Subsequent to the Separation, we will 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.

Overview of Cash Flows and Liquidity

	Years ended December 31,		For the Six Months ended June 30,	
	2018	2017	2019	2018
	(amounts in thousands)			
Net cash used in operating activities	$ (59,751)	$ (43,272)	$ (39,158)	$ (31,263)
Net cash used in investing activities	$ (3,452)	$ (1,287)	$ (1,717)	$ (1,860)
Net cash provided by financing activities	$ 63,203	$ 44,559	$ 40,875	$ 33,123

Comparison of the Years Ended December 31, 2018 and December 31, 2017

Uses of cash flow for operations increased $16.5 million during 2018 as compared to 2017. Uses of operating cash flows were primarily driven by greater net operating losses in 2018 related to pre-commercial activities, including manufacturing costs related to the anticipated launch of IV meloxicam. Changes in accounts payable, accrued expenses, and other liabilities also contributed to the increase by $2.1 million year over year. Uses of cash for investing activities was higher by $2.2 million year over year, which primarily related to cash paid for property and equipment. Net cash provided by financing activities increased $18.6 million in 2018 as compared to 2017, as more cash was transferred from Recro to fund the operations of our business in 2018.

Comparison of the Six Months Ended June 30, 2019 and June 30, 2018

Uses of cash flow for operations increased $7.9 million during the six months ended June 30, 2019 as compared to the comparable prior year period primarily related to the decrease in accounts payable, accrued expenses (including accrued restructuring costs), and other liabilities. This was partially offset by lower net operating losses in the six months ended June 30, 2019, excluding the change in contingent consideration, related to decreased pre-commercial activities, including manufacturing costs, related to IV meloxicam. Uses of cash for investing activities were lower by $0.2 million in the six months ended June 30, 2019 as compared to the comparable prior year period due to a decrease in capital expenditures initiatives. Net cash provided by financing activities increased $7.8 million in the six months ended June 30, 2019 as compared to the comparable prior year period, as more cash was transferred from Recro to fund the operations of our business in the 2019 period.

Contractual Commitments

The table below reflects our contractual commitments as of June 30, 2019:

	Payments Due by Period (in thousands)				
Contractual Obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Purchase Obligations (1):	$ 4,609	$ 882	$ 47	$ –	$ –
Operating Leases (2)	1,404	483	735	187	–
Other Long-Term Liabilities					
Other License Commitments and Milestone payments (3), (4)	53,765	40	130	170	225
Alkermes Payments (5)	130,000	–	–	–	–
Employment Agreements (6)	925	925	–	–	–
Total Contractual Obligations	$ 190,703	$ 2,330	$ 912	$ 357	$ 225

(1) These obligations consist of cancelable and non-cancelable purchase commitments related to capital expenditures and other goods or 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. In accordance with U.S. GAAP, these obligations are not recorded on our Combined Balance Sheets. See Note 10(e) to the Combined Financial Statements included in this information statement.

(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 10(d) to the Combined Financial Statements included in this information statement.

(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 10(a) to the Combined Financial Statements included in this information statement. 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 Combined Balance Sheets.

(4) We license the NMBAs from Cornell 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 10(a) to the Combined Financial Statements included in this information statement.

(5) Pursuant to the purchase and sale agreement governing the Gainesville 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 Combined Balance Sheets. See Note 10(b) to the Combined Financial Statements included in this information statement.

(6) We have entered into employment agreements with certain of our named executive officers. As of June 30, 2019, these employment agreements provided for, among other things, annual base salaries, net of allocations, in an aggregate amount of not less than this amount, from that date through March 2020. In accordance with U.S. GAAP, these obligations are not recorded on our Combined Balance Sheets. See Note 10(f) to the Combined Financial Statements included in this information statement.

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 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.

Transition from Recro and Costs to Operate as an Independent Company

The combined financial statements reflect our operating results and financial position as it was operated by Recro, rather than as an independent company. We will incur 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 will also incur 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.

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.

Transactions with Related and Certain Other Parties

Prior to or concurrently with the Distribution, we expect to enter into certain agreements with Recro resulting from and relating to the Separation, including the Separation Agreement, a transition services agreement, a tax matters agreement and an employee matters agreement. The terms of these agreements, including information on the business purpose of such agreements, transaction prices, related ongoing contractual commitments and any related special risks or contingencies are discussed in greater detail under "Certain Relationships and Related Party Transactions" appearing elsewhere in this information statement.

Off-Balance Sheet Arrangements

We do not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, that would have been established for the purpose of facilitating off-balance sheet arrangements (as that term is defined in Item 303(a)(4)(ii) of Regulation S-K) or other contractually narrow or limited purposes. As such, we are not exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in those types of relationships. We enter into guarantees in the ordinary course of business related to the guarantee of our own performance.

New Accounting Pronouncements

For a discussion of new accounting pronouncements see Note 3, *Summary of Significant Accounting Principles,* of the combined financial statements appearing elsewhere in this information statement.

BUSINESS

Overview

We are a specialty 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 long-acting 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 for the management of moderate to severe pain. 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. We are engaged in resolution of the IV meloxicam CRL, and 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. We are consulting with regulatory counsel and expert advisors on both process and potential language for the IV meloxicam product label. We are working to prepare a comprehensive response to the FDA that includes refiling the NDA with proposed labeling that addresses the FDA's concerns and to provide the relevant evidence from the filed NDA that supports the proposed label. We anticipate that this process will continue until late 2019 or early 2020 and will require an estimated $1.3 million to $1.8 million in capital.

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. We are pursuing a Section 505(b)(2) regulatory strategy for IV meloxicam.

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 Dex an alpha-2 adrenergic agonist that we are evaluating for possible partnering.

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 for the management of moderate to severe pain.

- *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 previously established 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 IV meloxicam in a Phase IIIb program that includes clinical trials in colorectal surgery patients and orthopedic surgery patients. We anticipate the Phase IIIb program to be completed during 2019.

- *Entering into strategic partnerships to maximize the potential of IV meloxicam and other product candidates outside of the United States*. We intend to pursue strategic collaborations with other pharmaceutical companies to develop and commercialize IV meloxicam outside of the United States. We believe that our development expertise and unique product candidates make us an attractive partner to potential strategic collaborators.

- *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 Product Candidates

Our Lead Product Candidate - IV Meloxicam

Meloxicam is a long-acting, 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 which provides a faster onset of action of meloxicam, 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 the potential to be an effective analgesic for up to 24 hours after a single dose. 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 the 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 build a sales force with approximately 80 to 100 representatives who would market IV meloxicam to health care professionals at targeted institutions. In addition, we would either build medical, account-based and reimbursement teams to maximize the commercial success of IV meloxicam. 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 IV meloxicam in Phase IIIb clinical trials in colorectal surgery patients and orthopedic surgery patients. 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 IRB review.

At the end of July 2017, we submitted an NDA to the FDA for IV meloxicam 30mg for the management of moderate to severe pain. In May 2018, we received a 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 Chemistry, Manufacturing and Controls 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. We are engaged in resolution of the IV meloxicam CRL, and 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. We are consulting with regulatory counsel and expert advisors on both process and potential language for the IV meloxicam product label. We are working to prepare a comprehensive response to the FDA that includes refiling the NDA with proposed labeling that addresses the FDA's concerns and to provide the relevant evidence from the filed NDA that supports the proposed label.

Phase IIIb Clinical Trials

We are currently evaluating IV meloxicam in a Phase IIIb program that includes 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. We anticipate completion of the Phase IIIb program during the summer of 2019.

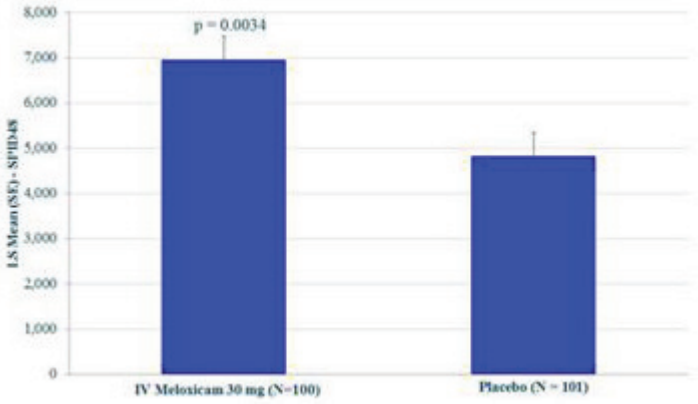
Phase III Clinical Trials

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.

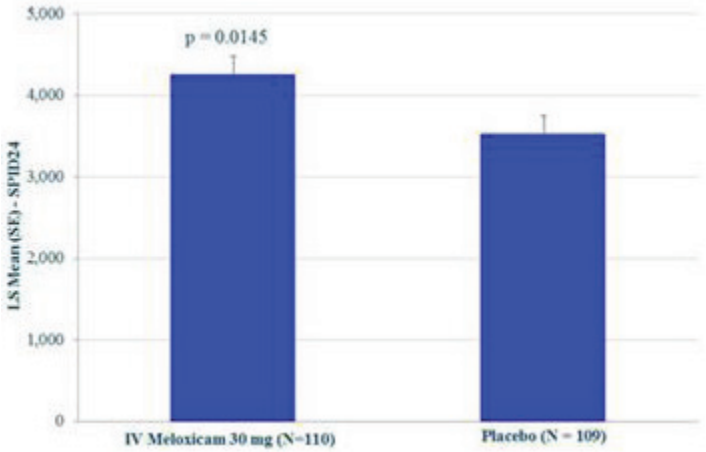
The safety results demonstrated that IV meloxicam was well tolerated with no SAEs or bleeding events in the IV meloxicam-treated patients. The most common AEs occurring in at least 3% of IV meloxicam-treated patients, were nausea, headache, pruritus, constipation, vomiting, dizziness, flushing and somnolence, 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 ≥30% improvement at 24 hours (p=0.0178), number of times patients required rescue in the first 24 hours after randomization (p=0.0275), as well as number of times rescued from 24 to 48 hours (p=0.0009), and several other pain relief metrics, compared to placebo.

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

The safety results demonstrated that IV meloxicam was well tolerated. Four SAEs were observed during the trial. The SAEs occurred in one IV meloxicam-treated patient and three placebo-treated patients. The IV meloxicam-treated patient experienced a post-procedural hemorrhage that was not viewed by the investigator as attributable to the drug. 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 (≥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-IND

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.

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

We intend to conduct a Phase I study with RP1000 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 compositions, including compositions produced using NanoCrystal® technology, method of making and method of treating. These issued patents expire in 2022 in the United States. We also in-license from Alkermes, on a perpetual, royalty-free basis, composition and methods of making patents, one of which we anticipate to be Orange-Book listable, and patent applications (specifically directed to the prevention of flake like aggregates), 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. 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 hold patent applications directed to the analgesia indication, formulations and intranasal and transmucosal methods of use of Dex, and we are progressing through the patent application process globally, including the United States. Several patent applications have issued as patents outside the United States for transmucosal methods, and the resulting patent protection will last into 2030, subject to any disclaimers or extensions. In addition, a patent related to intranasal methods has issued in the United States, 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 intend to pursue strategic collaborations with other pharmaceutical companies to continue the development and commercialization of IV meloxicam and our other product candidates. We believe that our development expertise and unique product candidates make us an attractive partner to potential strategic collaborators. 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 previously established 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, Purdue Pharma, L.P., Mallinckrodt plc, Teva Pharmaceutical Industries, Inc., 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, 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.

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; 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 CDMO business.

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

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

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

If the Section 505(b)(2) NDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the owner of the reference product and relevant patent holders within 20 days after the Section 505(b)(2) NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement suit against the Section 505(b)(2) applicant. Under the FDCA, the filing of a patent infringement lawsuit within 45 days of receipt of the notification regarding a Paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA for 30 months, beginning on the date the patent holder receives notice, or until the patent expires or a court deems the

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

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

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

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

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages, or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling, and the agency also may require a REMS if it determines that a REMS is necessary to assure

that the benefits of a drug outweigh its risks. In addition, the FDA may require Phase IV testing, which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA approval, and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specific circumstances of FDA marketing approval of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. Subject to certain limitations, the patent term restoration period is generally equal to one-half of the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. However, each phase of the regulatory review period may be reduced by any time that the FDA finds the applicant did act not act with due diligence. Only one patent applicable to an approved drug is eligible for the extension, 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 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.

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 Maximillian 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 US. 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

Baudax Bio was incorporated as a Pennsylvania corporation on September 13, 2019. The contribution of Recro's acute care business to Baudax Bio is occurring over a period of time prior to the Distribution. At the time of the Distribution, the address of Baudax Bio's principal executive offices will be 490 Lapp Road, Malvern, PA 19355. Baudax Bio's telephone number will be (484) 395-2470. Baudax Bio will also maintain a website at .

Employees

We currently have 20 full-time employees. None of our employees are covered by collective bargaining agreements, and we consider relations with our employees to be good.

Legal Proceedings

We may be involved, from time to time, in various claims and legal proceedings arising in the ordinary course of our business. We are not currently a party to any such claims or proceedings that, if decided adversely to it,

would either individually or in the aggregate have a material adverse effect on our business, financial condition or results of operations.

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 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 and directors 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. On June 26, 2019, the judge heard oral arguments on the motion to dismiss.

As consideration for the acute care assets contributed to us by Recro, Recro assigned and we accepted the assignment 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.

MANAGEMENT

Directors and Executive Officers

The following table sets forth the names and ages, as of November 8, 2019, and titles of the individuals we currently expect to serve as our executive officers and members of our board of directors at the time of the Separation. Certain biographical information with respect to those executive officers and directors follows the table.

Name	Age	Position
Gerri Henwood	67	President and Chief Executive Officer and Director
Ryan D. Lake	42	Chief Financial Officer
Alfred Altomari	60	Director
William L. Ashton	70	Director
Winston J. Churchill	79	Director
Wayne B. Weisman	63	Director

Executive Officers

Gerri Henwood will serve as our President and Chief Executive Officer and a member of our board of directors upon completion of the Separation. Ms. Henwood currently serves as Recro's President and Chief Executive Officer and a member of the Recro Board. She has held these positions since Recro's inception in 2008. From 2006 to 2013, Ms. Henwood served as the President of Malvern Consulting Group, or MCG, a pharmaceutical incubator and consulting firm. From 1999 to 2006, Ms. Henwood was the President and Chief Executive Officer of Auxilium Pharmaceuticals, Inc., or Auxilium, a biopharmaceutical company she founded in late 1999. From 1985 to 1999, Ms. Henwood was the founder and Chief Executive Officer of IBAH, Inc., or IBAH, a contract research organization. Ms. Henwood began her career with Smith Kline & French, now GlaxoSmithKline plc. She rose through the ranks to be a Brand Manager, then the head of Regulatory and Medical Affairs for the U.S. business and then to the position of Group Director—Marketing in the International Pharmaceutical Division. Ms. Henwood currently serves on the board of directors of Tetraphase Pharmaceuticals, Inc., a clinical stage biopharmaceutical company, a position she has held since May 2015, and she previously served on the board of directors of Alkermes, Inc. and its successor company, Alkermes plc, a global biopharmaceutical company, from 2003 until March 2015, and on the board of directors of MAP Pharmaceuticals, Inc., a biopharmaceuticals company, from 2004 until its acquisition by Allergan, Inc. in March 2013. Ms. Henwood also serves on the compensation committee of the board of directors of Tetraphase Pharmaceuticals, Inc. Ms. Henwood holds a B.S. in Biology from Neumann University. Ms. Henwood's expertise in developing, financing and providing strong executive leadership to numerous biopharmaceutical companies, her strong background in pharmaceutical marketing and commercialization, clinical and product development and substantial knowledge of the pharmaceutical industry, her corporate governance experience as a board member of multiple publicly-traded and privately-held companies, as well as her extensive knowledge of our business, contributed to the Recro Board's conclusion that she should serve as a director of our company.

Ryan D. Lake will serve as our Chief Financial Officer upon completion of the Separation. Mr. Lake currently serves as Recro's Chief Financial Officer. He has held this position since January 2018. He had previously served as Recro's Senior Vice President of Finance and Chief Accounting Officer since June 2017. Prior to joining Recro, Mr. Lake served as Chief Financial Officer and Vice President of Finance of Aspire Bariatrics, Inc., a privately-held, commercial stage, medical device company from July 2015 to May 2017. From 2012 to 2015, Mr. Lake held executive management and senior finance positions, including Director of the Natural Materials Division, Controller and Senior Director of Finance, at DSM Biomedical (successor to Kensey Nash Corporation after its acquisition in 2012), a division of Royal DSM (listed on Euronext Amsterdam), a global science-based company active in health, nutrition and materials. From 2002 to 2012, Mr. Lake held various senior financial positions of increasing responsibility, most notably Senior Director of Finance and Interim Chief Financial Officer, with Kensey Nash Corporation, a medical device company. Earlier in his career, Mr. Lake worked at Deloitte & Touche, LLP. Mr. Lake has a B.S. degree in Accounting from West Chester University of Pennsylvania and is a certified public accountant and chartered global management accountant.

Non-Employee Directors

We expect to appoint the following non-management directors to serve on our board of directors upon completion of the Separation:

Alfred Altomari has been a member of the Recro Board since 2014. Mr. Altomari has served as Chairman, President and Chief Executive Officer of Agile Therapeutics, Inc., or Agile, a specialty pharmaceutical company focused on the development and commercialization of new prescription contraceptive products, since October 2010. Mr. Altomari is also a member of the board of directors of Agile and prior to being named President and Chief Executive Officer, he served as Agile's Executive Chairman from 2004 to 2010. From 2008 to September 2010, Mr. Altomari also served as a consultant. From 2003 to 2008, Mr. Altomari held multiple senior management positions, including Chief Commercial Officer, Chief Operating Officer, and Chief Executive Officer, at Barrier Therapeutics, Inc., a pharmaceutical company that developed and marketed dermatology products. In 2008, in his role as Chief Executive Officer and as a member of Barrier's board of directors, Mr. Altomari completed the successful sale of Barrier to Stiefel Laboratories, which was subsequently acquired by GlaxoSmithKline plc. From 1982 to 2003, Mr. Altomari held numerous executive roles in general management, commercial operations, business development, product launch preparation and finance with Johnson & Johnson. Mr. Altomari also serves on the board of directors of Insmed Incorporated. Mr. Altomari received an M.B.A. from Rider University and a B.S. from Drexel University. Mr. Altomari's extensive experience in the pharmaceutical industry, in senior leadership positions at both large and specialty pharmaceutical companies as well as his experience in the development, commercialization and launch of numerous pharmaceutical products, contributed to the Recro Board's conclusion that he should serve as a director of our company.

William L. Ashton has been a member of the Recro Board since 2009. Since the beginning of 2013, Mr. Ashton has been a principal at Harrison Consulting Group, Inc., a privately-held biopharmaceutical consulting firm. From August 2009 to June 2013, Mr. Ashton was the senior vice president of external affairs reporting to the president and an assistant professor at the University of the Sciences in Philadelphia, Pennsylvania. From August 2005 to August 2009, Mr. Ashton was the founding Dean of the Mayes College of Healthcare Business and Policy. Mr. Ashton has 29 years' experience in the biopharmaceutical industry. From 1989 to 2005, Mr. Ashton held a number of positions at Amgen Inc., a biotechnology company, including vice president of U.S. sales and vice president of commercial and government affairs. Mr. Ashton currently serves on the board of directors of Spectrum Pharmaceuticals, Inc. since February 2018, and previously served on the board of directors of Galena Biopharma, Inc. from April 2013 until January 2018. He is also a member of the board of directors of the Academy of Notre Dame and Loyola University. Mr. Ashton holds a B.S. in Education, from the California University of Pennsylvania and an M.A. in Education, from the University of Pittsburgh. Mr. Ashton's extensive experience with pharmaceutical and biological product commercialization, including developing and leading a commercial sales force, as well as his governance experience as a board member of public and privately-held

companies and his reimbursement expertise contributed to the Recro Board's conclusion that he should serve as a director of our company.

Winston J. Churchill has been a member of the Recro Board since 2008. Since 2007, Mr. Churchill has been a director of the corporate general partner of the common general partner of SCP Vitalife Partners II, L.P. and SCP Vitalife Partners (Israel) II, L.P., collectively referred to herein as SCP Vitalife, which beneficially owns 13.2% of Recro's outstanding stock as of March 15, 2019. He has also served as a managing member of SCP Vitalife Management Company, LLC, which by contract provides certain management services to the common general partner of SCP Vitalife. Mr. Churchill has also served since 1993 as the President of CIP Capital Management, Inc., the general partner of CIP Capital, L.P., an SBA-licensed private equity fund. Prior to that, Mr. Churchill was a managing partner of Bradford Associates, which managed private equity funds on behalf of Bessemer Securities Corporation and Bessemer Trust Company. From 1967 to 1983, Mr. Churchill practiced law at the Philadelphia firm of Saul Ewing, LLP, where he served as Chairman of the Banking and Financial Institutions Department, Chairman of the Finance Committee and was a member of the Executive Committee. Mr. Churchill is a director of Innovative Solutions and Support, Inc., Amkor Technology, Inc. and various SCP Vitalife portfolio companies and he previously served as a director of Griffin Industrial Realty from April 1997 until May 2016. In addition, he serves as a director on the boards of a number of charities and as a trustee of educational institutions including the Gesu School and Young Scholars Charter School and is a Trustee Fellow of Fordham University. From 1989 to 1993, Mr. Churchill served as Chairman of the Finance Committee of the Pennsylvania Public School Employees' Retirement System. He was awarded a B.S. in Physics, summa cum laude, from Fordham University followed by an M.A. in Economics from Oxford University, where he studied as a Rhodes Scholar, and a J.D. from Yale Law School. Mr. Churchill's insight into financial and investment matters from his experience in private equity investing in life sciences companies, his financial and corporate governance experience from serving on numerous public and private boards of directors, as well as his long service as a director on the Recro Board, where he gained extensive knowledge of Recro's business and history, contributed to the conclusion of the Recro Board that he should serve as a director of our Company.

Wayne B. Weisman has been a member and the chairman of the Recro Board since 2008. Since 2007, Mr. Weisman has been a director of the corporate general partner of the common general partner of SCP Vitalife, which beneficially owns approximately 13.2% of Recro's outstanding stock as of March 15, 2019. He has also served as a managing member of SCP Vitalife Management Company, LLC, which by contract provides certain management services to the common general partner of SCP Vitalife. He has also led the activities of SCP Private Equity Partners II, L.P., a venture capital fund of which he and Mr. Churchill are principals, in the life sciences area; these activities include investments in the United States and Israel. He has also led several other technology investments for SCP Private Equity Partners II, L.P. He has been a member of the investment committee of the Vitalife Life Sciences funds since their inception in 2002 and has worked closely with these funds since then. Mr. Weisman was a member of the board of directors of CIP Capital, L.P., a small business investment company licensed by the U.S. Small Business Administration since its inception in 1991 until 2017. From 1992 to 1994, Mr. Weisman was executive vice president and member of the board of a public drug delivery technology company. In addition, he also operated a management and financial advisory firm focusing on the reorganization and turnaround of troubled companies and began his career practicing reorganization law at a large Philadelphia law firm. Mr. Weisman possesses extensive experience in venture capital investing, particularly in the life sciences area. In addition to being our Chairman, Mr. Weisman serves on the board of directors of ReWalk Robotics Ltd. and on the board of directors for a number of private companies. He is the Vice Chairman of the board of trustees of Young Scholars Charter School. He is also an advisory board member of the Philadelphia-Israel Chamber of Commerce and Mid-Atlantic Diamond Ventures, the venture forum of Temple University. Mr. Weisman holds a B.A. from the University of Pennsylvania, and a J.D. from the University of Michigan Law School. Mr. Weisman's leadership as a director of various pharmaceutical and healthcare companies, his experience serving on the board of directors of life sciences companies, his insight into the legal issues facing our business, as well as his in-depth knowledge of our business and history as a long time director of Recro, contributed to the conclusion of the Recro Board that he should serve as a director of our Company.

Board Composition and Independence

Our business and affairs are managed under the direction of our board of directors. Upon completion of the Separation, our board of directors will consist of five members and will be divided into three classes. Each class will be as equal in number as is possible. The directors designated as Class I directors will have terms expiring at the first annual meeting of shareholders following the distribution, which we expect to hold in 2020. The directors designated as Class II directors will have terms expiring at the following year's annual meeting of stockholders, which we expect to hold in 2021, and the directors designated as Class III directors will have terms expiring at the following year's annual meeting of shareholders, which we expect to hold in 2022. Class I will be comprised of Ms. Henwood and Mr. Altomari; Class II will be comprised of Mr. Ashton and Mr. Weisman; and Class III will be comprised of Mr. Churchill. Commencing with the first annual meeting of shareholders following the Separation, directors for each class will be elected at the annual meeting of shareholders held in the year in which the term for that class expires and thereafter will serve for a term of three years. Our directors hold office until their successors have been elected and qualified or until their earlier death, resignation or removal. There are no family relationships among any of our directors or executive officers. It is anticipated that a majority of our board of directors will satisfy the independence standard established by the listing standards of the Nasdaq Capital Market as well as the corporate governance principles to be adopted by our board of directors.

Board Committees

Upon the completion of the Separation, our board of directors will have three standing committees: an audit committee, or the Audit Committee, a compensation committee, or the Compensation Committee, and a nominating and corporate governance committee, or the Governance Committee, each of which will operate pursuant to a charter to be adopted by our board of directors.

Each of the Committees will have the authority, as its members deem appropriate, to engage legal counsel or other experts or consultants in order to assist the Committee in carrying out its responsibilities.

Audit Committee

The Audit Committee will consist of Alfred Altomari, William Ashton and Winston Churchill. Our board has determined that each member of the audit committee is independent under the Nasdaq Listing Rules and Rule 10A-3(b)(1) of the Exchange Act except Mr. Churchill, with respect to Rule 10A-3(b)(1) of the Exchange Act. We are permitted to phase in our compliance with the independent audit committee requirements of Rule 10A-3 of the Exchange Act, which requires all members of the audit committee to be independent within one year of listing. We intend to rely on this phase-in period and within one year of our listing, we will have an audit committee comprised solely of independent directors pursuant to Rule 10A-3(b)(1) of the Exchange Act and the applicable Nasdaq Listing Rules. The chair of the Audit Committee will be Alfred Altomari. Our Board has determined that Alfred Altomari is an "audit committee financial expert" as such term is currently defined in Item 407(d)(5) of Regulation S-K. This designation does not impose any duties, obligations or liabilities that are greater than are generally imposed on members of the Audit Committee and our board of directors. The Audit Committee will, among other things, assist the Board by providing oversight of our financial management, independent auditor and financial reporting procedures. The responsibilities of the Audit Committee will be more fully described in our Audit Committee Charter and are expected to include, among other duties:

- appointing, retaining, compensating, overseeing, evaluating, and, when appropriate, terminating our independent registered public accounting firm;
- discussing with management and the independent registered public accounting firm our annual and quarterly financial statements and related disclosures;
- periodically reviewing policies and procedures with respect to data privacy and security we employ in conducting our business;

- reviewing with management its assessment of our internal control over financial reporting, disclosure controls and procedures;
- reviewing our code of business conduct and ethics and recommending any changes to the Board;
- overseeing our risk assessment and risk management processes;
- reviewing and ratifying all related party transactions, based on the standards set forth in our Related Party Transactions Policy; and
- preparing and approving the Audit Committee report required to be included in our annual proxy statement.

Compensation Committee

The Compensation Committee will consist of Alfred Altomari, William Ashton, Winston Churchill and Wayne Weisman, each of which is a non-employee director, as defined by Rule 16b-3 promulgated under the Exchange Act and meets the requirements for independence under the current Nasdaq Listing Rules. The chair of the Compensation Committee will be William Ashton. The Compensation Committee will, among other things, review the performance and development of our management in achieving corporate goals and objectives and assures that our executive officers (including our CEO) are compensated effectively in a manner consistent with our strategy, competitive practice and shareholder interests. The responsibilities of the Compensation Committee will be more fully described in our Compensation Committee Charter and are expected to include, among other duties:

- annually reviewing and recommending to the Board for approval the corporate goals and objectives applicable to the compensation of our CEO and other executive officers and evaluating at least annually our CEO's and other executive officers' performance in light of those goals and objectives;
- annually reviewing and approving our peer group for compensation benchmarking;
- determining and approving our CEO's and other executive officers' compensation level (including salary, cash and equity-based incentive awards and any personal benefits);
- administering, or where appropriate, overseeing the administration of, executive and equity compensation plans and such other compensation and benefit plans that will be adopted by us from time to time;
- determining stock ownership guidelines for our CEO and other executive officers and monitoring compliance with such guidelines, if deemed advisable by our Board or the Compensation Committee; and
- overseeing risks and exposures associated with executive compensation plans and arrangements.

Nominating and Corporate Governance Committee

The Governance Committee will consist of Alfred Altomari, William Ashton, Winston Churchill and Wayne Weisman, each of which meets the requirements for independence under the current Nasdaq Listing Rules. The chair of the Governance Committee will be Wayne Weisman. The Governance Committee will be tasked with providing oversight of the corporate governance affairs of the Board. In addition, the Governance Committee will identify qualified individuals for membership on the Board, recommend to the Board the director nominees to fill vacancies on the Board and to stand for election at the next annual meeting of shareholders and develop and recommend to the Board a set of corporate governance guidelines for the Board. The responsibilities of the Governance Committee will be more fully described in our Nominating and Corporate Governance Committee Charter and are expected to include, among other duties:

- developing and submitting to the Board for its adoption a list of selection criteria for new directors to serve on the Board;

- identifying, reviewing and evaluating candidates, including candidates submitted by shareholders, for election to the Board and recommending to the Board (i) nominees to fill vacancies or new positions on the Board and (ii) the slate of nominees to stand for election by the Company's shareholders at each annual meeting of shareholders;

- developing, recommending, and overseeing the implementation of and monitor compliance with, our corporate governance guidelines, and periodically reviewing and recommending any necessary or appropriate changes to our corporate governance guidelines;

- annually recommending to the Board (i) the assignment of directors to serve on each Committee; (ii) the chairperson of each Committee and (iii) the chairperson of the Board or lead independent director, as appropriate;

- periodically assessing the appropriate size and composition of the Board as a whole, the needs of the Board and the respective committees of the Board, and the qualification of director candidates in light of these needs;

- reviewing the adequacy of our articles of incorporation and bylaws and recommending to the Board, as conditions dictate, amendments for consideration by the shareholders;

- reviewing any proposals submitted by shareholders for action at the annual meeting of shareholders and make recommendations to the Board regarding action to be taken in response to each proposal; and

- implementing policies with respect to governance risk oversight, assessment and management of risk associated with the independence of our Board and director nominees, potential conflicts of interest of members of our Board and our executive officers and the effectiveness of the Board and the committees thereof.

The Governance Committee will also be responsible for identifying individuals that the Committee believes are qualified to become Board members, as described above in the section entitled "Board Composition and Independence."

Our board of directors may establish other committees from time to time.

Risk Management

Upon completion of the Separation, we expect the Board's role in risk oversight to be consistent with our anticipated leadership structure, with management having day-to-day responsibility for assessing and managing our risk exposure and the Board actively overseeing management of our risks—both at the Board and Committee level. The risk oversight process will include receiving regular reports from Committees and our executive officers to enable our Board to understand our risk identification, risk management and risk mitigation strategies with respect to areas of potential material risk, including operations (including cyber-security), finance, legal, regulatory, strategic and reputational risk.

The Board will focus on the overall risks affecting us. Each Committee will be delegated the responsibility for the oversight of specific risks that fall within its areas of responsibility. For example:

- The Audit Committee will oversee management of financial reporting, compliance and litigation risks, including risks related to our insurance, information technology, cybersecurity, human resources and regulatory matters, as well as the steps management has taken to monitor and control such exposures.

- The Compensation Committee will be responsible for overseeing the management of risks relating to our executive compensation policies, plans and arrangements and the extent to which those policies or practices increase or decrease risk for the Company.

- The Governance Committee will manage risks associated with the independence of the Board, potential conflicts of interest and the effectiveness of the Board.

While each Committee will be responsible for evaluating certain risks and overseeing the management of such risks, the entire Board will be regularly informed through Committee reports about such risks. Matters of significant strategic risk will be considered by our entire Board.

Compensation Committee Interlocks and Insider Participation

During the fiscal year ended December 31, 2018, Baudax Bio did not exist and did not have a compensation committee or any other committee serving a similar function. Prior to the Separation, decisions as to the compensation of those who are expected to serve as our executive officers were made by the Recro Compensation Committee.

Corporate Governance Principles and Code of Business Conduct and Ethics

In connection with the Separation and the Distribution, our board of directors will adopt corporate governance principles that set forth the responsibilities of the board of directors and the qualifications and independence of its members and the members of its standing committees. In addition, in connection with the Separation and Distribution, our board of directors will adopt, among other codes and policies, a code of conduct setting forth standards applicable to all of our companies and our directors, officers and employees. The corporate governance principles and code of conduct will be available on our website at www.baudaxbio.com. Any amendment to the code, or any waivers of its requirements, will be disclosed on our website.

EXECUTIVE COMPENSATION

Executive Compensation

Overview

The following tables and discussion relate to the compensation paid to or earned by Gerri Henwood, who currently serves as Chief Executive Officer of Recro and will serve as our Chief Executive Officer, and Ryan Lake, who currently serves as Chief Financial Officer of Recro and will serve as our Chief Financial Officer. Ms. Henwood and Mr. Lake are referred to collectively in this information statement as our "named executive officers."

Prior to the Separation, the compensation of our named executive officers for their service to Recro was designed and determined by Recro and the Recro Compensation Committee. Prior to the Separation, the Recro Compensation Committee may determine to adopt new or alternative compensation arrangements to attract and retain talented executives at Baudax Bio, and in connection with or following the Separation, our Compensation Committee may adopt such compensation arrangements or adopt its own compensation arrangements to attract and retain talented executives.

Summary Compensation Table

The following table sets forth information about certain compensation awarded to, earned by or paid to our named executive officers under Recro's compensation and benefit plans and programs during fiscal year 2018:

Name and Principal Position	Salary ($)	Bonus ($)(1)(2)	Non-Equity Incentive Plan ($)(2)	Stock Awards ($)(3)(5)	Option Awards ($)(3)	All Other Compensation ($)(4)	Total ($)
Gerri Henwood President and Chief Executive Officer	598,662	—	183,600	1,008,000	600,000	37,172	2,427,434
Ryan Lake Chief Financial Officer	309,231	—	63,240	231,840	138,000	41,823	784,134

(1) Reflects discretionary bonus amounts paid for performance in excess of corporate and individual objectives under our annual performance cash bonus plan.

(2) The amounts represent annual performance cash bonuses earned in 2018 and paid in the following year.

(3) Reflects the grant date fair value determined in accordance with the Financial Accounting Standards Board Accounting Standards, Codification Topic 718, Compensation — Stock Compensation, or ASC 718. The assumptions made in these valuations are included in Note 16 of the Notes to the Annual Financial Statements included in Recro's Annual Report on Form 10-K for the year ended December 31, 2018.

(4) These amounts consist of 401(k) matching contributions, the cost of medical benefits and life and disability insurance premiums.

(5) The 2018 amounts reflect both time-based and performance-based restricted stock awards, of which certain performance-based awards were forfeited and canceled due to unmet 2018 performance criteria. Refer to the Outstanding Equity Awards at Fiscal Year-End table for more information.

Non-Equity Incentive Plan Compensation

Each of the named executive officers will be eligible to receive an annual performance cash bonus based on the achievement of pre-established corporate and individual objectives as determined by our Compensation Committee and upon review of the recommendations of our CEO for our other named executive officers. Each officer will be assigned a target bonus expressed as a percentage of his or her base salary. Actual bonus payments may be higher or lower than the target bonus amount, as determined by our Board or Compensation Committee, based on the achievement of corporate and individual objectives.

The target bonus amount in 2018 as set by the Recro Compensation Committee for Ms. Henwood and Mr. Lake were 60% and 40%, respectively.

In determining the amount of performance bonus awards, our Compensation Committee will determine the level of achievement of the corporate goals and individual goals for each year. In determining the level of achievement for our other named executive officers, our Compensation Committee will review and consider the recommendations of our CEO. These achievement levels will be used to determine each named executive officer's bonus.

Actual bonus amounts that were paid to each named executive officer by Recro are reflected in the "Non-Equity Incentive Plan" column of the Summary Compensation Table above.

Equity-Based Compensation

We will award equity compensation to our named executive officers based on their performance in the form of time-vesting stock options and time- and performance-vested restricted stock units. We will determine our equity award guidelines based on information and recommendations provided by our compensation consultant. With respect to our named executive officers other than our CEO, we will also utilize recommendations provided by our CEO. In determining the amount of awards, we will not consider an employee's current equity ownership in our common stock or the prior awards that are fully vested. Rather, we will evaluate each employee's awards based on the recommendation received from our CEO and reference to other competitive market factors in our industry.

Our stock option awards will typically vest over a four-year period subject to the continued service of the employee with us. Our time-based restricted stock unit awards will typically vest in equal annual installments over a four-year period subject to the continued service of the employee with us. Our performance-based restricted stock unit awards will include vesting criteria relating to the achievement of certain development, commercialization and financial goals. We believe these vesting arrangements will encourage our named executive officers to continue service with us for a longer period of time and remain focused on our multi-year long-term drug development and commercialization programs.

Agreements with our Named Executive Officers

Each of Ms. Henwood and Mr. Lake entered into employment agreements with Recro that, among other things, entitled them to receive certain benefits in the event of termination without cause or such named executive officer resigns for certain reasons within 12 months of a change of control (each as defined in the respective agreement). We intend to enter into employment agreements with each of Ms. Henwood and Mr. Lake that are consistent in all material respects with their respective Recro employment agreements as described below and the form of employment agreement filed with the Registration Statement on form 10 of which this Information Statement forms a part.

Recro's employment agreements with its named executive officers provide for annual base salaries for each of Recro's named executive officers, subject to adjustment from time to time, in the discretion of the Recro Board and compensation committee. In addition to base salaries, the Recro employment agreements provide that each

of Recro's named executive officers is eligible to participate in Recro's incentive bonus program. The Recro Board and compensation committee consider a cash bonus opportunity each year for its named executive officers and potential target cash bonuses to Ms. Henwood and Mr. Lake. Mr. Lake has a prescribed target bonus under his Recro employment agreement of 40% of base salary.

For 2018, the Recro Board and compensation committee established target bonuses of 60% and 40% of base salary, respectively, for Ms. Henwood and Mr. Lake, with actual payment dependent upon performance factors.

Each of the Recro employment agreements is for an initial term of one year and automatically renews for one-year periods, unless terminated by either party by delivery of 30 days written notice to the other party. Pursuant to each of the employment agreements, if Recro terminates one of the named executive officers' employment without cause (as defined below) or such named executive officer resigns for certain reasons described below within 12 months after a change of control (as defined below), such named executive officer will be entitled to receive:

(i) such executive officer's base salary and health insurance benefits, at Recro's expense, for a period of 12 months following the date of termination;

(ii) with respect to Mr. Lake, any accrued but unused vacation and paid time off, any earned but unpaid bonus, reimbursement of any proper business expenses as of the date of termination and, with respect to Ms. Henwood, reimbursement of any proper business expenses as of the date of termination (referred to as the Accrued Benefits);

(iii) with respect to Mr. Lake, 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 Mr. Lake's termination of employment; and

(iv) with respect to Mr. Lake, outplacement services for a period of 12 months following the date of termination, which shall not exceed $25,000.

If a named executive officer's employment is terminated as a result of such named executive officer's disability or death, such named executive officer or such named executive officer's estate will be entitled to receive:

(i) such executive officer's base salary and health insurance benefits, at Recro's expense, for a period of 6 months following the date of termination;

(ii) the Accrued Benefits; and

(iii) with respect to Mr. Lake, a pro-rata target bonus in respect of the fiscal year in which the effective date of termination occurs, with such annual bonus (if any) paid within 30 days of termination.

If the severance and other benefits provided in a named executive officer's employment agreement or otherwise payable to a named executive officer would be subject to excise tax under Section 280(G) of the Code, then the named executive officer's severance benefits will be either delivered in full or delivered as to such lesser extent that would result in no portion of the severance benefits being subject to such excise tax, whichever results in the receipt by the named executive officer on an after-tax basis of the greatest portion of such total severance and other benefits.

For purposes of the Recro employment agreements, "cause" generally means an named executive officer's (1) commission of an act of fraud or dishonesty against Recro; (2) failure to substantially perform his or her

duties or material violation of the employment agreement, which failure or violation continues for 30 days or more following written notice to such named executive officer; (3) loss of any permit, license, accreditation or other authorization necessary for such named executive officer to perform his or her duties; (4) conviction of a felony or a plea of "no contest" to a felony; or (5) conduct that is likely, in the judgment of the Recro Board, to materially adversely affect its reputation; with regard to Mr. Lake, his employment agreement requires his conduct under item (2) above to be willful, and for his conduct to continue for five days or more following written notice by Recro of the conduct under item (5) above.

For purposes of the Recro employment agreements, a "change of control" shall be deemed to have occurred upon the happening of any of the following events: (1) the consummation by Recro of a plan of dissolution or liquidation; (2) the consummation of the sale or disposition of all or substantially all of Recro's assets; (3) the consummation by Recro of a merger, consolidation or other shareholder-approved fundamental business transaction in which Recro is a participant with another entity where Recro shareholders, immediately prior to the referenced transaction, will not beneficially own, immediately after the referenced transaction, shares or other equity interests entitling such shareholders to more than 50% of all votes to which all equity holders of the surviving entity would be entitled in the election of directors; (4) the date any entity, person or group, (within the meaning of Section 13(d)(3) or Section 14(d)(2) of the Exchange Act), (other than (A) Recro or any of its subsidiaries or any employee benefit plan (or related trust) sponsored or maintained by Recro or any of its subsidiaries or (B) any person who, on the date the plan is effective, is the beneficial owner of Recro outstanding securities), shall have become the beneficial owner of, or shall have obtained voting control over, more than fifty percent (50%) of Recro's outstanding shares of the common stock; or (5) the first day after the date hereof when directors are elected such that a majority of the Recro Board shall have been members of the Recro 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. A named executive officer will receive the payments and benefits described above if they terminate within 12 months after a change of control and during such twelve-month period Recro and/or its successor: (1) materially and adversely change such named executive officer's status, responsibilities or perquisites, subject to a 30 day cure period; (2) with regard to Mr. Lake, reduce such named executive officer's base salary except as part of an across the board decrease in which such executive officer's reduction is not more than any other executive officer; or (3) require such officer to be principally based at any office or location more than 50 miles from such named executive officer's principal office prior to the change of control.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information regarding Recro equity awards held by our named executive officers as of December 31, 2018.

	Option Awards				Stock Awards			
Name	**Number of Securities Underlying Unexercised Options (#) Exercisable**	**Number of Securities Underlying Unexercised Options (#) Unexercisable**	**Option Exercise Price ($)**	**Option Expiration Date**	**Number of Time-Based Shares or Units of Stock That Have Not Vested (#)(1)**	**Market Value of Time-Based Shares or Units of Stock That Have Not Vested ($)(2)**	**Number of Performance-Based Shares or Units of Stock That Have Not Vested (#)(1)**	**Market Value of Performance-Based Shares or Units of Stock That Have Not Vested ($)(2)**
Gerri Henwood	60,000	-	8.00	03/11/2024				
	40,000	-	7.00	04/07/2024				
	123,500	-	2.47	12/16/2024				
	123,500	-	2.47	12/16/2024				
	78,975	26,325 (3)	8.41	12/15/2025				
	105,300	-	7.86	12/01/2026				
	69,335	75,365 (3)	7.33	01/17/2027				
	22,917	77,083 (3)	9.04	01/01/2028				
					15,000	106,500		
					50,000	355,000		
							50,000 (5)	355,000
Ryan Lake	24,375	40,625 (4)	7.58	06/04/2027				
	5,271	17,729 (3)	9.04	01/01/2028				
					7,500	53,250		
					11,500	81,650		
							11,500 (6)	81,650

(1) The restricted stock units vest in four equal annual installments beginning on the date that is one year from the date of grant, subject to continued employment with Recro.

(2) The market value is based on the closing stock price of $7.10 on December 31, 2018 (the last trading date in the 2018 fiscal year).

(3) The stock option vests in equal monthly installments over 48 months, beginning on the date that is one month from the date of grant, subject to continued employment with Recro.

(4) The stock option vests in equal monthly installments over 48 months, beginning on the date that is one month from the date of grant, subject to continued employment with Recro. The stock option is an inducement grant under Nasdaq listing rule 5635(c)(4).

(5) The vesting of the performance-based restricted stock units was based upon meeting certain 2018 performance criteria, subject to continued employment with Recro. All of such performance-based restricted stock units were forfeited and canceled based on failure to meet the 2018 performance goals. The performance-based restricted stock units are shown here at the target level of performance.

(6) The vesting of the performance-based restricted stock units was based upon meeting certain 2018 performance criteria, subject to continued employment with us. 5,750 of such performance-based restricted stock units vested in January 2019 upon determination of Recro's Compensation Committee that certain of such performance criteria were met. The performance-based restricted stock units are shown here at the target level of performance.

Director Compensation

Following the Distribution, we will adopt a non-employee director compensation program, based on market and peer data, setting forth the compensation that members of our board of directors will be eligible to receive going forward in respect of their service to us.

2019 Compensation Plans

Prior to the Distribution, our board of directors intends to adopt the 2019 Equity Incentive Plan, or our 2019 Plan. The following summaries describe what we anticipate to be the material terms of our 2019 Plan. These summaries are not a complete description of all of the terms of our 2019 Plan and are qualified in their entirety by reference to our 2019 Plan, which will be filed as an exhibit to the registration statement of which this information statement is a part.

Purpose. The 2019 Plan is intended as an additional incentive to current and prospective employees, consultants and directors to enter into or remain in the service or employ with us or any affiliate, to devote themselves to our success, and to encourage the creation of shareholder value. Under the 2019 Plan, we may provide such persons with opportunities to acquire or increase their interests in us through options to purchase our common stock, grants of stock appreciation rights and awards of our common stock. Under the 2019 Plan, we may grant (i) incentive stock options, (ii) nonqualified stock options, (iii) stock appreciation rights, (iv) stock awards, (v) restricted stock awards, and (vi) restricted stock units.

Authorized Shares. A total of 3,000,000 shares of our common stock will be reserved for issuance under the 2019 Plan. In addition, on January 1 of each year, the number of shares of common stock reserved for issuance under the 2019 Plan will be automatically increased, without the necessity of further approval from our shareholders or our Board, by an amount equal to no greater than five percent (5%) of our issued and outstanding common stock on such date. If any award under the 2019 Plan expires, lapses, terminates unexercised, becomes unexercisable or is forfeited, or if shares underlying an award are tendered or withheld in payment of the exercise price of an award or the taxes payable with respect to the exercise, then such unpurchased, forfeited, tendered or withheld shares shall thereafter be available for further awards under the 2019 Plan unless, in the case of stock options granted under the 2019 Plan, related stock appreciation rights are exercised. With respect to stock appreciation rights that are settled with shares, upon settlement, only the number of shares delivered to a participant upon the exercise of the stock appreciation right shall count against the number of shares issued under the 2019 Plan. Awards under the 2019 Plan that are settled in cash shall not be counted against the foregoing maximum share limitations.

In the event that any reorganization, recapitalization, stock split, reverse stock split, stock dividend, combination of shares, merger, consolidation, distribution of assets, or any other change in our corporate structure or our shares affects shares such that an adjustment is appropriate in order to prevent dilution or enlargement of the rights of participants under the 2019 Plan, the Board shall make such equitable adjustments in any or all of the following in order to prevent such dilution or enlargement of rights: the number and kind of shares or other property available for issuance under the 2019 Plan (including, without limitation, the total number of shares available for issuance under the 2019 Plan), the number and kind of awards or other property covered by awards, and the exercise price of outstanding options and stock appreciation rights.

Eligibility. Awards under the 2019 Plan may be granted to our employees or employees of any parent or subsidiary affiliate. Awards may also be made to our consultants and members of our Board. Only employees may be granted incentive stock options.

Administration. The Compensation Committee will administer the 2019 Plan (except with respect to any award granted to non-employee directors, which is administered by our full Board). Subject to the terms and conditions of the 2019 Plan, our Compensation Committee will have the authority to select the persons to whom awards are

to be made, to determine the type or types of awards to be granted to each person, determine the number of awards to grant, determine the number of shares to be subject to such awards, and the terms and conditions of such awards, and to interpret the 2019 Plan.

Awards. The 2019 Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, stock awards, restricted stock awards and restricted stock units. Each award is set forth in a separate award agreement with the person receiving the grant, which agreement indicates the type, terms, restrictions and conditions of the award. A recipient may receive more than one award of stock options, stock appreciation rights, stock awards, restricted stock or restricted stock units.

Stock Options. Stock options entitle the holder to purchase from us a stated number of shares of common stock. The 2019 Plan permits the grant of stock options that are intended to qualify as incentive stock options, or ISOs, and nonstatutory stock options, or NSOs.

The exercise price of a stock option granted under the 2019 Plan may not be less than 100% of the fair market value of the common stock subject to the stock option on the date of grant and, in some cases (see "Limitations on Incentive Stock Options" below), may not be less than 110% of such fair market value.

The term of stock options granted under the 2019 Plan may not exceed ten years and, in some cases (see "Limitations on Incentive Stock Options" below), may not exceed five years. Acceptable forms of consideration for the purchase of our common stock pursuant to the exercise of a stock option under the 2019 Plan will be determined by the Board and may include payment: (1) by cash, (2) by certified check payable to us, (3) by payment through a broker in accordance with the procedures permitted by Regulation T of the Federal Reserve Board; (4) by delivery of shares of common stock, as permitted in the discretion of the Board, (5) by a net exercise arrangement (for NSOs only); (6) in other legal consideration approved by the Board and permitted for the issuance of shares under the Pennsylvania Business Corporation Law, as amended; or (7) any combination of the foregoing.

Stock options granted under the 2019 Plan may become exercisable in cumulative increments, or "vest," as determined by the Board or at the rate specified in the stock option agreement.

Unless otherwise provided in an award agreement or determined by the Compensation Committee, if a participant terminates employment with us due to death or disability, the participant's unexercised options may be exercised, to the extent they were exercisable on the termination date, for a period of twelve months from the termination date or until the expiration of the original award term, whichever period is shorter. If the participant terminates employment with us (or our affiliates) for cause, (i) all unexercised options (whether vested or unvested) shall terminate and be forfeited on the termination date, and (ii) any shares in respect of exercised options for which we have not yet delivered share certificates will be forfeited. If the participant's employment terminates for any other reason, any vested but unexercised options may be exercised by the participant, to the extent exercisable at the time of termination, for a period of three months from the termination date or until the expiration of the original option term, whichever period is shorter. Unless otherwise provided by the Compensation Committee, any options that are not exercisable at the time of termination of employment shall terminate and be forfeited on the termination date.

Limitations on Incentive Stock Options

The aggregate fair market value, determined at the time of grant, of shares of our common stock with respect to ISOs that are exercisable for the first time by a participant during any calendar year under all of our stock plans may not exceed $100,000. The stock options or portions of stock options that exceed this limit or otherwise fail to qualify as ISOs are treated as NSOs. No ISO may be granted to any person who, at the time of grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any affiliate unless the following conditions are satisfied:

- the exercise price of the ISO must be at least 110% of the fair market value of the common stock subject to the ISO on the date of grant; and

- the term of the ISO must not exceed five years from the date of grant.

Stock Appreciation Rights. Stock appreciation rights represent the right to receive, upon exercise, any appreciation in a share of common stock over a particular time period and may be granted in connection with options or on a standalone basis pursuant to stock appreciation right agreements. The appreciation amount may be settled in shares of our common stock, cash or a combination thereof. The strike price of each stock appreciation right will be determined by the Board. The Board may also impose restrictions or conditions upon the vesting of stock appreciation rights that it deems appropriate. Stock appreciation rights will be subject to the same conditions upon termination of continuous service and restrictions on transfer as stock options under the 2019 Plan.

Stock Awards. Stock awards consist of transferred shares of our common stock without payment or any other consideration. Stock awards shall be subject to the terms and conditions as the Board determines, including restrictions on sale or other disposition and our rights to reacquire such shares subject to a stock award upon termination of continuous services with us.

Restricted Stock Awards. Restricted stock awards are grants of our common stock pursuant to restricted stock award agreements, which may impose limitations on such shares, including any limitation on the right to vote shares or receive any dividend, other rights or property. Shares of our common stock acquired under a restricted stock award may be subject to forfeiture conditions to be determined by the Board. If the specified conditions are not attained, the participant will forfeit the portion of the restricted stock award with respect to which those conditions are not attained, and the underlying common stock will be forfeited. If the conditions, if any, have been satisfied, the restrictions imposed will lapse with respect to the applicable number of shares.

Restricted Stock Unit Awards. Restricted stock unit awards, or RSUs, may be granted pursuant to restricted stock unit award agreements. RSUs are granted in reference to a specified number of shares of common stock and entitle the holder to receive, subject to satisfaction of forfeiture conditions, if any, one share (or the value of one share) of common stock (at the time of distribution) for each such share of common stock covered by the RSU. Unless otherwise provided in an award agreement or determined by the Compensation Committee, upon termination of service a participant will forfeit all RSUs that then remain subject to forfeiture, subject to pro rata vesting upon a termination due to retirement, death or disability.

Extension of Time to Exercise Options. Our Board may extend the period of time that a non-qualified stock option may be exercised by a person whose employment with the Company and its affiliates has terminated, provided that the time to exercise an option may not be extended beyond the original term of such option.

Change of Control. Unless otherwise provided in a recipient's employment or service agreement, in the event of a Change of Control (as defined in the 2019 Plan), our Board may take whatever action with respect to outstanding awards it deems necessary or desirable, including, without limitation, accelerating the vesting of an award or terminating or redeeming an award. If options or stock appreciation rights granted pursuant to the 2019 Plan are accelerated, such awards shall become immediately exercisable in full.

Amendment and Termination. The 2019 Plan will automatically terminate ten years from the date of its adoption by the Board, unless terminated at an earlier time by the Board. Our Board may also amend the 2019 Plan from time to time and in such manner as it deems advisable, Notwithstanding the foregoing, any amendment that would change the individuals eligible to receive awards under the 2019 Plan, extend the expiration date of the 2019 Plan, reduce the exercise price of an option or stock appreciation rights award, exchange an option or stock appreciation rights award which has an exercise price that is greater than the fair market value of a share for cash or shares, cancel an option or stock appreciation rights award in exchange for a replacement option or another award with a lower exercise price or increase the maximum number of shares of common stock available for issuance under the 2019 Plan (other than as a result of a yearly increase not in excess of five percent (5%) of our issued and outstanding common stock) will only be effective if approved by a majority of our outstanding voting stock then outstanding.

Federal Income Tax Consequences

The following is a summary of the United States federal income tax consequences that generally will arise with respect to awards granted under the 2019 Plan, This summary is based on the federal tax laws in effect as of the date of this information statement. In addition, this summary assumes that all awards are exempt from, or comply with, the rules under Section 409A of the Code regarding nonqualified deferred compensation. Changes to these laws could alter the tax consequences described below.

Incentive Stock Options. A participant in the 2019 Plan will not have income upon the grant of an incentive stock option. Also, except as described below, a participant will not have income upon exercise of an incentive stock option if the participant has been employed by us at all times beginning with the option grant date and ending three months before the date the participant exercises the option. If the participant has not been so employed during that time, then the participant will be taxed as described below under "Nonqualified Stock Options." The exercise of an incentive stock option may subject the participant to the alternative minimum tax.

A participant will have income upon the sale of the shares acquired under an incentive stock option at a profit (if sales proceeds exceed the exercise price), The type of income will depend on when the participant sells the shares, If a participant sells the shares more than two years after the option was granted and more than one year after the option was exercised, then all of the profit will be long-term capital gain. If a participant sells the shares prior to satisfying these waiting periods, then the participant will have engaged in a disqualifying disposition and, if the sales proceeds exceed the value of the shares on the date of exercise, all or a portion of the profit will be ordinary income and the portion (if any) by which the sales proceeds exceed the exercise date value will be capital gain. This capital gain will be long-term if the participant has held the shares for more than one year and otherwise will be short-term. If a participant sells the shares at a loss (sales proceeds are less than the exercise price), then the loss will be a capital loss. This capital loss will be long-term if the participant held the shares for more than one year and otherwise will be short-term.

Nonqualified Stock Options. A participant will not have income upon the grant of a nonqualified stock option. A participant will have compensation income upon the exercise of a nonqualified stock option equal to the value of the shares on the day the participant exercised the option less the exercise price. Upon sale of the shares, the participant will have capital gain or loss equal to the difference between the sales proceeds and the value of the shares on the day the option was exercised. This capital gain or loss will be long-term if the participant has held the shares for more than one year and otherwise will be short-term.

Stock Appreciation Rights. A participant will not have income upon the grant of a stock appreciation right. A participant generally will recognize compensation income upon the exercise of a stock appreciation right equal to the amount of the cash and the fair market value of any shares received, Upon the sale of the shares, the participant will have capital gain or loss equal to the difference between the sales proceeds and the value of the shares on the day the stock appreciation right was exercised. This capital gain or loss will be long-term if the participant held the shares for more than one year and otherwise will be short-term.

Restricted Stock Awards. A participant will not have income upon the grant of restricted stock unless an election under Section 83(b) of the Code is made within 30 days of the date of grant. If a timely 83(b) election is made, then a participant will have compensation income equal to the value of the shares less the purchase price. When the shares are sold, the participant will have capital gain or loss equal to the difference between the sales proceeds and the value of the shares on the date of grant. If the participant does not make an 83(b) election, then when the shares vest the participant will have compensation income equal to the value of the shares on the vesting date less the purchase price. When the shares are sold, the participant will have capital gain or loss equal to the sales proceeds less the value of the shares on the vesting date. In each case, any capital gain or loss will be long-term if the participant held the shares for more than one year and otherwise will be short-term,

Restricted Stock Units. A participant will not have income upon the grant of a restricted stock unit. When the restricted stock unit vests, the participant will have income on the vesting date in an amount equal to the fair market value of the shares on such date less the purchase price, if any. When the shares are sold, the participant will have capital gain or loss equal to the sales proceeds less the value of the shares on the vesting date. Any capital gain or loss will be long-term if the participant held the shares for more than one year and otherwise will be short-term.

Other Stock-Based Awards. The tax consequences associated with any other stock-based award granted under the 2019 Plan will vary depending on the specific terms of such award. Among the relevant factors are whether or not the award has a readily ascertainable fair market value, whether or not the award is subject to forfeiture provisions or restrictions on transfer, the nature of the property to be received by the participant under the award and the participant's holding period and tax basis for the award or underlying common stock.

Tax Consequences to us. There will be no tax consequences to us with respect to awards made under the 2019 Plan, except that we will be entitled to a deduction when a participant has compensation income (or upon a disqualifying disposition of an incentive stock option).

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

Relationship with Recro

Prior to the completion of the Separation, all of our outstanding shares of common stock are owned by Recro. Following the completion of the Separation, Recro will no longer own any shares of our common stock. See "Risk Factors—Risks Related to the Separation" and "The Separation and Distribution."

Following the Distribution, Baudax Bio and Recro will operate separately, each as an independent public company. In connection with the Separation, we and Recro have entered or will enter into certain agreements that will affect the separation of our business from Recro and govern our relationship with Recro after the Separation. The following is a summary of the terms of the material agreements that we intend to enter into with Recro prior to the completion of the Separation, which will be filed as exhibits in a subsequent amendment to the registration statement on Form 10 of which this information statement is a part. These summaries set forth the terms of the agreements that we believe are material and are qualified in their entirety by reference to the full text of such agreements.

Changes to these agreements, some of which may be material, may be made prior to the Distribution.

Agreements with Recro

Separation Agreement

We intend to enter into the Separation Agreement with Recro prior to the Distribution. The Separation Agreement will set forth our agreements with Recro regarding the principal actions to be taken in connection with the Separation, including the Distribution. The Separation Agreement will identify assets to be transferred, liabilities to be assumed and contracts to be assigned to each of Baudax Bio and Recro as part of the Separation, and it will provide for when and how these transfers, assumptions and assignments will occur.

Transfer of Assets and Assumption of Liabilities. The Separation Agreement will identify assets to be transferred, liabilities to be assumed and contracts to be assigned to each of Recro and us, and it will provide for the transfer of such assets, assumption of such liabilities and assignment of such contracts upon the execution of the Separation Agreement to the extent such transfers and assignments have not already occurred. The Separation Agreement is intended to provide for those transfers of assets and assumptions of liabilities that are necessary so that after the Distribution we and Recro have the assets necessary to operate our respective businesses and retain or assume the liabilities related to those assets. The Separation Agreement will also provide for the settlement or extinguishment of certain liabilities and other obligations between us and Recro.

The allocation of liabilities with respect to taxes, except for payroll tax withholding and reporting and other tax matters expressly covered by the employee matters agreement, are solely covered by the tax matters agreement.

Further Assurances. Each party will agree to use commercially reasonable efforts to take or to cause to be taken all actions, and to do, or to cause to be done, all things reasonably necessary under applicable law or contractual obligations to consummate and make effective the transactions contemplated by the Separation Agreement and other transaction agreements.

The Distribution. The Separation Agreement will govern the rights and obligations of the parties with respect to the Distribution and certain actions that must occur prior to the Distribution. Recro will cause its agent to distribute to holders of shares of Recro's common stock as of the record date for the Distribution all of the issued and outstanding shares of our common stock. Recro will have the sole and absolute discretion to determine (and change) the terms of, and whether to proceed with, the Distribution and, to the extent it determines to so proceed, to determine the date of the Distribution.

The Capital Contribution. The Separation Agreement will set forth the terms of the $19 million capital contribution from Recro to Baudax Bio prior to or upon completion of the Distribution.

Conditions. The Separation Agreement will provide that the Distribution is subject to several conditions that must be satisfied (or waived by Recro, in its sole and absolute discretion). For further information regarding these conditions, see "The Separation and Distribution— Conditions to the Distribution."

Indemnification. The Separation Agreement will provide for releases, with respect to pre-Distribution claims, and cross-indemnities, with respect to post-Distribution claims, that, except as otherwise provided in the Separation Agreement, are principally designed to place financial responsibility for the obligations and liabilities allocated to us under the Separation Agreement with us and financial responsibility for the obligations and liabilities allocated to Recro under the Separation Agreement with Recro. The Separation Agreement will also specify procedures with respect to claims subject to indemnification and related matters. Indemnification with respect to taxes will be governed by the tax matters agreement described below.

Term/Termination. Prior to the Distribution, Recro will have the unilateral right to terminate, modify or amend the terms of the Separation Agreement and amend, modify or abandon the Distribution. After the effective time of the Distribution, the Separation Agreement may only be terminated, modified or amended with the prior written consent of both Recro and us.

Other Matters Governed by the Separation Agreement. Other matters governed by the Separation Agreement include, without limitation, access to financial and other information, insurance, confidentiality and access to and provision of records.

Transitional Services Agreement

We intend to enter into a transition services agreement with Recro prior to the Distribution that will set for the terms of which we will provide Recro, and Recro will provide to us, on a transitional basis, certain services or functions that the companies historically have shared. Transition services will include various corporate, administrative and information technology services. The transition services agreement will provide for the provision of specified transition services for an initial term of twelve months and will thereafter automatically renew for subsequent twelve month periods unless one of the parties provides three months' written notice of its intent to not renew the agreement.

Tax Matters Agreement

We intend to enter into a tax matters agreement with Recro prior to the Distribution which will generally govern Recro's and our respective rights, responsibilities and obligations after the Distribution to pay taxes for any tax period ending on or before the distribution date, as well as tax periods beginning before and ending after the distribution date. In addition, the tax matters agreement will address the allocation of liability for taxes, if any, that are incurred as a result of the Restructuring.

Employee Matters Agreement

We intend to enter into an employee matters agreement with Recro prior to the Distribution that will govern each company's respective compensation and benefit obligations with respect to current and former employees, directors and consultants. The employee matters agreement will set forth general principals relating to employee matters in connection with the Separation, such as the assignment of employees, the assumption and retention of liabilities and related assets, expense reimbursements, workers' compensation, leaves of absence, the provision of comparable benefits, employee service credit, the sharing of employee information and the duplication or acceleration of benefits.

The employee matters agreement generally will allocate liabilities and responsibilities relating to employee compensation and benefit plans and programs with Recro retaining liabilities (both pre- and post-Distribution) and responsibilities with respect to Recro employees who remain with Recro and with us assuming liabilities and

responsibilities with respect to Recro employees who will transfer to us in connection with the Separation. The employee matters agreement will provide that, following transfer of employment to us, our active employees generally will no longer participate in benefit plans sponsored or maintained by Recro and will commence participation in our benefit plans.

The employee matters agreement will also provide that (i) the Distribution does not constitute a change in control under Recro's plans, programs, agreements or arrangements and (ii) the Distribution and the assignment, transfer or continuation of employment of employees with another entity will not constitute a severance event under applicable plans, programs, agreements or arrangement.

Related Party Transactions Policy

In connection with the Separation, we plan to adopt a related party transactions policy that will govern the review and approval of related party transactions following the Separation. Pursuant to this policy, if we want to enter into a transaction with a related party or an affiliate of a related party, our audit committee will review the proposed transaction to determine, based on applicable rules of Nasdaq and the SEC, whether such transaction requires pre-approval by our audit committee or our board of directors. If pre-approval is required, the proposed transaction will be reviewed at the next regular or special meeting of our audit committee or our board of directors, as applicable. We may not enter into a related party transaction unless our audit committee has specifically confirmed in writing that either no further reviews are necessary or that all requisite corporate reviews have been obtained.

Each of the agreements between us and Recro and its subsidiaries that have been entered into prior to the completion of the Separation, and any transactions contemplated thereby, will be deemed to be approved and not subject to the terms of such policy.

SECURITY OWNERSHIP BY CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

Prior to the Distribution, all of the outstanding shares of our common stock will be owned beneficially and of record by Recro. The following tables set forth information with respect to the expected beneficial ownership of our common stock immediately following the Distribution by: (i) each person who we believe will be a beneficial owner of more than five percent of our common stock, (ii) each of our expected directors and named executive officers and (iii) all of our expected directors and executive officers as a group. Except as noted below, we based the share amounts on each person's beneficial ownership of Recro common stock as of October 22, 2019. Immediately following the Distribution, we estimate that 9,078,700 shares of our common stock will be issued and outstanding based on the number of shares of Recro common stock outstanding as of October 31, 2019. The actual number of our outstanding shares of our common stock issued in the Distribution will be determined on November 15, 2019, the record date. Unless otherwise indicated, the address of each beneficial owner is in care of Recro Pharma, Inc., 490 Lapp Road, Malvern, PA 19355.

Security Ownership of Certain Beneficial Owners

Based solely on the information publicly available reporting beneficial ownership of Recro common stock, we anticipate the following shareholders will beneficially own more than five percent of our common stock following the Distribution.

Name of Beneficial Owner	Number of Shares of Our Common Stock	Percent of Shares Outstanding
SCP Vitalife Partners II, L.P.(1) 1200 Liberty Ridge Drive Suite 300 Wayne, PA 19087	869,160	9.6%
SCP Vitalife Partners (Israel) II, L.P.(1) 15 Hatidhar St. P.O. Box 2138 Raanana 4366517 Israel	290,422	3.2%
Broadfin Capital, LLC(2) 300 Park Avenue New York, NY 10022	819,210	9.0%
Newtyn Management, LLC(3) 405 Park Avenue, Suite 1104, New York, New York 10022	640,000	7.0%

(1) Based upon information set forth in the Schedule 13D filed on March 21, 2014 and information set forth in Form 4s filed through October 22, 2019 by SCP Vitalife Partners II, L.P., or SCP Vitalife Partners, SCP Vitalife Partners (Israel) II, L.P., or SCP Vitalife Israel, SCP Vitalife II Associates, L.P., or SCP Vitalife Associates, SCP Vitalife II GP, LTD (SCP Vitalife GP), Winston J. Churchill, Jeffrey Dykan, and Wayne B. Weisman. SCP Vitalife Partners beneficially owns 2,172,900 shares of Recro common stock and SCP Vitalife Israel beneficially owns 726,055 shares of Recro common stock. As the general partner of SCP Vitalife Partners and SCP Vitalife Israel, SCP Vitalife Associates may be deemed to beneficially own 2,898,955 shares of Recro common stock. As the general partner of SCP Vitalife Associates, SCP Vitalife GP may be deemed to beneficially own 2,898,955 shares of Recro common stock. As directors of SCP Vitalife GP, Messrs. Churchill, Dykan and Weisman may be deemed to beneficially own 2,898,955 shares of Recro common stock. SCP Vitalife Partners shares dispositive and voting power with respect to the 2,172,900 shares of Recro common stock owned. SCP Vitalife Israel shares dispositive and voting power with respect to the 726,055 shares of Recro common stock owned. SCP Vitalife Associates, SCP Vitalife GP, Messrs. Churchill, Dykan and Weisman have shared dispositive and voting power with respect to the aggregate 2,898,955 shares of common stock owned by SCP Vitalife Partners and SCP Vitalife Israel.

(2) Based upon information set forth in the Schedule 13G/A and Form 4s filed on May 24, 2018 by Broadfin, Broadfin Healthcare Master Fund, Ltd., or Master Fund, and Kevin Kotler. Broadfin, Master Fund and Mr. Kotler have shared voting and dispositive power over 2,048,025 shares of Recro common stock. Broadfin and Mr. Kotler each disclaim beneficial ownership of the shares reported herein except to the extent of its or his pecuniary interest therein.

(3) Based upon information set forth in the Schedule 13G filed on February 14, 2019, by Newtyn Management LLC. Newtyn Management, LLC is the investment manager to Newtyn Partners, LP, or NP, and Newtyn TE Partners, LP, or NTE. Newtyn Management LLC., as the investment manager to NP and NTE, has sole power to direct the vote and the sole power to direct the disposition of the 1,600,000 shares of Recro common stock held in the aggregate by NP and NTE.

Security Ownership of Directors and Executive Officers

The following table provides information regarding beneficial ownership of our named executive officers, our expected directors and all of our expected directors and executive officers as a group.

Name of Beneficial Owner	Number of Shares of Our Common Stock	Percent of Shares Outstanding
Gerri Henwood(5)	99,256	1.1%
Ryan Lake	12,611	*
Alfred Altomari	8,382	*
William L. Ashton	7,782	*
Winston J. Churchill(6)(7)	1,167,364	12.9%
Wayne B. Weisman(8)	1,170,164	12.9%
Directors and Officers as a Group (6 persons)	1,305,977	14.4%

* Less than one percent

(5) Includes 20,000 shares of our common stock that will be held by Ms. Henwood's husband, Thomas Henwood following the Distribution. As spouses, Mr. and Ms. Henwood may be deemed to beneficially own the shares of our common stock that are held by the other spouse. Mr. and Ms. Henwood disclaim beneficial ownership of the shares of our common stock that are held by the other spouse.

(6) Mr. Churchill has shared voting and investment power with respect to 1,159,582 shares of our common stock that will be held by SCP Vitalife following the Distribution, of which he is a partner.

(7) Mr. Churchill disclaims beneficial ownership of 33,465 shares of our common stock that are will be held by the Sharbaugh Trust for the benefit of his son following the Distribution.

(8) Mr. Weisman has shared voting and investment power with respect to 1,159,582 shares of our common stock that will be held by SCP Vitalife following the Distribution, of which he is a partner.

THE SEPARATION AND DISTRIBUTION

Overview

In August 2019, Recro announced its plans to separate its acute care business from its CDMO business through a pro rata distribution of Baudax Bio common stock to shareholders of Recro. The Distribution generally will be taxable to Recro shareholders for U.S. federal income tax purposes.

In furtherance of this plan, on November 4, 2019, the Recro Board approved the distribution of all of the issued and outstanding shares of Baudax Bio common stock on the basis of one share of Baudax Bio common stock for every two and one-half shares of Recro common stock issued and outstanding as of the close of business on November 15, 2019, the record date for the Distribution. As a result of the Distribution, Baudax Bio and Recro will become two independent companies.

On November 21, 2019, the distribution date, each Recro shareholder will receive one share of Baudax Bio common stock for every two and one-half shares of Recro common stock held of record at the close of business on the record date, as described below. Registered shareholders will receive cash in lieu of any fractional shares of Baudax Bio common stock that they would have received as a result of the application of the distribution ratio. Shareholders will not be required to make any payment, surrender or exchange their Recro common stock or take any other action to receive shares of Baudax Bio common stock in the Distribution.

The Distribution as described in this information statement is subject to the satisfaction or waiver of certain conditions. For a more detailed description of these conditions, see this section under "—Conditions to the Distribution."

Reasons for the Separation

The Recro Board determined that separating the acute care business from Recro would be in the best interests of Recro and its shareholders and approved the plan of separation. A wide variety of factors were considered by the Recro Board in evaluating the Separation. Among other things, the Recro Board considered the following potential benefits of the Separation:

- the Separation will allow each business to pursue its own operational and strategic priorities and more quickly respond to trends, developments and opportunities in its respective markets;
- the Separation will give each business opportunity and flexibility by pursuing its own investment, capital allocation and growth strategies consistent with its long-term objectives;
- the Separation will create two separate and distinct management teams focused on each business's unique strategic priorities, target markets and corporate development opportunities;
- the Separation will enable the boards and management teams of each business to better align corporate performance goals with the specific vision, strategy and objectives of each business; and
- the Separation will allow investors to separately value each business based on the unique merits, performance and future prospects of each business, providing investors with two distinct investment opportunities.

The Recro Board also considered a number of potentially negative factors in evaluating the Separation, including the following factors impacting Baudax Bio:

- Recro and Baudax Bio may not achieve the anticipated benefits of the Separation for a variety of reasons, including: (i) the Separation will require significant amounts of management's time

and effort, which may divert management's attention from operating and growing the Recro and Baudax Bio businesses and (ii) following the Separation, each business will be less diversified than Recro's business prior to the Separation;

- costs and liabilities that were less significant to Recro as a whole will be more significant for Baudax Bio as a standalone company, and after the Distribution, as a separate, independent entity, Baudax Bio may be unable to obtain goods, services and technologies at prices or on terms as favorable as those Recro obtained prior to the Distribution;

- Baudax Bio will incur costs in connection with the transition to being a standalone public company that will include establishment of accounting, tax, auditing, legal and other professional services costs, recruiting and relocation costs associated with hiring personnel new to Baudax Bio and costs to separate information systems; and

- the trading prices of Baudax Bio and Recro common stock following the Separation, and whether the combined market value of shares of Baudax Bio common stock and shares of Recro common stock will be less than, equal to, or greater than the market value of shares of Recro common stock prior to the Separation, cannot be predicted with certainty.

The Recro Board concluded that the potential benefits of the Separation outweighed these factors. However, neither Recro nor Baudax Bio can assure you that, following the Separation, any of the benefits described above or otherwise will be realized to the extent anticipated or at all. For more information on the risks involved in the separation process, see "Risk Factors—Risks Related to the Separation."

Contribution of Acute Care Business

As part of the plan to create two independent public companies, Recro plans to transfer the assets and liabilities of the acute care business to Baudax Bio prior to the Distribution through an internal reorganization.

When and How You Will Receive the Distribution

With the assistance of the distribution agent, Recro expects to distribute Baudax Bio common stock on November 21, 2019, the distribution date, to all holders of outstanding Recro common stock as of the close of business on November 15, 2019, the record date. Broadridge will serve as the distribution agent in connection with the Distribution.

If you own Recro common stock as of the close of business on the record date, Baudax Bio common stock that you are entitled to receive in the Distribution will be issued electronically, as of the distribution date, to you in direct registration form or to your bank or brokerage firm on your behalf. If you are a registered holder, the distribution agent or the transfer agent will then mail you a direct registration account statement that reflects your shares of Baudax Bio common stock. "Direct registration form" refers to a method of recording share ownership when no physical share certificates are issued to shareholders, as is the case in this Distribution.

Commencing on or shortly after the distribution date, if you hold physical share certificates that represent your Recro common stock and you are the registered holder of the shares represented by those certificates, the distribution agent will mail to you an account statement that indicates the number of shares of Baudax Bio common stock that have been registered in book-entry form in your name, and the distribution agent will mail you a check for any cash in lieu of fractional shares you are entitled to receive. If you sell Recro common stock in the "regular way" market up to and including the distribution date, you will be selling your right to receive shares of Baudax Bio common stock in the Distribution.

Most Recro shareholders hold their common stock through a bank or brokerage firm. In such cases, the bank or brokerage firm would be said to hold the shares in "street name" and ownership would be recorded on the bank

or brokerage firm's books. If you hold your Recro common stock through a bank or brokerage firm, your bank or brokerage firm will credit your account for the Baudax Bio common stock that you are entitled to receive in the Distribution. Your bank or brokerage firm will receive, on your behalf, your pro rata share of the aggregate net cash proceeds of the sales and will distribute to your account your share of such proceeds. If you have any questions concerning the mechanics of having shares held in "street name," please contact your bank or brokerage firm.

Results of the Distribution

After the Separation, Baudax Bio will be an independent company. The actual number of shares to be distributed will be determined on November 15, 2019, the record date for the Distribution, and will reflect any exercise of Recro options between the date the Recro Board declares the Distribution and the record date for the Distribution. The Distribution will not affect the number of outstanding shares of Recro common stock or any rights of Recro's shareholders. Recro will not distribute any fractional shares of Baudax Bio common stock.

Prior to the Distribution, Baudax Bio intends to enter into a Separation Agreement and certain other agreements with Recro, including a tax matters agreement, an employee matters agreement, and a transition services agreement under which Baudax Bio and Recro will temporarily provide certain services to each other. These agreements will provide for the separation between Recro and Baudax Bio of the assets, liabilities and obligations (including employee benefits, intellectual property and tax-related assets and liabilities) attributable to periods prior to, at and after the Distribution and will govern the relationship between Recro and Baudax Bio after the Separation. For a more detailed description of these agreements, see "Certain Relationships and Related Person Transactions— Agreements with Recro."

The Number of Shares of Baudax Bio Common Stock You Will Receive

For every two and one-half shares of Recro common stock that you own at the close of business on November 15, 2019, the record date, you will receive one share of Baudax Bio common stock on the distribution date. Recro will not distribute any fractional shares of Baudax Bio common stock to its shareholders. Instead, the distribution agent will aggregate fractional shares into whole shares, sell the whole shares in the open market at prevailing market prices and distribute the aggregate cash proceeds (net of discounts and commissions) of the sales pro rata (based on the fractional share such holder would otherwise have been entitled to receive) to each holder who otherwise would have been entitled to receive a fractional share in the Distribution. The distribution agent, in its sole discretion, without any influence by Recro or Baudax Bio, will determine when, how, through which broker-dealer and at what price to sell the whole shares. Broadridge is not an affiliate of either Recro or Baudax Bio. Any broker-dealer used by the transfer agent will not be an affiliate of either Recro or Baudax Bio. Neither Baudax Bio nor Recro will be able to guarantee any minimum sale price in connection with the sale of these shares. Recipients of cash in lieu of fractional shares will not be entitled to any interest on the amounts of payment made in lieu of fractional shares.

The aggregate net cash proceeds distributed to Recro shareholders in lieu of fractional shares will be taxable for U.S. federal income tax purposes. See "Material U.S. Federal Income Tax Consequences" for an explanation of the material U.S. federal income tax consequences of the Distribution. If you hold physical certificates for Recro common stock and are the record holder, you will receive a check from the distribution agent in an amount equal to your pro rata share of the aggregate net cash proceeds of the sales. Baudax Bio estimates that it will take approximately two weeks from the distribution date for the distribution agent to complete the distributions of the aggregate net cash proceeds. If you hold your Recro common stock through a bank or brokerage firm, your bank or brokerage firm will receive, on your behalf, your pro rata share of the aggregate net cash proceeds of the sales and will distribute to your account your share of such proceeds.

Transferability of Shares You Receive

Shares of Baudax Bio common stock distributed to holders through the Distribution will be transferable without registration under the Securities Act, except for shares received by persons who may be deemed to be

Baudax Bio affiliates. Persons who may be deemed to be Baudax Bio affiliates after the Distribution generally include individuals or entities that control, are controlled by or are under common control with Baudax Bio, which may include certain of Baudax Bio executive officers, directors or principal shareholders. Securities held by Baudax Bio affiliates will be subject to resale restrictions under the Securities Act. Baudax Bio affiliates will be permitted to sell shares of Baudax Bio common stock only pursuant to an effective registration statement or an exemption from the registration requirements of the Securities Act, such as the exemption afforded by Rule 144 promulgated under the Securities Act.

Market for Baudax Bio Common Stock

There is currently no public trading market for Baudax Bio common stock. Baudax Bio has applied for listing on the Nasdaq Capital Market under the symbol "BXRX." Baudax Bio has not and will not set the initial price of its common stock. The initial price will be established by the public markets.

Baudax Bio cannot predict the price at which its common stock will trade after the Distribution. In fact, the combined trading prices, after the Distribution, of the shares of Baudax Bio common stock that each Recro shareholder will receive in the Distribution and Recro common stock held at the record date may not equal the "regular way" trading price of a share of Recro common stock immediately prior to the Distribution. The price at which Baudax Bio common stock trades may fluctuate significantly, particularly until an orderly public market develops. Trading prices for Baudax Bio common stock will be determined in the public markets and may be influenced by many factors. See "Risk Factors—Risks Related to Ownership of Our Common Stock."

Trading Between the Record Date and Distribution Date

Beginning on or shortly before the record date and continuing up to and including through the distribution date, we expect that there will be two markets in Recro common stock: a "regular way" market and an "ex-distribution" market. Shares of Recro common stock that trade on the "regular way" market will trade with an entitlement to Baudax Bio common stock distributed pursuant to the Separation. Shares of Recro common stock that trade on the "ex-distribution" market will trade without an entitlement to Baudax Bio common stock distributed pursuant to the Distribution. Therefore, if you sell Recro common stock in the "regular way" market up to and including through the distribution date, you will be selling your right to receive Baudax Bio common stock in the Distribution. If you own Recro common stock at the close of business on the record date and sell those shares on the "ex-distribution" market up to and including through the distribution date, you will receive the shares of Recro common stock that you are entitled to receive pursuant to your ownership as of the record date of Recro common stock.

Furthermore, we anticipate that trading in our common stock will begin on a "when issued" basis on or shortly before the record date for the Distribution and will continue up to and including the distribution date. "When issued" trading in the context of a separation refers to a sale or purchase made conditionally on or before the distribution date because the securities of the separated entity have not yet been distributed. The "when issued" trading market will be a market for Baudax Bio common stock that will be distributed to holders of Recro common stock on the distribution date. If you owned Recro common stock at the close of business on the record date, you would be entitled to Baudax Bio common stock distributed pursuant to the Distribution. You may trade this entitlement to shares of Baudax Bio common stock, without Recro common stock you own, on the "when issued" market. On the first trading day following the distribution date, "when issued" trading with respect to Baudax Bio common stock will end, and "regular way" trading will begin.

Conditions to the Distribution

We expect that the Distribution will be effective at 12:01 a.m., Eastern Time, on November 21, 2019, the distribution date, provided that certain conditions shall have been satisfied or waived by Recro in its sole and absolute discretion:

- the SEC declaring effective Baudax Bio's registration statement on Form 10 of which this information statement forms a part, and no stop order relating to the registration statement shall be in effect and no proceedings for such purpose shall be pending before or threatened by the SEC, and the distribution of the information statement (or the Notice of Internet Availability of the Information Statement) to all holders of record of shares of Recro common stock as of the close of business on the record date;

- the receipt and continuing validity of an opinion from an independent appraisal firm to the Recro Board, that is in form and substance acceptable to Recro in its sole and absolute discretion, confirming the solvency of Baudax Bio after the Distribution;

- the shares of our common stock to be delivered in the Distribution shall have been approved for listing on the Nasdaq Capital Market, subject to official notice of issuance;

- all permits, registrations and consents required under the securities or blue sky laws of states or other political subdivisions of the United States or of other foreign jurisdictions in connection with the Distribution shall have been received;

- no order, injunction, or decree issued by any court of competent jurisdiction or other legal restraint or prohibition preventing the consummation of the Distribution or any of the related transactions shall be pending, threatened, issued or in effect;

- the Recro Board shall have declared the Distribution and approved all related transactions (and such declaration and approval not having been withdrawn);

- Baudax Bio shall have executed and delivered the transaction agreements relating to the Separation; and

- no other event or development existing or having occurred that, in the sole and absolute judgment of the Recro Board, makes it inadvisable to effect the Distribution and other related transactions.

Recro and Baudax Bio cannot assure you that any or all of these conditions will be met and, to the extent permissible under applicable law, Recro in its sole discretion may waive any of the conditions to the Distribution. In addition, Recro will have the sole and absolute discretion to determine (and change) the terms of, and whether to proceed with, the Distribution and, to the extent it determines to so proceed, to determine the record date for the Distribution and the distribution date and the distribution ratio. Recro does not intend to notify its shareholders of any modifications to the terms of the Separation that, in the judgment of its board of directors, are not material. For example, the Recro Board might consider changes to the distribution ratio, the assets to be contributed or the liabilities to be assumed in the Separation as material changes. To the extent that the Recro Board determines that any modifications by Recro materially change the material terms of the Distribution or to abandon the Distribution, Recro will notify Recro shareholders in a manner reasonably calculated to inform them about the modification as may be required by law, by, for example, publishing a press release, filing a Current Report on Form 8-K, or circulating a supplement to this information statement.

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES

General

The following describes certain United States federal income tax consequences relevant to the Distribution for U.S. Holders and Non-U.S. Holders (as defined below). This discussion is based upon the Internal Revenue Code of 1986, as amended, or the Code, existing and proposed United States Treasury regulations, administrative pronouncements and judicial decisions, all as in effect on the date hereof and changes to which could materially affect the tax consequences described herein and could be made on a retroactive basis.

This discussion deals only with Recro shares that are held as capital assets and does not deal with all tax consequences that may be relevant to holders in light of their particular circumstances or to holders subject to special tax rules (including, without limitation, dealers in securities or commodities, traders in securities that elect to mark their holdings to market, financial institutions, regulated investment companies, real estate investment trusts, U.S. expatriates, U.S. Holders (as defined below) whose functional currency is not the United States dollar, insurance companies, tax-exempt organizations, partnerships or other pass through entities and investors therein or persons who hold shares as part of a hedging, conversion or constructive sale transaction or as a position in a straddle). In particular, different rules may apply to shares acquired as compensation. This discussion does not address the consequences of the alternative minimum tax, Medicare contribution tax, or any state, local or foreign tax consequences of participating in the Distribution. Holders of shares should consult their tax advisors as to the particular consequences to them of participation in the Distribution.

As used in this section, a "U.S. Holder" means an owner of shares that is for United States federal income tax purposes: (a) an individual who is a citizen or resident of the United States, (b) a corporation (or any other entity treated as a corporation for United States federal income tax purposes) created or organized under the laws of the United States, any state thereof or the District of Columbia, (c) an estate the income of which is subject to United States federal income taxation regardless of its source, or (d) a trust if it (x) is subject to the primary supervision of a court within the United States, and one or more United States persons have the authority to control all substantial decisions of the trust or (y) has a valid election in effect under applicable United States Treasury regulations to be treated as a United States person.

As used herein, a "Non-U.S. Holder" means a beneficial owner of shares that is neither a U.S. Holder nor a partnership (or any other entity treated as a partnership for United States federal income tax purposes).

If a partnership holds shares, the tax treatment of a partner will generally depend upon the status of the partner and the activities of the partnership. Holders that are partners of a partnership holding shares should consult their own tax advisors.

U.S. Holders.

It is our expectation that the Distribution by Recro of the Baudax Bio shares is not a tax free transaction. Each U.S. Holder will generally be treated as having received a distribution in an amount equal to the fair market value of the Baudax Bio stock received in the Distribution (including any fractional share that is deemed to be received by and sold on behalf of the U.S. Holder). The Distribution will be (a) taxable as a dividend to the extent of the U.S. Holder's allocable share of Recro's current and accumulated earnings, then (b) a reduction in the U.S. Holder's tax basis in the Recro stock (but not below zero), to the extent the Distribution exceeds the amount in (a), and then (c) gain from the sale or exchange of Recro common stock to the extent the Distribution exceeds the amounts in (a) and (b). Provided certain holding period requirements are satisfied, non-corporate U.S. Holders generally will be subject to United States federal income tax at a reduced rate on the gross amount treated as dividends. To the extent that the Distribution is received by a U.S. Holder that is a corporation for tax purposes, it will be eligible for a dividends-received deduction to the extent the amount received is described in (a) in the preceding sentence (subject to applicable limitations), except that it may be subject to the "extraordinary

dividend" provisions of the Code in which case the dividend will not be eligible for the dividends received deduction and corporate U.S. Holders may be subject to adverse tax consequences.

Recro believes that it has no accumulated earnings and profits, and, based on current projections, it does not anticipate having current earnings and profits. That is, however, subject to finalization and it is possible that Recro may have current earnings and profits. Current earnings and profits for 2019 will not be finally determined until after December 31, 2019. Current earnings and profits will be reported on the IRS Form 1099-DIV that will be filed in 2020 for the relevant U.S. Holders.

Under the United States federal income tax backup withholding rules, 24% of the value of the Distribution payable to a U.S. Holder or other U.S. payee, pursuant to the Distribution, must be withheld and remitted to the United States Treasury, unless the U.S. Holder or other U.S. payee provides his or her correct taxpayer identification number (employer identification number or Social Security number) to the distribution agent, certifies as to no loss of exemption from backup withholding and complies with applicable requirements of the backup withholding rules, or such U.S. Holder or other U.S. payee is otherwise exempt from backup withholding. Therefore, unless an exemption exists and is proven in a manner satisfactory to the distribution agent, each U.S. Holder should complete and sign the IRS Form W-9 included as part of the Letter of Transmittal so as to provide the information and certification necessary to avoid backup withholding. Certain U.S. Holders (including, among others, corporations) are not subject to these backup withholding requirements.

U.S. Holders are urged to consult their own tax advisors regarding the application of United States federal income, state and local tax consequences of the receipt of the Distribution.

Non-U.S. Holders.

A Non-U.S. Holder is subject to tax to the extent the Distribution is supported by the allocable share of current or accumulated earnings and profits of Recro. Because, as described above, we will not know the current earnings and profits before the close of 2019, the Distribution agent will withhold United States federal income taxes equal to 30% of the fair market value of the Distributions payable to a Non-U.S. Holder or his or her agent unless the distribution agent determines that a reduced rate of withholding is available. The withholding would be satisfied by withholding and selling a portion of the Baudax Bio shares otherwise deliverable to the Non-U.S. Holder, or withholding from any cash distributions otherwise payable to the Non-U.S. Holder.

Generally, to establish an applicable exemption from, or reduced rate of, United States federal withholding tax, a Non-U.S. Holder must deliver to the distribution agent either (i) IRS Form W-8BEN or W-8BEN-E, as applicable (or other acceptable evidence under Treasury regulations) in which the holder certifies that it is eligible for a lower tax treaty rate with respect to dividends on the Recro shares or (ii) an IRS Form W-8ECI in which the holder certifies that amounts it receives are effectively connected with the conduct of a trade or business within the United States (and, if required by a tax treaty, are attributable to a permanent establishment that it maintains within the United States). The distribution agent may generally determine a holder's status as a Non-U.S. Holder and eligibility for a reduced rate of, or exemption from, withholding by reference to any outstanding certificates or statements concerning eligibility for a reduced rate of, or exemption from, withholding (e.g., an applicable IRS Form W-8) unless facts and circumstances indicate that such reliance is not warranted. A Non-U.S. Holder may be eligible to obtain a refund of all or a portion of any tax withheld if there are no current earnings and profits for 2019. The IRS Form 1042 filed with the IRS and the Non-U.S. Holder for 2019 will identify the amount of the Distribution that is supported by current earnings and profits. Backup withholding generally will not apply to amounts paid to a Non-U.S. Holder that provides the distribution agent with an applicable IRS Form W-8 (or other acceptable certification).

Non-U.S. Holders are urged to consult their own tax advisors regarding the application of United States federal income tax withholding, including eligibility for a withholding tax reduction or exemption, and the refund procedure.

Under Sections 1471 through 1474 of the Code, commonly referred to as "FATCA," and administrative guidance, a United States federal withholding tax of 30% generally will be imposed on dividends that are paid to "foreign financial institutions" and "non-financial foreign entities" (as specifically defined under these rules) unless specified requirements are met. Because, as discussed above, the distribution agent will treat amounts paid to Non-U.S. Holders as dividends for United States federal income tax purposes, such amounts may also be subject to withholding under FATCA if such requirements are not met. In such case, any withholding under FATCA may be credited against, and therefore reduce, any 30% withholding tax on dividend distributions as discussed above. Non-U.S. Holders should consult with their tax advisors regarding the possible implications of these rules on their receipt of the Distribution.

DESCRIPTION OF BAUDAX BIO'S CAPITAL STOCK

General

The following description of our capital stock and provisions of our amended and restated articles of incorporation, amended and restated bylaws and the PBCL are summaries and are qualified in their entirety by reference to our amended and restated articles of incorporation and the amended and restated bylaws that will be in effect at the closing of the Separation, which will be filed as exhibits to the Form 10 of which the information statement is part. The description of our capital stock reflects changes to our capital structure that will occur upon the closing of the Separation.

Upon the closing of the Separation and the filing of our amended and restated articles of incorporation, our authorized capital stock will consist of 100,000,000 million shares of our common stock and 10,000,000 shares of our preferred stock, to be designated from time to time by our board of directors.

As of June 30, 2019, we had 100 shares of common stock and no shares of preferred stock issued and outstanding and had one shareholder of record.

Common Stock

Holders of our common stock will be entitled to one vote for each share held on all matters submitted to a vote of shareholders, including the election of directors, and will not have cumulative voting rights. Accordingly, the holders of a majority of the outstanding shares of common stock in person or represented by proxies in any election of directors will be able to elect all of the directors standing for election, if they so choose, other than any directors that holders of any preferred stock that we may issue may be entitled to elect.

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

Holders of our common stock will have no preemptive, subscription, redemption or conversion rights. All outstanding shares of our common stock will be, duly authorized, validly issued, fully paid and non-assessable. The rights and privileges of the holders of the common stock will be subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

We have applied to have our common stock listed on the Nasdaq Capital Market under the trading symbol "BXRX."

Preferred Stock

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

among other things, have the effect of delaying, deferring or preventing a change in our control and may adversely affect the market price of the common stock and the voting and other rights of the holders of our common stock. We have no current plans to issue any shares of preferred stock.

Anti-takeover Effects of Our Amended and Restated Articles of Incorporation and Our Amended and Restated Bylaws

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

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

Our amended and restated articles of incorporation also provide that, unless we consent in writing to the selection of an alternative forum, a state or federal court located within the County of Philadelphia in the Commonwealth of Pennsylvania will be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of our company, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees or our shareholders, (iii) any action asserting a claim arising pursuant to any provision of the PBCL, or (iv) any action asserting a claim peculiar to the relationships among or between our company and our officers, directors and shareholders.

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

Anti-Takeover Provisions under Pennsylvania Law

Pennsylvania Anti-Takeover Law

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

- we may not engage in a business combination with an "interested shareholder," generally defined as a holder of 20% of a corporation's voting stock, during the five-year period after the interested shareholder became such except under certain specified circumstances;

- holders of our common stock may object to a "control transaction" involving us (a control transaction is defined as the acquisition by a person or group of persons acting in concert of at least 20% of the outstanding voting stock of a corporation), and demand that they be paid a cash payment for the "fair value" of their shares from the "controlling person or group";

- holders of "control shares" will not be entitled to voting rights with respect to any shares in excess of specified thresholds, including 20% voting control, until the voting rights associated with such shares are restored by the affirmative vote of a majority of disinterested shares and the outstanding voting shares of the Company; and

- any "profit," as defined, realized by any person or group who is or was a "controlling person or group" with respect to us from the disposition of any equity securities of within 18 months after the person or group became a "controlling person or group" shall belong to and be recoverable by us.

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

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

Transfer Agent and Registrar

The transfer agent and registrar for our common stock will be Broadridge.

Indemnification of Directors and Officers

Our amended and restated bylaws provide that, to the fullest extent permitted by Pennsylvania law, any of our officers or directors who was or is a party or is threatened to be made a party to, any threatened, or pending or completed action, suit or proceeding, whether civil, criminal, administrative, or investigative, by reason of fact that he/she is or was acting as our representative, or is or was serving at the request or for our benefit as a director, officer, employee, agent, partner, or fiduciary of, or in any other capacity for, another corporation or any partnership, joint venture, trust, employee benefit plan or other enterprise, shall be indemnified by us for any losses or expenses (including attorneys' fees) reasonably incurred in connection with service as our officer or director, if the director or officer acted in good faith and in a manner he reasonably believed to be in, or not opposed to, our best interests and, with respect to any criminal proceeding, had no reasonable cause to believe his conduct was unlawful.

Pennsylvania law requires that to the extent that one of our directors or officers has been successful on the merits or otherwise in defense of any action or proceeding referred to above or in defense of any claim, issue or matter therein, that director or officer shall be indemnified against expenses (including attorney fees) actually and reasonably incurred by him in connection therewith. Our amended and restated bylaws further provide that the right to indemnification includes the right to have expenses reasonably incurred in defending any action or proceeding described above paid by us in advance of the final disposition of the action or proceeding to the fullest extent permitted by Pennsylvania law; provided that, if required by Pennsylvania law, the payment of such

expenses incurred in advance of the final disposition of the action or proceeding shall be made only upon delivery to us of an undertaking to repay all amounts so advanced without interest if it is ultimately determined that the director or officer is not entitled to be indemnified.

Indemnification shall not be made in respect of any claim, issue or matter as to which the person has been adjudged to be liable to us unless and only to the extent that a court determines that, despite the adjudication of liability but in view of all the circumstances of the case, the person is fairly and reasonably entitled to indemnity for the expenses that the court deems proper. Nor shall indemnification be made in any case where the act or failure to act giving rise to the claim for indemnification is determined by a court to have constituted willful misconduct or recklessness.

Sale of Unregistered Securities

In the past three years, Baudax Bio has not sold any securities, including sales of reacquired securities, new issues, securities issued in exchange for property, services or other securities and new securities resulting from the modification of outstanding securities.

WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form 10 with the SEC with respect to the shares of our common stock being distributed as contemplated by this information statement. This information statement is a part of, and does not contain all of the information set forth in, the registration statement and the exhibits and schedules to the registration statement. For further information with respect to us and our common stock, please refer to the registration statement, including its exhibits and schedules. Statements made in this information statement relating to any contract or other document are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract or document. You may review a copy of the registration statement, including its exhibits and schedules, on the Internet website maintained by the SEC at www.sec.gov.

As a result of the Distribution, we will become subject to the information and reporting requirements of the Exchange Act and, in accordance with the Exchange Act, we will file periodic reports, proxy statements and other information with the SEC, which will be available at www.sec.gov.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors
Recro Pharma, Inc.:

Opinion on the Combined Financial Statements

We have audited the accompanying combined balance sheets of the Recro Pharma Acute Care Business (the Company) as of December 31, 2018 and 2017, the related combined statements of operations, parent company net investment, and cash flows for each of the years then ended, and the related notes (collectively, the combined financial statements). In our opinion, the combined financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Emphasis of a Matter

As discussed in Note 1 to the combined financial statements, the combined financial statements reflect the Company's historical financial position, results of operations and cash flows as the business was operated as part of Recro Pharma, Inc. (Recro). Recro's plans to spin-off the Company as a standalone entity and the risks associated with the approval and commercialization of the Company's lead product candidate are disclosed in Note 2 to the combined financial statements.

Basis for Opinion

These combined financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these 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 and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the combined financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the 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 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 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
June 24, 2019

Recro Pharma Acute Care Business
Combined Balance Sheets

(amounts in thousands)	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Prepaid expenses and other current assets	$ 2,514	$ 2,468
Total current assets	2,514	2,468
Property, plant and equipment, net	3,982	1,766
Intangible assets	26,400	26,400
Goodwill	2,127	2,127
Total assets	$ 35,023	$ 32,761
Liabilities and Parent Company Net Investment		
Current liabilities:		
Accounts payable	$ 2,653	$ 7,155
Accrued expenses and other current liabilities	9,773	5,541
Current portion of contingent consideration	10,354	32,054
Total current liabilities	22,780	44,750
Other long-term liabilities	32	109
Long-term portion of contingent consideration	80,558	50,359
Total liabilities	103,370	95,218
Commitments and contingencies (Note 10)		
Parent company net investment	(68,347)	(62,457)
Total liabilities and parent company net investment	$ 35,023	$ 32,761

See accompanying notes to combined financial statements.

Recro Pharma Acute Care Business
Combined Statements of Operations

(amounts in thousands)	For the Year ended December 31, 2018	2017
Operating expenses:		
Research and development	$ 35,583	$ 28,635
General and administrative	29,453	19,626
Change in contingent consideration valuation	8,499	12,839
Total operating expenses	73,535	61,100
Operating loss	(73,535)	(61,100)
Other income (expense):		
Other income (expense)	(132)	16
Net loss	$ (73,667)	$ (61,084)

See accompanying notes to combined financial statements.

Recro Pharma Acute Care Business
Combined Statements of Parent Company Net Investment

(amounts in thousands)	Parent Company Net Investment
Balance, December 31, 2016	$ (49,344)
Net loss	(61,084)
Net transfers from parent	44,559
Parent allocation – share based compensation	3,412
Balance, December 31, 2017	(62,457)
Net loss	(73,667)
Net transfer from parent	63,203
Parent allocation – share-based compensation	4,574
Balance, December 31, 2018	$ (68,347)

See accompanying notes to combined financial statements.

Recro Pharma Acute Care Business
Combined Statements of Cash Flows

(amounts in thousands)	For the Year ending December 31, 2018	2017
Cash flows from operating activities		
Net loss	$ (73,667)	$ (61,084)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	4,574	3,412
Depreciation expense	396	72
Acquired in-process research and development charges	—	766
Change in contingent consideration valuation	8,499	12,839
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(46)	(1,894)
Accounts payable, accrued expenses and other liabilities	493	2,617
Net cash used in operating activities	(59,751)	(43,272)
Cash flows from investing activities:		
Purchase of property and equipment	(3,370)	(768)
Acquisition of license agreement	(82)	(519)
Net cash used in investing activities	(3,452)	(1,287)
Cash flows from financing activities:		
Investment from parent	63,203	44,559
Net cash provided by financing activities	63,203	44,559
Net (decrease) increase in cash and cash equivalents	—	—
Cash and cash equivalents, beginning of year	—	—
Cash and cash equivalents, end of year	$ —	$ —
Supplemental disclosure of cash flow information		
Purchase of property, plant and equipment included in accrued expenses and accounts payable	$ 280	$ 1,039

See accompanying notes to combined financial statements.

(1) Nature of Business and Basis of Presentation

Recro Pharma, Inc. or Recro, was incorporated in Pennsylvania on November 15, 2007. Recro is a pharmaceutical company that operates through two business segments: a revenue-generating contract development and manufacturing, or CDMO business and an Acute Care Business. Recro plans to separate its Acute Care pharmaceutical segment, referred to herein as the Recro Pharma Acute Care Business or the Company, including certain assets and liabilities associated with its pharmaceutical pipeline programs into an independent, publicly traded company. Following the separation the Company intends to focus on developing innovative products for hospital and other acute care settings, including its product candidate intravenous, or IV, meloxicam, for which the Company is pursuing resolution of a Complete Response Letter, or CRL, received from the U.S. Food and Drug Administration, or FDA, regarding the New Drug Application, or NDA, for IV meloxicam. See Note 15.

The accompanying combined financial statements are derived from Recro's consolidated financial statements and accounting records. The Recro Pharma Acute Care Business did not consist of a separate, standalone group of legal entities in the periods presented and, accordingly, allocations were required. These combined financial statements 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 planned spin-off, in conformity with U.S. generally accepted accounting principles, or U.S. GAAP.

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

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 statement 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 will be retained by Recro and will not be assumed by the Company.

Historically, certain corporate level activity costs have been incurred and reported within the legal entity that includes the Recro Pharma Acute Care Business. A portion of these costs have been allocated out and the Company's combined financial statements include a remaining allocation of expenses related to these certain Recro corporate functions that pertain to the Company, including senior management, legal, human resources, finance, and information technology. These expenses are included in general and administrative expense and have been allocated based on direct usage or benefit where identifiable, with the remainder allocated on a pro rata basis of expenses, headcount, or other measures. The Company considers the expense allocation methodology and results to be reasonable for all periods presented, however, the allocations may not be indicative of the actual expense that would have been incurred had the Company operated as an independent, publicly-traded company for the periods presented. For the years ended December 31, 2018 and 2017, a total of $5,165 and $4,598 of general and administrative costs have been allocated to the CDMO business.

The income tax amounts in these combined financial statements 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. 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.

Recro maintains its stock-based compensation plan at a corporate level. The Company's employees participate in those programs and a portion of the cost of those plans is included in these 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 Pharma 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.

(2) Development-Stage Risks and Liquidity

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 plans to contribute an amount of cash to the Company immediately prior to the spin-off, that management believes is sufficient to maintain operations of the Company for at least one year from the date of the spin-off. Recro has not committed any additional funding to the Company beyond the amount to be contributed as of the spin-off date and the Company may be required to raise additional funds needed to operate as a standalone entity beyond one year from the spin-off date. The initial cash contribution from Recro is contingent upon certain approvals of third parties, such as Recro's lender, which are expected to occur prior to the spin-off but have not yet occurred as of the date of these combined financial statements. 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 development, commercialization or expansion activities, including personnel. The Company may raise such funds 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 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. The Company may be required to wind down operations if IV meloxicam is not approved 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) Property and Equipment

Property and equipment are recorded at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which are as follows: three to seven years for furniture, office and computer 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.

(c) Business Combinations

In accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or 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, or 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.

(d) 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 on its 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, and competitive environments. As of December 31, 2018, no impairment exists.

(e) 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, 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.

(f) Stock-Based Awards

Share-based compensation is based upon the Recro share-based compensation plan. The Recro plan includes grants of stock options, time-based vesting restricted stock units (RSUs) and performance-based vesting RSUs. These carve out financial statements reflect share-based compensation related to stock options and RSUs issued to Acute Care employees as well as an allocation of a portion of share-based compensation issued to corporate employees and members of the Board of Directors.

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.

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 the historical volatility of our 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.

The Company has elected to account for forfeitures as they occur.

(g) Income Taxes

The income tax amounts in these combined financial statements 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. 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.

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.

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.

(h) Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In January 2017, the FASB issued ASU No. 2017-04 "*Intangibles – Goodwill and Other (Topic 350): Simplifying the Accounting for Goodwill Impairment*," or ASU 2017-04. ASU 2017-04 allows companies to apply a one-step quantitative test and record 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 amendments of the ASU are effective for annual or interim goodwill impairment tests in fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company adopted this guidance as of October 1, 2018 and there was no impact on its combined financial statements.

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.

In February 2016, the FASB issued ASU No. 2016-02, "*Leases (Topic 842)*," or ASU 2016-02. ASU 2016-02 establishes a wholesale change to lease accounting and introduces a lease model that brings most leases on the balance sheet. It also eliminates the required use of bright-line tests in current U.S. GAAP for determining lease classification. In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842), *Targeted Improvements*, which provides an alternative transition method permitting the recognition of a cumulative-effect adjustment on the date of adoption rather than restating comparative periods in transition as originally prescribed by Topic 842. The new guidance is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted. The Company adopted this guidance in the first quarter of 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 elected certain practical expedients permitted under the transition guidance. On January 1, 2019, the Company recorded a right-of-use asset of $1,174 and an operating lease liability of $1,219.

(4) Acquisitions

Gainesville Facility and Meloxicam

On April 10, 2015, Recro completed the Gainesville Transaction. The consideration paid in connection with the Gainesville 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, according to the original agreement. In addition, according to the original agreement, Recro may be required to pay up to an additional $125,000 in milestone payments including $45,000 upon regulatory approval, as well as net sales milestones related to injectable meloxicam and a percentage of future product net sales related to injectable meloxicam between 10% and 12% (subject to a 30% reduction when no longer covered by patent). Under the acquisition method of accounting, the consideration paid and

the fair value of the contingent consideration and royalties are 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 Gainesville Transaction were allocated to the Acute Care Business and CDMO business as of the date of the acquisition. The accompanying financial statements reflect the IPR&D asset of $26,400 and goodwill of $2,127 that were recorded by the Acute Care Business related to the Gainesville transaction. The liability for the contingent consideration will be assumed by the Company following the spin-off and is included in the Company's Combined Balance Sheets. The warrant associated with the transaction remains on Recro's Consolidated Balance Sheets as the equity plan is held at the corporate level.

In December 2018, the Company entered into an Amendment to the Purchase and Sale Agreement 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. In addition, the Company amended the warrant agreement with Alkermes, which decreased the exercise price of the warrant to $8.26 per share.

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 due January 19, 2019 (30 days after signing such amendment) and (ii) a $5,000 payment due by April 23, 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.

The fair value of the first and second contingent consideration components 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, Recro acquired the exclusive global rights to two novel neuromuscular blocking agents, or NMBAs, and a proprietary chemical 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 Phase I clinical trials and two other agents, a novel short-acting NMBA, and a rapid-acting reversal agent proprietary to these NMBAs. This license agreement is included in the Company's pipeline product candidates.

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, Recro 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. Recro 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, Recro will reimburse Cornell ongoing patent costs related to prosecution and maintenance of the patents related to the Cornell patents for the NMBA Related Compounds. This obligation will be transferred to the Company in connection with the spin-off.

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

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

The Company has classified 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, 2017:			
Liabilities:			
Contingent consideration (See Note 4)	$ —	$ —	$ 82,413
	$ —	$ —	$ 82,413
At December 31, 2018:			
Liabilities:			
Contingent consideration (See Note 4)	$ —	$ —	$ 90,912
	$ —	$ —	$ 90,912

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

	Contingent Consideration
Balance at December 31, 2016	$ 69,574
Remeasurement	12,839
Balance at December 31, 2017	82,413
Remeasurement	8,499
Total at December 31, 2018	$ 90,912
Current portion as of December 31, 2018	$ 10,354
Long-term portion as of December 31, 2018	$ 80,558

The current portion of the contingent consideration approximates the probability adjusted fair value amount that the Company currently expects to become payable within one year as of December 31, 2018 (see Note 4 for additional information). The Company plans to continue to reevaluate this classification and measurement as it progresses through discussions with the FDA and the appeals process regarding IV meloxicam.

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, 2018, the financial assets and liabilities recorded on the Combined Balance Sheets that are not measured at fair value on a recurring basis include accounts payable and accrued expenses, which approximate fair value due to the short-term nature of these instruments.

(7) Property, Plant and Equipment

Property, plant and equipment consists of the following:

	December 31, 2018	December 31, 2017
Building and improvements	$ 196	$ 78
Furniture, office and computer equipment	1,688	360
Manufacturing equipment	101	101
Construction in progress	2,469	1,303
	4,454	1,842
Less: accumulated depreciation and amortization	472	76
Property, plant and equipment, net	$ 3,982	$ 1,766

Depreciation expense for the years ended December 31, 2018 and 2017 was $396 and $72, respectively.

(8) Intangible Assets

The following represents the balance of the intangible assets at December 31, 2018 and 2017:

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

There was no amortization expense for the years ended December 31, 2018 and 2017.

(9) Accrued Expenses

Accrued expenses consist of the following:

	December 31 2018	December 31 2017
Clinical trial and related costs	$ 683	$ 383
Professional and consulting fees	671	1,010
Payroll and related costs	2,172	3,969
Property plant and equipment	278	—
Pre-commercialization scale-up costs	4,445	—
Other research and development costs	678	—
Other	846	179
	$ 9,773	$ 5,541

(10) Commitments and Contingencies

(a) License and Supply Agreements

Recro is party to an exclusive license with Orion for the development and commercialization of Dexmedetomidine, or 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. Recro is required to pay Orion lump sum payments of up to €20,500 ($23,460 as of December 31, 2018) 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, 2018, no such milestones have been achieved.

Recro is also party to an exclusive license agreement with Orion for the development and commercialization of Fadolmidine, or Fado, for use as a human therapeutic, in any dosage form in the Territory. Recro is required to pay Orion lump sum payments of up to €12,200 ($13,961 as of December 31, 2018) 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, 2018, no such milestones have been achieved.

Recro is party to a license agreement with Cornell. Recro 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.

These obligations will be transferred to the Company in connection with the spin-off.

(b) Contingent Consideration for the Gainesville Transaction

Pursuant to the purchase and sale agreement and subsequent amendment governing the Gainesville Transaction (see Note 4), 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 injectable 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).

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

(c) Litigation

The Company and Recro are involved, from time to time, in various claims and legal proceedings arising in the ordinary course of their respective businesses. 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 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) 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 and directors 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. No hearing date has been set. The Company and Recro 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 the Company and Recro.

(d) Leases

The Company is a party to various operating leases in Malvern, Pennsylvania and Dublin, Ireland for office space and office equipment. Rent expense includes rent as well as additional operating and tenant improvement expenses.

As of December 31, 2018, future minimum lease payments excluding operating expenses and tenant improvements for the leases, are as follows:

2019	$	517
2020		414
2021		367
2022		373
Total	$	1,671

(e) Purchase Commitments

As of December 31, 2018, the Company had outstanding non-cancelable and cancelable purchase commitments of $15,417 related to capital expenditures and other goods and services, including pre-commercial/manufacturing scale-up and clinical activities.

(f) Certain Compensation and Employment Agreements

Recro has entered into employment agreements with certain of its named executive officers. As of December 31, 2018, these employment agreements provided for, among other things, annual base salaries in an aggregate amount of not less than $188 from that date through calendar year 2019, which represents the allocated portion to the Company.

(11) Stock-Based Compensation

Certain employees of the Company participate in Recro's stock-based compensation plan, which provides for the grants of stock options and RSUs. The expense associated with the Company's employees who participate in the plan is included in the accompanying combined statements of operations. A portion of these costs have been allocated out of the Company as they relate to employees responsible for corporate level activities that historically were incurred by the entity that represents the Company. Additionally, the entity that represents the Company historically incurred the costs related to the board of directors, which has also been partially allocated out of the Company.

In October 2013, Recro established the 2013 Equity Incentive Plan, or the 2013 Plan, which allows for the grant of stock options, stock appreciation rights and stock awards for a total of 600,000 shares of common stock. In June 2015, Recro's shareholders approved the Amended and Restated Equity Incentive Plan, or the A&R Plan, which amended and restated the 2013 Plan and increased the aggregate amount of shares available for issuance to 2,000,000. On December 1st of each year, pursuant to the "Evergreen" provision of the A&R Plan, the number of shares available under the plan may be increased by the Recro Board by an amount equal to 5% of the outstanding common stock on December 1st of that year. In December 2018 and 2017 the number of shares available for issuance under the A&R Plan was increased by 1,082,972 and 956,341, respectively. The total number of shares authorized for issuance under the A&R plan as of December 31, 2018 is 8,119,709.

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, 2018, 3,777,352 shares are available for future grants under Recro's A&R Plan.

All shares described herein represent shares of Recro. The share information included in this disclosure includes 100% of the shares issued to Acute Care Business employees, corporate employees and Board members of Recro; however, a portion of the expenses related to the corporate employees and Board members of Recro have been allocated out of share-based compensation expense in these carve out financial statements using an allocation methodology similar to the allocation methodology used to allocate cash compensation expense.

The weighted average grant-date fair value of the options awarded to employees during the years ended December 31, 2018 and 2017 was $6.07 and $5.42, respectively. The fair value of the options was estimated on the date of grant using a Black-Scholes option pricing model with the following assumptions:

	December 31,	
	2018	2017
Range of expected option life	5.5 - 6 years	6 years
Expected volatility	73.26% - 82.00%	75.10 - 84.71%
Risk-free interest rate	2.32 - 3.03%	1.87 - 2.27%
Expected dividend yield	—	—

The following table summarizes stock option activity during the year ended December 31, 2018:

	Number of shares	Weighted- average exercise price per share	Weighted-average remaining contractual life
Balance, December 31, 2017	3,015,032	$ 6.77	6.9 years
Granted	803,294	9.14	
Exercised	(350,268)	5.15	
Expired/forfeited/cancelled	(375,452)	8.79	
Balance, December 31, 2018	3,092,606	$ 7.32	7.3 years
Vested	1,881,989	$ 6.71	6.5 years
Vested and expected to vest	3,092,606	$ 7.32	7.3 years

Included in the table above are 950,000 options granted outside the plan. The grants were made pursuant to the Nasdaq inducement grant exception in accordance with Nasdaq Listing Rule 5635(c)(4).

The following table summarizes restricted stock units activity during the year ended December 31, 2018:

	Number of shares
Balance, December 31, 2017	262,593
Granted	894,557
Vested and settled	(131,268)
Expired/forfeited/cancelled	(44,429)
Balance, December 31, 2018	981,453
Expected to vest	768,510

Included in the table above are 47,000 time-based RSUs granted outside the plan. The grants were made pursuant to the Nasdaq inducement grant exception in accordance with Nasdaq Listing Rule 5635(c)(4).

Stock-based compensation expense related to the employees of the Company for the twelve months ended December 31, 2018 and 2017, net of allocations, was $4,574 and $3,412, respectively.

As of December 31, 2018, net of allocations, there was $8,509 of unrecognized compensation expense related to unvested options and time-based RSUs that are expected to vest and will be expensed over a weighted average period of 1.9 years. As of December 31, 2018, net of allocations, there was $1,929 of unrecognized compensation expense related to unvested performance-based RSUs that will be expensed if the performance criteria are met.

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, 2018, the aggregate intrinsic value of the vested and unvested options was $2,143 and $100, respectively.

(12) Income Taxes

The components of loss before income tax are as follows:

	December 31,	
	2018	**2017**
Domestic	$ (43,505)	$ (33,477)
Foreign	(30,162)	(27,607)
Loss before income taxes	$ (73,667)	$ (61,084)

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

	December 31,	
	2018	**2017**
Current:		
Federal	$ —	$ —
State and local	—	—
Foreign	—	—
	$ —	$ —
Deferred:		
Federal	$ (10,034)	$ (3,928)
State and local	(4,026)	(1,144)
Foreign	(3,770)	3,451
	(17,830)	(1,621)
Change in valuation allowance	17,830	1,621
	$ —	$ —

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,	
	2018	2017
U.S. federal statutory income tax rate	21.0%	34.0%
Foreign tax rate differential	(3.5)%	(9.7)%
State taxes, net of federal benefit	5.5%	1.9%
Nondeductible expenses	0.3%	—
Research and development credits	0.7%	0.8%
Change in federal tax rate	0.1%	(13.0)%
Change in valuation allowance	(24.2)%	(14.0)%
Other	0.1%	—
Effective income tax rate	—	—

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

	December 31,	
	2018	2017
Net operating loss carryforwards	$ 24,384	$ 11,943
Research and development credits	972	472
Capitalized start-up costs	1,489	1,431
Intangibles	206	—
Contingent consideration	9,746	6,588
Stock-based compensation	3,924	2,345
Other temporary differences	161	91
Gross deferred tax asset	40,882	22,870
Valuation allowance	(40,618)	(22,788)
Net deferred tax asset	264	82
Deferred tax liability	(264)	(82)
Net deferred taxes	$ —	$ —

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.

Within the Company's deferred tax assets 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 are included here, based on the separate return methodology, and the amounts disclosed will not carry forward to the Company subsequent to the transaction.

In 2018 and 2017, 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 for both 2018 and 2017. 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 Company will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2018, 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.

On December 22, 2017, the Tax Cuts and Jobs Act (H.R. 1) (the "Tax Act") was signed into law. The Tax Act contains significant changes to corporate taxation, including (i) the reduction of the corporate income tax rate to 21%, (ii) the acceleration of expensing for certain business assets, (iii) the one-time transition tax related to the transition of U.S. international tax from a worldwide tax system to a territorial tax system, (iv) additional limitations on the deductibility of interest expense, and (v) expanded limitations on executive compensation. The most significant impacts on the Company are as follows:

- The Company remeasured its existing U.S. federal deferred tax assets and liabilities at the rate that the Company expects to be in effect when those deferred taxes will be realized, which is now 21%. In 2017, the Company recognized a one-time net expense from the deferred tax remeasurement of approximately $7,900.
- A one-time tax is due on certain accumulated foreign earnings (Deemed Repatriation Tax), which is payable over eight years. The tax rate is generally 15.5% on the portion of the earnings held in cash and cash equivalents and 8% on the remainder. As the Company has an accumulated foreign deficit for its operations in Ireland, it is not currently subject to this Deemed Repatriation Tax.
- The Company will be able to claim an immediate deduction for investments in qualified fixed assets acquired and placed in service beginning September 27, 2017 through 2022. This provision phases out through 2026.
- Given the Company's taxable losses in the U.S., it will be limited in its ability to deduct future interest expense, if any. Any disallowed interest expense for future tax years will result in an indefinite carry forward until such time as the Company meets the taxable income thresholds required to deduct interest expense.

(13) 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 $309 and $151 of expenses for the twelve months ended December 31, 2018 and 2017, respectively. A portion of the amount relates to consultancy services provided by the Non-Executive Director.

(14) Retirement Plan

Recro has a voluntary 401(k) Savings Plan (the 401(k) Plan) in which all employees are eligible to participate. Recro's policy is to match 100% of the employee contributions up to a maximum of 5% of employee compensation. Total contributions related to employees of the Company to the 401(k) plan for the year ended December 31, 2018 and 2017 were $540 and $469, respectively.

(15) Subsequent Events

In March of 2019, Recro received a second CRL from the FDA regarding the NDA for IV meloxicam. The Company plans to pursue resolution of the IV meloxicam CRL, including appeal to one or more levels of

the FDA, if required. On April 3, 2019, Recro implemented a strategic restructuring initiative, and corresponding reduction in workforce, aimed at reducing operating expenses, while maintaining key personnel needed to select a partner and obtain FDA approval of IV meloxicam. The restructuring initiative includes a reduction of a majority of Recro's Acute Care Business workforce, which encompasses the entities that represent the Company, by approximately 50 positions. Recro estimates that it will incur approximately $4,000 of costs in connection with the reduction in workforce related to severance pay and other related termination benefits. Recro communicated the workforce reduction on April 3, 2019 and expects the majority of the costs to be incurred during the quarter ending June 30, 2019.

Recro Pharma Acute Care Business
Combined Balance Sheets
(unaudited)

(amounts in thousands)	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Prepaid expenses and other current assets	$ 3,586	$ 2,514
Total current assets	3,586	2,514
Property, plant and equipment, net	5,091	3,982
Right of use asset	943	—
Intangible assets	26,400	26,400
Goodwill	2,127	2,127
Total assets	$ 38,147	$ 35,023
Liabilities and Parent Company Net Investment		
Current liabilities:		
Accounts payable	$ 352	$ 2,653
Accrued expenses and other current liabilities	4,233	9,773
Current operating lease liability	400	—
Current portion of contingent consideration	—	10,354
Total current liabilities	4,985	22,780
Long-term operating lease liability	587	—
Other long-term liabilities	—	32
Long-term portion of contingent consideration	61,762	80,558
Total liabilities	67,334	103,370
Commitments and contingencies (Note 10)		
Parent company net investment	(29,187)	(68,347)
Total liabilities and parent company net investment	$ 38,147	$ 35,023

See accompanying notes to combined financial statements.

Recro Pharma Acute Care Business
Combined Statements of Operations
(unaudited)

(amounts in thousands)	For the Six Months ended June 30, 2019	2018
Operating expenses:		
Research and development	$ 16,734	$ 15,826
General and administrative	17,284	19,062
Change in contingent consideration valuation	(19,150)	2,916
Total operating expenses	14,868	37,804
Operating loss	(14,868)	(37,804)
Other income (expense)		
Other income (expense)	(49)	(90)
Net loss	$ (14,917)	$ (37,894)

See accompanying notes to combined financial statements.

Recro Pharma Acute Care Business
Combined Statements of Parent Company Net Investment
(unaudited)

(amounts in thousands)	Parent Company Net Investment
Balance, December 31, 2017	$ (62,457)
Net loss	(37,894)
Net transfer from parent	33,123
Parent allocation – share-based compensation	2,102
Balance, June 30, 2018	$ (65,126)
Balance, December 31, 2018	$ (68,347)
Net loss	(14,917)
Net transfers from parent	50,875
Parent allocation – share-based compensation	3,202
Balance, June 30, 2019	$ (29,187)

See accompanying notes to combined financial statements.

Recro Pharma Acute Care Business
Combined Statements of Cash Flows
(unaudited)

(amounts in thousands)	For the six months ended June 30, 2019	2018
Cash flows from operating activities:		
Net loss	$ (14,917)	$ (37,894)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	3,202	2,102
Depreciation expense	246	112
Change in contingent consideration valuation	(19,150)	2,916
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,074)	(20)
Right-of-use asset	231	—
Accounts payable, accrued expenses and other liabilities	(7,464)	1,521
Operating lease liability	(232)	—
Net cash used in operating activities	(39,158)	(31,263)
Cash flows from investing activities:		
Purchase of property and equipment	(1,635)	(1,778)
Acquisition of license agreement	(82)	(82)
Net cash used in investing activities	(1,717)	(1,860)
Cash flows from financing activities		
Payment of contingent consideration	(10,000)	—
Investment from parent	50,875	33,123
Net cash provided by financing activities	40,875	33,123
Net (decrease) increase in cash and cash equivalents	—	—
Cash and cash equivalents, beginning of year	—	—
Cash and cash equivalents, end of period	$ —	$ —
Supplemental disclosure of cash flow information:		
Purchase of property, plant and equipment included in accrued expenses and accounts payable	$ —	$ 202

See accompanying notes to combined financial statements.

(1) Nature of Business and Basis of Presentation

Recro Pharma, Inc. or Recro, was incorporated in Pennsylvania on November 15, 2007. Recro is a pharma services and pharmaceutical company that operates through two business segments: a revenue-generating contract development and manufacturing, or CDMO segment and the Acute Care pharmaceutical segment. Recro plans to separate its Acute Care pharmaceutical segment, referred to herein as the Acute Care Business or the Company, including certain assets and liabilities associated with its pharmaceutical pipeline programs into an independent, publicly traded company named Baudax Bio, Inc. Following the separation, Baudax Bio, Inc., or the Company, intends to focus on developing innovative products for hospital and other acute care settings, including its product candidate intravenous, or IV, Meloxicam, for which the Company is pursuing resolution of a Complete Response Letter, or CRL, received from the U.S. Food and Drug Administration, or FDA, regarding the New Drug Application, or NDA, for IV meloxicam.

The accompanying unaudited combined financial statements are derived from Recro's consolidated financial statements and accounting records and should be read in conjunction with the annual audited financial statements and related notes as of and for the year ended December 31, 2018 included in Recro's Annual Report on Form 10-K for the fiscal year ended December 31, 2018. The Recro Pharma Acute Care Business did not consist of a separate, standalone group of legal entities for public company reporting and certain other corporate functions in the periods presented and, accordingly, allocations were required. These combined financial statements 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 planned spin-off, in conformity with U.S. generally accepted accounting principles (U.S. GAAP).

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

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 will be retained by Recro and will not be assumed by the Company.

Historically, certain corporate level activity costs have been incurred and reported within the legal entity that includes the Recro Pharma Acute Care Business. A portion of these costs have been allocated out and the Company's combined financial statements include a remaining allocation of expenses related to these certain Recro corporate functions, including senior management, legal, human resources, finance, and information technology. These expenses are included in general and administrative expense and have been allocated based on direct usage or benefit where identifiable, with the remainder allocated on a pro rata basis of expenses, headcount, or other measures. The Company considers the expense allocation methodology and results to be reasonable for all periods presented, however, the allocations may not be indicative of the actual expense that would have been incurred had the Company operated as an independent, publicly-traded company for the periods presented. For the six months ended June 30, 2019 and 2018, a total of $4,951 and $2,609 of costs have been allocated to the CDMO business.

The income tax amounts in these combined financial statements 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. 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.

Recro maintains its stock-based compensation plan at a corporate level. The Company's employees participate in those programs 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 Pharma 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.

In April 2019, after receipt of the second CRL for IV meloxicam, the Company announced it had implemented a strategic restructuring initiative, and corresponding reduction in the Acute Care segment workforce, aimed at reducing operating expenses, while maintaining key personnel needed to partner and obtain FDA approval of IV meloxicam (Note 9).

(2) Development-Stage Risks and Liquidity

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 plans to contribute $19,000 to the Company immediately prior to the spin-off, that management believes is sufficient to maintain operations of the Company for at least one year from the date of the spin-off. Recro has not committed any additional funding to the Company beyond the $19,000 to be contributed as of the spin-off date and the Company may be required to raise additional funds needed to operate as a standalone entity beyond one year from the spin-off date. The $19,000 contribution is contingent upon certain approvals of third parties, such as Recro's lender, which are expected to occur prior to the spin-off but have not yet occurred as of the date of these combined financial statements. The Company's ability to generate cash inflows is highly dependent on the approval 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 development, commercialization or expansion activities, including personnel. The Company may raise such funds 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 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. The Company may be required to wind down operations if IV meloxicam is not approved or cannot be successfully commercialized.

(3) Summary of Significant Accounting Principles

(a) Basis of Preparation

The accompanying unaudited combined financial statements of the Company have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP, for interim financial information and with the instructions of Form 10-Q and Article 10 of Regulation S-X and, therefore, do not include all of the information and notes required by U.S. GAAP for complete annual financial statements. The Company's combined financial statements have been prepared on a carve out basis for the Acute Care Business (Note 1). All intercompany accounts and transactions have been eliminated. In the opinion of management, the accompanying combined financial statements include

all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company's results for the interim periods. Operating results for the six months ended June 30, 2019 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2019.

The accompanying unaudited interim combined financial statements should be read in conjunction with the annual audited financial statements and related notes as of and for the year ended December 31, 2018 included herein.

(b) Use of Estimates

The preparation of financial statements and the notes to the financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from such estimates.

(c) Property and Equipment

Property and equipment are recorded at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, which are as follows: three to seven years for furniture, office and computer 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, or FASB, Accounting Standards Codification, or 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, or 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 on its 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, and competitive environments. Due to the receipt of the CRL, 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. There have been no further triggering events as of June 30, 2019. The Company will perform its annual test as of November 30, 2019.

(f) 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, 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.

(g) Stock-Based Awards

Share-based compensation is based upon the Recro share-based compensation plan. The Recro plan includes grants of stock options, time-based vesting restricted stock units (RSUs) and performance-based vesting RSUs. These carve out financial statements reflect share-based compensation related to stock options and RSUs issued to Acute Care employees as well as an allocation of a portion of share-based compensation issued to corporate employees and members of the Board of Directors.

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.

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 the historical volatility of our 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. The Company has elected to account for forfeitures as they occur.

(h) Income Taxes

The income tax amounts in these combined financial statements 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. 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. 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.

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.

(i) Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In June 2018, the FASB issued ASU No. 2018-07, "*Compensation – Stock Compensation (Topic 718)*" or ASU 2018-07. ASU 2018-07 simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The new guidance expands the scope of ASC 718 "*Compensation – Stock Compensation*" to include share-based payments granted to nonemployees in exchange for goods or services used or consumed in an entity's own operations and supersedes the guidance in ASC 505-50 "Equity-Based Payments to Non-Employees". The guidance is effective for public business entities in annual periods beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted, including in an interim period for which financial statements have not been issued, but not before an entity adopts ASU 2014-09 "*Revenue from Contracts with Customers (Topic 606)*". The Company adopted this guidance effective June 30, 2018. There was no impact upon adoption.

In May 2017, the FASB issued ASU No. 2017-09, "*Stock Compensation – Scope of Modification Accounting*" or ASU 2017-09. ASU 2017-09 provides guidance on which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The new standard was effective for fiscal years beginning after December 15, 2017. The Company adopted the guidance effective January 1, 2018. There was no impact upon adoption.

In January 2017, the FASB issued ASU No. 2017-04 "*Intangibles – Goodwill and Other (Topic 350): Simplifying the Accounting for Goodwill Impairment*," or ASU 2017-04. ASU 2017-04 allows

companies to apply a one-step quantitative test and record 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 amendments of the ASU are effective for annual or interim goodwill impairment tests in fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company adopted this guidance as of October 1, 2018 and there was no impact on its combined financial statements.

In February 2016, the FASB issued ASU No. 2016-02, "*Leases (Topic 842)*," or ASU 2016-02. ASU 2016-02 establishes a wholesale change to lease accounting and introduces a lease model that brings most leases on the balance sheet. It also eliminates the required use of bright-line tests in current U.S. GAAP for determining lease classification. In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842), *Targeted Improvements*, which provides an alternative transition method permitting the recognition of a cumulative-effect adjustment on the date of adoption rather than restating comparative periods in transition as originally prescribed by Topic 842. The new guidance is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted. The Company adopted this guidance as of January 1, 2019. The Company elected the optional transition method to account for the impact of the adoption with a cumulative-effect adjustment in the period of adoption and did not restate prior periods. The Company opted to elect the package of practical expedients to not reassess prior conclusions related to contracts containing leases, lease classification and initial direct costs, and certain other practical expedients, including the use of hindsight to determine the lease term for existing leases and in assessing impairment of the right-of-use asset, and the exception for short-term leases. For its current classes of underlying assets, the Company did not elect the practical expedient under which the lease components would not be separated from the nonlease components. At January 1, 2019, the Company recorded a right-of-use asset of $1,174 and an operating lease liability of $1,219. For additional information regarding how the Company is accounting for leases under the new guidance, refer to Note 10 (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) Acquisitions

Gainesville Facility and Meloxicam

On April 10, 2015, Recro completed the Gainesville Transaction. The consideration paid in connection with the Gainesville 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, according to the original agreement. In addition, according to the original agreement, the Company may be required to pay up to an additional $125,000 in milestone payments including $45,000 upon regulatory approval, as well as net sales milestones related to injectable meloxicam and a percentage of future product net sales related to injectable meloxicam between 10% and 12% (subject to a 30% reduction when no longer covered by patent). Under the acquisition method of accounting, the consideration paid and the fair value of the contingent consideration and royalties are 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 Gainesville Transaction were allocated to the Acute Care Business and CDMO business as of the date of the acquisition. The accompanying financial statements reflect the IPR&D asset of $26,400 and goodwill of $2,127 that were recorded by the Acute Care Business related to the Gainesville transaction. The liability for the contingent consideration will be assumed by the Company following the spin-off and is included in the Company's Combined Balance Sheets. The warrant associated with the transaction remains on Recro's Consolidated Balance Sheets with no allocation to the Company as it is a warrant to purchase Recro common stock.

In December 2018, the Company entered into an Amendment to the Purchase and Sale Agreement 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. In addition, the Company amended the warrant agreement with Alkermes, which decreased the exercise price of the warrant to $8.26 per share.

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.

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, Recro 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 Phase I clinical trials and two other agents, a novel short-acting NMBA, and a rapid-acting reversal agent specific to these NMBAs. This license agreement is included in the Company's pipeline product candidates.

The transaction was accounted for as an asset acquisition, with the total cost of the acquisition of $766 allocated to acquired IPR&D. Recro 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, Recro 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. Recro 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, Recro will reimburse Cornell ongoing patent costs related to prosecution and maintenance of the patents related to the Cornell patents for the NMBA Related Compounds. This obligation will be transferred to the Company in connection with the spin-off.

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

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

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

	Fair value measurements at reporting date using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
At December 31, 2018:			
Liabilities:			
Contingent consideration (See Note 4)	$ —	$ —	$ 90,912
	$ —	$ —	$ 90,912
At June 30, 2019:			
Liabilities:			
Contingent consideration (See Note 4)	$ —	$ —	$ 61,762
	$ —	$ —	$ 61,762

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

	Contingent Consideration
Balance at December 31, 2018	$ 90,912
Payment of contingent consideration	(10,000)
Remeasurement	(19,150)
Total at June 30, 2019	$ 61,762
Current portion as of June 30, 2019	$ —
Long-term portion as of June 30, 2019	$ 61,762

The current portion of the contingent consideration approximates the probability adjusted fair value amount that the Company currently expects to become payable within one year as of June 30, 2019 (see Note 4 for additional information). The Company plans to continue to reevaluate this classification and measurement as it progresses through discussions with the FDA and appeals process regarding IV meloxicam.

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 June 30, 2019, the financial assets and liabilities recorded on the Combined Balance Sheets that are not measured at fair value on a recurring basis include accounts payable and accrued expenses, which approximate fair value due to the short-term nature of these instruments.

(7) Property, Plant and Equipment

Property, plant and equipment consists of the following:

	June 30, 2019	December 31, 2018
Building and improvements	$ 196	$ 196
Furniture, office and computer equipment	1,671	1,688
Manufacturing equipment	101	101
Construction in progress	3,814	2,469
	5,782	4,454
Less: accumulated depreciation and amortization	691	472
Property, plant and equipment, net	$ 5,091	$ 3,982

Depreciation expense for the six months ended June 30, 2019 and 2018 was $246 and $112, respectively.

(8) Intangible Assets

The following represents the balance of the intangible asset at June 30, 2019 and 2018:

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

There was no amortization expense for the six months ended June 30, 2019 and 2018.

(9) Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	June 30, 2019	December 31, 2018
Clinical trial and related costs	$ 124	$ 683
Professional and consulting fees	813	671
Accrued restructuring costs	1,836	—
Payroll and related costs	1,126	2,172
Property plant and equipment	—	278
Pre-commercialization scale-up costs	—	4,445
Other research and development costs	205	678
Other	129	846
	$ 4,233	$ 9,773

After receipt of the second CRL, the Company incurred approximately $7,200 in restructuring costs, of which $1,836 remains accrued and unpaid as of June 30, 2019.

(10) Commitments and Contingencies

(a) Licenses and Supply Agreements

Recro 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. Recro is required to pay Orion lump sum payments of up to €20,500 ($23,301 as of June 30, 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 June 30, 2019, no such milestones have been achieved.

Recro 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. Recro is required to pay Orion lump sum payments of up to €12,200 ($13,867 as of June 30, 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 June 30, 2019, no such milestones have been achieved.

Recro 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.

These obligations will be transferred to the Company in connection with the spin-off.

(b) Contingent Consideration for the Gainesville Transaction

Pursuant to the purchase and sale agreement and subsequent amendment governing the Gainesville 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 injectable 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 June 30, 2019, the Company has paid $10,000 in milestone payments to Alkermes.

Recro is party to a Development, Manufacturing and Supply Agreement, or Supply Agreement, with Alkermes (through a subsidiary of Alkermes), that will be assumed by the Company following the spin-off pursuant to which Alkermes will (i) provide clinical and commercial bulk supplies of injectable meloxicam formulation and (ii) provide development services with respect to the Chemistry, Manufacturing and Controls section of an NDA for injectable meloxicam. Pursuant to the Supply Agreement, Alkermes will supply the Company with such quantities of bulk injectable meloxicam formulation as shall be reasonably required for the completion of clinical trials of injectable meloxicam. During the term of the Supply Agreement, the Company will purchase its clinical and commercial supplies of bulk injectable 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 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) 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 and directors 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. On June 26, 2019, the judge heard oral arguments on the motion to dismiss. The judge asked the plaintiffs to file a supplemental brief by August 30, 2019, and Recro will have 30 days to submit a reply brief. Recro and the Company believe that the lawsuit is without merit and intends 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 and Recro.

(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 between 1 and 4 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, Recro'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 Combined Balance Sheets. Lease expense is recognized on a straight-line basis over the lease term.

As of June 30, 2019, undiscounted future lease payments for non-cancellable operating leases are as follows:

	Lease payments
2019	$ 244
2020	403
2021	362
2022	374
Total lease payments	1,383
Less imputed interest	(396)
Total operating liabilities	$ 987

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

2019	$ 517
2020	414
2021	367
2022	373
Total	$ 1,671

For the six months ended June 30, 2019, the weighted average remaining lease term was 3 years and the weighted average discount rate was 16%.

The components of the Company's lease cost were as follows for the six months ended June 30, 2019:

Operating lease cost	$	242
Short-term lease cost		14
Total lease cost	$	256

(e) Purchase Commitments

As of June 30, 2019, the Company had outstanding non-cancelable and cancelable purchase commitments in the aggregate amount of $4,609 related to capital expenditures 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.

(f) Certain Compensation and Employment Agreements

The Company has entered into employment agreements with certain of its named executive officers. As of June 30, 2019, these employment agreements provided for, among other things, annual base salaries in an aggregate amount of not less than $925, from that date through March 2020, which represents the allocated portion to the Company.

(11) Stock-Based Compensation

Certain employees of the Company participate in Recro's stock-based compensation plan, which provides for the grants of stock options and RSUs. The expense associated with the Company's employees who participate in the plan is included in the accompanying combined statements of operations. A portion of these costs have been allocated out of the Company as they relate to employees responsible for corporate level activities that historically were incurred by the entity that represents the Company. Additionally, the entity that represents the Company historically incurred the costs related to the board of directors, which has also been partially allocated out of the Company.

In October 2013, Recro established the 2013 Equity Incentive Plan, or the 2013 Plan, which allows for the grant of stock options, stock appreciation rights and stock awards for a total of 600,000 shares of common stock. In June 2015, Recro's shareholders approved the Amended and Restated Equity Incentive Plan, or the A&R Plan, which amended and restated the 2013 Plan and increased the aggregate amount of shares available for issuance to 2,000,000. On December 1st of each year, pursuant to the "Evergreen" provision of the A&R Plan, the number of shares available under the plan may be increased by the Recro Board by an amount equal to 5% of the outstanding common stock on December 1st of that year. In December 2018 and 2017 the number of shares available for issuance under the A&R Plan was increased by 1,082,972 and 956,341, respectively. The total number of shares authorized for issuance under the A&R plan as of June 30, 2019 is 8,119,709.

Stock options are exercisable generally for a period of 10 years from the date of grant and generally vest over four years. As of June 30, 2019, 2,666,387 shares are available for future grants under Recro's A&R Plan.

All shares described herein represent shares of Recro. The share information included in this disclosure includes 100% of the shares issued to Acute Care Business employees, corporate employees and Board members of Recro; however, a portion of the expenses related to the corporate employees and Board members of Recro have been allocated out of share-based compensation expense in these carve out financial statements using an allocation methodology similar to the allocation methodology used to allocate cash compensation expense.

The weighted average grant-date fair value of the options awarded to employees for the six months ended June 30, 2019 and 2018 was $5.53 and $6.18, respectively. The fair value of the options was estimated on the date of grant using a Black-Scholes option pricing model with the following assumptions:

	June 30,	
	2019	2018
Range of expected option life	5.5 - 6 years	5.5 - 6 years
Expected volatility	79.11% - 81.54%	73.26% - 82.00%
Risk-free interest rate	2.23 – 2.66%	2.32 – 2.89%
Expected dividend yield	—	—

The following table summarizes stock option activity during the six months ended June 30, 2019:

	Number of shares	Weighted average exercise price per share	Weighted average remaining contractual life
Balance, December 31, 2018	3,092,606	$ 7.32	7.3 years
Granted	1,094,756	$ 7.95	
Exercised	(235,823)	$ 8.93	
Expired/forfeited/cancelled	(637,376)	$ 7.84	
Balance, June 30, 2019	3,314,163	$ 7.62	6.9 years
Vested	2,027,552	$ 7.30	5.7 years
Vested and expected to vest	3,314,163	$ 7.62	6.9 years

Included in the table above are 594,820 options outstanding as of June 30, 2019 that were granted outside the plan. The grants were made pursuant to the NASDAQ inducement grant exception in accordance with NASDAQ Listing Rule 5635(c)(4).

As a result of the Company's reduction in workforce announced in April 2019, the Company cancelled approximately 600,000 unvested stock options upon termination, which are reflected in the table above. The Company expects an additional approximately 300,000 shares related to stock options to be affected in which the shares will be cancelled if not exercised within the exercisable period in the termination agreements.

The following table summarizes restricted stock units activity during the six months ended June 30, 2019:

	Number of shares
Balance, December 31, 2018	981,453
Granted	664,210
Vested and settled	(408,343)
Expired/forfeited/cancelled	(431,586)
Balance, June 30, 2019	805,734
Expected to vest	554,534

Included in the table above are 25,500 time-based RSUs outstanding as of June 30, 2019 that were granted outside the plan. The grants were made pursuant to the NASDAQ inducement grant exception in accordance with NASDAQ Listing Rule 5635(c)(4).

As a result of the Company's reduction in workforce announced in April 2019, the Company cancelled approximately 300,000 shares related to RSUs upon termination, which is reflected in the table above.

Stock-based compensation expense related to the employees of the Company for the six months ended June 30, 2019 and 2018, net of allocations, was $3,202 and $2,102, respectively.

As of June 30, 2019, net of allocations, there was $8,646 of unrecognized compensation expense related to unvested options and time-based RSUs that are expected to vest and will be expensed over a weighted average period of 2.2 years. As of June 30, 2019, net of allocations, there was $1,621 of unrecognized compensation expense related to unvested performance-based RSUs and will be expensed if the performance criteria are met.

The aggregate intrinsic value represents the total amount by which the fair value of the common stock subject to options exceeds the exercise price of the related options. As of June 30, 2019, the aggregate intrinsic value of the vested and unvested options was $5,980 and $2,657, respectively.

(12) 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 $104 and $253, in consideration for such services, respectively. A portion of the amount relates to consultancy services provided by the Non-Executive Director.

(13) 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 six months ended June 30, 2019 and 2018 were $236 and $274, respectively.